中国外商投资企业协会药品研制和开发行业委员会
China Association of Enterpriscs with Foreign Investment
R&D-based Pharmaceutial Association Committee

《国家医保谈判药品在各省实施政策研究》

课 题 报 告

Research on Local Implementation of National Reimbursement Negotiated Drugs in China

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《国家医保谈判药品在各省实施政策研究》

课　题　报　告

国家药物政策与医药产业经济研究中心(NDPE)

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序 言

2016 年，习近平总书记在 “全国卫生健康大会”中指出：“健康是促进人的全面发展的必然要求，是经济社会发展的基础条件，是民族昌盛和国家富强的重要标志，也是广大人民群众的共同追求”。《“健康中国 2030”规划纲要》作为新时期国家优先发展的战略部署规划了包括建立分级诊疗制度、建立全民医保制度、以及建立药品供应保障制度等重点制度建设任务，旨在建立高效、优质、可持续的医疗服务体系，满足广大人民群众的医疗服务需求，保障经济社会的健康发展。

2017 年，人社部实施了首次国家医保创新药谈判，36 种药品通过谈判形成了医保支付标准，并要求各地执行谈判结果，将 36 种谈判药纳入国家医保药品目录乙类报销范围，且不得调整限定支付范围。截至 2017 年 12 月底，所有省市已将谈判药品全部纳入乙类目录，由基本医疗保险基金和参保人员共同支付，同时各地严格执行人社部要求的支付范围限制。然而，谈判药品的执行在大部分地区仍然存在医保报销、地方采购、医院准入和渠道等诸多障碍，影响了医保准入谈判落地执行的效果。

2018 年，国家医疗保障局通过谈判将 17 种抗癌药纳入国家医保药品目录乙类报销范围，并确定了医保支付标准。各地医保、人力资源社会保障、卫生健康等部门及时根据职责对谈判药品执行情况做出具体工作安排，大大提高了肿瘤患者对抗癌药品的可及性，减轻患者的医疗费用负担。

中国外商投资企业协会药品研制和开发行业委员会（RDPAC）于 2018 年委托中国药科大学国家药物政策与医药产业经济研究中心（NDPE）开展了《国家医保谈判药品在各省实施政策研究》的课题，希望通过政策梳理、制度比较、实证调研等方法对我国谈判药品医保准入的实施情况进行研究，重点调研分析执行谈判结果较差和较好的地区，总结各地政策实施经验、分析各省市现存问题，基于对经验教训的反思提出相关改进与完善建议，并为下一轮谈判厘清地方准入障碍，提供经验。

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第一章 研究背景、目的及意义

一、研究背景

2017 年，新一版医保药品目录发布后，人社部实施了首次国家医保创新药谈判，通过谈判的药品形成了医保支付标准，并纳入医保乙类目录管理。同年 7 月，人社部发布《关于将 36 种药品纳入国家基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》（54 号文），要求各地执行谈判结果，将 36 种谈判药纳入乙类报销范围，且不得调整限定支付范围。同时要求各省（区、市）积极探索多种方式加强有关药品管理，促进合理用药。对规定需“事前审查后方可使用”或其他需要严格管理的药品，要建立统一的事前审查规定；对用量大、费用高的药品要纳入基本医疗保险医疗服务智能监控系统进行重点监控，并做好费用分析；要采取有效措施鼓励定点零售药店为参保人员提供药品，发挥药店在医保药品供应保障方面的积极作用。

54 号文发布以后，各地相应出台措施执行谈判结果。截至 2017 年 12 月底，国家谈判药品在全国 31 个省市都已全部落地执行，所有省市已将谈判药品全部纳入乙类目录，由基本医疗保险基金和参保人员共同支付，同时各地严格执行人社部要求的支付范围限制。其中执行较好的省份包括浙江、江苏、北京、广东、河南等地。然而，谈判药品的执行在大部分地区任然存在医保报销、地方采购、医院准入和渠道等诸多障碍，例如报销比例过低、基层准入受基药目录限制、医院二次议价、药占比、零售渠道开放受阻等。如重庆、山东、贵州、河南等地区对药品使用的医疗机构、医师资格、报销比例、患者资质、病种等方方面面均进行了较为严格的限制，在此背景下，谈判品种报销政策的覆盖范围大大缩小，患者的药品使用与报销情况、谈判药品医保准入的落地实施效果未得到良好反馈。

本项目希望通过政策梳理、制度比较、实证调研等方法对我国谈判药品医保准入的实施情况进行研究，重点调研分析执行谈判结果较差和较好的地区，总结各地政策实施经验、分析各省市现存问题，基于对经验教训的反思提出相关改进与完善建议，在政策落地效果相对欠佳的地区进行推广，帮助谈判药品更好地惠及患者、提高药品的可支付性，并为下一轮谈判厘清地方准入障碍，提供经验。

二、研究目的及意义

（一）研究目的

本课题运用政策梳理、文献研究、调研访谈的方法，研究各地谈判结果准入政策、实施情况以及面临的障碍，在实地调研的基础上，借鉴落地政策执行较好省市的经验，为落地政策执行较差省份提供政策建议。总目的是为了帮助各地区应对执行创新药品谈判结果所面临的挑战，改善谈判药品在地方的准入环境，为下一轮谈判厘清地方准入障碍提供经验。同时希望解决以下几个问题：

①目前各省市谈判品种整体落地情况如何？

②典型地区谈判品种政策执行的经验与教训？可借鉴与可完善之处？

③医保谈判政策执行过程中面临哪些困境？如何解决？

④如何提出完善谈判药品落地政策的建议？

（二）研究意义

1 减轻患者费用负担，提高谈判药品可及性

基于对国家的谈判药医保准入的政策分析，通过目前各省的谈判落地情况进行实证研究，尝试优化各地谈判药品的地方准入政策，为其设立准入新环境，让具有临床高价值的药品在各地快速落地实施，减轻患者医疗负担，提高谈判药物可及性，从而实现社会医疗资源福利最优化。

2 促进谈判药品监管政策的优化完善

通过对我国典型省份谈判药品落地执行情况的实施现状和实施效果进行考察，反馈目前各地谈判准入政策和措施对患者用药的影响，促进谈判药品监管政策的完善，对宏观层面制度设计与优化具有重要意义。

3 构建谈判药品准入政策的改革发展新路径

在本轮各地谈判药品医保目录准入的落地实施情况的基础上，总结遇到的障碍及得到的经验，完善医保谈判机制，尝试提出下一阶段谈判药品准入政策的改革发展新路径。

第二章 国家药品谈判实施效果

一、药品谈判背景

自 2015 年至今，国家共进行了三次药品价格谈判。第一次主体负责部门为国家卫生计生委，并于 2016 年 5 月 23 日联合 7 个部门印发通知，同时公布了首批国家药品价格谈判结果。第二次谈判的主体变为了医保部门，在 44 个品种中最终纳入了 36 个，价格降幅非常可观，平均达到 44%；2017 年 7 月 13 日人社部发布通知，正式标志着国家医保谈判成果进入落实阶段。最后一次谈判主要针对抗癌药，2018 年 10 月 10 日，经过 3 个多月的谈判，17 个品种成功纳入医保报销目录，价格平均降幅达 56.7%。

三次谈判的主体、机制、价格降幅、对象虽有所不同，但是主旨均是希望通过政府谈判，提高高价值、高价格药品的可及性，惠及广大患者。

二、三次谈判总体情况

（一）第一次药品谈判

1 政策背景

2015 年 2 月，国务院办公厅下发《关于完善公立医院药品集中采购工作的指导意见》，提出对药品进行分类采购，对部分专利药品、独家生产药品，建立公开透明、多方参与的价格谈判机制，该文件从国家层面首度明确“国家谈判”。此后，国家卫计委起草了《建立药品价格谈判机制试点工作方案(征求意见稿)》（以下简称《方案》），对谈判具体操作流程进行了详细说明。2015 年 10 月，经国务院批准，由国家卫计委牵头的 16 个部委（局）共同建立了药品价格谈判部际联席会议制度，11 月即启动了首次国家药品价格谈判。2016 年 5 月 20 日，经国家药品价格谈判部际联席会议审议通过，首批谈判结果向社会公布。

2 谈判成效

（1）成功率

首批国家药价谈判包括 5 个品种，最终 3 个品种成功入选，成功率达 60%。该 5 个品种包括治疗晚期非小细胞肺癌的吉非替尼、厄洛替尼和埃克替尼，治疗慢性乙肝的韦瑞德和治疗多发性骨髓瘤的来那度胺，涉及制药企业分别为阿斯利康、罗氏、贝达、葛兰素史克和新基制药。在针对非小细胞肺癌的药品要“三选二”的竞争规则下，罗氏的厄洛替尼没能进入名单，另外两种价格更为优惠的药

品成功入选，而新基制药的罕见病药品则告知只是“暂未公布”。

（2）价格降幅

谈判试点 3 种药品，平均降幅 59%，最高降幅 67%。韦瑞德、易瑞沙和凯美纳三种药品降价幅度分别达到 67%、55%和 54%，与周边国家（地区）趋同[1]。此前，上述药品的月均药品费用分别为 1500 元、12000 元和 15000 元人民币，降价后分别为 490 元、5500 元、7000 元。具体情况见表 1。

表 1 谈判试点 3 种药品情况

通用名（商品名）	生产企业	治疗领域	月均费用降价情况	降价幅度
替诺福韦酯(韦瑞德)	葛兰素史克	慢性乙肝一线治疗	1500 元→490 元	67%
吉非替尼(易瑞沙)	阿斯利康	非小细胞肺癌靶向治疗	12000 元→5500 元	55%
埃克替尼(凯美纳)	贝达药业	非小细胞肺癌靶向治疗	15000 元→7000 元	54%

3 谈判过程

（1）组织形式

谈判实施组织由“二委二库”构成。《方案》中提出，价格谈判由以下三个组织负责实施：①国家药品价格谈判指导委员会。由国家卫生计生委牵头，成员包括发改、教育、工信部、财政、人社部、商务、审计、海关、税务、工商、CFDA、知识产权、保险监管、总后卫生等部委及领导等。负责审定谈判药品品种、谈判实施方案和采购价格等重大事项。②国家药品价格谈判监督委员会。成员主要由相关政府部门，驻国家卫生计生委纪检组监察局、相关利益方代表、部分人大代表、政协委员组成。负责对谈判工作的全称监督，受理检举和投诉。③建立国家药品价格谈判专家库和药品价格信息库，参与谈判的专家每次随机从专家库中抽取，同一位专家只能参加药品价格谈判的一个环节。

（2）谈判流程

本次谈判按照“一药一策”的思路，组织开展首批国家药品价格谈判试点工作。谈判小组研究细化了每一个企业、每一种药品的谈判策略和流程，为确保谈判过程规范公正，还对谈判全程进行了录音或录像，建立了备忘录。

程序包括制定谈判方案、成立谈判小组、遴选谈判药品、发布谈判公告（国家药品供应保障综合管理信息系统平台发布）、生产企业递交相关技术资料和其它材料、谈判、结果公布（国家药品供应保障综合管理信息系统平台、省级药品

1 国家药品价格谈判有关情况说明
http://www.nhfpc.gov.cn/yaozs/s3578/201605/fc76991a7161418ebd2ce093cc1fea02.shtml

集中采购平台和指定的媒体上公布）、组织采购（注意：部队医院也沿用谈判结果进行采购）、配送和结算、价格监测[2]。

4 实施效果

在市场上基本实现了“以价换量”的目的。

据 GSK 负责人季海威介绍，在 2016 年各省相继执行药价谈判结果后，替诺福韦酯在全国范围内的销量增长了 3 倍，在谈判价格落地的城市中，销量上涨了 4-5 倍。而据浙江贝达公开数据，2016 年，凯美纳销量首次突破 10 亿元，相比 2015 年同期增长 13.4%。2017 年，凯美纳进入国家医保目录，由于落地衔接和仿制药的上市，销售额较 2016 年有轻微的下跌，但销量大增 42%。2018 年半年度业绩预告显示，公司持续推进各地医保政策落地，除了巩固大城市市场外，还深度挖掘潜在市场，向二三线城市市场拓展，报告期内凯美纳销售继续放量，销量同比增长 28.54%。

（二）第二次药品谈判

1 政策背景

2017 年 4 月 14 日，人社部牵头开展了纳入医保目录范围品种谈判工作，确定了 44 个品种，选择的主要是基于临床必需、疗效突出、价格较高，群众负担比较重等标准。2017 年 7 月 19 日，谈判结果公布。

2 谈判成效

（1）成功率

2017 年第二次价格谈判，谈判对象主要为高价、临床急需药品，促使谈判药品真正落地，是解决重病患者药品供应保障，让群众有切实获得感的重要举措。本次谈判对象可以分为中药和西药，诊疗范围囊括了心脑血管疾病、罕见病、慢性肾病、精神疾病、感染、肿瘤等多个领域，44 个品种最终 36 个品种入选，成功率达 81.8%，具体见表 2。

表 2 第二次谈判药品及治疗领域名单

分类	具体分类	治疗领域	药品名称	
西药	重大疾病或慢性病用药	心脑血管	重组人脑利钠肽（西藏药业）	重组人尿激酶原（天士力）
			替格瑞洛（阿斯利康）	阿利沙坦酯（信立泰）
		抗感染	泊沙康唑（默沙东）	吗啉硝唑氯化钠（江苏豪森）
		眼科	雷珠单抗（诺华制药）	康柏西普（康弘药业）

2 关于药品价格谈判机制的几个要点及思考 http://www.zyzhan.com/news/detail/45851.html

		AMD		
		慢性肾病	碳酸镧（夏尔制药）	司维拉姆（赛诺菲）
		精神疾病	喹硫平（阿斯利康）	帕罗西汀（葛兰素）
		糖尿病	利拉鲁肽（诺和诺德）	
		其他	托伐普坦（大冢制药）	
	肿瘤治疗药	肿瘤	利妥昔单抗（罗氏）	阿帕替尼（恒瑞医药）
			曲妥珠单抗（罗氏）	西达本胺（微芯生物）
			贝伐珠单抗（罗氏）	氟维司群（阿斯利康）
			索拉非尼（拜耳）	阿比特龙（强生）
			硼替佐米（强生）	依维莫司（诺华制药）
			厄洛替尼（罗氏）	来那度胺（Celgene）
			尼妥珠单抗（百泰生物）	拉帕替尼（葛兰素）
			重组人血管内皮抑制素（山东先声）	
	罕见病用药	罕见病	重组人凝血因子Ⅶa（诺和诺德）	重组人干扰素β-1b（拜耳）
中成药	肿瘤治疗药	肿瘤	参一胶囊（吉林亚泰）	复方黄黛片（亿帆医药）
			注射用黄芪多糖（天津赛诺）	
	重大疾病或慢性病用药	心脑血管	银杏内酯注射液（成都百裕）	银杏二萜内酯葡胺注射液（康缘药业）

（2）价格降幅

国家希望“以价换量”，实现临床急需、高值药品的可及，在谈判的推动下，谈判试点 36 种药品，平均降幅 44%，最高降幅 70%，大部分进口药品谈判后的支付标准低于周边国际市场价格，大大减轻了我国患者的医疗费用负担[3]。大量药品价格超过 40%，具体见表 3。

表 3 第二次谈判药品价格情况

治疗领域	品名/公司	药品企业	规格	最低招标价（元）	谈判支付价（元）	降幅
心脑血管	重组人脑利钠肽	西藏药业	0.5mg	1709	585	42.02%
抗感染	泊沙康唑	默沙东	105ml:4.2g	4905	2800	42.9%
糖尿病	利拉鲁肽	诺和诺德	3ml:18mg	723	410	44.3%
其他	托伐普坦	大冢制药	15mg*5 片	840	495	41.1%
肿瘤	利妥昔单抗	罗氏	50ml:0.5g	16041	8289.87	48.3%
	曲妥珠单抗	罗氏	20ml:440mg	21613	7600	64.8%
	贝伐珠单抗	罗氏	4ml:0.1g	5176	1998	61.4%
	索拉非尼	拜耳	200mg	23280	12180	47.7%

3 人社部发布医保药品目录准入谈判结果 http://www.mohrss.gov.cn/SYrlzyhshbzb/dongtaixinwen/buneiyaowen/201707/t20170719_274189.html

	硼替佐米	强生	1mg*1 瓶	4842.5	2344.26	51.6%
			3.5mg	12512.4	6116	51.1%
	厄洛替尼	罗氏	150mg	3220	1365	57.6%
	注射用黄芪多糖	天津赛诺	250mg	494	278	43.72%
	氟维司群	阿斯利康	5ml:250mg	5419.6	2400	55.72%
	阿比特龙	强生	250mg	36925	17390.4	52.9%
	来那度胺	Celgene	25mg*21 粒	58787.2	23141.79	60.6%
			10mg	46170.5	18186	60.6%
	拉帕替尼	葛兰素	250mg	8300	4900	41%

数据来源：根据 PDB 数据库、天风证券研报综合整理

3 谈判过程

（1）谈判流程

4 月份，人社部公布了 44 个拟谈判药品名单，随后成立了专门的工作组和监督组负责承担具体工作和开展全程监督，并组织专家与相关企业进行了谈判。

主要可以分为以下环节：

①制定严谨周密的谈判规则：包括明确谈判主体，明确政策条件即明确谈判成功的药品纳入药品目录乙类范围、全国统一执行谈判确定的医保支付标准，明确申报、评估谈判三分离，明确客观评价与专家评估相结合，明确具体谈判流程。

②组织专家开展评估测算：人社部内部设立了两个完全独立的评估专家组，分别从药物经济性和医保基金承受能力两个方面开展评估测算。一个是药物经济学评估组，主要是通过药品的临床价值、国际国内价格比较、同类药品参比等角度的分析，运用药物经济学的方法提出建议。另一个是医保基金支撑能力测算组，通过对 44 个谈判药品在 68 个统筹地区的 309 万条医保数据进行收集测算分析。最终通过既定规则确定出医保预期支付价格，体现了谈判的公平公正[4]。

③按照规定程序进行谈判：谈判企业随机分组；监督组现场进行监督、谈判全程录像；工作组现场根据药学组、医保组预估的支付标准来确定最终的医保预期支付价格，同时用信封密封后专人送达谈判现场。

（2）谈判亮点

此次国家药品谈判有两大创新举措：一是有法律顾问全程参与保证合法合规，通过聘请对医药领域和医保领域比较熟悉的法律专业人士，对前期资格审查，后

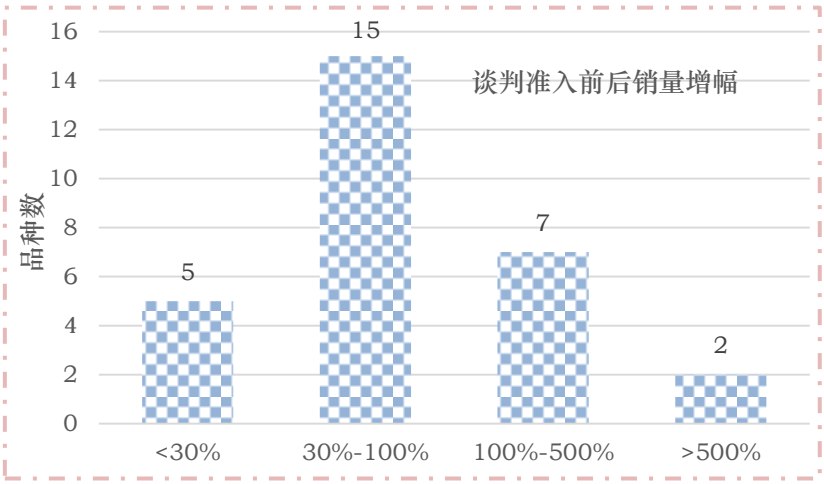
4 张苗. 解密国家药品谈判[J]. 中国社会保障, 2017(08): 16-19.

续谈判环节及协议签署环节进行合法性把关、规范，保证谈判过程的权威性；二是首次利用医保大数据测算帮助制定医保政策的制定，这一举措也有利于保证医保基金的可持续性。

4 落地情况

（1）药品销售情况——企业角度

根据汇总结果，销量增幅在 30%-100%间的较多，更有的药品销量增幅在 500%以上，但是也不排除有销量增幅并不十分理想的情况。



序号	药品名称	序号	药品名称
1	阿帕替尼	16	贝伐珠单抗
2	阿利沙坦酯	17	厄洛替尼
3	康柏西普	18	碳酸司维拉姆
4	重组人尿激酶原	19	泊沙康唑
5	银杏二萜内酯	20	重组人凝血因子VIIa
6	重组人脑利钠肽	21	利拉鲁肽
7	银杏内酯注射液	22	依维莫司
8	氟维司群	23	雷珠单抗
9	替格瑞洛	24	西达苯胺
10	喹硫平缓释片	25	碳酸钙咀嚼片
11	索拉非尼	26	血管内皮抑制素
12	尼妥珠单抗	27	来那度胺
13	托伐普坦	28	阿比特龙
14	拉帕替尼	29	硼替佐米
15	曲妥珠单抗		

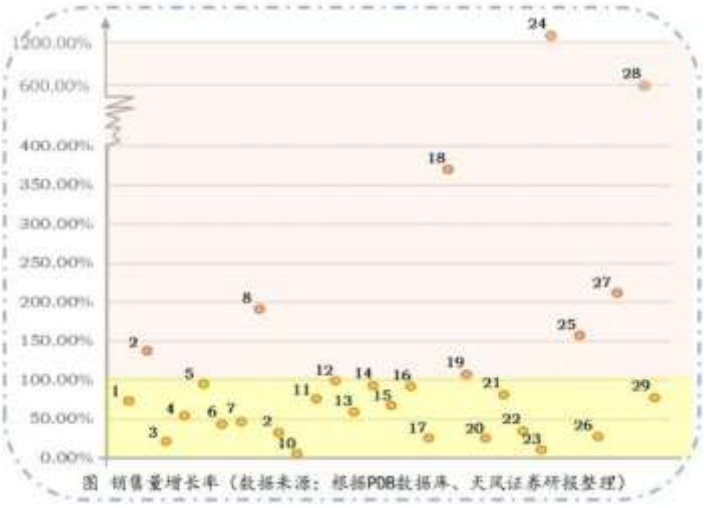


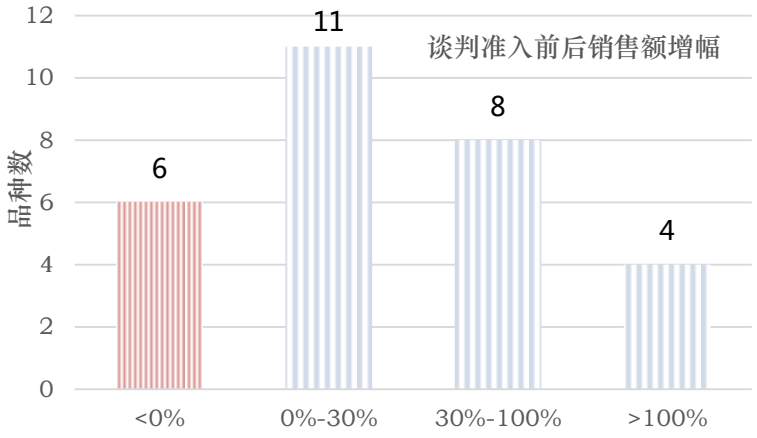
图 1 第二次谈判准入前后药品销量增幅

虽然各省已经发布文件促进谈判药政策的落地实施，但是药品“进得了医保进不了医院”的难题依旧棘手。一方面，零差率政策发布后，药品从原来的盈利主体变为了现在的成本主体，医院缺少谈判药品准入的驱动力和积极性；另一方面，虽然部分省份声明谈判药品不计入药占比指标的计算，但是具体这一政策的落实情况并不乐观，省里各市、医院实施过程中存在不执行或难以执行的情况。

再有，各医院用药目录调整周期长、单次调整品种少也使得谈判品种无法及时更新进入医院采购和使用目录。这些，都导致医院无法达到谈判药供应保障的目标，也就无法让患者切实感受到医保谈判所带来的福利。

通常认为，综合医院的投资规模、管理难度要大于专科医院，而盈利能力、可获得性和可复制性则明显弱于专科医院，因此在谈判政策落地效果来看，专科医院也毫不意外地优于综合医院。北京医院药学部药师胡欣强调，所有进入医保目录的药品并非在大的综合型医院都能买到，因为全中国范围内没有一家医院能把目录中的药品全部配齐。每家医院有自己的定位，需考虑到科室的强弱之分[5]。

此外，企业主体也普遍反映谈判后的销售情况并没有达到预期效果。药品价格通过谈判模式平均降低 44%，但是由于受限于医院准入的迟滞性，企业销售额并没有实现稳步增长的目标，有相当一部分企业销售额的增长率为负值，如图 2。



序号	药品名称	序号	药品名称
1	阿帕替尼	16	贝伐珠单抗
2	阿利沙坦酯	17	厄洛替尼
3	康柏西普	18	磷酸可维拉姆
4	重组人尿激酶原	19	泊沙康唑
5	银杏二萜内酯	20	重组人凝血因子VIIa
6	重组人脑利钠肽	21	利拉鲁肽
7	银杏内酯注射液	22	依维莫司
8	氟维司群	23	雷珠单抗
9	替格瑞洛	24	西达苯胺
10	唑硫平缓释片	25	磷酸铜咀嚼片
11	索拉非尼	26	血管内皮抑制素
12	尼妥珠单抗	27	来那度胺
13	托伐普坦	28	阿比特龙
14	拉帕替尼	29	醋酸亮丙瑞林
15	曲妥珠单抗		

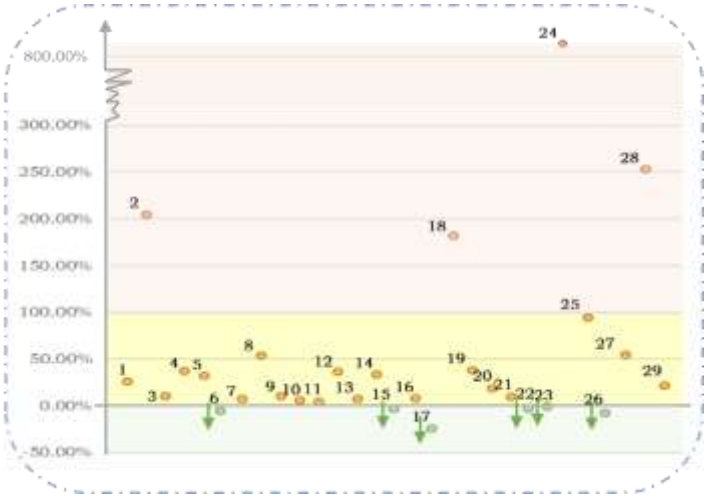


图 2 谈判药销售额增长情况

5 澎湃新闻. 17 种抗癌药腰斩式降价入医保 患者要获益仍需破关[EB/OL]. http://news.sina.com.cn/o/2018-10-11/doc-ifxeuwws3204879.shtml. [2018-10-11/2018-11-14].

部分药品在谈判后虽然销售额保持增长，但是与谈判前相比其销售额增长的环比增速是呈下降趋势或与之前持平。这无疑也是对企业今后进行谈判工作积极性的一种打击。

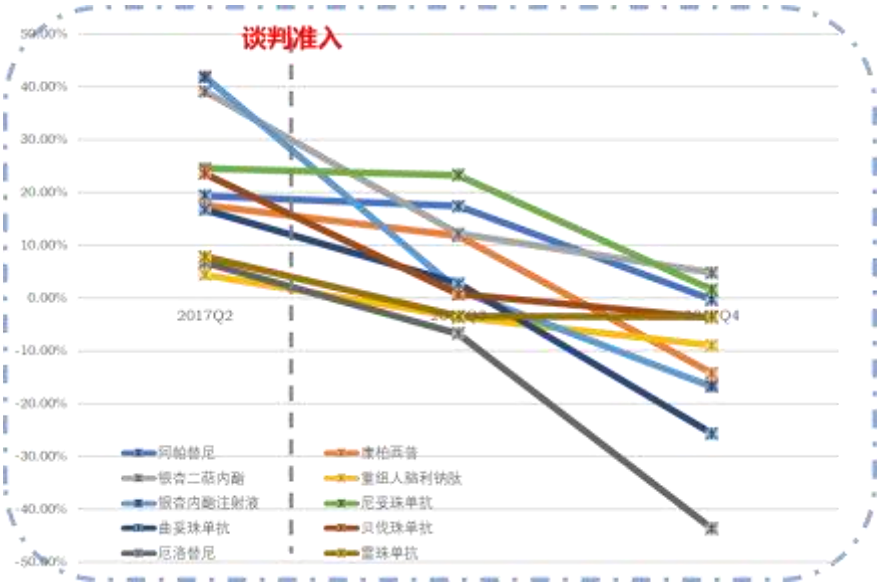


图 3 部分谈判药品销售额增长率变化情况
数据来源：根据 PDB 数据库、天风证券研报整理

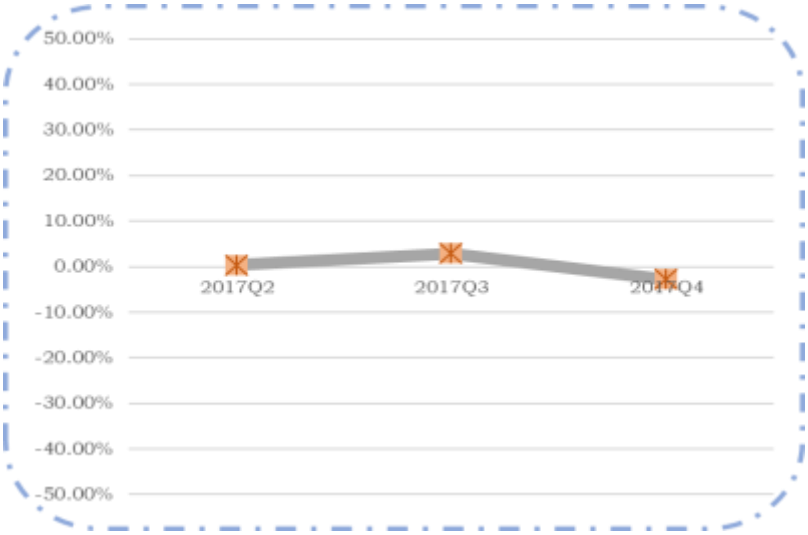


图 4 重组人凝血因子 VIIa 销售额增长率变化情况
数据来源：根据 PDB 数据库、天风证券研报整理

（2）政策实施情况——政府角度

国家谈判和地方落地实施是一个整体，谈判是上半场，落地实施是下半场，同样关键。从各省发文情况来看，各省严格执行 54 号文要求，大部分省份鼓励药店作为医保谈判药品供应和报销的通道，部分省市在药品分类管理、药占比、

医保总控等相关配套政策方面做出了有效的探索。此外各地都非常重视合理用药的问题，采取有效措施鼓励谈判药品在医院的合理使用。同时对医保额度超医保总量的给予一定的倾斜和考虑。各地保障谈判药品落地主要有以下几方面措施：

①落地规范文件

截止 2017 年 12 月底，国家谈判药品在全国 31 个省/市都已全部落地执行，31 个省/市已将谈判药品全部纳入到乙类目录，由基本医疗保险基金和参保人员共同支付，同时各地严格执行人社部要求的支付范围限制。

表 4 各省谈判药品落地政策

省份	发文时间	落地文件	执行时间
江苏	2017年8月2日	《江苏省人力资源社会保障厅关于将36种药品纳入基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》（苏人社发〔2017〕265号）	2017年9月1日
浙江	2017年8月23日	关于执行《国家基本医疗保险、工伤保险和生育保险药品目录（2017年版）》等有关事项的通知（浙人社发〔2017〕100号）	2017 年 9 月 1 日
上海	2017年11月15日	《上海市基本医疗保险、工伤保险和生育保险药品目录（2017年版）》的通知（沪人社医〔2017〕430号）	2017年12月1日
山东	2017年8月21日	山东省人力资源和社会保障厅关于执行《国家基本医疗保险、工伤保险和生育保险药品目录（2017 年版）有关问题的通知》（鲁人社发〔2017〕34 号）	2017年9月1日
	2017年9月1日	山东省人力资源和社会保障厅《关于做好省直医疗保险与 2017 年国家医疗保险药品目录调整政策衔接有关问题的通知》（鲁人社办发〔2017〕74 号）	
广东	2017年9月25日	《关于执行2017年版国家基本医疗保险、工伤保险和生育保险药品目录有关问题的通知 》（粤人社发〔2017〕221号）	2017年10月1日
甘肃	2017年9月25日	《甘肃省关于执行国家36种谈判药品谈判结果的通知》（甘医改办发〔2017〕32号）	2017年11月1日
	2017年10月20日	《关于印发甘肃省城镇职工基本医疗保险工伤保险和生育保险药品目录（2017年版）的通知》	
贵州	2017年11月22日	关于《2017年贵州省基本医疗保险、工伤保险和生育保险药品目录调整工作方案（征求意见稿）》公开征求意见的通知（黔人社厅发〔2017〕22号）	2017年12月20日

北京	2017年8月28日	《关于调整完善本市基本医疗保险门诊特殊疾病政策有关问题的通知》（京人社医发〔2017〕179号）	2017年9月1日
	2017年8月28日	《关于将多拉司琼注射液等药品纳入本市基本医疗保险、工伤保险和生育保险药品报销范围有关问题的通知》（京人社医发[2017]180号）	
	2018年3月1日	《关于印发北京市基本医疗保险工伤保险和生育保险药品目录（2017年版）的通知》（京人社医发[2018]40号）	
陕西	2017年8月23日	陕西省人社厅关于执行《国家基本医疗保险、工伤保险和生育保险药品目录（2017年版）》和国家谈判药品纳入支付范围的通知	2017年9月1日
安徽	2018年5月16号	关于印发《安徽省基本医疗保险、工伤保险和生育保险药品目录(2018年版)的通知》（皖人社发〔2018〕24号）	2017年9月1日
	2017年8月14日	转发人力资源社会保障部《关于将36种药品纳入国家基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》	
重庆	2017年12月22日	《重庆市人力资源和社会保障局关于将36种国家谈判药品纳入重庆市基本医疗保险、工伤保险和生育保险药品目录有关事宜的通知》（渝人社发〔2017〕266号）	2017年9月1日
四川	2018年06月21日	《关于印发四川省基本医疗保险、工伤保险和生育保险药品目录（2018年版）的通知》(川人社发〔2018〕29号)	2017年9月1日
	2017年11月07日	关于省本级执行36种国家谈判药品和《国家基本医疗保险、工伤保险和生育保险药品目录（2017版）》有关问题的通知	
吉林	2018年1月10日	《吉林省关于执行2017年版国家基本医疗保险、工伤保险和生育保险药品目录的通知》(吉人社办字〔2017〕89号）	2017年9月1日
	2017年9月6日	《关于印发吉林省基本医疗保险特殊药品管理暂行办法的通知》（吉人社办字〔2017〕58号）	
辽宁	2017年8月10日	《转发人力资源社会保障部关于将36种药品纳入国家基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》（辽人社〔2017〕171号）	2017年9月1日

②采购规范文件

对于 36 种谈判药品采购，国家卫生计生委办公厅、人力资源和社会保障部

办公厅发布《关于做好 36 种谈判药品集中采购的通知》（国卫办药政函〔2017〕856 号）。为此，各省市在执行 36 个谈判药品的相关文件中对于谈判药品采购做出了相应的规定。其中，江苏、浙江、广东、甘肃、辽宁等省在文件中明确规定这些药品采取直接挂网采购的方式，而陕西、新疆采用限价挂网采购的方式，其他省份还没有明确的规定。尽管谈判药品已经纳入医保支付范围，但常有患者反映所就诊的医院不采购，致使患者无法购买到所需药品，直接影响到谈判药品的落地执行。

表 5 个别省份谈判药品采购规定

省份	政策文件	采购方式
黑龙江	《关于做好 36 中国家谈判药品集中采购的通知》	直接挂网
广东	《关于执行 2017 年版国家基本医疗保险、工伤保险和生育保险药品目录有关问题的通知》	直接挂网
陕西	《关于 36 种国家谈判药品挂网有关工作的通知》	限价挂网
新疆	《关于将 36 中药品纳入国家基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》	限价挂网
江苏	《关于做好 36 种谈判药品集中采购工作的通知》	直接挂网
浙江	《关于国家谈判药品纳入浙江省药品采购交易平台在线交易的通知》	直接挂网

③可操作性规定

A 规范使用条件

54 号文中要求各省（区、市）要积极探索多种方式加强有关药品管理，促进合理用药。对此，各省在相关文件中都对谈判药品管理作出了具体的要求。一些省份将谈判药纳入特殊药品管理，例如甘肃省、贵州省、江苏省、山东省重庆市等省市。

其中，江苏省、山东省还对这些谈判药品实行“三定”管理，定医疗机构、定责任医师、定零售药店。江苏省关于国家 36 种谈判药品的通知文件中表明由国家卫计委组织谈判并纳入《国家基本医疗保险、工伤保险和生育保险药品目录（2017 版）》和人社部发 54 号文件中的抗肿瘤分子靶向药纳入特药管理。此外，《关于印发江苏省城镇医疗保险特药管理实施方案的通知》（苏人社〔2013〕278 号）中要求，特药治疗使用实行定医疗机构、定责任医师、定零售药店等“三定”管理。医保特药“三定”名单需报省医保经办机构备案。山东省人力资源和社会保障厅关于执行《国家基本医疗保险、工伤保险和生育保险药品目录（2017 年版）》有关问题的通知（鲁人社发〔2017〕34 号）要求：对部分国家和我省确定的谈

判药品和其他有关高值药品，逐步参照大病保险特殊药品管理方法实行“三定”管理。同时，要发挥协议管理药店在药品供应保障方面的积极作用。

贵州省将 36 种谈判药品纳入特殊药品管理，实行定医院、定医师、定患者、定药品、定用量的“五定”管理，并严格执行限制使用条件。建立用药备案登记制度,鼓励有条件的地区可探索延伸至指定定点药店售药。

贵州省对于五定管理的具体要求如下：

①对于定医院，贵州省要求各统筹地区需要根据本地实际情况确定定点医疗机构。原则上，经办机构将委托三级医院为参保人办理特殊药品用药资格，但对于一些没有三级医院的地区，管理规范的二级医院也可为参保人办理用药资格。

②对于定医师，贵州省要求指定医疗机构需要申报本院有资格为参保人员开具特殊药品用药处方和办理特殊药品用药资格的医师为指定医师。原则上，指定医师需要为副主任医师及以上职称，并且只负责与自身疾病诊治专业方向相对应的特殊药品处方开具及资格办理。

③对于定患者，贵州省要求参保患者使用特殊药品前须进行用药资格认定，取得资格后，凭统筹区内指定医师开具的特殊药品用药处方购药，费用方可报销。患者具体申请流程如下：首先，参保人需要找指定医生为其填报特殊药品的资格申请表，同时该医生需把参保患者的相关病历、资料等交到医院医保部门，然后由本院医保部门进行审核。审核通过以后，医院将需将相关信息（包括病人基本信息、疾病信息、用药信息、指定医生信息、指定医院和可能需要指定的特殊药品药店信息）录入医保信息系统并上传。之后，医保信息系统自动把病人信息和药品、医院、医师、药店相关联。最后，患者进行结算，这时，只要各项信息匹配一致，就可以用社保卡刷卡结算，并享受医保待遇。

④对于定药品，贵州省要求参保患者只能使用与其适应症相对应的特殊药品。

⑤对于定用量，贵州省社保局对每一种特殊药品设定了医保支付最大量，超过最大量部分不予支付。目前采用两种方式：一是按照疗程设置用量；二是按照时间点设置用量。贵州医保运用“双限制”的方法：首先，按月设计总量。考虑到用药衔接问题，通常按照指定药品每个月最大用量再加上一周用量。同时，按年度设置一个总量（一年零三个月的月最大用量），超出部分需患者自行支付。

重庆市对于谈判药品中的 18 个药品建立限医院（药店）、限医师、限病种、

强监管的事前审查制度。这 18 个药品具体为曲妥珠单抗、贝伐珠单抗、尼妥珠单抗、利妥昔单抗、厄洛替尼、索拉非尼、拉帕替尼、阿帕替尼、硼替佐米、重组人血管内皮抑制素、西达本胺、阿比特龙、氟维司群、重组人干扰素 β-1b、依维莫司、来那度胺、康柏西普、雷珠单抗。

陕西省的相关通知文件中要求，各市要积极探索谈判药品管理办法，可实行分类管理来促进合理用药。对规定需“事前审查后方可使用”或其他需要严格管理的药品，可采取病例实名备案、定医院或零售药店集中供货、定责任医师负责、定结算条件、定结算流程等多种方式来确保药品流通、使用环节可控可查。

在规范使用条件中，部分省市针对国家谈判药品的不同品种进行精细化管理，如福建省在《通知》中指出，“将国家谈判药品按照所属类别进入门诊特殊病种可支付的用药范围。司维拉姆口服常释剂型和碳酸镧咀嚼片增补纳入“重症尿毒症门诊透析医保可支付的用药范围”。

对于肿瘤用药，山西省发布《关于将曲妥珠单抗注射液等 32 种谈判药品纳入省直医疗保险门诊大额疾病用药范围管理的通知》，《通知》中将重组人凝血因子Ⅶa 纳入血友病用药范围、碳酸镧和司维拉姆纳入尿毒症透析用药范围。

B 自付比

人社部发 54 号文中规定，医保支付标准包括基本医疗保险基金和参保人员共同支付的全部费用，基本医疗保险基金和参保人员的分担比例由各统筹地区确定。规定的支付标准有效期截至 2019 年 12 月 31 日，有效期满后按照医保药品支付标准有关规定进行调整。截止目前，关于报销比例， 14 个省市在全省统一设定了医保支付比例，个人自付比例基本在 20%-50%之间，16 个省市由各个统筹地区自行确定医保支付比例[6]。

表 6 各省市谈判药品报销情况

省份	文件发布时间	文件号	文件执行时间	报销比例
江苏	2017 年 8 月 2 日	苏人社发〔2017〕265 号	2017 年 9 月 1 日	54 号文件的规定执行，支付标准包括基本医疗保险基金和参保人员共同支付的全部费用，基本医疗保险基金支付比例由各设区市统一确定并报省厅备案

6 中国医疗保险：国家医保谈判药品实施现状、问题以及完善思路 https://mp.weixin.qq.com/s/pKgJIF-3weAUDiS7zFsANg.

浙江	2017 年 8 月 23 日	浙人社发〔2017〕100 号	2017 年 9 月 1 日	统一纳入浙江省医保乙类药品管理
上海	2017 年 11 月 15 日	沪人社医〔2017〕430 号	2017 年 12 月 1 日	具体医保支付标准按照人社部发〔2017〕54 号文件规定执行
广东	2017 年 9 月 25 日	粤人社发〔2017〕221 号	2017 年 10 月 1 日	由基本医疗保险、工伤保险和生育保险按规定支付
山东	2017 年 8 月 21 日	鲁人社发〔2017〕34 号	2017 年 9 月 1 日	支付标准按照国家规定执行；个人自付比例由各设区的市人力资源社会保障局统一制定，并报省厅备案
甘肃	2017 年 9 月 25 日	甘医改办发〔2017〕32 号	2017 年 11 月 1 日	各地按本统筹地区乙类药品报销比例报销
贵州	2017 年 11 月 22 日	黔人社厅发〔2017〕22 号	2017 年 12 月 20 日	先由参保人员自付一定的比例，再按各统筹地区基本医疗保险的规定支付；其中个人先行自付比例实行全省统一的标准，个人先行自付比例可根据发病率和医保基金等情况动态调整
河南	2017 年 8 月 11 日	豫人社厅发〔2017〕68 号	2017 年 9 月 1 日	36 个品种的个人自付比例暂定为 20%；新版河南省《药品目录》在 2018 年 1 月 1 日起正式执行。新版《药品目录》发布后，各地再按规定确定乙类药品个人自付比例。
北京	2017 年 8 月 31 日	京人社医发〔2017〕180 号	2017 年 9 月 1 日	医保支付标准包括基本医疗保险基金和参保人员共同支付的费用
陕西	2017 年 9 月 11 日	——	2017 年 9 月 11 日	具体支付比例由各统筹地区确定
安徽	2017 年 8 月 16 日	皖人社发〔2017〕41 号	2017 年 9 月 1 日	按乙类药品支付，限定支付范围按国家规定执行
重庆	2017 年 12 月 22 号	渝人社发〔2017〕266 号）	2017 年 9 月 1 日	各市（州）按照分类管理的原则合理确定医疗保险和参保人员的分担比例
吉林	2017 年 7 月 31 日	吉人社办字〔2017〕55 号	2017 年 9 月 1 日	暂按医疗保险现行支付方式和标准予以支付
辽宁	2017 年 8 月 10 日	辽人社〔2017〕171 号	2017 年 9 月 1 日	自付比例为 30%

各省的自付比例存在一定差异。河南省是全国第一个明确国家谈判药品自付比例的省份，自付比例暂定为 20%。辽宁省对于纳入国家价格谈判的药品，执行

国家谈判价格，不再另行组织谈判议价。一个医疗年度内，每名参保患者限选一家定点供药单位购药，原则上不予变更，参保人员在定点供药单位购药个人先行自付 30%后，职工医保统筹基金按照 80%支付，居民医保统筹基金按照 70%支付。而重庆市规定参保人先自付 10%后纳入医保报销范围。

四川省对于36种药品的自付比例分为两类:对于谈判药品中的20种药品(重组人凝血因子Ⅶa等)不计起付线,实行基本医疗保险统筹基金按药品单行支付,基本医疗保险统筹基金 1 年内为每个参保人员按药品单行支付的药品费用累计不超过 15 万元。例如成都市，对于这 20 种药品，城镇职工基本医疗保险统筹基金支付比例为 70%;城乡基本医疗保险统筹基金为高档缴费人员支付比例为 60%，为低档缴费人员支付比例为 55%。对于另外的 16 种药品（利拉鲁肽等），按照四川省的乙类药品规定执行。例如成都市，对于这 16 种药品，城镇职工基本医疗保险参保人员个人首先支付 10%;城乡居民基本医疗保险参保人员个人首先支付 20%。

C 政策衔接

谈判药品的落地需要地方出台实际的配套政策给予落实和保证,而原有地方政策管理和国家新政策要求之间出现的不一致性需要全方位的政策衔接,包括原大病谈判地区从大病谈判药品转化成目录内乙类药品,谈判涉及品种原有的慈善赠药模式如何妥善解决，需要各省出台相应政策，做好政策衔接工作。为此，甘肃、贵州、山东、四川等省对于政策衔接做出了具体的规定。

甘肃省谈判药品落地执行文件中规定：省人社厅发布的《关于将乳腺癌患者特殊用药纳入基本医疗保险用药支付范围的通知》（甘人社通〔2016〕389 号）和《关于将白血病患者特殊用药纳入基本医疗保险用药支付范围的通知》（甘人社通〔2016〕390 号）中有关药品纳入 36 种国家谈判药品的，自 2017 年 11 月 1 日起按照国家谈判价格执行，原谈判协议自然终止。但截至 2017 年 11 月 1 日，上一捐赠周期尚未结束的患者，仍按原规定执行，在本捐赠周期结束后按照国家谈判价格执行。

贵州省关于《2017 年贵州省基本医疗保险、工伤保险和生育保险药品目录调整工作方案（征求意见稿）》公开征求意见的通知（黔人社厅发〔2017〕22 号）中规定:《贵州省基本医疗保险、工伤保险和生育保险药品目录（2017）》从 2017

年 12 月 20 日起执行。目录执行后，《贵州省基本医疗保险、工伤保险和生育保险药品目录（2010 年版）》以及补充下发的相关文件、《关于慢性粒（髓）细胞白血病门诊特殊治疗实行定额结算的通知》（黔人社厅通〔2016〕143 号）一并废止。

山东省对于原有的大病保险与 36 个谈判药品的衔接做出了相应的规定。对山东省大病保险支付范围现已纳入 2017 年版《国家药品目录》和国家确定的 36 种谈判药品的药品，实行过渡期政策，按原规定执行到 2017 年 12 月 31 日。要求各市对经大病保险支付后的个人自付部分，再按乙类药品政策规定由基本医疗保险基金予以补助，确保参保人员实际待遇水平不降低。具体的过渡办法如下：①地西他滨、达沙替尼、吉非替尼、埃克替尼、重组人凝血因子 IX 等 5 种药品继续按山东省的谈判价格执行；②硼替佐米、来那度胺、厄洛替尼、重组人血管内皮抑制素、贝伐珠单抗、曲妥珠单抗、阿帕替尼等 7 种药品自 9 月 1 日起执行国家谈判价格。以上 12 种药品，参保人自 2017 年 9 月 1 日后购药产生的费用，大病保险支付后的个人自付部分（含起付线）再由基本医保基金给予 50%的补助。过渡期结束后，自 2018 年 1 月 1 日起，这 12 种药品的自付比例为 20%。替诺福韦二吡呋酯纳入省直基本医疗保险乙类药品管理，按基本医疗保险政策规定支付。③关于赠药方案的政策衔接：对使用有慈善捐助（赠药）方案药品的患者，2017 年 9 月 1 日前已使用药品但未进入慈善捐助（赠药）流程的，9 月 1 日起按国家谈判价格购药，并可继续申请慈善捐助（赠药），具体方案以各慈善组织和药品供应商发布为准。

四川省关于执行 36 种谈判药品的文件中规定：四川省 2017 年版基本医疗保险、工伤保险和生育保险药品目录发布前，《四川省基本医疗保险、工伤保险和生育保险药品目录》（2010 年版）及有关补充文件继续执行（2017 年版《国家药品目录》调整时删除的药品不再执行），其中与 2017 年版《国家药品目录》不一致的暂按照我省现行规定执行。在地方执行层面，成都市调出重特大疾病药品目录中与 2017 版国家目录中重叠的 6 个品种、与 36 种国家谈判药品重叠的 8 个品种，由成都市医疗保险经办机构制定待遇衔接办法。

④特殊待遇

A 不计入医保总控和药占比

为了控制医疗费用的增长和促进合理用药 ，国家采取了一系列措施，例如控制药占比、费用总额控制等。《国务院办公厅关于城市公立医院综合改革试点的指导意见》提出：“力争到 2017 年试点城市公立医院药占比（不含中药饮片）总体降到 30%左右。” 国家对医疗收入总额增长幅度进行限制，要求公立医院年医疗收入增长不超过 10%。但是由于 36 个谈判药品中一部分药品价格较高，如果将这些药品纳入药占比、费用总额测算将会阻碍医院引进这些药品，阻碍谈判药品的落地执行。

为进一步保障国家谈判药品临床使用，提高药物可及性，部分省市考虑到谈判药品纳入医保支付初期患者人数尚不确定的情况，为保障谈判药品的临床使用，在合理用药的基础上，国家谈判药品暂不纳入医疗机构药占比和医保总额控制考核。例如，2017 年 11 月 15 日，安徽省卫计委发布《关于加强药品采购使用管理的通知》提出，国家谈判药品暂不纳入医疗机构药占比考核，实行单独核算、合理调控。据统计，截止 2018 年上半年，天津、海南、宁夏等省市均明确国家谈判药品不纳入药占比或单独核算要求，全国已有 22 省/市明确该要求。各省/市关于谈判药品药占比的规定见表 7：

表 7 各省国家谈判药品不纳入药占比药占比或单独核算情况

省份	具体内容
江苏	采购周期内，医疗机构的采购数量暂实行单独核算、合理调控
	人力资源和社会保障部门要做好医保政策衔接，指导医疗机构做好谈判药品结算，维护和保障参保人员权益
浙江	采购周期内，医疗机构的采购数量暂实行单独核算、合理调控
上海	本市医保、卫生计生行政管理部门对参保人员使用相关药品实行定医院、定医生、定指征的“三定”管理，同时在药占比、医保总量考核上与其他药品区别对待，确保合理使用
	考虑到部分药品纳入医保支付初期，因患者人数尚不确定，为切实减轻参保人员药费负担，在合理用药基础上，暂不纳入医院的药占比和医保总控考核
广东	对于医疗机构在采购周期内采购国家谈判药品的相关数据，在合理用药的基础上，我省将在医改等相关考核中暂实行单独核算、合理调控
	药占比=医院药品收入（不含中药饮片收入、国家谈判药品 收入）/医疗总收入×100%
河南	国家谈判药品（包括谈判药品仿制药）和重特大疾病特定药品暂不纳入医疗机构药占比和医保总额控制考核
甘肃	在 2016-2017 年采购周期内，各部门不再组织谈判议价，医疗机构的采购数量可暂实行单独核算，合理调控第一批不纳入药占比
	将国家谈判药品纳入特殊用药管理，首批谈判药品采购周期内，医疗机构的采购数量暂实行单独核算（不占药占比考核），合理调控，且费用不计入住院或

	门诊医保补偿支付限额
	将国家谈判药品纳入特殊用药管理，谈判药品暂不纳入医疗机构药占比考核
陕西	医疗机构的采购数量暂实行单独核算、合理调控
安徽	国家谈判药品暂不纳入医疗机构药占比考核，实行单独核算、合理调控
	在 2016—2017 年采购周期内，不再另行组织谈判议价，医疗机构采购数量暂实行单独核算、合理调控
重庆	采购周期内，市卫生计生委对国家谈判药品暂实行单独核算、合理调控
	国家首批公布的谈判药品采购周期为 2016—2017 年。在采购周期内，市卫生计生委对国家谈判药品暂实行单独核算，各医疗机构统计、填报药占比指标时不计算此 3 个药品
四川	采购周期内，医疗机构的采购数量实行单独核算、合理调控
	36 种国家谈判药品自 2017 年 9 月 1 日起执行。省医保局制定 36 种国家谈判药品补报具体办法，严格补报审核。定点医疗机构在 2017 年产生的 36 种国家谈判药品费用不计入总额控制
吉林	在 2016-2017 年采购周期内，医疗机构的采购数量暂实行单独核算、合理调控
	将 36 种谈判药品纳入特殊用药管理范围，特药纳入医保支付范围初期，因患者人数尚不确定，为切实减轻参保人员药费负担，在合理用药基础上，暂不纳入医疗机构医疗保险总额控制指标考核
辽宁	医疗机构与企业签订采购合同，明确采购数量，按谈判价格直接网上采购。采购周期内，医疗机构的采购数量暂实行单独核算、合理调控
	采购周期内医疗机构的国家谈判药品采购数量暂实行单独核算，即医疗机构在统计用药数量和金额占比时，将国家谈判药品单独进行核算
	各医疗卫生机构要正确理解国家和省有关规定，医疗机构在采购周期内的采购数量单独核算

B 定点药房供给

人社部 54 号文中要求各省要采取有效措施鼓励定点零售药店为参保人员提供药品，发挥药店在医保药品供应保障方面的积极作用。为此各省发布的 36 种谈判药品执行文件中鼓励定点零售药店销售谈判药品，加强对定点药店的协议管理，建立谈判药品供应的“双渠道”，提高谈判药品的可及性。

表 8 全国各省谈判药品流通渠道

省份	政策文件描述
甘肃	鼓励定点零售药店销售谈判药品
江苏	各地要采取有效措施鼓励零售药店为参保人员提供药品，发挥药店在医保药品供应保障方面的积极作用；对在定点零售药店销售的谈判药品，要切实加强对定点零售药店的协议管理
贵州	建立用药备案登记制度,有条件的地区可探索延伸至指定定点药店售药
山东	要采取有效措施鼓励定点零售药店为参保人员提供药品，发挥药店在医保药品供应保障方面的积极作用
辽宁	鼓励定点零售药店为参保人员提供药品
吉林	建立特药定点零售药店管理机制，要逐步创造条件，采取有效措施鼓励定点

	零售药店为参保患者提供特药服务
陕西	对规定需“事前审查后方可使用”或其他需要严格管理的药品，可采取病例实名备案、定医院或零售药店集中供货
青海	参保人员使用谈判药品，可在门诊（定点零售药店）购买

一些地市的门诊（定点零售药店）谈判药品报销政策也正逐步铺开。例如，广东省珠海市的门诊患者可凭医院外购处方到药店自费购药，之后再凭发票到珠海医保中心，按住院待遇享受报销。浙江宁波、台州等则可由系统直接结算，患者只付自付部分。

本课题在对全国 31 个省/市的谈判药品落地情况进行评估时，以各省落地政策和采购政策为政策保障，从落地时的可操作性规定到各省对谈判药品的特殊待遇为落地实施情况的重要参考因素，对全国 31 个省/市谈判药品落地情况进行评价。

在政策保障中包括落地政策和采购政策，打分时以省一级是否有规范文件对落地和采购进行规范，有文件即加分；在落地的具体规定中主要包括：操作细则、规范使用条件、自付比、药占比、医保总额控制、社会药房供给。打分的评价依据分别是省级落地政策中对政策可操作性的规定、省级是否对使用做出规定，如“三定”、“五定”、省一级是否统一自付比、省级是否表明谈判药品不计入药占比考核、省级是否不将谈判药品计入医疗机构的医保总额控费、省级是否为谈判药品开设社会药房供药等。

表 9 落地评价依据及标准

指标	评判依据	合分标准	分值
政策保障			
落地政策	省级是否有规范文件对落地进行规范	有文件记 √	√：11 —：0
采购政策	省级是否有规范文件对谈判药品采购进行规范	有文件记 √	√：11 —：0
具体规定			
操作细则	省级落地政策中对政策可操作性的规定	有规定记 √	√：13 —：0
规范使用条件	省级是否对使用做出规定，如“三定”、“五定”，是否对目录内药品精细化分类管理，并且有详细管理要求	有规定记 √	√：5，3，3，2 —：0
自付比	省一级是否统一自付比	省级规定记 √； 省级无规定，市级有规定记〇	√：13 〇：6.5 —：0

药占比	省级是否表明谈判药品不计入药占比考核	不计入记√	√：13 —：0
医保总额控制	省级是否不将谈判药品计入医疗机构的医保总额控费	不计入记√	√：13 —：0
社会药房供给	省级是否为谈判药品开设社会药房供药	开设记√	√：13 —：0

在满分为 100 分的情况下，落地政策和采购政策作为落地执行情况的基本要素，并且据统计，几乎我国的全部省份都曾出台相关政策文件，所以将政策文件的分值设置的较具体规定项低，有文件则即 11 分。在具体规定项中，6 项具体的规定设置分数统一，为 13 分。其中在部分省/市的自付比相关规定中，出现在省一级文件中未明确自付比，但在省级下设市/区级对自付比作出规定，对于这种情况，对该省评估时，自付比一项记 6.5 分，省级层面明确自付比记 13 分。

在规范使用条件中，若该省份有对国家谈判药品的使用做出规定，则记 5 分，若对谈判药品精细分类管理，分为慢病管理和肿瘤用药管理的，各记 3 分，省级文件中对规范使用条件的“三定”“五定”做出具体细化规定的，记 2 分。规范使用条件一项共 13 分。

表 10 全国 31 个省份医保谈判政策整体执行情况汇总

省份	落地政策 11	采购政策 11	操作细则 13	规范使用条件 13				自付比	药占比	医保总额控制	社会药房供给	总分
				有无（5）	慢病（3）	肿瘤用药（3）	是否细化（2）	13	13	13	13	
西藏	√	√	—	—	—	—	—	—	—	—	—	22
青海	√	√	—	√	—	√	—	√	√	—	√	69
河北	√	√	√	—	—	—	—	√	√	—	—	61
广西	√	√	—	—	—	—	—	—	—	—	—	22
海南	√	√	—	—	—	—	—	√	√	—	—	48
内蒙古	√	√	—	—	—	—	—	—	√	—	—	35
山西	√	√	—	√	—	√	√	—	√	—	—	45
北京	√	√	√	√	—	√	√	—	—	—	√	58
江苏	√	√	√	√	—	√	√	〇	√	—	√	77.5
浙江	√	√	√	√	—	—	—	—	√	—	√	66
上海	√	√	√	√	√	√	√	√	√	√	—	87
山东	√	√	√	√	—	√	√	√	—	—	√	71
甘肃	√	√	—	√	—	√	—	—	√	—	√	56
贵州	√	√	√	√	—	√	—	√	—	—	√	69
广东	√	√	√	√	—	—	—	√	√	—	—	66
陕西	√	√	—	√	—	—	—	〇	√	—	√	59.5

安徽	√	√	—	√	—	—	—	√	√	—	√	66
重庆	√	√	√	√	—	√	√	√	√	—	√	84
四川	√	√	√	√	—	—	—	√	√	√	√	92
吉林	√	√	—	√	—	—	√	√	√	√	√	81
辽宁	√	√	—	—	—	—	—	√	√	—	√	61
河南	√	—	√	√	√	√	√	√	√	√	—	76
云南	√	√	—	√	—	—	—	√	√	—	—	53
福建	√	√	√	√	√	—	—	√	—	—	—	56
黑龙江	√	√	—	√	—	√	—	〇	√	—	√	62.5
湖南	√	√	—	√	—	√	—	〇	√	—	√	62.5
江西	√	√	—	—	—	—	—	—	√	—	—	35
湖北	√	√	√	√	—	√	√	〇	—	—	√	64.5
天津	√	√	√	—	—	—	—	√	√	√	√	87
新疆	√	√	—	√	—	—	—	〇	—	—	—	33.5
宁夏	√	√	√	—	—	—	—	—	√	—	—	48

如表 10，根据以上 8 个指标打分统计后，具有 6 个及以上指标（≥75）的省份为落地执行好的省份，具有 4 个及以上指标（50-74）的省份为落地执行较好的省份，具有 3 个及以上指标（26-49）的省份为落地执行较差的省份，具有 2 个及以下指标（≤25）的省份为落地执行差的省份。

具体省份落地药品执行情况如下：

①落地执行好的省份有：江苏、上海、四川、重庆、吉林、河南、天津；

②落地执行较好的省份有：北京、山东、广东、浙江、青海、河北、甘肃、贵州、陕西、安徽、辽宁、湖南、云南、湖北、福建、黑龙江；

③落地情况较差的省份有：海南、山西、江西、宁夏、新疆、内蒙古；

④落地情况差的省份有：西藏、广西

⑤典型地区谈判药品落地情况分析

在国家出台一系列政策后，地方能否真正贯彻执行是谈判药品能否落地的决定性因素。在落地执行过程中，各省执行情况参差不一，部分省执行较好，例如河南省、江苏省，值得其他省市借鉴和参考。

A 河南省谈判药品落地执行情况

2017 年 8 月 11 日，河南省成为全国第一个明确国家 36 种谈判药品个人自付比例（20%）的省份。截止 2018 年 7 月 3 日，包括 2015 年谈判的 3 种药品，所有 39 种谈判药品已经全部纳入河南省医保支付范围。2018 年 9 月国家针对抗癌药进行专项谈判，将 17 种抗癌药纳入《国家基本医疗保险、工伤保险和生育

保险药品目录（2017 年版）》乙类范围，并确定了医保支付标准，要求各省确保在 11 月底前开始执行。2018 年 11 月 30 日前，按照国家政策要求，河南省将 17 种抗癌药全部纳入药品乙类目录。

a.落地执行政策

河南省为了保障谈判药品落地，发布一系列政策。

表 11 河南省谈判药品落地执行政策

政策规定	文件名	发布日期	具体内容
自付比	河南省人力资源和社会保障厅关于执行国家基本医疗保险、工商保险和生育保险药品目录（2017 版）有关问题的通知	2017-08-08	新增乙类药品（含 36 种谈判药品）的个人自付比例，全省统一暂定为 **20%**；新版《药品目录》发布后，各地再按规定确定乙类药品个人自付比例
规范管理	河南省卫生计生委关于将国家谈判药品纳入新农合报销范围的通知	2016-08-26	定期对参合患者进行必要的检查评估，并根据评估情况合理开具特定药品；每次开具特定药品处方剂量不得超过 **3 个月** 实行特定药品**包装回收**制度：定点医疗机构要建立严格的特定药品管理、登记制度，并设立特定药品专柜
	河南省人力资源和社会保障厅关于印发河南省基本医疗保险、工伤保险和生育保险药品目录（2017 年版）的通知	2017-12-29	将 36 种国家谈判药品纳入《药品目录》乙类范围，和《药品目录》中埃克替尼、达沙替尼、吉非替尼、伊马替尼等肿瘤靶向药作为**特殊用药统一管理**
	河南省人力资源和社会保障厅 河南省卫生和计划生育委员会关于保障国家谈判药品临床使用的通知	2018-07-03	加强谈判药品管理:对用量大、费用高的药品要纳入基本医疗保险医疗服务智能监控系统进行**重点监控**，并做好费用分析
考核指标	河南省人力资源和社会保障厅 河南省卫生和计划生育委员会关于保障国家谈判药品临床使用的通知	2018-07-03	保障谈判药品的临床使用:国家谈判药品（包括谈判药品仿制药）和重特大疾病特定药品**暂不纳入医疗机构药占比**和**医保总额控制考核**

为切实降低肿瘤患者的用药负担，2018 年 11 月 2 日河南省人力资源和社会保障厅印发了《转发国家卫生健康委员会医政医管局关于做好 17 种国家医保谈判抗癌药配备使用工作的通知》，要求全省登记肿瘤科的三级医院和各级肿瘤专科医院，根据临床需求和诊疗能力，及时配备谈判药物，于 2018 年 11 月 30 日

前，落实谈判药品的配备工作。此外，通知强调，各地各单位要认真落实河南省人社厅、河南省卫生计生委《关于保障国家谈判药品临床使用的通知》相关要求，不得以医疗费用总控、医保费用总控、“药占比”等为由影响药品供应和使用，并将药品纳入药品处方集和基本用药供应目录，满足患者用药需求。

b.衔接政策

河南省《关于保障国家谈判药品临床使用的通知》（豫人社函〔2018〕225 号）提出要做好重特大疾病医疗保障与谈判药品使用的衔接。根据谈判药品临床适应症范围，对《河南省人力资源和社会保障厅关于增加河南省重特大疾病医疗保障门诊病种等有关问题的通知》（豫人社办〔2018〕19 号）新增的部分重特大疾病医疗保障门诊病种名称进行如下调整规范：

（一）“HER2 阳性乳腺癌”变更为“乳腺癌”。

（二）“晚期胃癌”变更为“胃癌”。

（三）“Ⅲ/Ⅳ期鼻咽癌”变更为“鼻咽癌”。

（四）“晚期肾癌”变更为“肾癌”。

表 12 重特大疾病医疗保障与谈判药品使用的衔接

原有重特大疾病门诊病种	谈判药品新增	调整后重特大疾病门诊病种范围
HER2 阳性乳腺癌	✧ HER2 阳性的转移性乳腺癌 ✧ HER2 过表达且既往接受过包括蒽环类、紫杉醇、曲妥珠单抗治疗的晚期或转移性乳腺癌 ✧ 芳香化酶抑制剂治疗失败后的晚期、激素受体（ER/PR）阳性乳腺癌治疗	乳腺癌
Ⅲ/Ⅳ期鼻咽癌	✧ 与放疗联合治疗表皮生长因子受体(EGFR)表达阳性的Ⅲ/Ⅳ期鼻咽癌	鼻咽癌
晚期胃癌	✧ HER2 阳性的晚期转移性胃癌 ✧ 限既往至少接受过 2 种系统化疗后进展或复发的晚期胃腺癌或胃-食管结合部腺癌患者	胃癌
晚期肾癌	✧ 不能手术的肾细胞癌 ✧ 接受舒尼替尼或索拉非尼治疗失败的晚期肾细胞癌成人患者 ✧ 不需立即手术治疗的结节性硬化症相关的肾血管平滑肌脂肪瘤（TSC-AML)成人患者	肾癌

B 江苏省谈判药品落地执行情况

a.落地执行政策

江苏省认真贯彻落实国家谈判药品政策，地方各市也积极发文保证谈判药品

顺利落地。

表 13 江苏省各市谈判药品落地执行情况

政策类型	省级文件要求	地方政策	地方政策具体内容
采购政策	《关于做好 36 种谈判药品集中采购工作的通知》（苏卫办药政〔2017〕8 号）：将人社部 36 种谈判药品按医保支付标准在“省医疗机构药品（耗材）网上集中采购与监管平台”直接挂网	南京市《关于做好 36 种谈判药品集中采购工作的通知》（宁医改办〔2017〕17 号）	36 种谈判药品实施直接挂网采购
自付比例	《关于将 36 种药品纳入基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》（苏人社发〔2017〕265 号）：基本医疗保险基金支付比例由各设区市统一确定并报省厅备案	无锡市《关于转发国家基本医疗保险、工伤保险和生育保险药品目录（2017 年版）相关文件的通知》（锡人社发〔2017〕251 号）	除曲妥珠单抗注射剂外的其余 35 种谈判药品自付比例暂定为 50%
规范管理	《关于将有关药品纳入医保特药用药管理的通知》（苏人社发〔2017〕346 号）:实施医保特药“三定”管理	无锡市《关于转发省人社厅将有关药品纳入医保特药用药管理的通知》（锡人社发〔2017〕365 号）	特药治疗使用严格执行定医疗机构、定责任医师、定零售药店“三定”管理
合理用药	《关于将 36 种药品纳入基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》（苏人社发〔2017〕265 号）：各地要积极探索多种形式加强对谈判药品管理，促进合理用药	南京市《关于做好 36 种谈判药品集中采购工作的通知》（宁医改办〔2017〕17 号）	各医疗机构要合理使用谈判药，及时调整本单位肿瘤治疗药目录及临床应用分级管理备案表，报市、区卫生计生行政部门备案
考核指标	《关于做好国家谈判药品集中采购工作的通知》（苏卫药〔2016〕7 号）：规范开展国家谈判药品集中采购。采购周期内，医疗机构的采购数量暂实行单独核算、合理调控	南京市转发省卫生计生委《关于做好国家谈判药品集中采购工作的通知的通知》（宁卫药事〔2016〕3 号）	在采购周期内，采购产品实行单独核算、合理调控

b.政策衔接

江苏省人力资源社会保障厅《关于将有关药品纳入医保特药用药管理的通知》，要求对于 36 种谈判药品中的抗肿瘤分子靶向药，各设区市要做好新老特药待遇政策衔接，统筹设计支付政策。为此，无锡市人力资源和社会保障局发布《关于转发国家基本医疗保险、工伤保险和生育保险药品目录（2017 年版）相关文件的通知》（锡人社发〔2017〕251 号）、苏州市人力资源和社会保障局《关于转发国家基本医疗保险、工伤保险和生育保险药品目录（2017 年版）相关文件的

通知》（苏人保医〔2017〕19 号）都要求：进行特药管理的曲妥珠单抗注射剂（国家目录编号 TX10）和伊马替尼口服常释剂型（国家目录编号西药 801），以及原无锡市医保合作项目吉非替尼口服常释剂型（国家目录编号西药 800），暂按原特药规定执行，其中赫赛汀（注射用曲妥珠单抗）增加治疗 HER2 阳性晚期转移性胃癌适应症。

（3）药品使用情况——患者角度

药品进入谈判目录之后能够按照医保目录乙类进行报销，大大降低了患者的经济压力，但是很多药品在进入谈判目录之前就已经参加了慈善援助项目（PAP），通过优惠和援助项目使药价有所下调，而进入谈判目录之后为了减少药价降低对企业带来的影响，大多数药品都取消原有的援助项目，药品实行国家谈判价格。

经统计，在 16、17、18 三年谈判的 64 个药品中，有 21 个药品在进入谈判目录之前就已经参加了慈善援助项目，而在药品通过谈判进入国家医保目录后，有 20 个慈善项目（见表 14）选择取消原有的援助项目，药品实行国家谈判价格。

表 14 谈判药品原有慈善援助项目

药品名（商品名）	制药企业	项目名称	进入谈判后状态
曲妥珠单抗（赫赛汀）	罗氏	赫赛汀患者援助项目（中国癌症基金会）	停止
贝伐珠单抗（安维汀）	罗氏	安维汀慈善援助项目（中华慈善总会）	停止
厄洛替尼（特罗凯）	罗氏	特罗凯(厄洛替尼)慈善赠药项目（中华慈善总会）	停止
雷珠单抗（诺适得）	诺华	雷珠单抗慈善援助项目（中国初级卫生保健基金会）	停止
尼洛替尼（达希纳）	诺华	格列卫全球患者援助项目（中华慈善总会）	停止
培唑帕尼（维全特）	诺华	维全特患者援助项目（中华慈善总会）	停止
索拉非尼（多吉美）	拜耳	多吉美患者援助项目（中华慈善总会）	停止
重组人干扰素β-1b（倍泰龙）	拜耳	倍泰龙患者援助项目（中华慈善总会）	停止
克唑替尼（塞可瑞）	辉瑞	赛可瑞患者援助项目-（中国癌症基金会）	停止
舒尼替尼（索坦）	辉瑞	索坦患者援助项目（中国癌症基金会）	停止
氟维司群	阿斯利康	芙仕得慈善援助项目	停止

（芙仕得）		（中国妇女发展基金会）	
吉非替尼（易瑞沙）	阿斯利康	易瑞沙慈善援助项目 （中华慈善总会）	停止
硼替佐米 （万珂）	强生	万珂患者援助项目 （中国癌症基金会）	停止
尼妥珠单抗 （泰欣生）	百泰生物	泰欣生鼻咽癌特殊患者援助项目 （青岛专项）	继续
阿帕替尼 （艾坦）	恒瑞	艾坦患者援助项目 （中国医药创新促进会）	停止
西达本胺 （爱谱沙）	微芯生物	西达本胺(爱谱沙)慈善援助项目 （北京仁泽公益基金）	停止
西妥昔单抗（爱必妥）	默克	爱必妥援助项目 （中华慈善总会）	停止
安罗替尼（福可维）	正大天晴	幸福可维—肺癌患者援助项目 （中国初级卫生保健基金会）	停止
伊布替尼（亿珂）	西安杨森	亿迎新生-淋巴瘤患者援助项目 ((中国初级卫生保健基金会))	停止
伊沙佐米（恩莱瑞）	武田制药	恩莱瑞患者援助项目 （中国癌症基金会）	停止
埃克替尼（凯美纳）	浙江贝达	凯美纳免费赠药慈善项目 （贝达药业&中国医药工业科研开发促进会）	停止

而在实行国家谈判价格的同时，暴露出以下问题：①在慈善援助项目的药价对比国家谈判药价，降幅并不明显；②药品从慈善援助项目出来进入谈判目录后，药价反增不降。

①降幅不显著

大多数的国家谈判品种在进入国家谈判目录之前均设有慈善援助项目（PAP），经过国家谈判之后，很多项目便通过取消赠药政策对冲降价影响。有赠药的政策时，药品已经有了一定的降价额度，在药品进入谈判目录之后，企业用药品的原价和医保进行谈判，最终得到的药价相较原价有了很大幅度的下降，但是对比原有优惠政策时的价钱并没有显著的降价幅度。

以国产品种安罗替尼为例进行分析。在降价前存在赠药政策条件下，非低保患者总共自购16盒药品共计99200元后便可获得终身赠药。在降价后取消赠药，则患者依据mOS的年用药费用为92140元，相比于45%的表观价格降幅，潜在实际价格降幅只有7.11%。所以很多药品进入谈判药品目录降价后的价格对患者而言并没有很大的改变。

表 15 安罗替尼取消赠药前后价格降幅对比[7]

项目	数值
规格	12mg/粒
医保支付标准	487 元
日用药量	12mg/粒
每疗程（21 天）用药量（每 2 周停 1 周）	14 粒
中位总生存期 mOS	9.46 月
考虑赠药	
患者年用药费用	99200 元
若取消赠药	
患者年用药费用	92140 元
表现价格降幅	45%
潜在实际价格降幅	7.11%

②药价不降反增

当前在谈判药品落地实施情况中，存在一个很突出的问题，药品进得了医保谈得了价格，但是进不了医院，而患者最终的用药场所大多是医院。在此背景下，很多谈判药在没有谈判之前还能进入医院，并且以赠药的形式销售，患者能够以优惠的价格购买到所需的谈判药品。但在谈判之后，由于药品价格固定，并且存在药占比、医保总额控费等指标的限制，使得原本可以进入医院的谈判药，在谈判之后无法进入医院销售，患者无法以国家谈判的价格购买到药品，只能自费到药店购买，这种现象使患者购药时的药价相较谈判前不降反增。

此外，有部分省/市规定只有住院患者可以报销谈判目录中的药品，患者为获得药品办理住院，额外的住院费也大大加剧了患者的经济压力。

以治疗多发性硬化症的药物倍泰龙为例，倍泰龙曾多次被曝光无法在医疗机构购买到，但早在 2017 年 7 月倍泰龙就进入了国家医保目录，但在一年多后，倍泰龙依然被北京、内蒙古、甘肃、陕西、江苏等省份的医院拒之门外，且由于国家已将药物纳入医保，慈善机构与药企设立的部分患者援助项目也随之暂停，患者只能去药房全额自费购药。

第二次谈判落地过程中，可待改善的方向可总结为以下几点：①部分省份无针对医保目录谈判品种使用、管理的具有可操作性的正式文件（仅采购文件中涉及 36 个品种的说明和招采规定）——西藏等；②部分省份将自付比、限定条件

7 数据来源：药品说明书、医保局、药智网、天风证券研究所

规定职权下放省内各地市，无后续落实或没有在省级层面对相关内容进行规定——黑龙江、西藏、河北、广西等；③部分省份没有对谈判药品的药占比和医保控费等问题进行单独规定——新疆、湖北、甘肃、贵州等；④部分省份零差率后医院进药积极性不高，符合条件的患者也无从买药——普遍存在；⑤而大部分谈判药品报销比例过低——苏州、福建等。综合来看，各省市政策可操作性不理想，加之落地过程中多个环节限制因素过多，导致患者获得感不高。

（三）第三次药品谈判

1 政策背景

2018 年 10 月 10 日，国家医疗保障局发布《关于将 17 种抗癌药纳入国家基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》，公布历时三个月的第三轮国家医保准入谈判结果。

2 谈判成效

（1）成功率

本次抗癌药准入专项谈判包括 18 个品种，最终除了诺华制药的芦可替尼片（捷恪卫）以外，17 个品种成功纳入医保目录，成功率达 94.1%。该 17 个品种有 11 个是 2017 年以后批准上市的新品。尤其是国产创新药品安罗替尼于 2018 年 5 月刚获批上市，9 月底即纳入国家医保报销目录，其医保准入周期仅为 4 个月，效率远高于发达国家平均 15 个月的水平。

（2）价格降幅

谈判纳入 17 种药品，平均降幅达 56.7%，最高降幅达 71%，大部分进口药品谈判后的支付标准低于周边国家或地区市场价格，平均低 36%左右。部分药品情况见表 16。

表 16 谈判药品中 8 种降幅超过 65%的药品情况

药品名称	生产企业	规格	谈判前价格	医保支付标准	降幅
西妥昔单抗	默克	100mg(20ml)/瓶	4240 元	1295 元	69.46%
阿昔替尼	辉瑞	5mg/片 1mg/片	708 元 207 元	207 元 60.4 元	70.76%
奥希替尼	阿斯利康	80mg/片 40mg/片	1760 元 1035 元	510 元 300 元	71.02%
克唑替尼	辉瑞	250mg/粒 200mg/粒	892 元 752 元	260 元 219.2 元	70.85%
尼洛替尼	诺华	200mg/粒 150mg/粒	300 元 241 元	94.7 元 76 元	68.46%

培唑帕尼	诺华	400mg/片 200mg/片	782 元 460 元	272 元 160 元	65.22%
舒尼替尼	辉瑞	50mg/粒 37.5mg/粒 25mg/粒 12.5mg/粒	1353 元 1085 元 796 元 468 元	448 元 359.4 元 263.5 元 155 元	66.88%
伊布替尼	西安杨森	140mg/粒	540 元	189 元	65.00%

3 谈判过程

（1）谈判流程

来自全国 20 个省份的 70 余名相关领域专家，认真高效地完成了品种遴选、临床疗效评估、经济学评价、未来基金使用测算与预算影响分析，并经最终现场谈判等多个关键环节。

①企业报送材料：企业按要求报送药品基本信息、疗效价格等方面资料。

②专家评估：国家医保局通过两组平行评估的方式从药物经济性和基金支撑能力两方面对谈判药品开展评估：一组是基金测算组，在充分利用 2017 年上一轮药品谈判中调取和收集的医保数据基础上，在很短的时间内又补充了 21 个统筹地区的最新数据，前后涉及 26 个省份 68 个统筹地区，共 1.7 亿条基础数据。此次谈判还引入了国际通行的评估方法，采用成本效用等药物经济学方法测算药品进入国家目录后的预期支付标准，并就销量增加情况作出定量预测。

③价格谈判：医保经办机构另行组织谈判专家与企业进行谈判。

（2）谈判亮点

此次谈判为药品供方强化了新的价值导向，即新药研发要以其临床价值、经济效率（成本效果）价值和基本医保基金可负担价值为导向，实现了医保作为服务购买者角色定位下的政策联动、行政职能联动和利益相关方联动。

（四）三次谈判的对比与思考

1 三次谈判情况对比

三次谈判情况的对比见表 17。

表 17 三次谈判总体情况对比

时间	谈判主体	成功率	平均降幅	谈判过程
2015	卫计委	60% （5 进 3）	59%	①国家卫计委牵头建立药品价格谈判指导委员会，并建立国家药品价格谈判专家库和药品价格信息库 ②程序包括制定谈判方案、成立谈判小组、遴选谈判药品、发布谈判公告、生产企业递交相关技术资料和其它材料、谈

				判、结果公布、组织采购、配送和结算、价格监测
2017	人社部	81.8% （44 进 36）	44%	①人社部成立了专门的工作组和监督组负责承担具体工作和开展全程监督，并组织专家与相关企业进行了谈判 ②程序包括制定严谨周密的谈判规则：如明确谈判成功的药品纳入药品目录乙类范围，全国统一执行谈判确定的医保支付标准 ③组织专家开展评估测算：两个完全独立的评估专家组，分别从药物经济性和医保基金承受能力两方面开展评估测算 ④按照规定程序谈判：谈判企业随机分组；监督组现场进行监督、谈判全程录像；工作组现场根据药学组、医保组预估的支付标准来确定最终的医保预期支付价格，同时用信封密封后专人送达谈判现场
2018	国家医保局	94.1% （17 进 16）	56.7%	①来自全国 20 个省份的 70 余名相关领域专家，认真高效地完成了品种遴选、临床疗效评估、经济学评价、未来基金使用测算与预算影响分析，并经最终现场谈判等多个关键环节 ②“企业报送材料”：企业按要求报送药品基本信息、疗效价格等方面资料→“专家评估”：专家团队从药物经济性和基金支撑能力两方面进行评估，提出评估意见→“价格谈判”：医保经办机构另行组织谈判专家与企业进行谈判

2 谈判药品都取得了较好的降价成效，并逐步发挥联动作用

首轮谈判药品品种非常有限，很难对同类药物的价格降低起到影响作用，第二轮谈判的品种数量激增，第三次谈判后“4+7”带量采购紧跟出台并实施，逐步发挥联动作用。

医保管理部门的精力有限，无法与众多厂家一一谈判，因此只能选取部分迫切需要的具有代表性的品种进行谈判，然后通过谈判药品的联动作用引导市场竞争机制，从而带动整个药品价格的革新，理顺现有药品价格体制。

3 政府和企业在三次谈判中积累了较好的谈判经验

（1）牵头主体的变换

首轮国家药品价格谈判由卫计委牵头，其优势在于拥有公立医院的销售渠道与药占比的把控权。第二次谈判由人社部牵头组织，其谈判力则在于医保准入与报销[8]。第三次谈判由新一轮机构改革中新成立的国家医疗保障局组织完成。其整合了三大职能，包括监督医保相关的医疗行为的监督职能，管理三大医保的支付职能和制定药品、医疗服务的价格和收费标准以及招标政策的定价职能，拥有更大的战略购买力，议价能力更强。

8 丁锦希, 陈烨, 李伟, 郑翠微, 董锐. 专利药国家谈判落实情况分析[J]. 中国医药工业杂志, 2017, 48(06): 910-917.

通过三次谈判情况的对比，发现牵头谈判主体的不同在一定程度上影响了谈判情况。从卫计委、人社部到医保局，前两次谈判中谈判主体和执行主体不统一，即药品的最终采购权和处方权不在谈判牵头主体手中，而主要掌握在医疗机构，这些地位不对等和信息不对称等因素，导致政府谈判优势未能有效整合。而后两次谈判工作由医保的主管部门牵头，相比第一次谈判更有利于工作的开展和落地的实施。由此发现，第三次国家医疗保障局组织的抗癌药准入专项谈判由于落地保障力度更为权威和说服力，谈判效果更为显著。

（2）谈判主体积极性越来越强，谈判药品迎来发展契机

随着全民医保制度的完善，各地医保的城乡一体化统筹加快，医保经办机构在谈判中的筹码也在增加，在谈判时更有底气，而对于药企而言，谈判药品类别和品种数量逐步扩大，销量普遍大幅增长也使得其积极性越来越强。专家普遍认为国家政策对医保药品谈判起到了明显的支持作用[9]。近年来，国家多次在医改重大文件中提倡和鼓励各地医保经办机构与医药供应方通过谈判建立共付机制，这推动着各地进行医保谈判探索实践。大病医保的全国推行、国家药品谈判的逐步开展、医保支付方式改革等多项新医改政策的实施，为谈判药提供了发展契机。

4 谈判制度、程序不断规范，在谈判实践中发现问题并尝试解决问题

（1）国家药品谈判规则愈加规范化

与后两次谈判相比，首轮谈判过程透明度欠缺。16 部委联合委员会的定价原则、药企在谈判中呈送的文件数据、评估专家成员情况、评估标准及意见、联合委员会和药企双方谈判具体过程等信息透露甚微[10]。再加上可操作性的落地保障不明确，故后期出现了与医保衔接不紧密而导致谈判结果在各地落实参差不齐的问题。部分省份由于担心医保支付的巨大负担，阻碍了谈判药的医保纳入进程。

通过三轮谈判实践可以发现，确定、合理且适当的谈判规则有利于保障谈判工作的高效和有序开展，同时也有益于保障各方主体的参与积极性，充分沟通相互诉求。

（2）谈判决策依据愈加科学

9 张湛, 杨建卫, 梁永晴, 陈唯, 夏苏建. 我国现行药品医保谈判机制的 PEST-SWOT 分析[J]. 医学与社会, 2017, 30(06): 30-33.

10 杨嵌, 王宝云, 王世宇. 关于我国药品价格谈判机制的研究[J]. 中药与临床, 2017, 8(04): 53-56+52.

2017 年人社部主导的医保药品谈判开创性地引入了 HTA 方法，鼓励企业采用药物经济学方法测算药品进入国家目录后的预期支付标准，并就销量增加情况作出定量预测[11]。2018 年抗癌药品医保支付标准评估过程则更加科学。在充分利用上一轮药品谈判中调取和收集的医保数据基础上，在很短的时间内又补充了 21 个统筹地区的最新数据。并且谈判还引入了国际通行的评估方法，采用成本效用等药物经济学方法测算药品进入国家目录后的预期支付标准，并就销量增加情况作出定量预测。

5 谈判药落地现存问题分析

（1）各环节法律法规

①药品上市准入

2013 年，前食药监总局发布《国家食品药品监督管理局关于深化药品审评审批改革进一步鼓励药物创新的意见》，表明要优化审评资源配置，改善创新药审评环境，调整仿制药审评资源的态度。

2015 年，国务院发布《国务院关于改革药品医疗器械审评审批制度的意见》，提出简化药品审批程序，改进药品临床试验审批，加快创新药审评审批，解决注册申请积压，并且开展药品上市许可持有人制度试点工作。

2015 年，前食药监总局发布《关于开展药物临床试验数据自查核查工作的公告》，要求申请人对已申报生产或进口的待审药品注册申请药物临床试验情况开展自查，保障上市药品的质量。

2015 年，前食药监总局发布《食品药品监管总局关于进一步规范药品注册受理工作的通知》，要求严格进行形式审查和现场检查，保证药品上市企业的产品质量过关。

2016 年，国务院发布《关于印发药品上市许可持有人制度试点方案的通知》，2017 年前食药监总局发布《总局关于推进药品上市许可持有人制度试点工作有关事项的通知》，在 10 个省和直辖市开展药品上市许可持有人制度试点工作，规定申请人和持有人条件与义务，受托生产企业条件与义务。进一步放开委托生产，允许批准文号转移，并且简化审批程序。

11 伍琳, 陈佳妮, 雷媛, 厉琴慧, 陈永法. 构建专利药价格谈判利益平衡机制的路径选择——基于德国、英国、韩国等典型国家药价谈判机制的启示[J]. 价格理论与实践, 2018(03): 83-86.

2016 年，国务院发布《关于开展仿制药质量和疗效一致性评价的意见》，明确评选对象和参比制剂，加强对一致性评价的管理，以保障上市仿制药的质量。

2017 年，前国家食药监发布《总局关于鼓励药品创新实行优先审评审批的意见》，将 7 种具有明显临床价值的药品注册申请列入优先审评审批范围，将防治罕见病和多发的疾病且具有明显临床优势的药品注册也列入优先审评审批范围。并对优先审评审批程序做出详尽规定，对各环节给出明确时限。给药品加速上市提供具体的操作指南。

2018 年，国务院发布了《国务院关于在全国推开“证照分离”改革的通知》，药监局同时也发布《关于贯彻落实国务院“证照分离”改革要求做好药品监管相关审批工作的通知》，明确要简化流程，优化审批服务，推进备案制，加强事中事后监管，加快药品上市。

2018 年，国务院印发《国务院办公厅关于印发深化医药卫生体制改革 2018 年下半年重点工作任务的通知》，要求有序加快境外已上市新药在境内的上市审批工作。

②药品医保准入

2016 年，前国家卫计委发布《国家卫生计生委办公厅关于公布国家药品价格谈判结果的通知》，要求鼓励优先采购和使用谈判药品，并且要求各地方政府进一步巩固完善医保制度和支付方式，抓紧做好与相关医保政策衔接工作。

2017 年，国务院印发《“十三五”深化医药卫生体制改革规划的通知》，要求增加国家药品价格谈判品种的数量，做好价格谈判与医保等政策的衔接。

2017 年，人力资源社会保障部发布《关于将 36 种药品纳入国家基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》，将利拉鲁肽注射剂等 36 种药品纳入医保目录乙类范围，并要求各省市做好落实工作。

2018 年，国务院印发《国务院办公厅关于印发深化医药卫生体制改革 2018 年下半年重点工作任务的通知》，要求对医保目录外的独家抗癌药推进医保准入谈判工作。

2018 年，国家医疗保障局印发《关于发布 2018 年抗癌药医保准入专项谈判药品范围的通告》，明确来自 12 家公司的 18 个品种纳入抗癌药医保准入专项谈判范围。

2018 年，国家医疗保障局印发《关于将 17 种药品纳入国家基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》，将经过谈判的 17 种抗癌药纳入医保报销目录，降低肿瘤患者的经济负担，并要求各省做好落实工作。

③药品流通采购

2015 年，国务院印发《国务院办公厅关于完善公立医院药品集中采购工作的指导意见》，要求根据药品供应保障情况实行分类采购，对不同药品分别采取双信封制公开招标采购、谈判采购、医院直接采购、定点生产等方式，拓展省级药品集中采购平台功能。以破除以药补医机制，降低药品虚高价格，减轻人民群众用药负担。

2016 年，国务院 8 个部门联合发布《关于在公立医疗机构药品采购中推行“两票制”的实施意见（试行）》，明确两票制的界定，并且要求公立医疗机构严格执行药品购销票据管理规定，推进两票制的落实并加强监督，以降低虚高药价。

2016 年，国务院办公厅发布《深化医药卫生体制改革 2016 年重点工作任务的通知》，要求全面推进公立医院药品集中采购。推广地方经验做法，鼓励和引导省际跨区域联合采购，综合医改试点省份内部可鼓励在一定区域间进行带量联合采购。通过集中采购降低药品、器械、耗材等费用。

2016 年，国家卫计委、发改委、工信部、人社部等多部委联合发布《关于做好国家谈判药品集中采购的通知》，要求做好国家谈判药品的集中采购工作，扩大谈判药品试点范围，降低药品虚高价格，减轻群众用药负担。并且将国家药品价格谈判结果在省级药品集中采购平台上公开挂网，明确采购数量。

2017 年，国务院印发《“十三五”深化医药卫生体制改革规划的通知》，要求坚持集中带量采购原则，推进实施公立医院药品分类采购，培育集中采购主体，鼓励跨区域联合采购和专科医院开展药品、高值医用耗材等联合采购。并且要求试点省份和医疗机构落实两票制，降低虚高药价。

2018 年，国家医保局发布《关于召开药品集中采购工作座谈会的通知》，传达将对医保目录内抗癌药实施省级专项采购，以及国家组织开展药品集中采购试点工作的动向。

2018 年，医保局和卫健委发布《关于开展抗癌药省级专项集中采购工作的通知》，要求以抗癌药为重点，对重大疾病药品进行专项集中采购工作，通过集

中带量采购降低价格，缓解群众用药负担。

2018 年，上海阳光医药采购网经国家医保局同意，发布《4+7 城市药品集中采购文件》，表明国家组织药品集中采购试点，以 4 个直辖市和 7 个省会城市为试点，对 31 个品种的药品进行约定采购量采购，进一步推动集中带量采购在国内的运行，并要求医疗机构须优先使用集中采购中选品种，确保完成 4+7 城市药品集中采购文件约定采购量。

④药品临床准入

2011 年，人社部发布《关于进一步推进医疗保险付费方式改革的意见》，要求各地政府按照基金支出总额，确定对每一种付费方式的总额控制指标，根据不同定点医疗机构级别、类别、特点以及承担的服务量等因素，落实到每一个定点医疗机构。结合基金预算管理加强付费总额控制。

2012 年，人社部发布《关于开展基本医疗保险付费总额控制的意见》，要求结合基本医疗保险基金预算管理的全面施行，开展基本医疗保险付费总额控制。加强和完善基金预算管理，合理确定统筹地区总额控制目标。

2015 年，国务院发布《关于城市公立医院综合改革试点的指导意见》，要求运用多种方法破除以药养医机制，严格控制医药费用不合理增长，力争到 2017 年试点城市公立医院药占比总体降到 30%左右。

2015 年，卫计委、发改委、人社部发布《关于控制公立医院医疗费用不合理增长的若干意见》，要求要有效控制公立医院医疗费用不合理增长，减轻群众医药费用负担。加强医疗费用监管，强化医疗机构内控，降低药品耗材虚高价格。

2016 年，国务院办公厅印发《深化医药卫生体制改革 2016 年重点工作任务的通知》，要求巩固公立医院取消药品加成的改革成果，新增试点城市所有公立医院取消药品加成。通过医保控费方式来降低药品、器械、耗材等费用，严格控制不合理检查检验费用，为调整医疗服务价格腾出空间。严格控制医疗费用不合理增长。对辅助性、营养性等高价药品不合理使用情况实施重点监控，初步遏制医疗费用不合理增长的势头。

2016 年，前卫计委发布《关于尽快确定医疗费用增长幅度的通知》，要求各省市根据当地医疗水平，确定本地区年度医疗费用增长幅度。根据费用指标监测结果，对本地区医院医疗费用增长情况进行排序。控费目标实行动态管理，每年

调整一次。力争到 2017 年底，全国医疗费用增长幅度降到 10%以下。

2017 年，国务院印发《“十三五”深化医药卫生体制改革规划的通知》，要求各省设定年度医疗费用增长控制目标，2017 年，全国公立医院医疗费用平均增长幅度控制在 10%以下。落实处方点评等制度。指导地方对辅助性、营养性等高价药品列出具体清单，实施重点监控。2017 年 9 月底前全面推开公立医院综合改革，所有公立医院全部取消药品加成。

2018 年，人社部发布《关于发布医疗保险按病种付费病种推荐目录的通知》，通过按病种控费，医院将主动控制成本，辅助用药大幅承压，达到控费的结果。合理制定医保付费病种支付标准，扎实做好费用结算工作。

2018 年，卫健委发布《关于做好 17 种国家医保谈判抗癌药配备使用工作的通知》，要求医院不得以医疗费用总控、医保费用总控、“药占比”和药品品种数量限制等为由影响谈判药品的供应保障与合理用药需求。同时，医院要按照有关诊疗规范、指南等合理使用谈判药品，提高合理用药水平。17 个谈判抗癌药不受药占比、医保费用总控等的限制。

2018 年，卫健委发布《关于做好 17 种国家医保谈判抗癌药执行落实工作的通知》，保障谈判药品的正常供应，确保患者可以用到纳入医保目录的谈判品种，不得以费用总控、“药占比”和医疗机构基本用药目录等为由影响谈判药品的供应与合理用药需求，做好谈判药品的供应保障工作。

（2）落地情况实证研究

①法律实证研究

所谓实证研究，即用客观得到的事实，来印证某个假设或者另外一个事实。更多地观察实际发生的事情，而并非去设想应当发生的或者理论上会发生的事情。而法律中的实证研究，立法者希望通过法律达到的效果，有时存在与现实中真正达到的效果出现偏差的情况。因此需要通过实证研究，将实际效果与应当想得到的效果靠近，以防止立法者出现立法“唯我”的心态。从某种角度来看，法律是自变量，而社会则是因变量，立法就相当于是一种法律试验，需要对因变量进行总结分析，再分析自变量的科学性。本报告也将通过对以上法律法规实际落地效果进行总结，来分析法律法规的科学性。

②药品上市

在药品上市方面，首先实行 MAH 制度试点，在北京、天津、河北、上海、江苏等 10 个省市进行试点，截至 2017 年 10 月，试点省市共受理试点品种各类申请共计 560 件,已完成审批 128 件，占 23%；已受理和正在审评审批的有 428 件，占 77%。缩短药品上市周期，减少重复建设，虽然还存在委托方受托方责任让渡问题和科研积极性需要进一步提高的问题，但试点仍有初步的成效，需要完善相配套的法规。

开展仿制药一致性评价与临床数据自查核查主要是为了保证上市药品的质量。截至 2018 年 11 月，289 目录品种一致性评价，仅有 105 个品种通过一致性评价，成果并不理想，证明我国在上市药品的质量方面还有很大的改进空间。而最新的 4+7 带量采购，将通过一致性指标作为硬指标，可见在今后，质量将会成为药品上市重要的一环。而在临床数据核查上，齐鲁制药、正大天晴、石药集团、浙江华海、恒瑞医药、江苏豪森自查的受理号数大于 10，一致性评价中，截至目前，通过仿制药一致性评价或视同通过仿制药一致性评价的 105 个品种中通过企业达 3 家及以上品种的已有 6 个，比如浙江华海。可以看出，一些制药企业确实在一致性评价和临床数据自查核查政策下重视自身质量，脱颖而出。

在审评方面，根据 2017 年药品审评报告，截至 2017 年底，药审中心共将 25 批 423 件注册申请纳入优先审评程序，IND 申请、NDA、ANDA 首轮审评平均用时分别为 39 个工作日、59 个工作日和 81 个工作日，化药各类注册申请审评审批用时显著下降，基本解决了仿制药注册申请积压的问题。2018 年 4 月，又有 24 个品种纳入优先审评名单，其中包括了 HPV 疫苗。可见关于加快审评流程，国家的法律法规是着实有效的，并且其程序设定具备一定的科学性。综上，政府希望药品上市能做到速度加快并且质量有所保障，在药品上市环节的法律政策都有一定成效，证明其具有科学性。

③纳入国家医保

在谈判品种纳入医保的效果方面，首先从国家方面看，2016 年 5 个品种 3 个谈判采购，2017 年 44 个品种中 36 个谈判成功进入目录，2018 年 18 个品种有 17 个进入目录，极大的扩充了医保目录药品的种类与范围，并且也保证了一定的降幅。而各省的推广，主要指标就是看各省的落地情况。对于 2017 年谈判进入目录的 36 个品种，自国家发布将 36 个品种纳入医保目录后，全国各地加速

36 个谈判品种的落实。截至 2017 年 9 月，安徽、北京、河南、福建、湖北等 19 省份明确了谈判品种纳入各省医保目录的办法。安徽、河北、河南、福建 4 省均明确了 36 个品种的自付比例，黑龙江已经着手于谈判品种的挂网采购。2017 年 10 月，36 个品种在全国各省全部落地。而 2018 年纳入国家医保的 17 个品种，截至 2018 年 11 月 7 日，福建、四川、新疆、浙江、湖南、天津、内蒙、辽宁均已开始执行将 17 个品种纳入当地目录，另外还有包括江苏、北京、河南等 13 个省份确定具体执行日期。因此，将谈判品种纳入医保，并要求各省分别纳入自己的医保目录，这一做法是具有可行性的。

④药品采购

纵观国家近几年发布的采购政策，无疑都是希望集中采购，保证采购药品的数量，降低虚高药价，达到以量换价的效果。此外，推行两票制是希望精简流通环节，降低虚高药价。4+7 要求必须做好一致性评价，之前的双信封招标也强调有“质量标”。因此国家的目的在于保证采购药品质量的同时尽可能压低药价。然而，双信封的实际情况便是“安徽模式”唯低价是取，造成药品质量风险。因此，带量采购的一大优势就在于将一致性评价作为门槛，保证参与招标的仿制药质量。希望在低价的前提下把握质量底线。本次集中采购，拟中选价平均降幅达到 52%，最高降幅达到 96%，原研药吉非替尼片降价 76%，福辛普利钠片降价 68%。恩替卡韦降价 90%，恒瑞厄贝沙坦降价 60%。京新药业氨氯地平降价至 0.14 元，正大天晴恩替卡韦分散片降价至 0.62 元。所以从降价这方面看，集中采购确实做到了在北京、上海、天津、重庆、广州、深圳、沈阳、大连、西安、成都、厦门等 11 个城市的药价大幅下降。虽然达到了降价的目的，但是同样也使一致性评价的溢价荡然无存，药企的利润空间遭到进一步的压低。此外，药品的临床用量需要根据具体情况来定，因此量的确定并不一定是实际需要的量。带量采购推行以来，医药股大幅下跌，因此从长远来看，带量采购虽然从一定程度上能达到降价和质量保障，但是长远来讲不利于药企的生存，政策的推行还需要进行调整，使之更具科学性。

⑤进入医院临床使用

国家采取了一系列政策来控制医疗费用不合理增长，如零差价、总额控费、设立药占比指标等，总额控制抑制了医疗费用的过快增长，医保基金支出增幅持

续大幅下降。根据数据，我国医院的药占比从 2008 年的 50%下降到了 2016 年的 39%。江苏省 2004 年至 2016 年药占比逐渐下降，但是医疗总费用仍保持上升。医保总额控费实际上效果不佳，2017 年，根据国家卫计委体改司通报，四川公立医院总医疗费用平均增长幅度为 13.15%，与国家 10%要求目标差距较大，位列全国倒数。此外，总额控费还造成有医院推诿病人的情况出现，而药占比，反而是让一些“中国神药”占据了医保基金,从而无法达到控费的作用。不仅如此，药占比还会限制一些高价药在医院的配备情况，比如倍泰龙。这些都与设立控费的初衷相违背，证明在医疗控费这一环节，政策仍需要修改的更具科学性。

为了防止谈判品种受到药占比等控费政策影响，多个省份发文要求松绑药占比，国家也发文要求 17 种谈判药品费用不纳入总额控制范围。截至 2018 年 7 月，23 个省明确发文提出对国家谈判药品实行单独核算、不纳入药占比统计。同时，2018 年 7 月，湖南医改小组发布通知，对纳入基本医保支付的国家谈判的药品以及该省大病保险谈判的药品采取协议定点医疗机构和定点特药零售药店“双通道”购取药模式。在很多已发文的省存在省级发文表明谈判药品不占药占比，但在各市具体落实中存在不落实或难落实的情况。安徽省 16 市，其中芜湖市和阜阳市在公开网站表明将落实省级不占药占比规定，其余均未发文。广东省 19 市，其中佛山市在公开网站表明将落实省级不占药占比规定，其余均未发文。因此在市一级落实情况并不好，基于这一事实进行实证分析，国家对于不纳入药占比与总费，需进一步制定配套政策，要保证地方上的落实，加强中间监管。

综上所述，三次药品价格谈判的存在问题可以总结为图 5 所示。

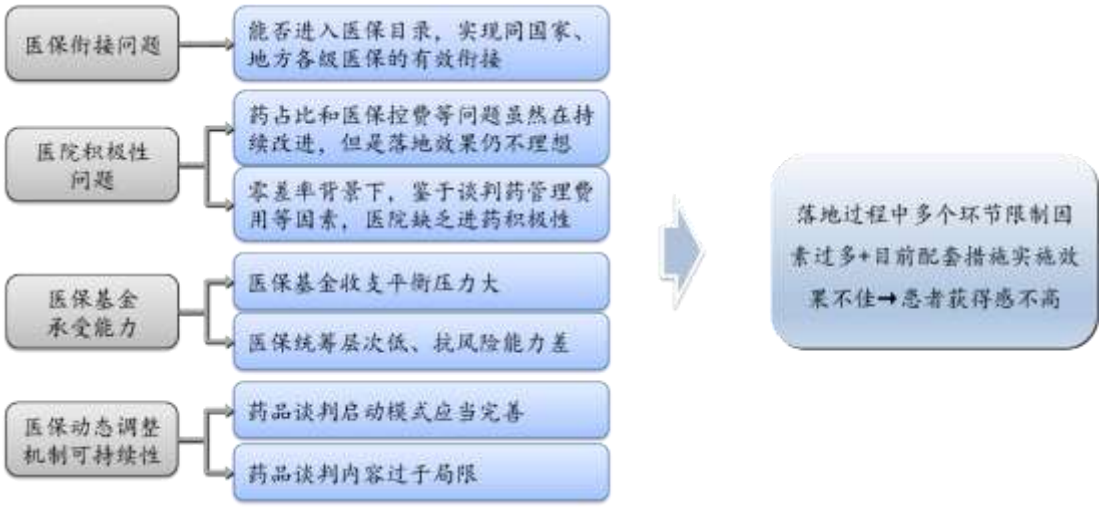


图 5 三次药品谈判核心问题

第三章 三次药品谈判核心问题分析

一、医院积极性不高

在谈判药品落地环节，首先面对的核心问题即医院积极性不高。患者在医院无法购买到谈判药品，其主要原因是：①药品零加成政策使得药房成为成本部门，增加仓储管理成本；②药占比、总额控费等考核指标限制医院开出谈判药处方；③医院药事管理委员会每年开会次数有限，药品进入医院需要一段等待期，并且每次开会调整品种较少，抗癌药调整品种尤其有限。

对应上述问题，课题组应用“三因素”理论进行研究。

针对积极性不高的问题，美国心理学家赫兹伯格 1959 年提出双因素理论（two factor theory），又称“激励—保健理论”。他把企业中有关因素分为两种，即满意因素和不满意因素。满意因素是指可以使人得到满足和激励的因素，即激励因素。激励因素与工作本身或工作内容有关，包括成就、赞赏、工作本身的意义及挑战性、责任感、晋升、发展等。不满意因素是指容易产生意见和消极行为的因素，即保健因素。保健因素的内容包括公司的政策与管理、监督、工资、同事关系和工作条件等。

我国著名心理学家俞文钊教授在赫兹伯格的基础上提出更加适合我国文化激励的三因素理论，又称激励与去激励因素连续带模式，包括激励、保健、去激励理论。他认为激励与去激励因素存在于连续的两个端点，其间还存在着许多强弱不等的激励形式，共同构成了一个连续带，保健因素位于激励去激励连续带的中间和过渡地带。

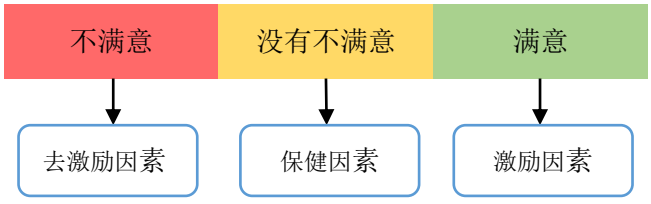


图 6 满意度与三因素对应图

在三因素理论中，这三个因素是可以统一区分的。激励因素引起强或较强激励，在职工心理上引起满意感，保健因素引起弱或较弱激励，在职工心理上引起的是没有不满意感，而去激励因素，则引起职工的不满意感，保健因素不是一个孤立的因素，位于激励、去激励连续带模式的中间过渡区。

表 18 三因素理论内涵

激励因素	保健因素	去激励因素
引起人们的满意感	不使人们产生不满意感	引起人的不满意感
提高人的积极性	保护人的积极性	使人的积极性降低
使工作效率提高	不会使工作效率提高	使工作效率降低

基于三因素理论，在谈判药品落地过程中，可以将药占比、总额控费、仓储成本等因素视为医院积极性不足的去激励因素；医院等次、级别、科室发展、医生的薪酬待遇等可视为保健因素，维持当前现状不会使得医院提高积极性，也不会产生消极情绪；目前暂无任何激励因素。

二、医保基金承受能力问题

（一）医保基金收支平衡压力大

虽然全国医保基金当年结余率一直保持稳定的增长水平，但是近几年来基本医保基金累计结余持续出现负增长，风险逐渐显现，2011 年上海和北京城镇职工医保基金都已出现收不抵支。中国社科院一项有关测算也表明，城镇职工医保将在 2017 年出现普遍赤字，也就是二线以上城市的城镇职工医保基金将无法做到当年平衡[12]。据医学界智库数据显示，我国不合理用药现象严重浪费医保基金。

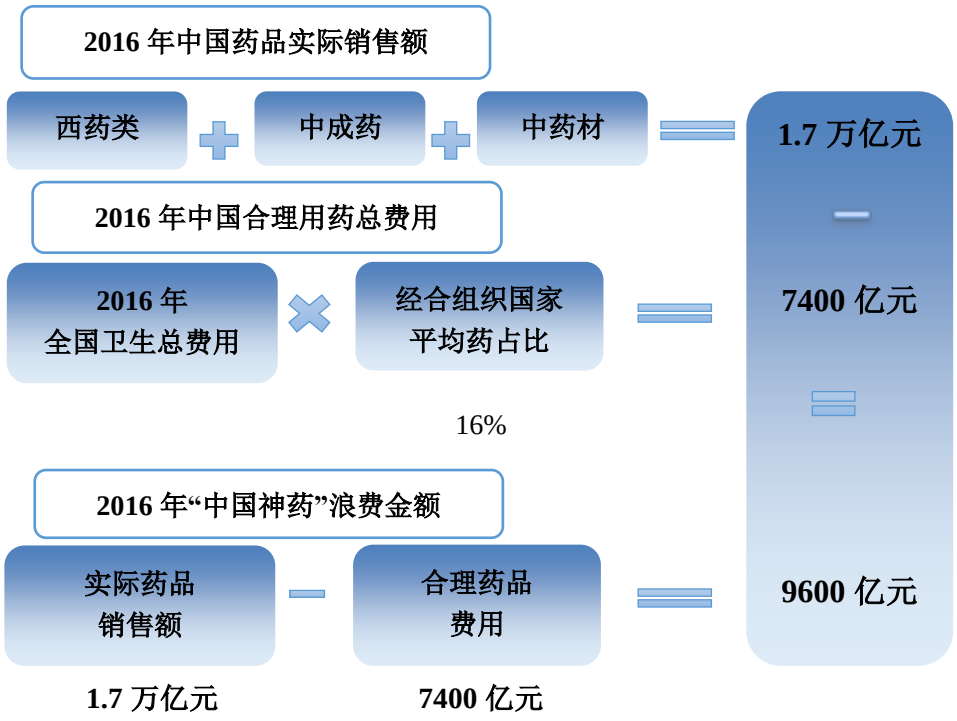


图 7 我国不合理用药现象严重浪费医保基金

12 罗健，方亦兵．我国基本医疗保险基金的抗风险能力与影响因素[J]．求索，2013(03): 264-266.

通过对 28 个省、166 个市和 569 个县（市、区）2015 年和 2016 年上半年的基金管理使用情况进行抽查，调查了 3715 个定点医疗机构、2002 个定点零售药店以及其他相关单位，具体抽查查情况如下：

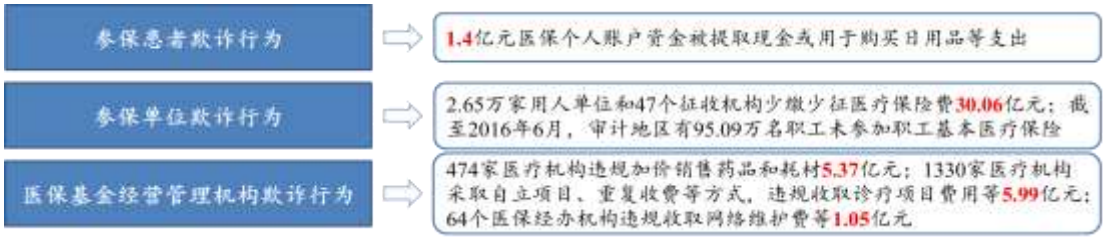


图 8 医保基金欺诈行为统计

（二）医保统筹层次偏低

1 概述

基本医疗保险，是一项用于补偿劳动者因疾病风险所导致经济损失的社会保险制度，其内涵为国家或社会在国民受到疾病损伤后，对其提供医疗服务或经济补偿。1998 年，我国颁布《关于建立城镇职工基本医疗保险制度的决定》，开始建立城镇职工基本医疗保险制度。而目前，我国主要的的基本医疗保险制度为城镇职工基本医疗保险制度、新型农村合作医疗制度和城镇居民基本医疗保险制度。截至 2017 年 10 月，根据人社部的报导，我国基本医保的覆盖人数已经超过 13 亿。实施基本医疗保险制度，不仅能调节收入差别，维护社会安定，推动社会文明进步，还能间接提高劳动生产率，促进生产的发展。

基本医疗保险基金原则上实行地市级统筹，覆盖城镇所有用人单位及其职工，也有部分省份在探索省级统筹的方式。医保在某个地区实现统筹的标志，就是能够做到在该地区缴费与待遇政策、医保基金的调剂使用，服务网络和经办流程都做到统一。而目前我国三种基本医疗保险的统筹级别均为区县级统筹，近年来逐步提高向市级统筹甚至省级统筹迈进，但推进速度较慢，各地区进展不同，在险种方面也未达成统一。对此，国家也在 2009 年发布的《中共中央国务院关于深化医药卫生体制改革的意见》中提出，基本医疗保险要“随着经济社会发展,逐步提高筹资水平和统筹层次,缩小保障水平差距,最终实现制度框架的基本统一”。

2 统筹层次低所带来的问题

（1）劳动力的流动受限制

在我国城镇化飞速发展的大环境之下，人口与劳动力的流动越来越频繁。而与之对应的基本医疗保险，尤其是职工医疗保险方面，其管理具有属地化的特征，导致了高流动性的劳动力在医保跨地区的转移接续等方面遇到很大的阻力，进而限制劳动力的自由流动。长此以往，低水平的统筹层级以及碎片化的模式将会大幅度削减一些高流动性劳动力，如进城务工劳动者的参保意愿，甚至阻碍一些人才的合理流动。这将会使社会福利的效果大打折扣，不利于医保体系的平稳运行与协调发展，同样也不利于各地区经济的均衡发展。

（2）制约医疗保险的共济效应，使得医保基金难以调剂使用

我国因为疆土广阔，不同省市县在发展速度与水平上都有所不同，包括经济水平、人口结构、医疗卫生资源的供给等方面。这些不同就会导致各地区医保基金的筹资水平不同，缴费负担也不同，这严重地违背了医保筹资的公平性原则，加剧了不同地区收入分配的差距。而同样，低层级的统筹会导致各地区基金规模较小，抗风险能力偏弱，大多数人抵御小风险的目标无法实现。既削弱了调节收入分配的功能，也不利于各地区公共服务均等化目标的实现，城镇化在质量提升方面受阻。

医保的基金统筹依照“大数法则”，即在一定范围内统一筹集资金并且能够调剂使用，将风险与医疗负担通过群众社会力量进行分担协调。因此我们可以发现，如果统筹级别变高，范围加大，则抵御风险的能力将变强。而低层级的统筹水平，因为范围较小，其抵御风险的能力与基金的共济效应将严重削弱。研究发现，在我国现在统筹层次较低的实际情况下，一些地方的基金结余无法统筹调剂使用，部分统筹地区累计基金结余率较高，而一些统筹地区累计基金结余率较少，甚至出现赤字。基金结余的结构性不平衡降低了基金使用效率。比如在 2011 年，漳州市云霄、平和分别超支 263 万元、37 万元，而市本级、长泰、常山结余率都超过 25%，彼此得不到调剂，降低基金的利用率和风险防范能力。2014 年福州市除了闽清、永泰以及福州市本级亏损近 1000 万元左右，其他县（市）均有赢余，福清、马尾、闽侯、长乐分别赢余 10467.30 万元、10766.00 万元、7000.00 万元、3456.00 万元。云南省在实施市级统筹之前也苦乐不均，比如 2010 年的大理州，洱源县统筹基金累计结余可支付 5.22 个月、剑川县为 5 个月。大理市和州本级两地以 53.7%的参保人员占了全州统筹基金结余的 73.27%；南涧县、洱

源县、剑川县 3 县 13.5%的参保人员只占了全州统筹基金结余的 2.82%；漾濞县、巍山县、永平县 3 县 11.79%的参保人员只占了全州统筹基金结余的 5.14%。由此可见，统筹层级较低，着实会影响不同地区的均衡发展，降低基金的使用效率，加剧社会不公平。

（3）异地就医困难

随着人口流动逐渐增多，异地就医也将更频繁地出现。而异地就医目前存在有医疗费用高、报销比例低等基础性问题之外，还有报销程序复杂，地区的待遇以及审核时间不同的问题。目前，各地区因为本地实际情况不同，其医保政策在缴费基数、起付线、封顶线、支付比例、医保目录等方面均有所区别，相应的，结算方式与操作系统也不同，在低统筹层级如县级统筹下信息不仅不统一，还不能够共享。在县级统筹级别下，病人若需离开本县县级统筹医院而到别的医院就诊，则必须经历异地就医的流程，不仅需要县级医院开具转诊转治申请，还需要等待县级医保经办机构审批通过。除此之外，例如增加转外治理费用，降低医保统筹支付额等因为基金统筹政策不一致而出现的情况也会在病人于上级医院就诊时经常发生。这些繁琐的程序与地区间的不统一，将大大增加了参保人的就医难度和经济负担。更为严重的是，因为统筹层次低导致的各地报销条件和比例不一致，管理系统不同，从而出现信息不对称的情况。滋生了部分人与异地医院的医生相互勾结，诈取医疗保险金的想法，给医保基金的不必要的流失造成威胁。

（4）其他

目前，由于我国医疗保险基金大多实行地市级统筹，但仍有不少区县级统筹，统筹层次越低，区域间的差距也越大，公平性也较差。因为不同地方制定的医保制度不同，比如同一城市不同县区的定点医院、起付标准、报销比例都有所不同，归纳起来就是待遇的不同，而医保待遇的不同必将引起人民心中的不平衡，这将有违医保原本希望社会和谐发展的初衷。从理性的角度分析，低层级的统筹会带来被监管对象数量的增多，而数量越多，监管的难度越大，成本越高。同时在保持低统筹层次的前提下，发展医疗保险所达到的效果只会是各地不断地对医疗保险管理系统进行修改甚至重建，这样造成了大量人力资源和资金的浪费，加大了经济成本和人员管理成本。这又为统筹层次的提高增加了难度，形成恶性循环。

三、医保动态调整机制的可持续性问题

（一）医保谈判准入的启动机制问题

我国现阶段医保准入的启动机制为遴选制。

2017 年我国医保谈判品种的确定首先由医保部门设置遴选渠道，选出符合医保特药概念或范围的药品，其次由医保部门邀请来自临床医学、药理学、卫生经济学、医疗保险等领域的专家组成独立专家团，最后专家基于药品价值评估、药物经济学评价的原则，就药品的临床疗效、安全性、使用费用等方面进行独立评审，最终专家投票或评分确定谈判对象。依此可以看出，我国目前的医保准入启动方式为专家遴选模式，即根据不同地区、不同背景、不同专业的专家观点从众多品种中投票遴选出最终的准入药品。

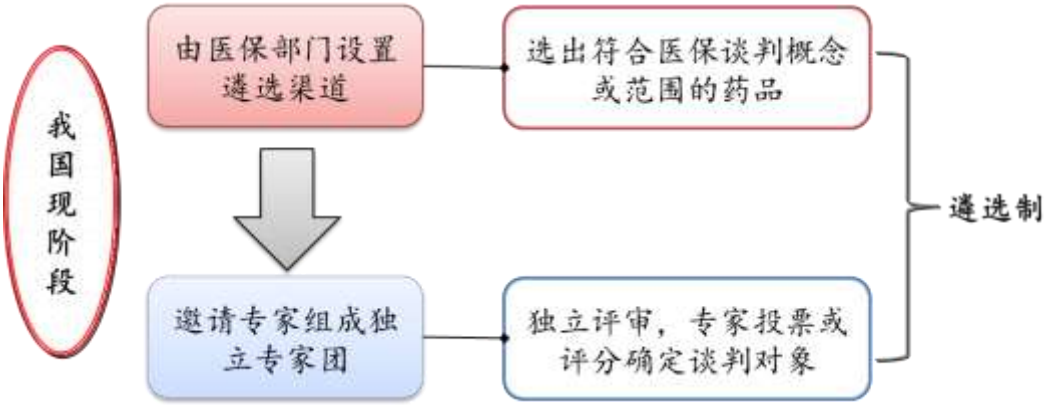


图 9 我国现阶段医保谈判准入启动机制

这种模式的优点是：①准入过程简单易行，耗时较短；②不会出现申报企业拥堵的情况；③结果明确，有利于主动选择优秀产品纳入遴选的范围。

但这种模式在操作上也存在一定问题：①并未强制性要求研发企业提供对应品种的药物经济性评价及循证医学方面的相关数据[13]，而遴选的依据主要是专家经验与集体讨论，无疑会在一定程度上增加审评结果的主观性；②每次目录的更新均是“运动式”的，每次调整都面临大动作的洗牌，审评小组、组织机构都是临时性的、非常态化的，制度带有动荡性和不确定性；③遴选标准模糊化，容易出现不公平申诉；④从发出谈判的邀约到提交材料的时间较短，企业难以充分准备材料；⑤谈判主体为国家医保，但实际支付主体为地方医保基金，地方医保的参与感不强。

申报制即药品企业根据自身情况向相关部门提出准入申请，依照谈判标准和

13 常精华，孙利华，董旻. 澳大利亚医保药物遴选的集中审评机制及启示[J]. 中国新药杂志, 2008, 17(17): 1465-1467.

材料审核规定自行准备药品材料并在申请的同时上交材料。

与遴选制对比之下，申报制有以下优点：①制度规范化，材料标准化，企业可进行材料的提前准备，结果与过程可预期；②审核标准确定、审核机构确定，申报流程确定，可以使制度形成长效机制；③规则明确，企业掌握主动权，有利于提高企业的谈判准入积极性；④程序化、常态化、透明化，有利于动态调整机制的构建。

与此同时，申请制的实施也存在担忧，比如①企业提交评审的品种水平层次不齐，需要专家组和监管部门进行大量前期初筛工作以确定入围品种范围，不符合谈判准入条件的品种将占用大量审评资源；②企业自行提交数据材料的真实性、完整性和科学性问题可能会干扰评审结果，企业数据、信息、材料的真实与科学性需要建立良好的制约与监督机制。

（二）医保谈判内容过于单一

目前我国医保谈判内容主要局限在价格上。招标采购、市场供应、效益承诺等内容并未得到足够重视（例如去年谈判药降价后，多地出现“赫赛汀”断供现象）；谈判过程短，无法充分实现沟通、达成共识，具体如图 10。

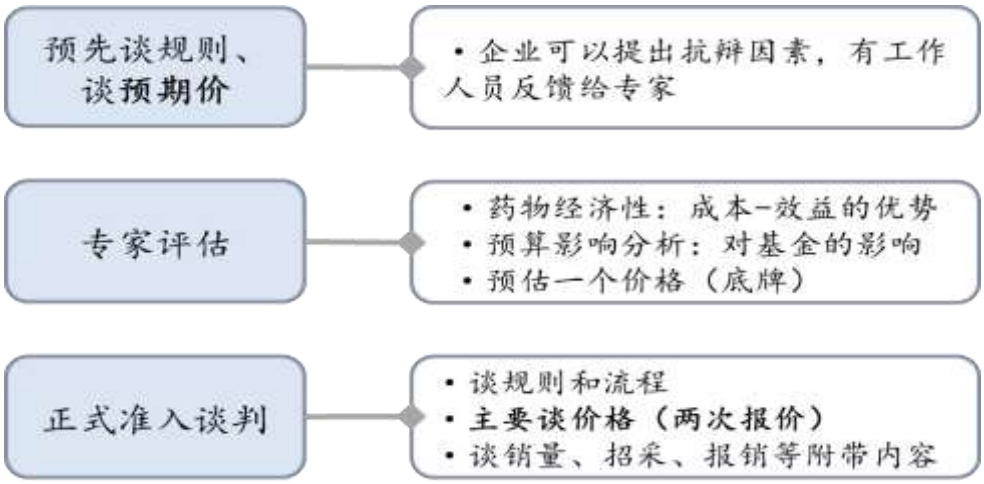


图 10 我国医保谈判内容现状

四、谈判药落地使用管理问题

（一）门诊报销与住院报销

1 门诊报销政策背景分析

在门诊就医的参保患者首先要确认自己是否符合门诊就医的报销资格，要确认自己是否在定点医院就医，要确定自己的就医项目在报销范围内。最后还要确

定就医的费用额度是否超过门诊医保报销的起付线。社保的门诊报销的起付线一般是 1800 元，最高限额为 2 万元，地区不同起付线会有不同。

除上述一般门诊报销种类（门诊统筹）外，还有门诊慢病、门诊特病、门诊精神疾病、门诊艾滋病、门诊大病等几种报销模式和规定。

对于慢性病、特殊疾病、大病而言，不同省市会对特定病种做出规定（一般列出清单），在清单中的疾病种类经过审核后，相应患者可以进行申请和报销。

对于报销地，一般应当是个人定点医院的诊疗、用药、医疗服务才能够获得门诊报销申请资格。下面（见表 19）以南京市为例，对门诊统筹、门诊其他报销项目的报销比例、起付标准、最高限额等进行汇总和分析。

表 19 南京市门诊报销政策[14]

<table>
<tr><th colspan="6">门诊统筹待遇</th></tr>
<tr><td colspan="2">人员类别</td><td>在职职工</td><td>退休（职）人员</td><td colspan="2">建国前老工人</td></tr>
<tr><td colspan="2">起付标准</td><td>1200 元</td><td>1000 元</td><td colspan="2">200 元</td></tr>
<tr><td rowspan="2">补助比例</td><td>社区医疗机构</td><td>70%</td><td>75%</td><td colspan="2">100%</td></tr>
<tr><td>其他医疗机构</td><td>60%</td><td>65%</td><td colspan="2">95%</td></tr>
<tr><td colspan="2">最高支付限额</td><td>2000 元</td><td>3000 元</td><td colspan="2">4000 元</td></tr>
<tr><th colspan="6">门诊慢性病</th></tr>
<tr><td colspan="6">具体疾病分为三类，第 I 类中包括高血压 II 期、高血压 III 期、心绞痛、心肌梗塞、癫痫、活动性肺结核、慢性萎缩性胃炎、重症肌无力等；第 II 类中包括慢性乙型肝炎、慢性丁型肝炎、慢性肾炎、慢性肾功能不全（非透析治疗）等；第 III 类包括系统性红斑狼疮、慢性再生障碍性贫血、运动神经元病等</td></tr>
<tr><td></td><td>在职职工</td><td>退休（职）人员</td><td>70 岁以上退休人员</td><td colspan="2">建国前老工人</td></tr>
<tr><td>起付标准</td><td>1000 元</td><td>800 元</td><td>600 元</td><td colspan="2">无</td></tr>
<tr><td rowspan="2">补助标准</td><td>社区医院:70%</td><td>社区医院:85%</td><td>社区医院:95%</td><td colspan="2">社区医院:100%</td></tr>
<tr><td>非社区医院:60%</td><td>非社区医院:75%</td><td>非社区医院:85%</td><td colspan="2">非社区医院:95%</td></tr>
<tr><td rowspan="4">补助限额</td><td>I 类</td><td>2000 元</td><td>3000 元</td><td>3500 元</td><td colspan="2">4000 元</td></tr>
<tr><td>II 类</td><td>4000 元</td><td>5000 元</td><td>5500 元</td><td colspan="2">6000 元</td></tr>
<tr><td>III 类</td><td>10000 元</td><td>10000 元</td><td>10000 元</td><td colspan="2">10000 元</td></tr>
<tr><td colspan="5">同时患有两种及两种（以序号病种为准）以上慢性病，在原最高补助限额基础上增加 2000 元</td></tr>
<tr><th colspan="6">慢性丙型肝炎门诊干扰素 α 治疗限额补助</th></tr>
<tr><td colspan="2">要求</td><td>起付标准</td><td>支付比例</td><td>最高限额</td><td colspan="2">备注</td></tr>
<tr><td colspan="2">慢性丙肝患者</td><td rowspan="2">补助不设起付标准</td><td rowspan="2">70%</td><td>3200 元/月</td><td colspan="2">每月限额费用当月有效，不滚存、不累计</td></tr>
<tr><td colspan="2">门诊抗病毒治疗</td><td></td><td colspan="2">在干扰素 α 治疗期间可</td></tr>
</table>

[14] 南京人力资源和社会保障网. 南京城镇职工医保报销比例/范围一览[EB/OL]. http://nj.bendibao.com/live/20141113/48096.shtm. [2018-07-13/2018-11-15].

				同时享受丙肝“门慢”待遇
使用干扰素α（含普通和长效）				住院期间不同时享受此项门诊限额补助

门诊特定项目

慢性肾衰竭门诊透析	**相关项目费用待遇**		**个人自付比例**				
	项目名称	补助限额	在职	退休（职）	70岁以上退休（职）	建国前参加革命工作老工人	
	透析费用	6.3万元/年	8%	5%	4%	无	
	辅助检查用药费用	1.2万元/年	10%	7%	5%	无	
	备注	①最高支付限额：透析费用指透析医疗费限额；辅助治疗费用指医保基金支付限额					
		②享受慢性肾衰竭门诊透析治疗待遇的参保人员，不再同时享受慢性肾炎和慢性肾功能不全（非透析治疗）的门诊慢性病限额补助待遇					
		③有自付比例的药品和项目需个人先按比例支付后，再按本表规定的个人分担比例支付					

人体器官移植术后门诊抗排异治疗	**相关项目费用待遇**			**个人自付比例**			
	项目名称	时间	医保基金最高支付限额	在职人员	退休（职）人员	70岁以上退休（职）人员	建国前老工人
	抗排异药物治疗	移植手术当年	8万元	8%	5%	4%	无
		移植手术后第1年	8万元	8%	5%	4%	无
		移植手术后第2年	7.5万元	8%	5%	4%	无
		移植手术后第3年	7万元	8%	5%	4%	无
		移植手术后第4年及以后	6.5万元/年	8%	5%	4%	无
	辅助检查和用药	移植手术当年	1万元	10%	7%	5%	无
		移植手术后第1年	1万元	10%	7%	5%	无
		移植手术后第2年	8000元	10%	7%	5%	无
		移植手术后第3年	6000元	10%	7%	5%	无
		移植手术后第4年及以后	4000元/年	10%	7%	5%	无
	备注	①“骁悉”按通用名“吗替麦考酚酯”纳入抗排异药物治疗限额内统一管理					
		②有自付比例的药品和项目需个人先按比例支付后，再按本表规定的个人分担比例支付					

造血干细	**相关项目费用待遇**			**个人自付比例**			
	项目名称	时间	医保基金最高支付限额	在职人员	退休（职）人员	70岁以上退休（职）人员	建国前老工人
	抗排	移植手术	8万元	8%	5%	4%	无

胞(异体)移植术后门诊抗排异治疗	异药物治疗	当年					
		移植术后第 1 年	8 万元	8%	5%	4%	无
	辅助检查和用药	移植手术当年	1 万元	10%	7%	5%	无
		移植术后第 1 年	1 万元	10%	7%	5%	无
	备注	①造血干细胞（异体）移植术后门诊抗排异治疗待遇在移植术后第一年年底截止，仍需继续治疗的，需经指定医院评估，再到市社保中心医保部办理审核登记手续后，医保基金参照器官移植术后门诊抗排异治疗对应年限待遇标准支付					
		②有自付比例的药品和项目需个人先按比例支付后，再按本表规定的个人分担比例支付					

	相关项目费用待遇			**个人自付比例**			
恶性肿瘤门诊治疗	项目名称	确诊后时间	医保基金最高支付限额	在职	退休（职）	70 岁以上退休（职）	建国前参加革命工作的老工人
	门诊放化疗（指定医院申请）	每年	15 万元	8%	5%	4%	无
	针对性药物治疗（指定医院申请）	每年	10 万元	8%	5%	4%	无
	辅助检查和用药（定点医院直接就诊，无需再申请）	病理确诊当年	2 万元	10%	7%	5%	无
		确诊后 1-3 年	2 万元/年	10%	7%	5%	无
		确诊后 4-5 年	1 万元/年	10%	7%	5%	无
		确诊后第 6 年及以后	4000 元/年	10%	7%	5%	无
	备注	有自付比例的药品和项目需要个人先按比例支付之后，再按本表规定的个人分担比例进行支付					

广州市人社局发布《广州市人力资源和社会保障局关于利拉鲁肽等药品纳入普通门诊、部分门诊特定项目和门诊指定慢性病药品目录的通知》，自 2018 年 6 月 1 日起，将 32 种国家谈判药品纳入普通门诊药品目录、6 种药品纳入门慢药品目录、7 种药品纳入门特药品目录。这 32 种药品，囊括了 2016 年 7 月首批谈判成功的 3 个药品：替诺福韦二吡呋酯、吉非替尼和埃克替尼，以及 2017 年 7 月 36 个谈判品种中的 29 个。

广州市人社局通知称，上述政策执行有效期为5年，政策实施后，对于新增药品目录中的药品，其个人先自付费用比例职工社会医疗保险按5%、城乡居民社会医疗保险按15%执行；药品实际价格低于医保支付标准的，按实际价格执行。

据媒体统计，如靶向药物没有纳入医保报销前，患者每月花费需1万-2万元的，在纳入医保后，其实质支出可控制在约 1000-2000 元。再以利拉鲁肽（3ml:18mg/支，预填充注射笔）为例，原价771.93元/支，纳入医保后支付标准为410元/支，降幅达46%。参保人可按410元的价格按比例报销，职工医保参保人，可能只需支付一两百元/支。

但是也有部分药品没有被纳入门诊医保。据悉，未纳入此次广州门诊目录的国家谈判品种包括：化药类的重组人尿激酶原、重组人凝血因子VIIa、重组人脑利钠肽、利妥昔单抗；中药类的银杏二萜内酯葡胺注射液、银杏内酯注射液、注射用黄芪多糖。

2 谈判药门诊报销影响分析

（1）门诊报销力度较小，影响药品落地使用

部分疾病治疗过程不需住院且专业医师注射使用，那么就可以门诊购药，但是如果依照门诊报销流程和规定，报销比例和金额有限，可能导致患者不乐意用药或者被迫住院购药，大大影响谈判药的落地与使用。

以诺华公司的雷珠单抗和康弘药业的康柏西普来说，其针对的是眼部疾病，一般不需住院治疗，只要在规定时期进行药物注射。那么就应当进行门诊购药和注射，而门诊统筹报销下有起付线、上有最高支付限额，报销额度非常有限。即便如康柏西普在山西省可以纳入门诊大病报销范畴，其相比住院治疗的报销情况也要差很多。康柏西普的销售增量增幅仅在 20%左右，而其销售额增量也仅在5%左右。同时考虑其竞品雷珠单抗，二者治疗适应症相似，那么门诊大病报销时必然会有一方无法得到政策优惠，则其销量和使用状况将受到较大冲击。

因此，对于门诊用药的品种，是否应当注重医保与高值药品的衔接，进一步放开门诊报销限制，值得进一步探讨。

（2）部分药品没有纳入门诊医保，门诊购药途径受限

各省的门诊报销情况均有不同，尤其是门诊慢病、门诊大病等政策规定各有特色，谈判药品虽进入了国家医保，但并不意味着在门诊当然的报销。而这些药

品如果不能够进入省级或市级门诊大病、门诊慢病等报销范畴，则其报销额度和保障力度非常有限。

例如，广州市人社局发布《广州市人力资源和社会保障局关于利拉鲁肽等药品纳入普通门诊、部分门诊特定项目和门诊指定慢性病药品目录的通知》后，经分析可以发现，化药类的重组人尿激酶原、重组人凝血因子 VIIa、重组人脑利钠肽、利妥昔单抗，中药类的银杏二萜内酯葡胺注射液、银杏内酯注射液、注射用黄芪多糖这几类谈判药品没有纳入门诊报销范围。再如上述提到的，如雷珠单抗和康柏西普，二者治疗适应症相似，那么门诊报销时必然会有一方无法得到政策优惠，而获得报销政策的药品由于可以报销，会受到大部分患者的青睐，导致其中另一方药品的销量和使用情况受到冲击。

因此，谈判药品与门诊保障的衔接应当予以改善，例如各省市积极将对应药品纳入门特、门慢、门诊大病范畴，适当提高报销比例等等。

（二）品种差异化管理

1 慢性病与大病品种差异化管理

谈判药品种，尤其是第二次谈判涉及肿瘤等大病用药、慢性病用药、罕见病用药等多个品种，国家及地方文件对其进行统一管理，缺乏分类管理科学设计的思想。如地方进行三定管理过程中，部分地区政策不区分慢病用药与大病用药而均设定医院、医生和患者“三定”限制，慢性病药品的报销与原医保目录慢性病药品报销不一致，不利于报销落地，降低慢性病患者的用药可及性。

2 罕见病药品管理

2018 年 5 月 22 日，国家卫生健康委员会、科技部、工业和信息化部、国家药品监督管理局、国家中医药管理局等五部门联合发布的《第一批罕见病》目录，共涉及 121 种疾病。《中国罕见病群体生存状况调研报告》显示，我国罕见病患者治疗时遇到最大的困难主要包括治疗费用过高、缺乏医疗技术以及无法购买到合适的药品或药价太高。种种原因导致目前我国医保目录内的罕见病药品品种较少，通过谈判准入的罕见病药品仅有第二次谈判中治疗血友病的重组人凝血因子 Ⅶa 和治疗多发性硬化症的重组人干扰素 β-1b，与罕见病目录涉及的疾病不相匹配，罕见病患者的健康权益保障无法到位。

此外，即使已通过谈判降低药价，该部分患病群体依然存在无力支付自付部分的药品费用而无法享受医疗保障的情况。

第四章 典型国家经验借鉴

一、典型国家医保基金抗风险能力研究

（一）美国

1 充分发挥了医保支付制度的控费作用

美国公共医保针对统筹需求方、供给方和支付方三方主体，分别设计和实施了医保控费措施。

在需求方上，美国根据人群差异性设计出差别化的保险计划，主要限定在老年人、儿童、军人等特殊群体进行控费。如针对老年人等弱势群体，美国的住院类保险给付按照住院天数确定医保支付和病人自付标准，90 天以内的大部分住院费用由住院类保险支付，剩余部分受益人需要自付，具体标准是：第 1 天~60 天受益人自付 1260 美元，第 61 天~90 天受益人每天自付 315 美元，第 90 天以上的受益人每天自付 630 美元，并且累计最多延长 60 天，第 150 天以上的住院病人全部自付[15]。与该设计不同的是，我国基于社会工资水平，以医保起付点为界限进行医保结算，而美国的医保支付模式真正做到了缩减住院病人的住院天数和住院费用，且美国住院类保险还为受益人支付出院后专业护理费用，更有利于减少医疗资源的占用和提高医疗资源使用效率，为我国医保支付方式设计带来了一些借鉴与启示。美国政府还通过立法鼓励消费者组建地区健康保险同盟，壮大需求方力量。

在供给方上，美国采取了多种医保控费手段：医生和医院的组织制度设计相互独立；鼓励保障健康维护组织（HMO）等私立管控型医疗组织发展，为公众提供更多选择，分摊公共医保支出的财政压力；推进责任医疗组织的建立，将医疗服务的质量和效率结合起来作为付费的标准；药械企业药品、耗材和器械的价格规制等。

在支付方上，美国则积极探索应用 DRGs 进行医保控费，实施后人均医疗费用支出增速得到了明显控制，如图 11。

15 刘平，扈彩霞. 美国公共医疗保险体系设计研究[J]. 医学与哲学(A), 2018, 39(11): 60-62.

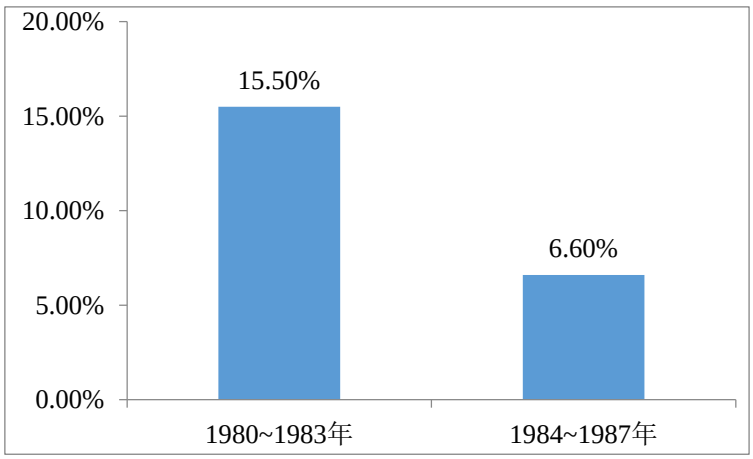


图 11 美国实施 DRGs 后人均医疗费用支出增速明显下降

（数据来源：健康届，张自然博士整理）

2 通过对医保医生的监管来控制医保支出

在医保基金支出方面，美国对医保医生的监管机制分为事前、事中和事后三个阶段，所对应体系分别为——服务监督系统，欺诈稽查系统和支付审计系统[16]。

服务监督系统是由专业人员在执业医师提供诊疗服务的过程中进行监督，杜绝虚假病例、过度检查、虚报人数等违规行为。为了在控制监管成本的同时保证监管效力，医保部门根据监管的密切程度将其划分为一般监督、直接监督和亲自监督。“一般监督”不要求监督医生在诊疗服务的现场出现，“直接监督”则要求监督医生必须穿着工作服，与接受诊疗服务的病人处在同一所医疗机构中，“亲自监督”最为苛刻，要求监督医生必须出现在诊疗服务现场。三个监督等级中，负责监督的医生都必须随时提供指导和帮助。

欺诈稽查系统发生于医保支付前，当医保医生提出索赔时，相关检查部门对索赔单进行数据分析，从而提前识别医保基金浪费和欺诈的行为，并在第一时间内进行阻止。如图 12。该系统的运作取得了显著的效果，2012 年，直接减少基金损失约 1.15 亿美元。

16 吴昱杉，申曙光，木公．国外医保医师监管镜鉴[J]．中国社会保障, 2013(05): 29-31.

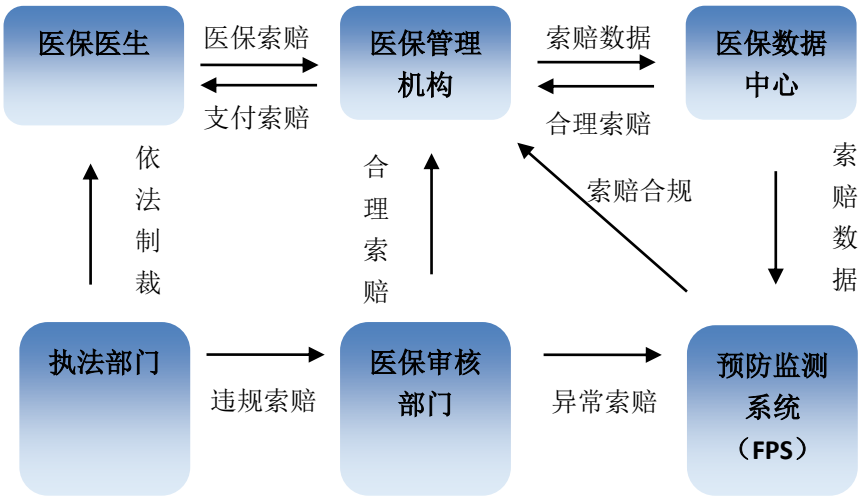


图 12 欺诈稽核系统操作流程

支付审计系统发生于医保支付后，通过对医生最近三年的索赔记录进行检查，以发现违规记录并追回损失。作为发现医保浪费和欺诈的最后一道防线，该体系严格审查医保医生过去三年的医保支付纪录，一旦发现存在诈骗或者浪费的行为，将会立即要求医生归还支付的费用，挽救医保损失。

事实上，尽管美国对于医保医生的监管机制比较健全，但在美国几乎不存在医务人员过度诊疗的现象。一方面，医院和医师之间没有雇佣关系，只有相互独立的法人合同关系，因此医院无法在经济上左右医师的诊断治疗行为；另一方面，医师本身拥有合理的高水平的医疗服务收入，故无需通过过度医疗等手段获取其他财富。但美国曾经也出现过医疗机构盲目扩大规模，升级设备的现象，为强化对该类支出的控制，美国政府是通过医疗机构、设施设备及医务人员的准入和建立同行评议（peer review）机制（依靠政府批准的专业标准评估组织的专业水准，降低与临床诊疗无关的行政成本）来有效预防医疗器械的滥用[17]。

3 严厉打击医保欺诈行为

美国对医保反欺诈十分重视。首先体现在司法实践上，医保欺诈在美国属于联邦重罪，一旦发现，就直接由联邦调查局负责调查，美国卫生及公共服务部(United States Department of Health and Human Services，HHS)和司法部进行联合执法，对所有的收受非法回扣行为处以“刑事指控、3 倍赔偿、罚款并踢出项目”。其次，美国政府还从其他各个层面加强医保反欺诈的力量配备。除上述司法活动

17 鄢广. 从理论到实践：医药费用控制的反思与规制[J]. 中国卫生法制, 2017, 25(01): 26-32+59.

中所涉主体外，美国社会医疗保险和医疗救助服务中心（Centers for Medicare and Medicaid services, CMS）也成立了诚信计划中心(CPI)，目的是监督所有 Medicare、Medicaid 和 CHIP 的欺诈、滥用和浪费的问题。此外，CMS 基于各类医疗信息数据库和电子健康档案提供的海量数据，通过数据建模、挖掘和可视化工具来发现欺诈。目前已经开发了预付预防(prepayment prevention)、预付调查(prepayment investigation)、追溯追回(retrospective recovery) 三个阶段的反欺诈软件，以识别医疗服务提供方、受益人的可疑赔付及欺诈行为[18]。

（二）英国

英国政府官网公布，2015 年英国医疗过程中出现的不必要的浪费高达数十亿英镑，这些浪费毫无疑问会转化为患者和社会的经济负担。我国虽然尚无医疗浪费及欺诈等的数据统计，但以我国的人口基数估计和网络曝光案件可见一斑。

英国在医疗费用监管上采用的是“政府购买服务”理论，指由政府代理全体国民承担“买方”角色，代表广大患者群体与医疗机构进行谈判，增强购买方的谈判能力[19]。作为第三方购买者，政府卫生部门针对不同医疗服务提供方采用不同的支付方式，对于城市大医院采取的是总额预算+政府补贴的方式，这样控制医疗费用的责任则落在医院方，医疗服务供方有动力去自觉控制医疗费用的增长，对于可能出现的超额医疗费用支出由政府补贴适当弥补，使得医院的运行有经费保障。对于初级医疗保健或服务的提供者，通过购买服务的方法来提高效率，只关心购买服务的内容与质量，而不关心提供者的身份是“公”还是“私”[20]。

在医药价格费用监督上，英国具有严格的执法力度。英国卫生部下设的 Monitor、NHS TDA、NHS England 担负着监管相对应的医疗服务机构的重要职责。如果医疗卫生机构不执行国家或地方收费标准，Monitor 等监管机构有权责令其限期整改甚至采取撤销行政许可等严厉措施。各医疗监管机构分工协作，取得了较好的监督执法效果。

（三）德国

德国一方面通过立法机构制定了药品参考定价制度、医疗保险用药费用分担制度、医药费用支付限额制度等一系列医保控费制度，另一方面通过政府和社会

18 李成志. 美国医疗保险制度对当前医改的几点启示[J]. 中国医疗保险, 2018(05): 68-71.
19 鄢广. 从理论到实践:医药费用控制的反思与规制[J]. 中国卫生法制, 2017, 25(01): 26-32+59.
20 朱计. 第三方医疗费用控制研究[D]. 浙江财经学院, 2012.

组织合作，政府主要负责政策、规划的制定和监督执行，社会管理组织包括保险经办机构及医生组织则通过理事会实行自治管理，在医保基金监管工作中发挥着重要的作用[21]。

1 药品参考定价制度

德国医保支付制度的精髓部分在于借助参考价格。德国将列入报销范围的药品，根据药物成分和效果划分成 3 类，即相同药物成分的、相似药物成分的和同疗效的药物[22]。其中每小类别又被分作若干子级别，然后制定适用于同类别每一子级别的报销价格，即参考价格。适用参考定价的药品，且药品的价格低于参考价格的，以及不适用参考价格的药品，由患者按照法律规定的比例分担药品费用，高出参考价格部分的费用由患者完全担负[23]。这种制度刺激了消费者的费用意识，降低了药品需求。而德国的医保实行的是实物待遇原则和报销原则，即参保人在接受医疗服务时不需要交费，直接接受医疗服务，医疗费用则由医疗保险局负责支付，实物待遇原则指导下的行为选择会激励医生使用低价药品，预付制的支付方式会抑制他们开大处方的冲动，加上严格的监督审查制度，医生会做出有利于自己的选择[24]。对于药品生产企业来说，由于定价和补偿机制紧密相连，如果生产厂商想要获得较大的药品销售量，就不得不按照同类药物的参考价格谨慎定价[25]。德国药品费用占卫生总费用的比值下降的相关 OECD 数据表明，参考价格体系结合部分负担机制以及其它配套机制，对于控制德国药品费用起到显著的效果[26]。

2 医药费用支付限额制度

在支付限额制度上，德国规定患者每次就诊购药时必须支付药价的 10%，且支付的总金额进行限制（最低 5 欧元，最高 10 欧元，特殊人群免单）[27]。另外，德国的法定医保基金对医保药品费用承担有限责任，对于超过预算额度的费

21 吴雅娟. 基于国外医保基金监管经验的我国医保基金监管完善对策研究[J]. 企业导报, 2016(19): 87.
22 申团结, 黄泰康. 医改进程中医保付费制度改革的重要性思考[J]. 中国卫生经济, 2014, 33(06): 8-10.
23 孙兆泉, 肖航. 国外医保药品费用支付管理概述[J]. 中国医疗保险, 2011(10): 68-69.
24 朱计. 第三方医疗费用控制研究[D]. 浙江财经学院, 2012.
25 向国春. 从德国实践看医保药品支付标准[J]. 中国社会保障, 2018(01): 80-81.
26 常峰, 崔鹏磊, 夏强, 张舰云. 德国药品参考价格体系对构建我国医保支付标准的启示[J]. 中国卫生政策研究, 2015, 8(07): 55-60.
27 向国春. 从德国实践看医保药品支付标准[J]. 中国社会保障, 2018(01): 80-81.

用不予承担。对于医生而言，当处方金额超过预算，医生会受到警告，如果超过115%，医生会被置于财务监督之下，并要求做出相应的书面检讨，如果超过 125%，医生则必须做出说明和解释，答复如果不能让人满意和信服，则该医生需要支付超过预算部分的费用。这一制度规范了医生的行为，对合理控制医疗费用起到很好的效果[28]。

3 通过理事会对医保医生自治管理

德国医保机构不直接对医生进行费用结算，而是通过保险医生联合会（KVB）对门诊费用进行结算。保险医生联合会负责成立监督执行委员会，专门负责协会内医生的监督管理。医生被要求根据联合会制定的“诊疗服务目录”对医疗患者进行诊治。监督执行委员会对于医生的审查分为“异常账单审查”和“偶然性审查”。具体工作是对医师诊疗过程中的服务项目报账单进行审核，并与原有平均数据进行对比。如果医师的诊疗费用远远超过平均水平，监督执行委员会将会代表 KVB 对此进行询问，并要医师提供相关证据。如果证据显示医师使用药品不合理，将由医师承担部分药费 [10,29]。

（四）新加坡

新加坡作为世界上储蓄式公积金制度的典型国家，其医疗制度以国家型的社会保险为核心，建立了政府与个人责任的合理分担机制，有利于医疗资源的高效利用。新加坡政府在设计医疗保障制度之初就较好地确立了国民必须对自己健康负责的意识。在新加坡三层次医保体系中，其中一个重要组成部分是个人医疗储蓄账户的设立，政府通过这种强制储蓄的方式，保证了每个人都要为自己的健康负责，这一设计能够有效防止过度消费，避免医疗资源的浪费[30]。事实证明，自从 1984 年医疗储蓄账户引进以来，新加坡医保运营结构健康，趋势良好。

同时，新加坡规定了个人账户启用和支付范围是“中等费用段”，所以小额医疗费用仍需患者用个人现金自付，这样能够有效保证个人账户积累的连续性[31]。而我国尽管也设有个人账户，但启用限制和医疗费用支付范围过于宽松，导致在大额医疗费用面前，个人账户难有剩余，抗风险能力较差。再加上我国对个人账

28 朱计. 第三方医疗费用控制研究[D]. 浙江财经学院, 2012.
29 吴昱杉, 申曙光, 木公. 国外医保医师监管镜鉴[J]. 中国社会保障, 2013(05): 29-31.
30 易龙飞. 英国、新加坡和中国香港全民医保的运行及启示[J]. 中国卫生政策研究, 2014, 7(05): 49-55.
31 楚廷勇. 中国医疗保障制度发展研究[D]. 东北财经大学, 2012.

户资金违规使用缺乏有效制约，造成诸多滥用医保资金现象，个人账户无法实现约束医疗消费行为的初衷。

为了杜绝由于账户上存款过多造成所有者不必要的提取和小病大治的道德风险，新加坡政府对医疗储蓄账户的总金额也作了限定，超出限额的资金自动转移到中央公积金的普通账户上，另作购房、投资等他途使用。

二、加拿大医保筹资模式

加拿大的医保制度在世界范围内也是最完善的之一，虽然我国与加拿大的国家性质、政治体系以及经济实力有很大的不同，但依然可以从加拿大医保筹资的方式中，选择出我们提升医保筹资层级的路径。

首先，加拿大的全民医保免费模式，都是由特定的省开始实行，最后再由国家政府制定政策。这种免费的医保制度首先来源于 1947 年由萨斯喀彻温省出台的 SHSP 计划，宣布该省居民住院医疗服务免费，随后加拿大很多省份也开始实行类似的计划。直到 1957 年，加拿大国会才规定各省公民的医疗费用包括住院费与诊断费，由省政府与联邦政府 1:1 分别支付，后改为拨款转移支付的方式。

1977 年，联邦政府为了鼓励各省增加各自的医疗消费，来调节总的医疗费用支付，通过改变协议的方式，各省增加对其他医疗服务项目的支付，如理疗、正骨、按摩、老年人适当的医药补贴，以及儿童的牙医保健等。为防止各省因增加项目向患者收取高昂的额外诊疗费，联邦政府会在转移支付的拨款中扣除该费用保障患者权益。

加拿大医保的资金由联邦政府和省政府共同征收来承担，来源通常为企业的所得税以及个人的所得税。除此之外，省政府还可以按本省实际情况，按一定的比例从征收的消费税、工资税中筹集医保资金。而国家方面，联邦政府又通过对各省所征收的税金，按一定的比例提取出国家的医保资金，这类资金的主要用途是对资金不足的省区进行转移支付，实际上就是调剂金的功能。

实际上加拿大医保制度的完善，也来源其高额的税收支持，我国政府不能够完全沿用，必须考虑国内的经济水平。加拿大为何能够成功实行这种统筹方式，在于其各地区医疗卫生设施差距不大，其国家到省政府的垂直管理体系也较为明确，便于管理。此外，加拿大各省的立法行政权与我国的省份不同，加拿大给予其省更大的独立立法权，使得当地省份可以明确按照自己省内的情况调节医保资

金的数量筹集。如果我国实行省级统筹，需要完善的是对地方机构的垂直监管力度，并且要实际了解各地方医疗机构的实际情况，同时要在保证省内经济水平以及医疗卫生资源能够匹配的上的前提下再实施我们的省级统筹。

第五章 谈判药品使用情况实证分析

本次研究共纳入563个分析对象，主要包括2016年的3个谈判药品、2017年的36个谈判药品（由于2018年的抗癌药谈判时间距离过近，因此未纳入分析）和根据各省辅助用药目录筛选出的典型辅助用药，具体品种名称如下表。按照类别其主要可以分为辅助用药、谈判药、谈判药品的仿制药以及其他（包含与谈判药治疗同疾病的药品）。由于我国医保目录按照通用名准入和确定补偿与否，因此分析过程中将谈判药的仿制药销售情况与费用支出纳入谈判品种一同计算。

表 20 研究对象汇总列表

分类	具体分类		药品名称
辅助用药	免疫类		小牛血清去蛋白
			小牛脾提取物
	心血管		蛇毒血凝酶
	神经系统		奥拉西坦、匹多莫德、脑蛋白水解物
			单唾液酸四己糖神经节苷脂
	中药注射液		参麦注射液、参芪扶正注射液、红花注射液
			丹红注射液、灯盏细辛注射液、脉络宁注射液
			醒脑静注射液、参附注射液、艾迪注射液
			疏血通注射液、注射用灯盏花素、注射用血栓通
			注射用红花黄色素
谈判药	2016年谈判药	富马酸替诺福韦二吡呋酯	韦瑞德（葛兰素史克）
			晴众（正大天晴）
			倍信（成都贝特）
			纳信得（齐鲁制药）
			正稳（安徽贝克）
		盐酸埃克替尼	凯美纳（贝达药业）
		吉非替尼	易瑞沙（阿斯利康）
			伊瑞可（齐鲁制药）
	2017年谈判药	拉帕替尼、阿帕替尼、厄洛替尼、索拉非尼、利拉鲁肽	
		替格瑞洛	倍林达（阿斯利康）
			信立泰（泰仪）
		重组人尿激酶原、重组人凝血因子Ⅶa、重组人脑利钠肽	
		托伐普坦、阿利沙坦酯、吗啉硝唑氯化钠、泊沙康唑、氟维司群	
		曲妥珠单抗、贝伐珠单抗、尼妥珠单抗、利妥昔单抗、重组人干扰素β-1b	
		硼替佐米	万珂（杨森）
			千平（正大天晴）
			昕泰（豪森）
			齐普乐（齐鲁制药）
		重组人血管内皮抑制素、西达本胺、阿比特龙、依维莫司	
		来那度胺	瑞复美（新基）

			立生（北京双鹭）
		喹硫平、帕罗西汀、康柏西普、雷珠单抗、司维拉姆、碳酸镧、参一胶囊	
		银杏二萜内酯葡胺注射液、银杏内酯注射液、复方黄黛片、注射用黄芪多糖	

一、谈判药品使用和销售情况

自 2017 年谈判结束，36 个谈判药品进入医保目录，正式可以获得国家报销。研究考虑到谈判效果的滞后效应，选取 2017 年 7 月谈判结果公布节点的前后 15 个月进行数据统计，具体如图 13。

从图 13 中可以看出，自 2017 年 7 月谈判结果公布起，大部分谈判药品的销售额均有所上升，且在谈判后上升幅度明显（线段斜率明显增大），同时可以观测到存在大约 4-5 个月的滞后效应（红线处是谈判结果公布节点）。

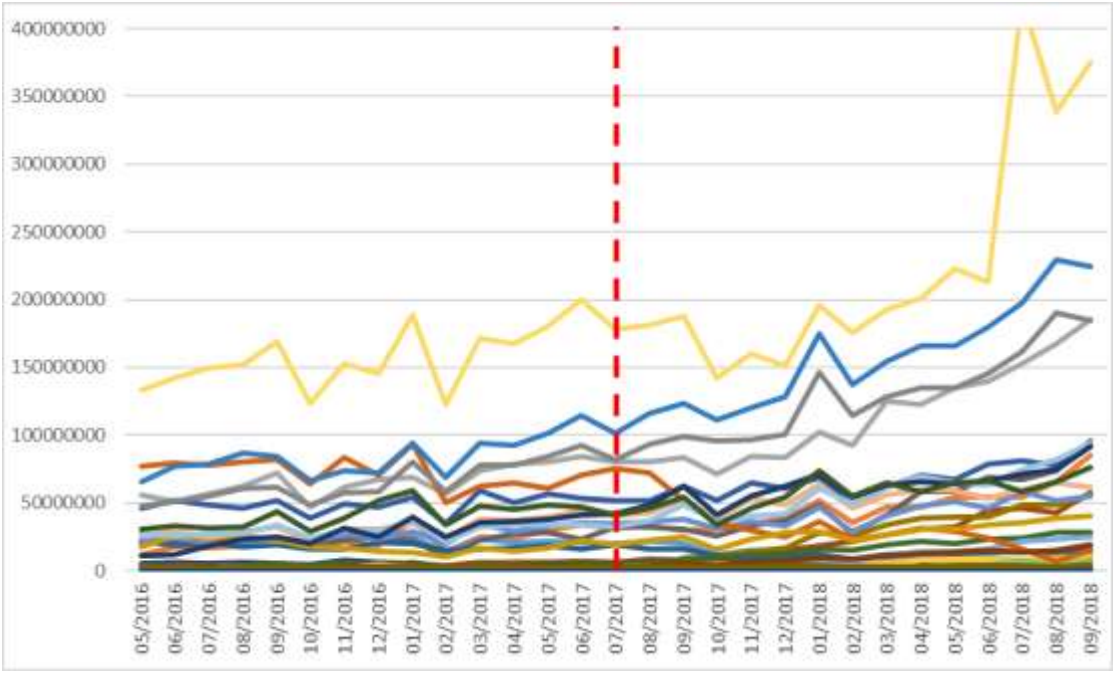


图 13　2017 谈判药医保准入前后销售额（单位：RMB）

研究同时对 36 个谈判品种的销售额增长率做了进一步分析，从图 14 中可以看出，虽然谈判药品的销售额有明显增幅，但是其销售额增长率却没有明显增长趋势。介于这些药品均是独家品种，企业可能对其市场抱有高期望，但是目前可能距离企业“以价换量”的目标仍有距离。

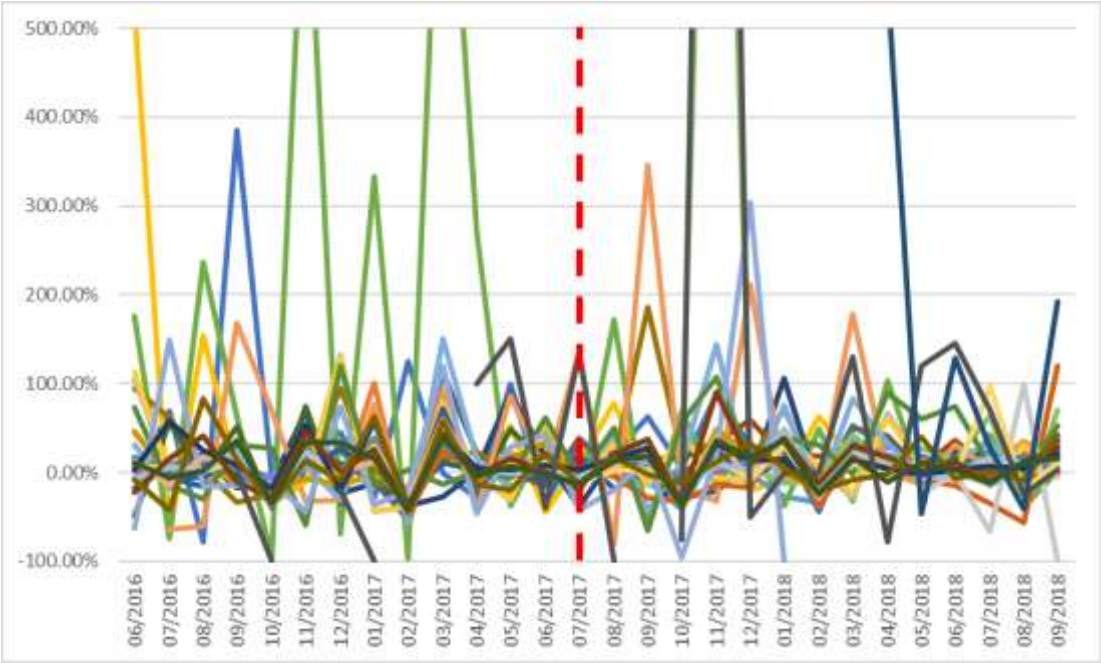


图 14　2017 谈判药医保准入前后销售额增速

2016 年的谈判效应与 2017 年类似（研究范围选取谈判结果公布的前后 15 个月）。2016 年主要包括替诺福韦酯、埃克替尼和吉非替尼三个品种，其谈判后由于价格的大幅降低，销售额也有明显的增长，如图 15 所示，在谈判结果公布（图中红线处）后，三个品种的销售额增幅较大，且存在一定滞后效应，滞后期在图中看约为 4-5 个月。

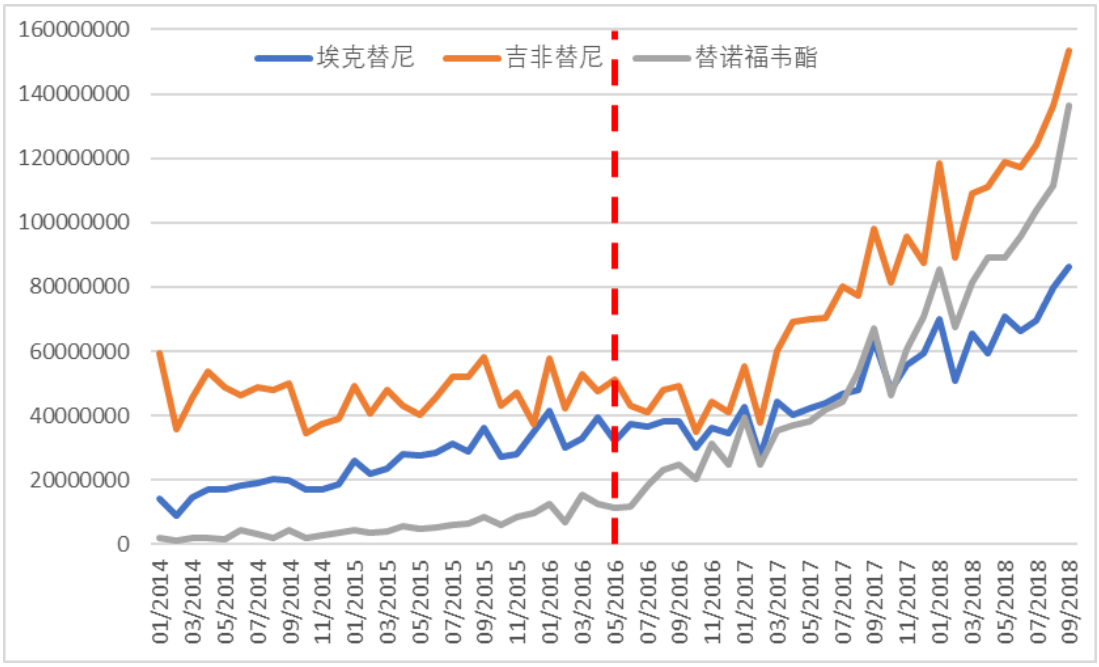


图 15　2016 谈判药医保准入前后销售额（单位：RMB）

同理，对 2016 年 3 个谈判品种销售额的增长率进行计算分析，发现与 2017

年类似，第一轮谈判的 3 个品种的销售额增长率也没有增长痕迹，呈不规则变动趋势（具体如图 16）。

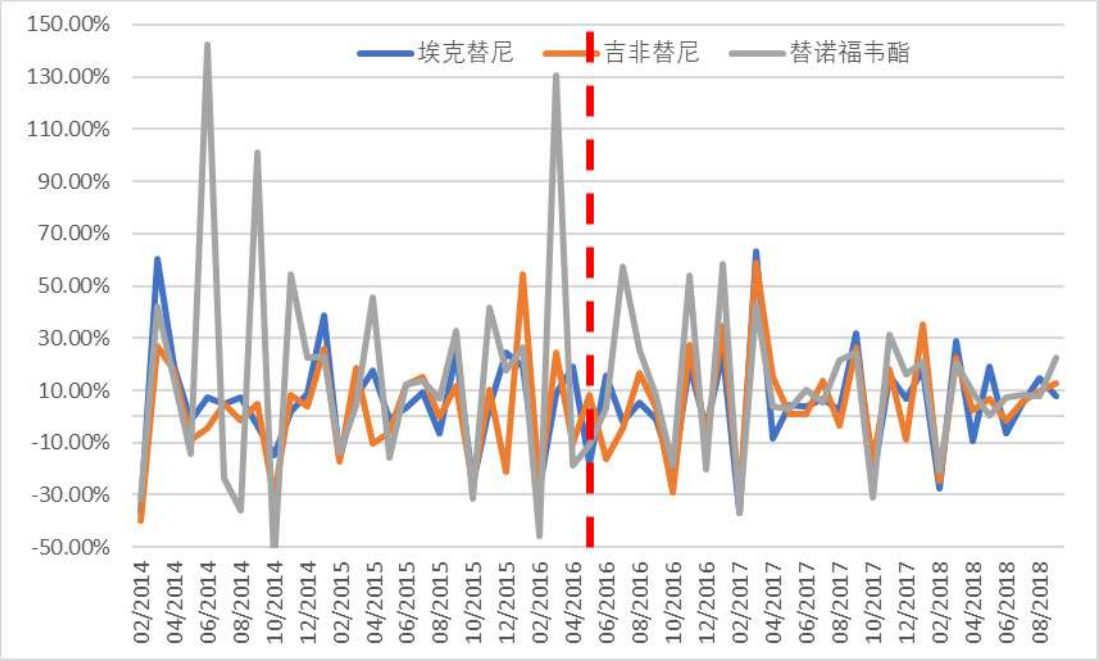


图 16　2016 谈判药医保准入前后销售额增速

二、谈判药与辅助用药的费用比较

研究根据上表中对辅助用药的筛选和列举，对其与谈判药费用情况做出具体计算和分析比较。时间跨度选取 2017 年 9 月至 2018 年 9 月，对在此期间列举出的辅助用药的总销售额和谈判药的总销售额做对比。每个月份的具体对比结果如图 17 所示。经过计算，在 2017 年 9 月至 2018 年 9 月间（36 个谈判药品谈判准入后），谈判品种（39 个）共计占用销售额空间 183.6 亿 RMB，而辅助用药用去 391.5 亿 RMB，可以看出 391.5 亿 RMB 远>183.6 亿 RMB。表明一些临床上无用的、滥用的、冗余的辅助用药是可以为临床急需、高值高价谈判药留出相当大的费用空间的。所以可以由此推断，谈判药的落地除了应当关注政策如“取消药占比”、“不占总额控费指标”等，还应当留意药品的合理使用。

Over		Total	Std. Err.	[95% Conf.	Interval]
DM					
	谈判	1.14e+09	2.49e+08	6.48e+08	1.62e+09
	辅药	3.97e+09	5.99e+08	2.79e+09	5.14e+09
	其他	1.26e+08	3.58e+07	5.59e+07	1.97e+08
DN					
	谈判	9.01e+08	1.98e+08	5.13e+08	1.29e+09
	辅药	2.73e+09	4.12e+08	1.92e+09	3.54e+09
	其他	9.89e+07	2.80e+07	4.40e+07	1.54e+08
DO					
	谈判	1.07e+09	2.21e+08	6.35e+08	1.50e+09
	辅药	3.39e+09	5.15e+08	2.38e+09	4.40e+09
	其他	1.20e+08	3.59e+07	5.00e+07	1.91e+08
DP					
	谈判	1.08e+09	2.18e+08	6.50e+08	1.51e+09
	辅药	3.15e+09	4.77e+08	2.22e+09	4.09e+09
	其他	1.17e+08	3.39e+07	5.09e+07	1.84e+08
DQ					
	谈判	1.41e+09	2.87e+08	8.43e+08	1.97e+09
	辅药	3.43e+09	5.05e+08	2.44e+09	4.42e+09
	其他	1.36e+08	3.98e+07	5.81e+07	2.14e+08
DR					
	谈判	1.09e+09	2.28e+08	6.44e+08	1.54e+09
	辅药	2.45e+09	3.66e+08	1.74e+09	3.17e+09
	其他	8.94e+07	2.63e+07	3.77e+07	1.41e+08
DS					
	谈判	1.34e+09	2.68e+08	8.13e+08	1.87e+09
	辅药	2.70e+09	4.07e+08	1.90e+09	3.50e+09
	其他	1.17e+08	3.42e+07	4.96e+07	1.84e+08
DT					
	谈判	1.45e+09	2.79e+08	8.97e+08	2.00e+09
	辅药	3.01e+09	4.61e+08	2.10e+09	3.91e+09
	其他	1.17e+08	3.42e+07	4.98e+07	1.84e+08
DU					
	谈判	1.51e+09	2.95e+08	9.32e+08	2.09e+09
	辅药	2.96e+09	4.49e+08	2.08e+09	3.84e+09
	其他	1.19e+08	3.34e+07	5.30e+07	1.84e+08
DV					
	谈判	1.55e+09	2.94e+08	9.73e+08	2.13e+09
	辅药	2.72e+09	4.13e+08	1.90e+09	3.53e+09
	其他	1.16e+08	3.34e+07	5.09e+07	1.82e+08
DW					
	谈判	1.84e+09	4.39e+08	9.81e+08	2.71e+09
	辅药	2.78e+09	4.20e+08	1.96e+09	3.61e+09
	其他	1.17e+08	3.33e+07	5.19e+07	1.83e+08
DX					
	谈判	1.87e+09	3.97e+08	1.09e+09	2.65e+09
	辅药	2.74e+09	4.13e+08	1.93e+09	3.55e+09
	其他	1.20e+08	3.48e+07	5.19e+07	1.88e+08
DY					
	谈判	2.11e+09	4.38e+08	1.25e+09	2.97e+09
	辅药	3.12e+09	4.75e+08	2.18e+09	4.05e+09
	其他	1.37e+08	3.95e+07	5.98e+07	2.15e+08

图 17　2017.09-2018.09 谈判药与辅助用药销售额比较

（单位：RMB；图中 e+n 表示×10^n，如 2.11e+09 表示 2.11×10^9）

进一步，以谈判药阿帕替尼和辅助用药参麦为例，谈判药阿帕替尼（癌症用药）在 2017 年 9 月至 2018 年 9 月间共计销售 6.278 亿 RMB，而辅助用药参麦

（口服液体&注射液）在 2017.09-2018.09 期间的销售额达到了 11.63 亿 RMB，远远高于阿帕替尼的销售额（每个月份具体的销售额比较情况如图 18）。

Over		Total	Std. Err.	[95% Conf.	Interval]
DM					
	阿帕替尼	2.98e+07	2.64e+07	-2.34e+07	8.29e+07
	参麦	1.17e+08	3.45e+07	4.74e+07	1.86e+08
DN					
	阿帕替尼	3.07e+07	2.84e+07	-2.65e+07	8.79e+07
	参麦	8.02e+07	2.27e+07	3.44e+07	1.26e+08
DO					
	阿帕替尼	3.45e+07	3.17e+07	-2.93e+07	9.82e+07
	参麦	9.60e+07	2.87e+07	3.82e+07	1.54e+08
DP					
	阿帕替尼	3.88e+07	3.46e+07	-3.09e+07	1.09e+08
	参麦	9.17e+07	2.62e+07	3.90e+07	1.44e+08
DQ					
	阿帕替尼	5.15e+07	4.73e+07	-4.38e+07	1.47e+08
	参麦	1.07e+08	3.24e+07	4.16e+07	1.72e+08
DR					
	阿帕替尼	3.57e+07	3.09e+07	-2.66e+07	9.80e+07
	参麦	7.60e+07	2.14e+07	3.30e+07	1.19e+08
DS					
	阿帕替尼	4.67e+07	4.32e+07	-4.04e+07	1.34e+08
	参麦	8.72e+07	2.64e+07	3.40e+07	1.40e+08
DT					
	阿帕替尼	4.73e+07	4.39e+07	-4.12e+07	1.36e+08
	参麦	8.62e+07	2.75e+07	3.08e+07	1.42e+08
DU					
	阿帕替尼	5.42e+07	4.92e+07	-4.49e+07	1.53e+08
	参麦	8.99e+07	2.71e+07	3.53e+07	1.44e+08
DV					
	阿帕替尼	5.45e+07	5.19e+07	-5.01e+07	1.59e+08
	参麦	8.09e+07	2.54e+07	2.98e+07	1.32e+08
DW					
	阿帕替尼	5.40e+07	5.05e+07	-4.77e+07	1.56e+08
	参麦	8.82e+07	2.65e+07	3.49e+07	1.42e+08
DX					
	阿帕替尼	6.53e+07	6.05e+07	-5.66e+07	1.87e+08
	参麦	8.09e+07	2.44e+07	3.18e+07	1.30e+08
DY					
	阿帕替尼	8.48e+07	8.07e+07	-7.78e+07	2.47e+08
	参麦	8.13e+07	2.59e+07	2.92e+07	1.33e+08

图 18　2017.09-2018.09 阿帕替尼与参麦销售额比较

（单位：RMB；图中 e+n 表示×10^n，如 8.48e+07 表示 8.48×10^7）

三、各城市谈判药落地情况比较

针对各省市谈判药政策落地情况的分析，本研究中选取了 41 个市和地区进

行分析，主要涵盖 2017 年的谈判药品。由于我国并未实现各地医保的省级统筹，因此在分析时主要以市为单位。

如图 19 所示，41 个样本城市和地区中，2017 年谈判工作完成后，相关谈判药品的环比增速（谈判后相对于谈判前，取前后各 14 个月）均值为 1241.55%，最小值为-100.00%，最大值为 91053.89%（以单个确定规格的药品为一条目）。

Variable	Obs	Mean	Std. Dev.	Min	Max
环比增速	947	12.41554	63.40593	-1	910.5389

图 19 谈判前后销售额环比增速总体情况

根据统计分析，不同城市和地区的环比增速存在统计学上的显著性差异（P=0.000<0.05，置信区间取 95%），即不同城市和地区由于地区本身环境、政治经济发展情况、政策落实、用药习惯等因素的不同，在谈判药的使用及其销售额增速方面存在差异（如图 20）。

Analysis of Variance

Source	SS	df	MS	F	Prob > F
Between groups	218901.318	40	5472.53295	1.38	0.0593
Within groups	3584313.48	906	3956.19589		
Total	3803214.8	946	4020.31163		

Bartlett's test for equal variances: chi2(40) = 2.5e+03 Prob>chi2 = 0.000

图 20 谈判前后不同地区谈判药销售额增速的对比

下图中提供了不同城市和地区谈判药销售额环比增速的具体数值。如上海、深圳、广州、扬州等地区的销售额环比增速数值较大，基本在 3000%以上；临沂、潍坊等地环比增速数值最小，呈负值；长春、无锡、西安等地增速也较慢，在 100%以下（具体如图 21）。

市名	Summary of 环比增速 Mean	Std. Dev.	Freq.
上海	32.862665	144.69821	35
临沂	-.10355436	1.015897	16
乌鲁木齐	7.7857176	24.108433	26
北京	3.8127692	7.3644035	41
南京	5.8071945	11.145906	32
南宁	2.4426671	3.3671996	19
南昌	10.591834	22.419673	24
合肥	4.8417116	11.382466	26
哈尔滨	5.9823732	23.665187	30
大连	1.6170024	3.9743336	21
天津	22.689565	83.454496	32
太原	2.3919056	6.9041072	19
宁波	10.415589	14.169693	6
常州	9.9459775	23.754249	15
广州	40.989915	119.86336	37
徐州	19.011475	44.571749	17
成都	4.4600153	10.921382	21
扬州	97.739078	201.20965	8
无锡	.27060489	.73977822	6
昆明	6.6554514	11.349485	20
杭州	21.692488	46.505897	18
武汉	2.02891	6.7771169	32
沈阳	2.1170005	5.3133564	30
济南	7.8969215	29.620499	31
济宁	3.6787185	4.1716553	19
浙江城市集群	44.209135	79.891562	11
深圳	47.459205	172.20373	24
温州	19.461679	53.906014	17
潍坊	-.2733873	.7597044	20
烟台	2.1365502	5.4281521	23
珠三角	2.3986254	3.0631106	22
石家庄	10.409783	29.645791	31
福厦泉	39.070664	165.11241	30
苏州	9.5956784	17.060289	17
西安	1.5181992	2.7487052	26
贵阳	7.9537668	16.527674	19
郑州	12.634604	22.531074	30
重庆	1.3021751	2.2215621	29
长春	.83250661	1.8443244	25
长沙	12.267529	45.950452	26
青岛	6.2386312	16.492047	16
Total	12.415538	63.405927	947

图 21 不同地区谈判药销售额的环比增速

接下来，在所有样本城市中依据上文政策制度落实打分结果的 4 个不同区间选择 7 个城市（每个区间选择 2 个，由于缺少西藏地区数据，因此最终共 7 个城市）。此外，由于我国省级统筹尚未达成一致，因此本部分用典型城市代表省份，结果仅做参考。如图 22、图 23 所示，北京、南宁、石家庄、南昌、上海、天津和乌鲁木齐共 7 个城市，谈判后相关药品的销售额增长情况较为明显（大约存在 4-5 个月的滞后效应）；同时也可以看出不同城市的增幅的确存在一定差距。

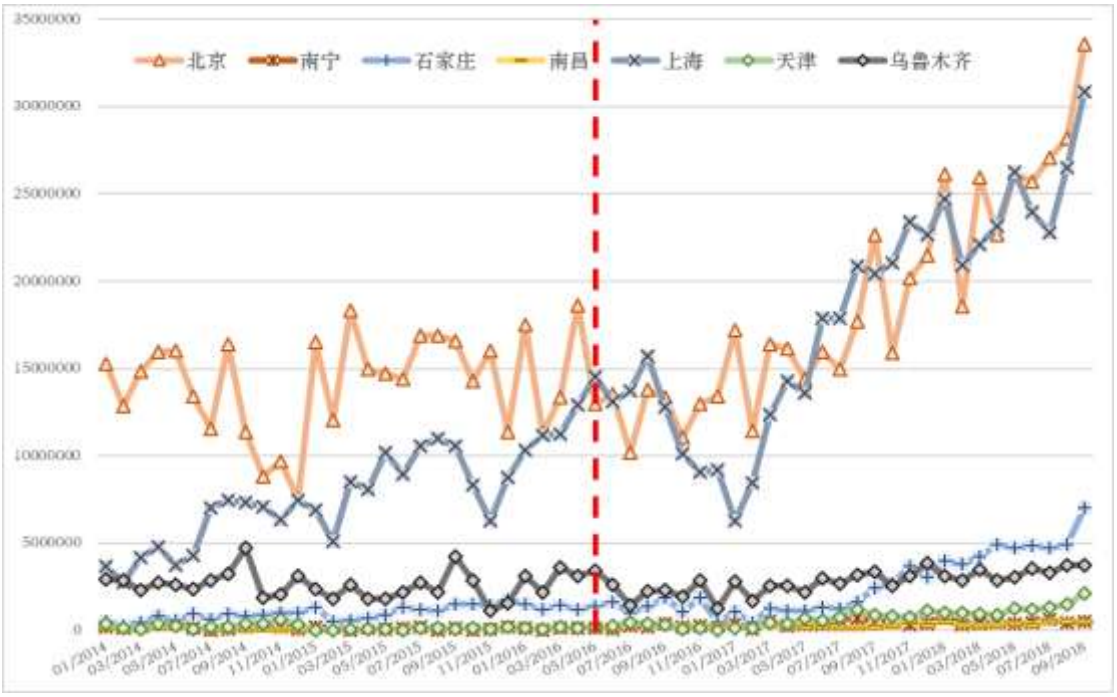


图 22 样本城市 2016 谈判药医保准入前后销售额（单位：RMB）

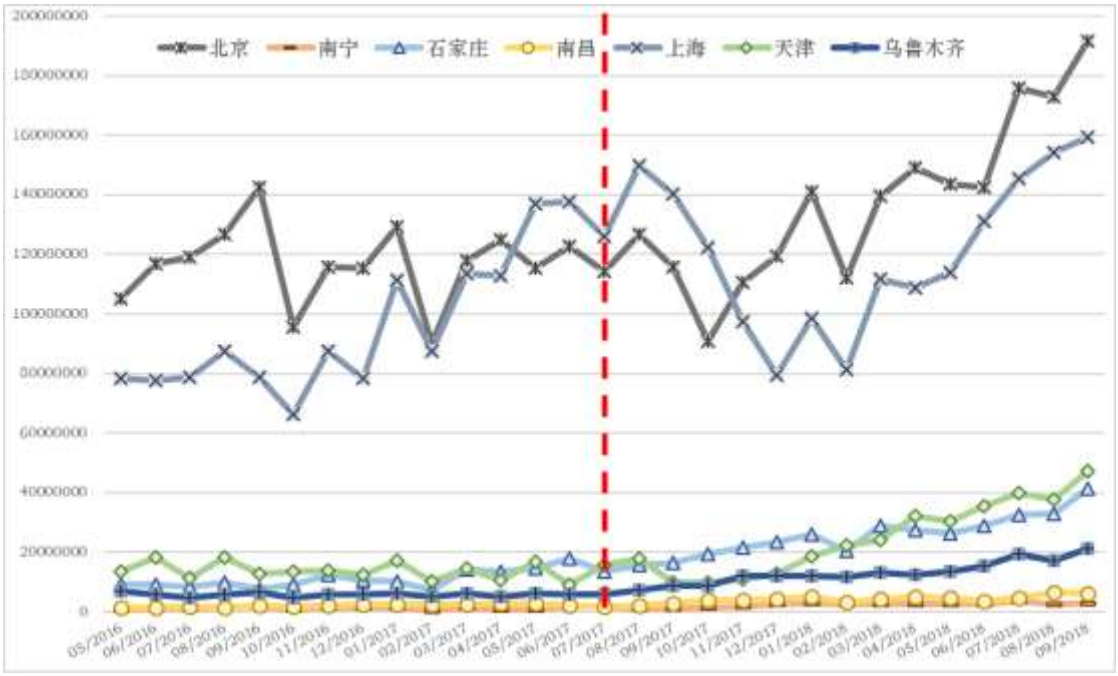


图 23 样本城市 2017 谈判药医保准入前后销售额（单位：RMB）

再观察药品增速的波动情况，可以看出，不论是 2016 年的价格谈判药品还是 2017 年的医保谈判药品，每个月间的增速波动并无明显规律，且各省市间无明显差别（具体如图 24、图 25）。

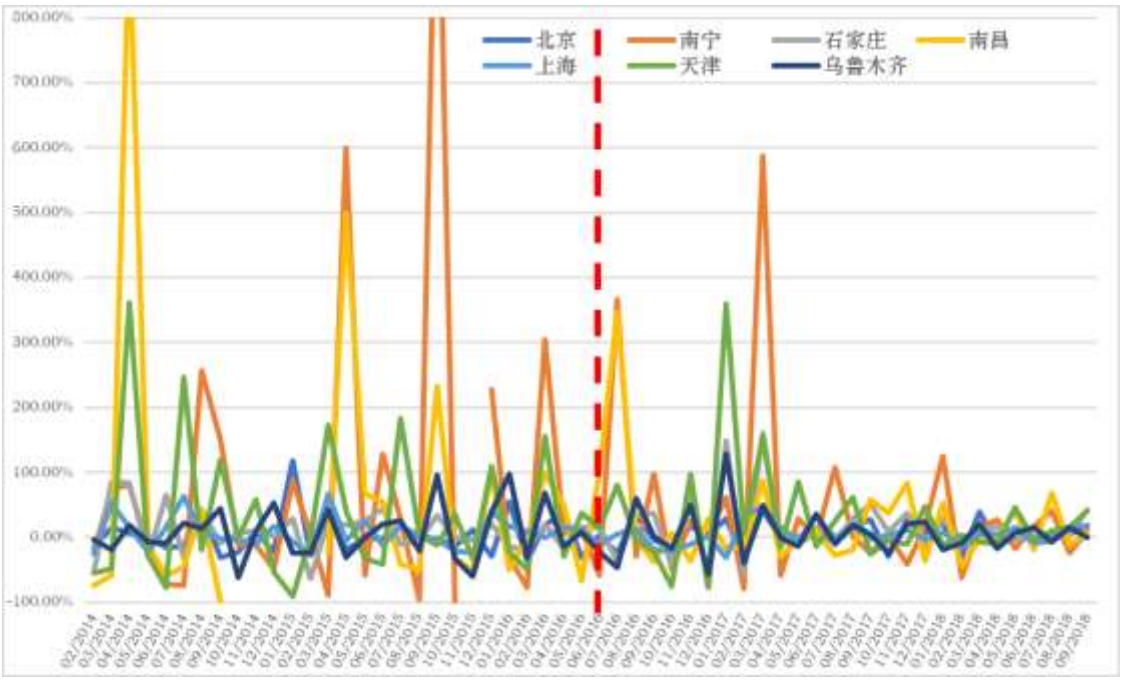


图 24 样本城市 2016 谈判药医保准入前后销售额增速

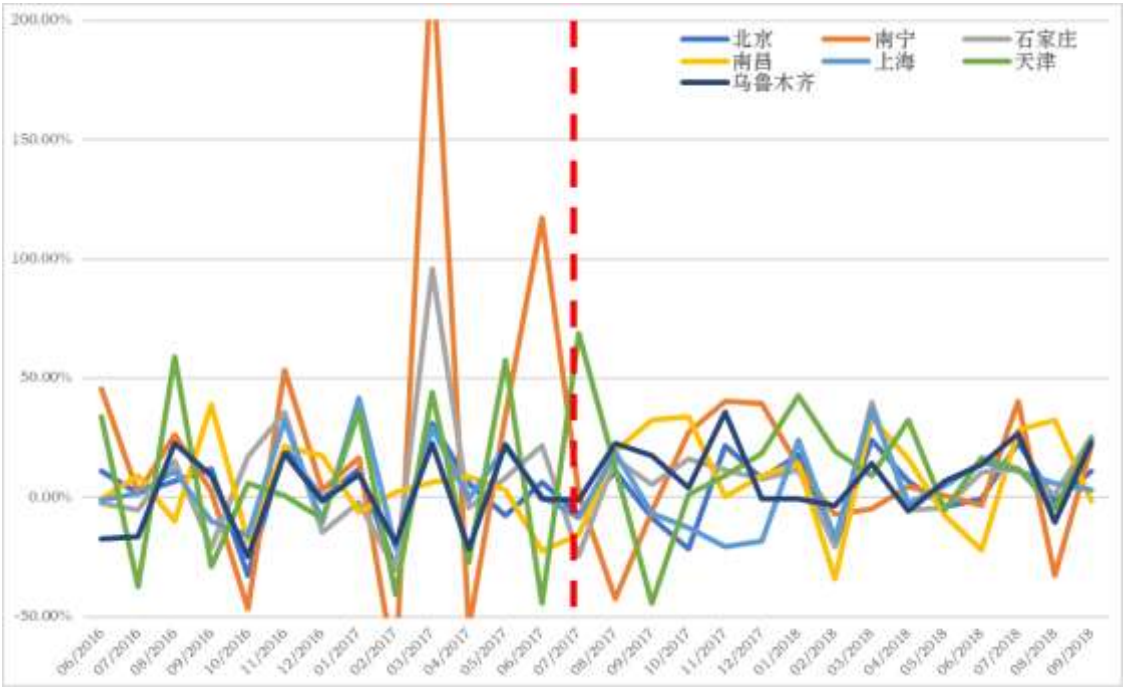


图 25 样本城市 2017 谈判药医保准入前后销售额增速

第六章 核心建议思考

一、改善医疗机构的激励环境——解决“进院难”问题

（一）消除谈判药品落地的“去激励因素”

对于医院药占比、总额控制问题，截止目前全国已有 22 省/市明确要求谈判药品不占药占比考核；部分省份为促进谈判药品的可及性、提高患者的获得感，规定不将国家谈判药品计入医院的医保总额预算，如图 26。

图 26 各省谈判药品药占比、总额控费政策规定

政策发布后，实际情况却并不理想。由于我国政策发布、制度实施主体条块分明，具体工作落实的主动权和决策权在市级甚至区县一级。而省级文件发布后，相应的市县落实到位的却少之又少。以安徽省和四川省为例，安徽省 16 市中，仅芜湖市和阜阳市在公开网站表明将落实省级不占药占比规定，占比 12.5%；四川省共 21 市/州，其中也只有泸州市、自贡市、南充市在公开网站表明将落实省级不占药占比规定，占比仅 14.3%，具体如图 27 所示。

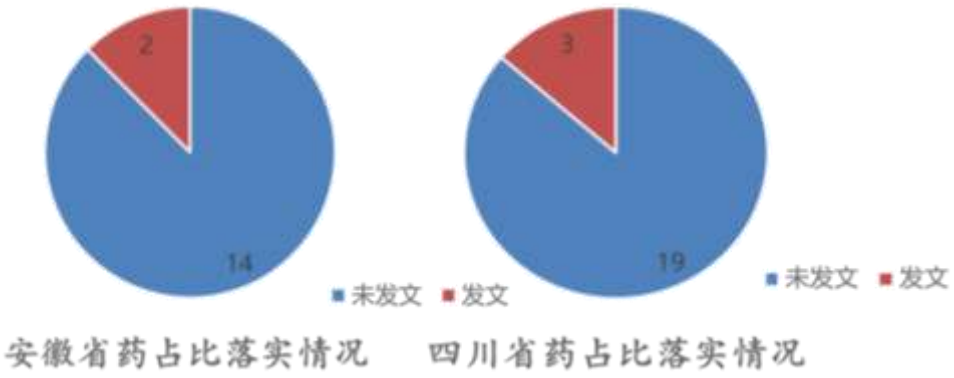


图 27 四川省和安徽省具体市县谈判药品药占比政策落实情况

在安徽省卫计委的《关于加强药品采购使用管理的通知》（卫药秘〔2017〕

526 号）中提出，“国家谈判药品暂不纳入医疗机构药占比考核，实行单独核算、合理调控。”在安徽省出台文件之后，我们对安徽省的 16 个市是否响应省级号召出台谈判药品不占药占比文件进行检索，检索发现，安徽省的 16 个市中只有阜阳和芜湖 2 市（见表 21）曾转发出台过有关谈判药品不占药占比的文件。

表 21 安徽省各市出台谈判药品不占药占比的文件

城市	文件	时间
阜阳市	转发《关于加强药品采购使用管理的通知》的函	2017-12-05
芜湖市	关于转发《关于加强药品采购使用管理的通知》的通知	2017-11-22

四川省在《关于省本级执行 36 种国家谈判药品和《国家基本医疗保险、工伤保险和生育保险药品目录（2017 版）》有关问题的通知（川人社办发〔2017〕958 号）》中表示，定点医疗机构在 2017 年产生的 36 种国家谈判药品费用不计入总额控制。之后我们对四川省的 21 个市/州进行检索有关谈判药品不占药占比的文件，检索发现四川省 21 个市/州中只有泸州、南充、自贡三市（见表 22）转发或出台过谈判药品不占药占比的文件，其余市都未曾出台文件响应省级谈判药品不占药占比的号召。

表 22 四川省各市出台谈判药品不占药占比的文件

城市	文件	时间
泸州市	关于转发省厅关于执行《国家基本医疗保险、工伤保险和生育保险药品目录（2017 版）和 36 种国家谈判药品有关问题的通知》的通知	2017-12-06
南充市	关于执行《国家基本医疗保险、工伤保险和生育保险药品目录（2017 年版）》和 36 种国家谈判药品有关问题的通知	2018-02-28
自贡市	关于执行《国家基本医疗保险、工伤保险和生育保险药品目录（2017 年版）》和 36 种国家谈判药品有关问题的通知（自人社办发[2018]1 号）	2018-01-31

应用三因素理论，首先应当消除去激励因素，即取消药占比、总额控费等考核指标。对比 2018 年的抗癌药谈判，自 2018 年 10 月 10 日国家医疗保障局发布《国家医疗保障局关于将 17 种抗癌药纳入国家基本医疗保险、工伤保险和生育保险药品目录乙类范围的通知》后，紧接着为防止医院采购和使用不积极的问题，卫生部门发布文件《国家卫生健康委医改医管局关于做好 17 种国家医保谈判抗癌药配备使用工作的通知》，强调医院不得以医疗费用总控、医保费用总控、“药占比”和药品品种限制等为由影响谈判药品的供应保障和合理用药需求。与此同时，其出台罚则——对于不能及时配备谈判药品、影响患者用药需求的，应当对

相应医院采取压缩相应肿瘤专科规模、限定业务量、降低医院等次、降低医院级别、考核和评价不合格等措施，直至其整改到位，以此督促医疗机构积极、合理使用谈判抗癌药物，保障供应与患者需求。

为解决“进院难”问题，国家、各省市应当贯彻落实上述文件内容和精神，积极落实文件中关于消除“药占比、医保总额控费”等去激励因素措施，并将该文件精神扩展至其他谈判品种。

（二）维持“保健因素”

激励因素与去激励因素存在于连续体的两个端点，是两种极端的情景。在这两种极端的激励与去激励因素之间，还应该存在着许多种强弱不等的激励形式，它们构成一个连续带；事实上存在着许多既非强去激励因素，又非强激励因素的中间过度地带。而保健因素就是在这种背景下提出的。

对于激励各医院采购、使用谈判药品而言，落实维持医院等次、级别科室发展、医生薪资等相关措施，应当属于“保健因素”的范畴。若医院能够按照要求和实际情况，积极合理地采购、使用谈判药品，则维持医院等次、级别科室发展和医生薪资；若医院无故不采购不使用或消极采购使用谈判药品，则采取降低其医院级别、科室评比扣分、扣除医生薪资等措施。

对于激励因素，如基于谈判药品处方量等给予相应补贴或薪酬等，一方面充分激励医院采购及使用谈判药品积极性，实现谈判药品落地，完成谈判药品进医院最后一公里，使患者真正享受谈判药品红利；但另一方面，容易使医生产生不合理用药隐患，造成医药资源浪费与滥用，给医保基金带来巨大压力。因此，关于是否增加激励因素有待进一步考量。

二、品种差异化管理

运用分类管理的思想，对慢性病、大病、罕见病药品在医院使用环节制定不同的管理策略。如慢性病药品取消三定管理的限制，提高患者用药便利性；其报销比例建议与基本医保乙类普通药品相一致，减轻患者用药负担。

对于治疗罕见病的谈判品种，可由权威机构、罕见病学会等可推荐罕见病药物进入谈判清单，经罕见病专家小组论证主动发起谈判，形成罕见病药品谈判的常态化机制。在药物遴选环节中，与《第一批罕见病目录》保持一致的药物优先进入谈判清单，从而缓解罕见病患者用药需求迫切性。

同时关注较普通人群支付能力更低的罕见病患病人群，建议国家筹集专项资金，进一步提高医保报销比例，建立患者自负金额封顶机制，确保此部分弱势群体患者中的可及性。

三、理顺“双通道”实施路径——打通定点药房购药渠道

药占比是公立医院的重要考核指标，高价抗癌药纳入医保乙类目录将造成医保支出的大幅增加，导致部分医院存在不敢开处方的问题，谈判药品在医院落地较为困难。谈判药品进医院困难一方面导致患者用药难，另一方面药企难以进入医院销售导致市场份额并未明显提升，没有实现以价换量，影响企业后续参与谈判的积极性。

为了解决这一问题，目前已有天津、浙江、河南、安徽等 23 省市明确国家谈判药品不纳入药占比或单独核算要求，但大多省份规定的是“暂不纳入”。但是这一阶段性的解决方案能否长期实施，并进一步在全国统一推行尚未可知。

因此，为了推进谈判药品落地，让医改红利惠及更多患者，建议开启谈判药品双通道模式，实行处方外配，患者通过定点药房进行医保报销。谈判药品实行双通道这一举措将有效解决谈判药品进医院困难、参保患者买不到药的困境，同时也会提高企业加入到后续高价药品谈判过程中来，实现多方共赢。

针对国家医保谈判的药品，我国目前共有 16 个省份采取定点药房供给模式，包括黑龙江、吉林、辽宁、天津、山东、陕西、青海、甘肃、四川、重庆、湖北、贵州、湖南、江苏、浙江、安徽。

（一）措施出台背景

以倍泰龙（重组人干扰素β-1b）为例，大部分患者、企业、医生反映，谈判药进得了医保进不了医院。但是通过曲折的途径，也有患者在医院买到了倍泰龙。内蒙古人赵磊今年 29 岁，患多发性硬化症 8 年多。2018 年 8 月，他在当地一家医院住院 15 天，这期间医院为他开了倍泰龙。不同寻常之处在于，名义上是“住院”，可他一天也没在病房里住过。每隔一天跑一趟医院，注射一次倍泰龙。赵磊能用上倍泰龙的奥秘恰恰在于“住院”。因为按当地医保规定，倍泰龙只能住院报销；而且住院能够降低药占比——账单是 12800 元，其中倍泰龙 7080 元，其余是护理费、床位费等，这样药占比仅 55%，比单纯买药的 100%降低近一半。但是白白多花的几千元住院费仍旧是医保在买单。

类似例子不在少数。比如，广东省珠海市的门诊患者可凭医院外购处方到药店自费购药，之后再凭发票到珠海医保中心按住院待遇享受报销。

对于慢性病患者而言，定点药店是药品流通的一个重要渠道。在约定的医保支付标准下，患者取药和医保支付在渠道上同时覆盖医院和药店，能更好地保障用药可及性，也有利于推进医药分开，就是现在热谈的“双通道”。目前，辽宁省、吉林省、陕西省、甘肃省、山东省、青海省等均在文件中明确了谈判药医院/药店的渠道倾向。

表 23 全国各省市谈判药流通渠道（举例）

省级区域	政策文件描述
辽宁省	鼓励定点零售药店为参保人员提供药品
吉林省	建立特药定点零售药店管理机制，要逐步创造条件，采取有效措施鼓励定点零售药店为参保患者提供特药服务
陕西省	对规定需“事前审查后方可使用”或其他需要严格管理的药品，可采取病例实名备案、定医院或零售药店集中供货
甘肃省	鼓励定点零售药店销售谈判药品，其价格不得高于挂网采购价格，医保部门纳入门诊统筹、特殊疾病门诊补助或个人账户报销范围
山东省	要采取有效措施鼓励定点零售药店为参保人员提供药品，发挥药店在医保药品供应保障方面的积极作用
青海省	参保人员使用谈判药品，可在门诊（定点零售药店）购买

一方面为消除药占比、医保总额控费等条件的约束，另一方面为更好地拓宽谈判药的使用渠道并进一步推进医药分开，针对国家医保谈判的药品，我国目前共有 16 个省份采取定点药房供给模式，包括江苏、浙江、山东、湖南等地。

图 28 部分省/市定点药房供给模式分布情况

（二）具体品种“双通道”可行性分析

本课题首先对 2017 年和 2018 年谈判的 36+17 个品种的剂型、给药途径进行统计，随后希望通过对药品性质、给药途径的进一步分析，对“双通道”这一模式的可行性及配套措施做深入研究。

表 24　2017 年 36 个谈判药品的剂型与给药途径汇总

种类	治疗领域	药品名称	剂型	给药途径
重大疾病或慢性病用药	心脑血管	重组人脑利钠肽（西藏药业）	注射剂（冻干粉）	采用按负荷剂量静脉推注本品，随后按维持剂量进行静脉滴注
		替格瑞洛（阿斯利康）	圆形、双凸、黄色包衣片	口服，饭前或饭后服用
		重组人尿激酶原（天士力）	注射剂（白色疏松体，复溶后为澄清、无色透明液体）	一次用 50 毫克，先将 20 毫克用 10 毫升生理盐水溶解后，3 分钟静脉推注完毕，其余 30 毫克溶于 90 毫升生理盐水，于 30 分钟内滴注完毕
		阿利沙坦酯（信立泰）	片剂，白色薄膜衣片	口服，不与食物同时服用
	抗感染	泊沙康唑（默沙东）	口服混悬液	口服
		吗啉硝唑氯化钠（江苏豪森）	注射剂：微黄绿色至黄绿色澄明液体	静脉滴注
	眼科 AMD	雷珠单抗（诺华制药）	眼用注射剂，透明至微乳白色液体	在有资质的医院和眼科医生中使用，在无菌条件下经玻璃体内注射给药
		康柏西普（康弘药业）	眼用注射液	经玻璃体腔内注射给药
	慢性肾病	碳酸镧（夏尔制药）	咀嚼片	口服，完全咀嚼后再吞咽，随餐或于餐后立即服用
		司维拉姆（赛诺菲）	片剂，白色至类白色椭圆形薄膜衣片	口服，药片应完整吞服，并且在服用前不应压碎、咀嚼或者打成碎片，随餐服用
	精神疾病	喹硫平（阿斯利康）	片剂	口服
		帕罗西汀（葛兰素）	片剂	口服
	糖尿病	利拉鲁肽（诺和诺德）	注射剂，无色	经皮下注射给药，注射部位

			或几乎无色澄明等渗液	可选择腹部、大腿或者上臂，不可静脉或肌肉注射
	其他	托伐普坦（大冢制药）	片剂，蓝色片	口服
其他西药	肿瘤	利妥昔单抗（罗氏）	注射剂	稀释后通过独立的不与其他药物混用的输液管静脉滴注，应在具有完备复苏设备的病区内进行，并在有经验的肿瘤医师或血液科医师的直接监督下进行
		曲妥珠单抗（罗氏）	注射剂	静脉输注给药，请勿静推或静脉快速注射
		贝伐珠单抗（罗氏）	静脉注射用无菌溶液	由专业卫生人员采用无菌技术稀释后才可输注
		索拉非尼（拜耳）	片剂	口服，空腹或伴低脂、中脂饮食服用，以一杯温开水吞服
		硼替佐米（强生）	注射剂	仅用于静脉注射给药，鞘内注射会导致死亡
		重组人血管内皮抑制素（山东先声）	注射液	匀速静脉点滴
		尼妥珠单抗（百泰生物）	注射剂	静脉输液给药，需密切监测患者的状况
		厄洛替尼（罗氏）	片剂，圆形、双凸、白色包衣片	口服，必须在有此类药物使用经验的医生指导下使用，至少在进食前 1 小时或进食后 2 小时服用
		阿帕替尼（恒瑞医药）	片剂	口服，应在有经验的医生指导下使用
		西达本胺（微芯生物）	片剂，类白色片	口服，需在有经验的医生指导下使用，用药期间需定期检测血常规（通常每周一次）
		氟维司群（阿斯利康）	注射剂，白色粉末	肌注，注射时应慢
		阿比特龙（强生）	片剂，椭圆形片一侧凹入 AA250	口服给药
		依维莫司（诺华制药）	片剂，白色或微黄色片	口服给药
		来那度胺（Celgene）	胶囊	口服，在有多发性骨髓瘤治疗经验的医生监督下开始

				并提供治疗用药
		拉帕替尼（葛兰素）	黄色片剂	口服
	罕见病	重组人凝血因子Ⅶa（诺和诺德）	冻干制剂	静脉推注给药，注射液的配制全部过程应无菌操作
		重组人干扰素β-1b（拜耳）	白色块状疏松体，用附带溶剂溶解后呈无色或微黄色澄明液体	皮下注射&剂量滴定，在有治疗该病经验的医生指导下进行
中成药	肿瘤	参一胶囊（吉林亚泰）	胶囊剂	饭前空腹口服
		注射用黄芪多糖（天津赛诺）	注射剂	静脉滴注，使用前需先做皮试，皮试阴性者方可使用
		复方黄黛片（亿帆医药）	薄衣糖片	口服
	心脑血管	银杏内酯注射液（成都百裕）	注射剂	静脉滴注，用药期间需严格控制滴速
		银杏二萜内酯葡胺注射液(康缘药业)	注射剂	静脉滴注

表 25　2018 年 17 个谈判药品的剂型与给药途径汇总

品种	药品名称	剂型	给药途径
抗癌药	尼洛替尼（诺华）	口服常释剂型，胶囊剂	口服，初始治疗应该在对 CML 患者有治疗经验的医师指导下进行，不得与食物一起服用——在服药前至少 2 小时以及服药后至少 1 小时内不得进食
	培唑帕尼（诺华）	口服常释剂型，片剂	口服，不应与食物同时服用，餐前至少 1 小时或餐后至少 2 小时服用本品
	塞瑞替尼（诺华）	口服常释剂型，胶囊剂	建议在有使用经验的医疗机构中并在特定的专业技术人员指导下使用，同时建议进行 ALK 基因评估，获得充分证实的 ALK 阳性评估结果
	奥曲肽（诺华）	微球注射剂	皮下注射
	阿昔替尼（辉瑞）	口服常释剂型，片剂	口服，有肿瘤治疗经验的医生才可使用阿昔替尼治疗，要根据患者安全性和耐受性的个体差异增加或降低剂量
	克唑替尼（辉瑞）	口服常释剂型，胶囊剂	口服，必须在有使用经验的医疗机构中并在特定的专业技术人员指导下使用，服用本品前必须获得经充分验证的检测方法证实的 ALK 阳性评估结果
	舒尼替尼（辉瑞）	口服常释剂型，胶囊剂	口服，与食物同服或不同服均可
	奥希替尼（阿斯利康）	口服常释剂型，浅褐色的薄膜衣片	口服，用水送服，应由在抗肿瘤治疗方面富有经验的医生处方使用
	瑞戈非尼（拜耳）	口服常释剂	口服

		型，片剂	
	阿法替尼（勃林格殷格翰）	口服常释剂型，深蓝色、圆形、双面凸起、边缘斜面的薄膜衣片	口服，应在经验丰富的医生指导下使用，开始治疗之前应采用经充分验证的检测方法确定 EGFR 的突变状态
	培门冬酶（江苏恒瑞）	注射剂	肌注；静滴
	维莫非尼（罗氏）	口服常释剂型，片剂	口服
	西妥昔单抗（默克）	注射剂	静脉滴注，首次使用前应进行抗组胺药物和皮质固醇类药物的预防用药，在用药过程中及用药结束后 1 小时内，需密切监测患者状况，并必须配备复苏设备
	伊沙佐米（武田）	口服常释剂型，胶囊剂	口服给药
	伊布替尼（西安杨森）	口服常释剂型，胶囊剂	口服给药
	阿扎胞苷（新基）	注射剂	静注或静滴
	安罗替尼（正大天晴）	口服常释剂型，胶囊剂	口服，应在有抗肿瘤药物使用经验医生的指导下使用

（三）具体品种“双通道”实施方法

双通道实施过程中涉及到五个主体，包括医保部门、医疗机构、定点药房、流通企业、患者。为保证谈判药品双通道顺利实施，需要做到以下几点：

①明确定点药房资质

实施双通道首先要遴选定点药房，保证谈判药品的供应以及使用的安全性。谈判药品相较普通药品对存储管理、处方审核以及专业服务有更高的要求。因此，定点药房需要配备相应的设施设备、药学服务人员、信息系统，以保证谈判药品的供应。

A 经营资格要求。属于社会医疗保险定点零售药店，严格执行社会医疗保险政策，在申请之日前 3 年内未受过食品药品监督、工商行政管理和人力资源社会保障部门处罚（含正在调查未有结论的事项）；销售谈判药品的社会药店所属的连锁总部需要取得《药品经营质量管理规范认证证书》，注册资金达 500 万元以上。

B 设施设备要求。要有独立的经营外购谈判药品的场所，自有药品物流配送中心，能够在 2 小时内调配规定范围内的谈判药品。连锁总部具备符合冷链要求的储存、使用区域及设备，具备完善的冷链质量管理体系。具备可联网接入医

疗保险信息系统的软、硬件条件，能确保医疗保险信息系统的正常运行，并能正确反映规定药品“进、销、存”情况。谈判药品生产企业要对药房进行验收，要求药房储存环境温度不超过 20℃，药品操作过程＜15 分钟。另外，对运输车辆和司机都要进行记录。药品到达药店后，要核对到货温度和数量。药品储存要求有医用冷藏箱，并配备 24 小时温湿度监控器，储藏温度控制在 2℃至 8℃的生物制剂稳定温度范围。同时药店具备短信报警功能，一旦发生断电情况，医用冷藏箱有备用电池，最低要求保证 4 台冷藏箱 3 小时的用电。此外要求定点药房连锁总部有不少于 2 台冷藏车进行冷链运输，保证药品的供应。

C 药学服务人员要求。定点药房经营场所至少配备 1 名执业药师并在岗提供药事服务。定点药房调配谈判药品前需对患者资质、证明材料等进行审核，并给予专业的用药指导。并对患者进行档案登记，每月至少回访一次，随时关注患者的用药情况及不良反应。此外，定点药房需要安排专门的管理人员对谈判药品进行入库、出库检查，库房管理，保证谈判药品的安全性。

②理顺双通道流程

确定定点药房后，患者就通过定点药房购买药品的操作流程见图 29：

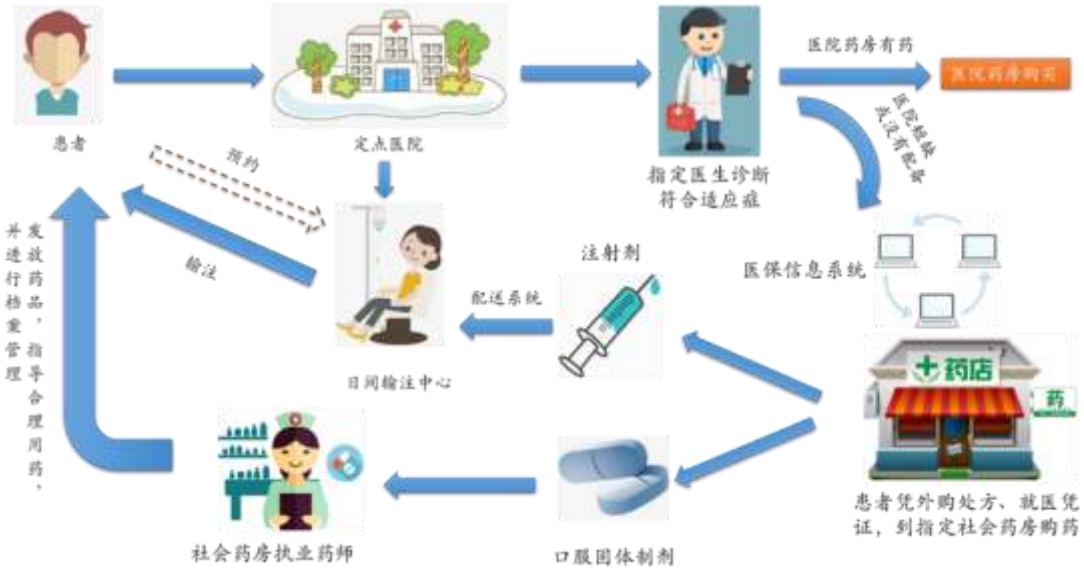


图 29 患者获取谈判药品流程

A 患者到定点医院取得购买资格。首先，参保病人按照规定，到指定的医院就医，经具有诊断资格的指定医师诊断。经医生诊断符合谈判药品的适应症后，开具外配处方，并在符合诊疗规范和参保病人病情需要的前提下，确定外配处方用量。

B 医生开具外配处方。参保病人就诊的指定医院按照上传外配处方的要求将外配处方上传至医院药剂科，由医院药剂科对处方进行初次审核。医院药剂科审核合格后，将处方上传至由医保、医院、社会药店共同建立的医保信息系统，医保信息系统平台再次对处方进行审核。

C 患者到定点药房购药。医保信息系统对处方再次审核合格后，将会发送短信通知患者可以取药的地点，取药金额，以及取药码。患者凭取药码、就医凭证、身份证在外配处方有效期内（例如 3 天内）到指定定点药房支付药费，取药。

D 药品的发放或配送。患者去医院如果购买的是固体口服制剂，不需要到医院使用，就可以直接发放给患者，并通过专业的执业药师对患者进行档案登记，方便对患者的随访，并指导患者合理用药。如果患者购买的是注射剂或必须在医院使用的药品，则需要配送至医院。定点药房通过配送系统将药品配送至指定医院，配送系统会发短信通知患者（包括配送医院、预计到达时间、取药码），患者可以实时关注药品配送状态。

E 患者预约输注。患者在定点药房购买药品后，可以预约指定的医院日间输注中心，并将输注时间、药品配送码上传至输注中心预约系统。

F 患者到医院日间输注中心注射。患者在约定的时间到医院输注中心办理输注手续，进行输注治疗。

③规范统筹报销

患者在购买使用谈判药品时，会涉及到药品的报销问题。主要包括两种报销途径：药店直接报销、就诊医院报销。

在实际的报销过程中，根据不同的情况需要实行不同的报销方式。符合条件的参保人在住院期间该谈判药品在医院出现短缺或医院没有配备该谈判药品，可以凭指定医院指定医生开具的“外配处方”到经批准的定点定点药房购买药品。住院患者外购谈判药品发生的药品费用由参保人先全额支付，然后再持外购药品发票回就诊定点医疗机构报销（须在购药当日或次日），并且外购药品费用(不含个人自负的部分)一并计入当次住院政策内医疗费用中，由定点医疗机构向社保经办机构申请费用结算。

符合条件的参保人申请门特、门慢待遇，明确需要使用“外购谈判药”时，待遇周期自批准之日的当月起计算（按治疗规范确定的治疗周期计算，含批准之日

的当月）。在门诊治疗周期内，参保人每次购药需凭当地定点医疗机构指定医生开具的“外购药处方”（每月或每个疗程开具一次）在 3 日内到“指定药店”购药，参保人只需支付个人应支付的药品费用。每个治疗周期结束时，经诊断需要继续使用“外购谈判药”治疗的，继续按此规定执行。

④消除处方外流障碍

2017 年 2 月 9 日，国务院办公厅发布《关于进一步改革完善药品生产流通使用政策的实施意见》。为落实该意见，全国已有 20 多个省市出台相关政策，提高药品质量疗效、规范药品流通和使用行为，要求医疗机构要按药品通用名开具处方，并主动向患者提供处方，患者可以自主选择在医疗机构或零售药店购药，医疗机构不得限制门诊患者凭处方到零售药店购药。

处方外流是为了“破除以药养医”机制，让医院回归医疗本质，弱化对处方的“独占性”。在实际过程中，处方外流面临着一系列阻碍，包括处方来源、医保统筹、使用管理等方面的障碍。

处方外流需要通过医院、医保、定点药房共同建立处方信息共享平台，实现医院处方的外流。一方面患者可以在药店购买谈判药品，增加谈判药品对患者的可及性，同时提高社会药店的经营收入；另一方面意味着医院、医生放弃了处方的独占权，会影响医院医生的积极性。在处方外流的过程中也要考虑的医生的利益，因此需要出台相应的政策为医生医务劳动规定出合理的薪酬价码，保证医生的劳动报酬不会受到处方外流的影响。

如果外配处方不能给医生带来利益，医生可能不愿意将处方外流。因此，在开具外配处方时，需要给予医生每个处方单一定金额的服务费补偿，这个费用可以由社会药店进行支付。外配处方支付给医生的劳动报酬体现了医生的劳动服务价值，提高医生开具外配处方的积极性。

⑤提升输注等配套服务的能力

2017 年和 2018 年谈判成功的 53 个药品中，注射剂占比达到 42%，但是目前各地正在逐步停止门诊输液服务，在定点药房购药患者急需正规输液渠道。

全国各地也在探索建立特药定点药房。2016 年 5 月，在南通肿瘤医院、罗氏制药和国控南通的共同推动下，全国第一家日间病房输注中心在南通肿瘤医院投入使用。南通市肿瘤医院通过与国药控股南通有限公司的资源整合，医院输注

中心与定点药房联动，患者携带定点药房所购买的特药无需办理住院手续就能在输注中心完成注射。输注中心配套了专业的医护人员和设备，确保特药调配和使用的安全性。

因此，总结和参考各地谈判药品定点药房实施方法，建议输注中心可以采取以下 3 种模式：定点药房建立输注中心、定点药房附近输注、定点药房与医院合作建立输注中心。这三种输注模式的建立需要考虑以下问题：建立定点药房输注中心需要配备专业的医师和药师以及输注配液的无菌操作室；在定点药房附近输注，增加了药品的运输风险，特别是一些需要全程冷链的药品；定点药房与医院合作建立输注中心，会存在定点药房与医院责任分担的问题，需要处理好责任与风险承担问题。患者凭外购处方在定点药房购买注射药品并在开具处方的医疗机构预约输注后，可以选择以上 3 种输注模式进行输注。

对于输注费用结算，需要制定收费标准，实行输注和付费的分离。患者在定点药房支付药品费用时将药品的输注费用同时结算，输注费用由定点药房与输注中心进行结算，患者只需到输注中心直接输注，减少办理输注缴费程序。

定点药房为谈判药品提供输注中心，不仅提高了谈判药品对患者的可及性，提高药品使用的安全性，节省住院费用，降低了医保基金的支出、提高了医保基金的使用效率。同时相关合作医院也可以通过提供输注服务增加收入，提高医院医护人员的积极性。

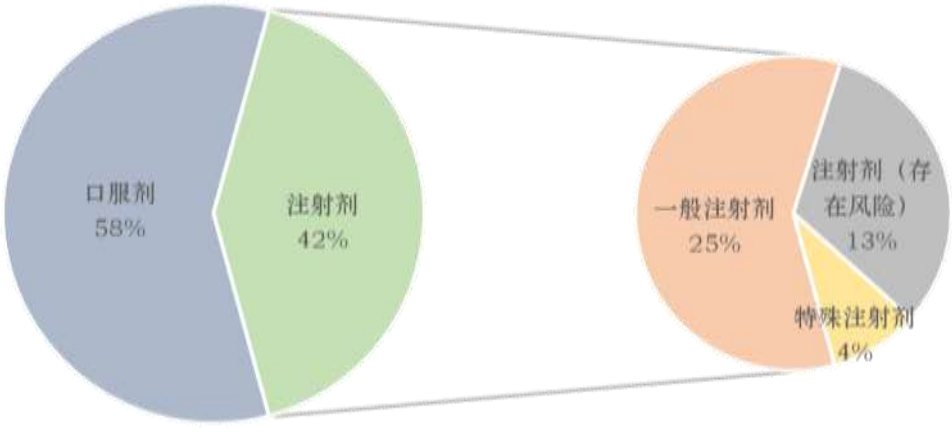


图 30　36+17 种谈判药剂型分布

对于 2017 年和 2018 年共 53 个谈判品种来说，部分药品可采取院外购药、家庭口服的模式；部分品种可以实行院外购药、院外注射（一般日间输注中心）；

或是院外购药、院外注射（三甲日间输注中心）；还有部分品种只能由有经验、有资质、了解病情的医生注射治疗（是否院外购药需要与患者协商）。具体如下：

①对于大部分口服药品（白色底纹），除住院患者外，其他门诊用药患者可以依据医师处方和医嘱进行院外拿药，并随时进行复查，疾病情况复杂者应当建立备案制度或开通网上用药服务，以便医师对患者的诊疗和用药进行实时观测和管理。

②对于注射剂而言，不论是静脉注射还是肌肉注射都应当在医师陪同和监督进行。不良反应较轻微、病情一般、注射操作易完成的（灰色底纹），患者可依据医师处方和医嘱进行院外拿药，注射地可以选择居住地附近的日间输注中心、基层医疗机构或社区诊疗中心，护理人员或医师注射后应当随时观察患者情况，有任何意外事件均应第一时间报告在场医师，医师进行紧急事件处理或急送附近医院。

③不良反应较为严重、病情紧急、注射操作易完成的（绿色底纹），患者可以依据医师处方和医嘱进行院外拿药，但是应当返回就诊医院的日间输注中心或是居住地附近级别较高医院的日间输注中心进行注射治疗，并应当配备如呼吸机、心肺复苏等应急器械和药品，以及经验丰富、诊疗水平较高的临床医师，随时观察患者情况。

④如雷珠单抗、康柏西普等特殊药品（红色底纹），需要经玻璃体腔内注射给药，要求在有资质的医院和眼科医生中使用，并要保证在无菌条件下进行的，实现“双通道”举措较有难度，还是应当院内用药、由有资质有经验的诊疗医师帮助用药（收取适当用药服务费用），最大限度保证用药效果和患者安全；如果与患者充分协商后，患者表示理解与同意，患者也可以进行院外定点药房购药后，回到指定医院由有资质、有经验的医师负责注射，采取分离模式。

表 26 谈判药实行“双通道”措施可行性分析

形式	药品使用特点	具体药品			
定点药店购药	•均为口服药，不需要注射 •药房执业药师应当就药品使用要求、不良反应、注意事项等对患者进行教育服务	替格瑞洛	碳酸镧	索拉非尼	复方黄黛片
		培唑帕尼	司维拉姆	厄洛替尼	尼洛替尼
		泊沙康唑	喹硫平	阿帕替尼	阿利沙坦酯
		托伐普坦	帕罗西汀	西达本胺	塞瑞替尼
		阿比特龙	参一胶囊	瑞戈非尼	阿昔替尼
		依维莫司	伊沙佐米	阿法替尼	克唑替尼
		来那度胺	伊布替尼	维莫非尼	舒尼替尼

		拉帕替尼	安罗替尼	奥希替尼	
定点药房 + 一般日间输注中心	•为使用风险较小的注射剂 •医护人员应当随时观察患者身体状况	利拉鲁肽	硼替佐米	氟维司群	重组人脑利钠肽
		奥曲肽	培门冬酶	注射用黄芪多糖	银杏二萜内酯葡胺注射液
		阿扎胞苷		银杏内酯注射液	重组人血管内皮抑制素
				吗啉硝唑氯化钠	重组人干扰素β-1b
定点药房 + 特殊日间输注中心	•为注射风险较大的注射剂 •应当配备专业药师和护理人员，足够了解患者病情，能够处理紧急状况	西妥昔单抗	曲妥珠单抗	重组人尿激酶原	重组人凝血因子Ⅶa
		尼妥珠单抗	贝伐珠单抗	利妥昔单抗	
院内购药注射	•为特殊操作要求的注射剂，规定有资质、有经验、有专业背景的医师进行操作	雷珠单抗	康柏西普		

在进行院外拿药过程中，需要保证：

①医保定点药店配备适量的执业药师。特药的销售，不同于 OTC 药品销售，也不同于一般的处方药销售，是属于比较高端的专业处方药，其用药的诊断相对复杂和高要求，既要有医生的明确诊断，也需要相关检查资料的佐证，有时还需要基因检测结论做依据等；另外，对于患者用药的各项疾病生理指标也要求是明确、清晰、具体的。以上这些都要求执业药师不仅具有一般的药学常识和技能，还需要其掌握药品的足够多的具体专业信息，包括治疗疾病的信息、药品本身的信息、竞品的信息、治疗方案及发展的信息；如此才可以做到专业、合理审核药品处方，并予以患者正确的配药服务和用药指导。一般在 DTC 药店的专业管理中，都会要求药店引入临床药学的服务支持，方式和途径可以是请大型综合医院或专科医院的临床药学专家定期坐诊，或来店培训驻店执业药师及药店其他药学服务人员，传授相关特殊疾病最新的临床药学知识，以更专业地服务于患者。

②药店执业药师审方时，不仅要对患者提供的处方进行常规的“几查几对”，还要特别注意处方的医院和医师是否是政策文件明文规定的指定医院和医师；如不是，就有可能导致患者的用药不能报销；要特别注意国家人社 2017 年的 54 号文及具体省份或统筹区域的相关“限制性规定”政策细节。再就是处方原件的保存管理问题，保存需要 3 年以上（一般是 DTP 药店管理要求中是 5 年），最好是电子版和纸质版同时留存；以备相关部门的核查，以及部分特药企业的审计。

当然还要留意处方的登录、登录审核、处方信息隐私管理、处方信息的使用管理等环节的合规精细化管理。

③打通医院和定点药店的信息系统，进行处方和医嘱的对接：应当保证药店药师能够了解患者的基本信息、疾病发展情况、用药注意事项、报销准入资格等等；并将定点药店信息系统与医保报销系统对接：明确患者报销比例、报销额度、自费比例等等。

（四）“双通道”具体实施风险分析

1 关注口服药品的服用注意事项

虽然相比注射剂而言，口服药品风险性较小，但是对于不同品种、不同适应症，患者的服药环境、要求、条件均不同。例如，辉瑞的克唑替尼要求服用前必须获得经充分验证的检测方法证实的 ALK 阳性评估结果，若患者盲目购药、医师没有担负起进行基因检测或想当然做决定，很可能导致患者服药无效、耽误最佳治疗时期、错失最佳治疗方式等，影响患者的康复与生命安全。再有者，例如夏尔制药的碳酸镧要求完全咀嚼后再吞咽、随餐或于餐后立即服用，拜耳的索拉非尼要求空腹或伴低脂、中脂饮食服用，医师开具处方后，患者院外购药，若药房药师资历、经验、水平不够、无法提供正确的药学服务和用药提醒，更有甚者没有对患者进行服药注意事项和要求的讲解，导致患者没有根据说明书用药，会在一定程度上影响药品疗效、降低患者依从性、药品治疗无法发挥应有的最大效益，延缓患者康复时间甚至耽误病程。

表 27　36+17 种谈判口服药品的用药注意事项分类

分类	具体注意事项
服药时间规定	进食前 1 小时/进食后 2 小时
	空腹/伴低脂、中脂饮食服用
	随餐服用
	饭前服用
	饭后服用
	饭前/饭后服用
	不与食物同服
服药形式规定	完全咀嚼后再吞咽
	完整吞服，切忌掰碎、捣碎、咀嚼后服用
辅助条件规定	温开水
处方医师规定	有经验的医师指导下
特殊规定	定期检测血常规
	用药前确认明晰的基金检测结果
	根据患者安全性/耐受性及时调整用药情况

2 完善注射剂保存、配置标准

对于注射剂而言，其一般需要将冻干剂或小剂量包装，由具体注射机构配置后再行滴注。在这个过程中，一是药店对于冻干剂或小剂量原装产品的储存易出现风险，二是在注射剂配置过程中，很多品种要求无菌操作，也易产生风险。以上两者不论哪一环节出现问题，都可能会导致滴入人体的注射剂被污染，导致不必要的伤亡和不良反应事件。例如，罗氏的贝伐珠单抗、诺和诺德的重组人凝血因子Ⅶa 等均要求配置过程保持无菌。

因此，药店方面应当配备冷藏设备，对部分需要冷链管理的品种给予冷藏储备并随时跟踪监控储存室温，保证全程冷链。而对于部分医院、基层医疗机构的日间输注中心，应当提高药品配置室硬件标准，建设无菌操作台；同时提高软件标准，对配置人员进行操作培训，以符合特殊品种的无菌配置要求。

3 提高注射护理人员的医学知识水平

部分注射剂的注射要求较为繁琐，具体如下：

（1）不同时间段对应不同注射方式，例如西藏药业的重组人脑利钠肽要求先按负荷剂量静脉推注本品、随后按维持剂量进行静脉滴注；强生的硼替佐米强调，鞘内注射会导致死亡；

（2）不同时间段对应不同滴速，例如天士力的重组人尿激酶原要求一次用 50 毫克，先将 20 毫克用 10 毫升生理盐水溶解后 3 分钟静脉推注完毕、其余 30 毫克溶于 90 毫升生理盐水于 30 分钟内滴注完毕；罗氏的曲妥珠单抗强调请勿静推或静脉快速注射；

（3）对注射部位有特殊要求，例如诺和诺德的利拉鲁肽要求经皮下注射给药，注射部位可选择腹部、大腿或者上臂，不可静脉或肌肉注射；

（4）要求单独使用注射设备，例如罗氏的利妥昔单抗要求稀释后通过独立的、不与其他药物混用的输液管静脉滴注；

（5）要求根据过敏性实验结果决定是否符合注射条件，例如天津赛诺的注射用黄芪多糖要求使用前先做皮试，皮试阴性者方可使用；默克的西妥昔单抗也要求使用前先进行过敏试验，因部分输液反应发生于后续用药阶段。

因为谈判药品大部分针对的疾病是风险高、病程复杂的病种，且患者多为病情复杂严重的群体，所以如果注射护理人员、地区医师不够了解相关药品的输注

注意事项，出现未进行过敏性实验、未单独使用注射器具、未控制滴速、注射方式或注射部位错误的情形，就可能会导致非常严重的过敏反应甚至伤亡。因此，日间输注中心的护理人员和值班医师应当提高自身医学知识水平、仔细阅读学习相关药品说明书、研究文献等，保障用药安全和有效。

4 提高注射中心急救能力水平

部分药品虽然是能够挽救生命、救人于水火的神药，但是同时也会存在不定的副作用或不良反应，亦或是由于不同人耐受能力的不同也会产生不一样的用药效果。例如，罗氏的利妥昔单抗要求应在具有完备复苏设备的病区内进行；百泰生物的尼妥珠单抗需密切监测患者的状况。这都是针对药品的不良反应、或特殊人群的例外事件做出的特别规定。因此，负责输注此类药品的机构应当配备如心肺复苏设备等的急救器械和资源，并配备急救人员，保证突发事件的止险和救治措施顺利、高效进行，最大程度保障患者生命安全和健康权益。

四、医保基金“开源”

针对医保基金结余情况不理想的现状，可以通过差异化筹资、医保筹资动态调整，扩大基金来源渠道进行基金开源。

（一）差异化筹资

差异化筹资基于城镇职工医疗保险、城镇居民医疗保险、新型农村合作医疗三险合一，在此基础上分为 A、B 套餐。A 套餐即当前的基本医疗保险保障水平与筹资水平。B 套餐细分为多个档次，以不同层次的筹资标准覆盖不同层次的报销药品范围，满足不同人群的医疗保障需求，实现差异化筹资，进而达到医保基金开源的目的。

表 28 各层级筹资与报销体系

套餐		报销药品范围	特点	筹资水平
A 套餐		医保目录药品	维持当前保障水平	维持现状
B 套餐	B1 档	A 基础上扩大对患者负担重的药品报销	以更高的筹资标准换取更大的保障范围	高于 A 套餐水平
	B2 档	B1 档基础上扩大对患者负担较重的药品报销		高于 B1 档水平
	B3 档	B2 基础上扩大对患者负担特别重的药品报销		高于 B2 档水平

（二）医保筹资动态调整

2016 年 1 月 12 日，《国务院关于整合城乡居民基本医疗保险制度的意见》（国发〔2016〕3 号）（以下简称《意见》）公布，要求整合城镇居民医疗保险与新农

合，建立统一的城乡居民基本医疗保险制度。城乡医保一体化的核心问题在于资金筹集。如果缺乏制度化和规范化的筹资调整机制，医保筹资调整的短期性和随意性行为，将影响医保制度的稳定和可持续发展。

医保筹资动态调整机制应当基于稳定性、可持续性、精算平衡原则，设立专门机构进行筹资标准确定，并对人口结构、疾病谱、医疗需求行为变动进行定期评估，同时对保障效果与基金风险进行日常监督，并以此为依据进行筹资标准动态调整，减少筹资标准调整的随意性。通过医保筹资动态调整机制，切实保证调整的科学性以及保障医保基金可持续性[32]。

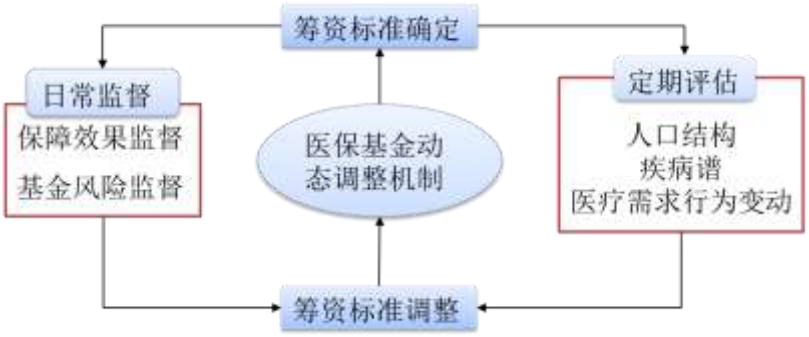


图 31 医保筹资动态调整机制

（三）扩大基金来源渠道

在强化政府、单位、个人缴费的同时，应当扩大筹资渠道。可以考虑以下渠道：一是财政税收支持。可考虑每年从烟酒税收、环保税收等的一部分，用于补充医保基金。二是调整财政支出结构，把每年财政收入增长额的一定比例用于建立类似于全国社会保障基金理事会基金的方式，建立基本医疗保险风险储备基金。三是土地收入及收益，从土地征用或转让的部分补偿收入及收益作为新农合（城乡居民医保）制度的一个重要资金来源渠道。四是发行医疗保障长期债券。可以考虑中央政府把以往大规模用于经济建设方面的部分资金，转向投入社会保障方面，应对人口老龄化时的支付风险。五是将经营性国有资产及其收益，及国有企业利润分红的一部分划转医保基金[33]。

五、医保基金“节流”

新英格兰卫生保健研究所（NEHI）曾表示，医疗浪费就是即使被削减也不

32 李亚青. 城乡居民基本医疗保险筹资动态调整机制的构建[J]. 西北农林科技大学学报(社会科学版), 2018(5).

33 谭中和. 完善职工医保筹资机制的思考[J]. 中国医疗保险, 2016(5): 13-17.

会降低医疗质量的医疗费用。据人民报报道，我国医疗机构滥开药、滥检查等现象导致医疗资源的浪费在 20％至 30％，如再加上药品回扣、药品虚高定价、乱收费等现象，医保基金浪费和流失比例不低于 50％。叶京云在全国疾病医疗保险参保人员医疗服务利用情况分析（2013）中统计，在不合理检查中，仅重复检查的病例数就高达 21.1%。

（一）解决基金浪费和利用率不高的问题

应当遵循用药指南和临床路径，减少医疗浪费。据报道，遵循规范治疗指南将显著获益——将提升 50%医疗服务质量、节省 70%医疗资源费用[34,35]。

应当完善医保支付方式改革，优化医疗资源配置。主要可以分为三个阶段，首先第一阶段以医保基金预算管理为基础，实施总额预算管理，但是逐步从相对粗放的直分法向点数法进行调整。综合考量多元化因素，建立合理的总额测算指标和公式；建立医药行业社会共治制度，构建法律框架下多方利益兼顾的协商决策机制；逐步构建多元支付体系。其次，第二阶段在实施点数法的过程中不断对病种分类和权重进行优化调整，为渐进式推行 DRGs 创造条件。最后第三阶段，全面推行以按病种付费为主的多元复合式医保支付方式，向精细化的支付和管理模式发展。

（二）增强医保基金抗风险能力

1 完善老人福利制度分散医疗风险

从国外经验来看，分散医疗费压力的有效办法是建立老年医疗制度和护理保险制度，把需要护理和康复的部分费用由护理保险出，或者由老人福利资金来分担。我国尚未建立老年护理保险，商业老年护理保险也很缺乏，所以老人的老后护理和康复主要由医保基金来负担，尤其是离休老干部的医疗费全部报销，有的一年大部分时间都在挂床住院，这为医保基金带来了很大的负担。同时，我国医疗保险费率（8%）偏低，进入超级老龄社会的德国为 14.9%，日本为 8.2%，医保基金收支平衡已遇到严峻的挑战，因此医保基金不应成为应对人口老龄化引发

34 WHO: Pharmaceuticals and Health Sector Reform in the Americas: An Economics Perspective, 1998.

35 Ford, Earl S., et al. Explaining the decrease in US deaths from coronary disease, 1980–2000. New England Journal of Medicine, 2007, 356(23): 2388-2398.

费用增长的措施[36]。所以建议我国加快护理保险制度和老人福利制度的建设。

2 转变医疗保障制度的理念

变“有病治病的消极医保理念”为“无病防病的积极的健康保险理念”，最后实现“全民健康，无疾而终”的终极目标，这对减轻医保支付压力，从源头上提高医保基金抗风险能力至关重要。为此，政府应该把预防和保健也作为医疗保险的重要内容，加大对预防和保健的投资和宣传力度。同时也可以有效发挥个人账户的作用，应该在现有的医疗消费领域内向预防健康延伸。规定个人医疗账户的适用范围，逐步扩大它的使用功能，如用于体检、免疫接种等保健服务。

（三）完善动态退出机制，“腾笼换鸟”

据不完全统计，W 市 2013 年到 2018 年上半年特药医保报销金额共计 1.5 亿元，而 S 省 2016 年单唾液酸四己糖神经节苷脂（单唾液酸四己糖神经节苷脂是用于治疗中枢神经系统损伤后，脑、脊髓的缺血及出血性疾病的辅助治疗药品）的采购额就达 6.5 亿元。由此可以推断，将占用医保基金比例大、临床价值低的药品调出医保目录，为临床需求大、价值高的药品提供空间是可行的。

为实现“腾笼换鸟”目标，需要加大医保基金使用监测力度和加强基金使用情况评估，通过对“医保数据”和“临床用药综合评价”数据的汇总与分析，不断优化医保目录和支付标准，对目录内品种实现动态退出、以及支付标准动态调整，起到杜绝基金浪费的节流作用。

1 加强信息建设，完善数据评估与分析

应当贯通药品采购数据系统、医保信息系统和院内处方系统，对数据进行整合，将药品的采购信息、使用情况与报销情况形成完整链条，通过药品使用量、处方合理性以及医保基金占用情况实现对药品品种的综合分析。

首先，应当将药品采购系统与医院用药信息系统有效衔接，进行医保基金的事前控制。以江苏省为例，在访谈调研中得知，江苏省药政部门已经开始实行药品采购系统与院内处方系统接通的试点工作，预计 2018 年年底在全部三级医院使用，2019 年实现全覆盖，希望通过对采购信息和处方信息的汇总及时发现标外采购、基金浪费的情形，控制风险。

其次，完善医院内部智能审方系统，实行基于数据的处方点评制度。目前大

36 杨燕绥，于淼．人口老龄化对医疗保险基金的影响分析[J]．中国医疗保险，2014(10): 12-15.

部分医院日常处方信息量大、临床用药复杂，人工处方点评存在工作效率低、覆盖面有限、抽样随机性不强、代表性不够等缺点，不能满足及时全面的监控和分析要求。基于商业智能技术的医院智能审方系统将对提升医院处方点评及用药动态监控的效率和效果起到积极作用[37]。解放军总医院、南昌大学第二附属医院、青岛市立医院等医院的智能审方系统都较为典型值得借鉴。智能审方系统是医院信息系统中的重要组成部分，与医院的其他应用系统有着紧密的联系，需要连接HIS 等系统，共享数据。并且智能审方系统是临床信息中的一部分，本身不能脱离医院信息系统大框架而独立存在，为了满足医院信息化管理要求，智能审方系统必须与医院现有信息系统整合在一起，实现无缝连接。医保部门应当与医院智能审方系统连接，实现数据共享、实时监控，切实保障医保基金的使用效率，着重关注使用金额大、用量多、处方点评不合格、滥用情况严重的药品。

最后，结合采购信息、处方监控和点评结果分析药品医保基金占用情况。以采购信息为基础，对占用医保基金比例大、临床监测后发现处方点评结果不理想、非临床必需的品种，约谈相关医师、企业，处以警告、约谈后仍旧存在问题的，与下述医保退出机制衔接，责令相关药品品种退出医保目录，将有限医保基金资源实现最大化、最优化效益产出。

2 完善医保目录动态退出机制

结合上述数据监测结果，将占用医保基金比例大、临床监测后发现处方点评结果不理想、非临床必需的品种，约谈相关医师、企业，处以警告、约谈后仍旧存在问题的药品名单列出，与药品再评价体系中的评估流程相衔接，进行医保目录退出的评价，经过评价后发现应当退出目录的，予以告知并动态调整出目录。

韩国在 2006 年至 2011 进行了药品目录的大型专项型评价，目的就是建立一个药品退出机制的范本，即如果药品综合评价结果证明不具有临床和经济价值，那么该药物将被从目录中删除。对于药品的退出与否，与众多国家不同的是，韩国先考虑药品的经济性，经济性审查完毕后，则主要参考以下指标：安全性、临床有效性、成本效果指标、对预算的影响、可用替代药物情况、针对疾病的严重性和其他国家同种药物的价格及报销情况。为了保证决策的公开透明，韩国的官方网站上公开了评估标准、评估过程的细节和最终的评估报告。药品生产企业可

37 徐梦丹, 陈文戈. 基于商业智能技术的医院处方点评与用药动态监控系统架构设计与应用[J]. 医学信息学杂志, 2014, 35(5): 33-37.

以在药物福利保障评估委员会的会议上提出他们的不同观点，如果他们对评估结果有异议，可以上诉申请重新评估。此外，法国医保目录的准入和退出以药品价格委员会与制药公司的协议为基础，4 年为限，若药品评价情况良好且销售数量与价格的关系符合其最初约定，则可在 4 年到期时进行续签，若上述指标出现问题则 4 年到期后，药品自动退出医保目录，协议终止。日本的再评价机制也是十分及时的，一旦在质量再评价、价格审查或常规再评价过程中发现目录内药品的相关指标已严重偏移，则会责令其退出报销目录，待整改或调价后经过再评价系统决定其是否可以再次进入。

在借鉴上述国家先进经验的同时，结合我国现有国情，基于数据化的监测，对药品采购情况、医院处方信息、处方点评结果、基金占用比例综合分析，将临床滥用情况严重、处方点评结果多次不合格的，且占用大量医保基金的药品经提示与警告后仍旧问题突出的，进行动态化的医保目录退出。企业应当有申诉权利，可以对药品使用评估结果提出异议但应提供足够证据，交与专家审核，审核结果关系到药品的退出与否。动态的医保退出机制，旨在通过数据化的评估依据和流程化的审评结论，对占用医保基金且非临床必需的产品予以剔除，最大限度节省医保基金，实现有效资源的合理分配。

3 实现医保支付标准动态调整

根据药政、医院和医保部门三方数据共享、汇总、分析的结果，将药品的采购情况、处方点评情况、基金占用情况进行综合评估，基于此实现医保支付标准的动态调整，将医保基金的分配更加合理化，基金支出的价值最大化。

首先，经过采购数据、临床使用数据、处方点评数据、医保报销数据的汇总，对采购行为合规、临床使用规范、价值评估结果良好的药品可以维持其原来的医保支付标准（价格），临床产出效益格外明显的品种可以适当上调其医保支付标准（价格）；其次，对采购行为合规、临床使用偶有瑕疵但及时改正、价值评估结果良好的品种，可以动态下调其医保支付标准（价格），其行为予以调整并审查回归后，可以调回原标准（价格）；再次，对于采购行为合规、临床出现严重滥用或处方点评严重不合格或价值评估结果不符合初始评估预期的，调出医保目录，相当于将医保支付标准（价格）下调为零点，根据企业准入再申请和整改情况再行决定药品的动态准入；最后，对于临床监测显示药品不良反应严重、安全

性存在严重问题的产品，可与药品监管部门及时沟通，做出撤市的评估与决定。

医保支付标准的动态调整，希望通过综合卫生部门药品采购信息、临床使用信息，药监部门药品再评价信息，医保部门基金报销信息以及医院内部处方点评结果，对医保支付标准（价格）做动态调整，优化药品的报销比例和医保基金分配，实现高价值、临床必需品种的落地使用，杜绝资源浪费。

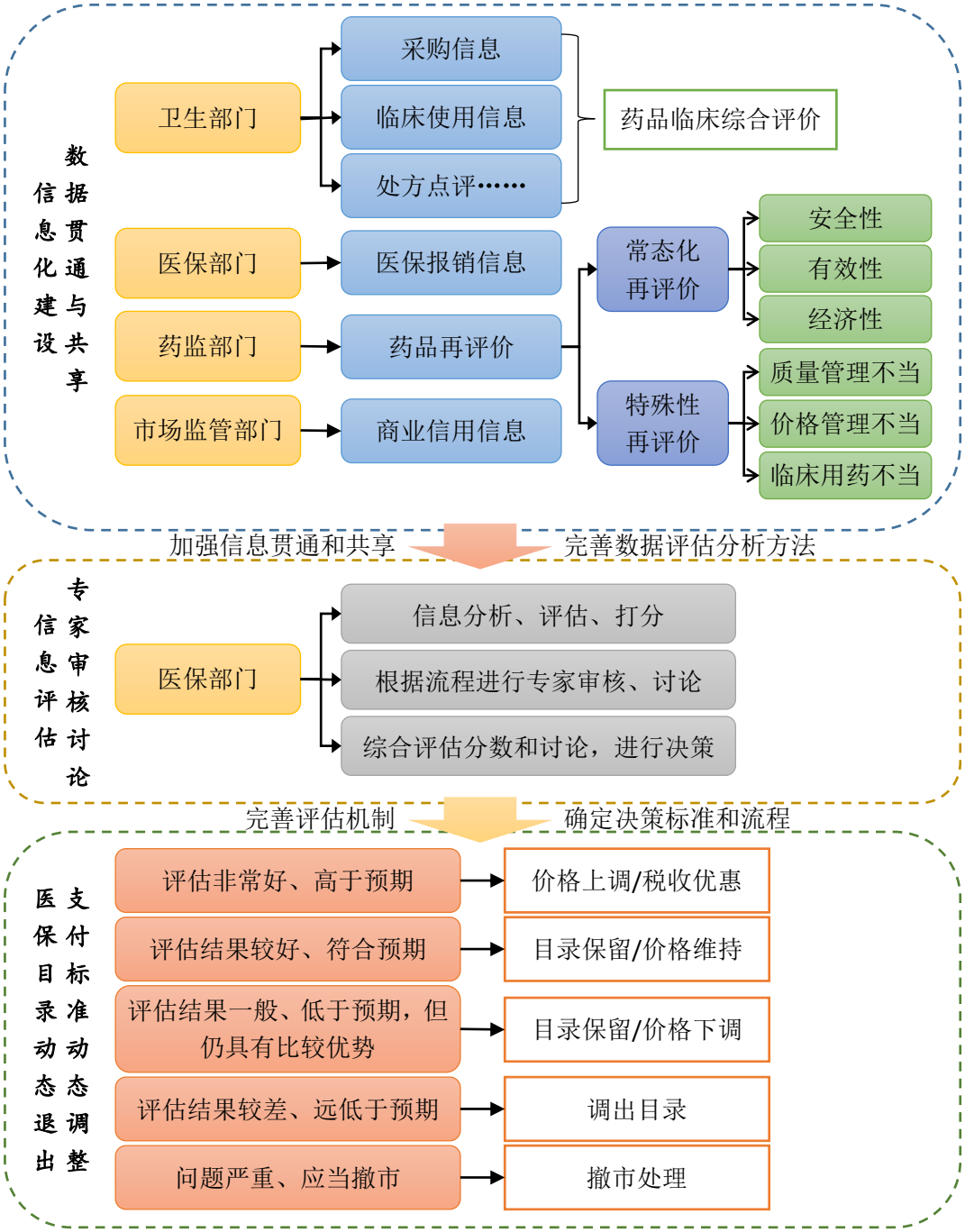


图 32 优化医保基金运行机制，实现“节流”目标机制图

六、“互助共济”——适当提高医保统筹级别

（一）提高统筹层级的难点与风险

1 职工医保改革阻力较多

目前我国三种基本医疗保险要进行统筹层次的改革难度较大，尤其是职工医疗保险，因为其缴费比例最高，保障效果最好，因此其所牵扯的经济利益问题最大。另外新农合与居民医保的筹资方式为个人缴费加上政府补助，而职工医保的筹资方式则为单位与员工共同缴费，因此如果提升统筹层级，可能会对许多用人单位造成影响，增加企业的用人成本，反而不利于地方的经济发展。

2 医疗支出压力增大、易造成过度医疗

提升医保统筹的另一大风险是可能会极大增加医疗费用的支出压力，进而增大医保基金的运行风险。客观来看，在一座城市中，其所包含的辖区内医疗水平与资源可能差别不大，但如果提升至省级统筹甚至全国统筹来看，由于各地经济发展状况存在差异，不同地区的医疗水平也存在较大差异。患者在就医时有了更大的选择空间，在政策差异消除以及就医报销便利的情况下，患者极有可能集中去省内甚至国内三甲医院这些优质的医疗资源，这不仅导致基层医疗资源被浪费，顶层医疗资源极度短缺，还容易出现极严重的过度医疗，使医疗支出压力陡增。因此在提升医保统筹层次的同时，一定要与当地参保人口、医疗保障水平和卫生费用等方面相互匹配，做好衔接工作。要分阶段、有步骤地提升。对于医疗水平较低的地区，应当加强政府责任，提高财政支持与医疗服务的配置，缩小各地区医疗保障水平。一定要秉持在提升统筹层次过程中不能损害参保人的医疗保险权益的原则，真正实现医保的公平性与共济性。

3 地方保护主义影响落实

在提升统筹层级的过程中，地方保护主义也会带来风险，尤其在调剂金制度方面会造成很大影响。按照原有的思路，如果已经落实好省级统筹与调剂，各市的基金盈余部分应当上缴至省级账户，当某市出现医保基金超支的情况再利用已收缴的调剂金进行调拨。而实际上，各地方政府因为地方保护，盈余时不愿上缴基金或者只上缴一部分，这样使省级医保基金规模降低，调剂金制度形同虚设，无法发挥其设立时抗风险与共济的初衷。同时，市县级的基金结余不断贬值，不能通过专业机构对全省范围的社保基金进行大规模运作，加大了基金保值增值的难度。基层部门管理水平低，加大了省级统筹难度。另外根据甘肃省的经验来看，

如果省级基金的规模较小，一旦出现两到三个地区基金出超时，基金与财政的压力就会剧增，解决的手段只能说省支付一部分之后，市县自己再支付一部分，但这种方法要么会导致医保公信力下降引起矛盾，要么就会助长地方医保基金自筹的风气，与省级统筹的初衷相违背。此外，由于统筹层级的上升带来的管理权力上移，高层级的医保经办机构不够了解地方的医疗机构，基金监管困难，并且不利于与地方医疗机构商议合理的支付价格。

（二）提升医保统筹级别

1 提升医保统筹级别的方法

在提升统筹层级方面，我国政府还是起到了主导作用。国家在 2009 年发布的《中共中央国务院关于深化医药卫生体制改革的意见》中提出“中央统一制定基本医疗保险制度框架和政策 ，地方政府负责组织实施管理 ，创造条件逐步提高统筹层次。有效整合基本医疗保险经办资源 ，逐步实现城乡基本医疗保险行政管理的统一 ”。这明确表明了国家在提高医保统筹层次方面的态度，并且强调了中央政府对于医保政策的设立制定的主导地位，以及地方政府的任务与定位。

具体该如何做到在高统筹层级实现政策统一，首先需要保证在区域内实行的是统一的医疗保险制度，来源可以是同级政府，也可以是上级政府下发的规范性文件，但必须保证区域内是统一的。具体表现为区域内缴费的基数与比例在同一项目内统一，起付标准要一致，报销比例要相同，定点医院要确立，操作系统要规范，做到信息的对称与共享。总体上来讲就是待遇标准与缴费标准在同一统筹区域内要保持一致。此外，还应当建立完善区域内调剂金制度，调基金的划拨也应当统一。

国家在《关于进一步加强医疗保险基金管理的指导意见》和《国务院关于印发医药卫生体 制改革近期重点实施方案 2009 一 2011 年的通知》中提出，“各地要根据本地实际情况 ，加快推进提高基本医疗保险统筹层次工作 ，基本实现市地级统筹 。实现市地级基金统收统支确有困难的地区 ，可以先建立市地级基金风险调剂制度，再逐步过渡。具备条件的地区，可 以探索实行省级统筹”。这给我们统筹层次的升级提供了一个很好的路径与方向。关于路劲在后文有详细分析，这里不再赘述。我们在这里提炼出的关键点就是，在提升统筹层次的方案设定与实施过程中，要明确我们的目标是降低不必要的成本以及减缓统筹层次低所带来

的矛盾，这就要求我们应当重视地方经济发展状况，循序渐进，做好政策的衔接，保证在提升过程中人民接受的医疗服务水平不下降。另外在调剂统筹方面，一定要明确统筹区域内各地区的责任，完善统筹管理的预算制度，并且落实好调剂金的额度设定、收缴、管理、使用工作。

2 路径选择

在选择路径之前，我们应当先分析每一种统筹方式的利弊，进而选择合适的提升统筹层次的路径。就此，我们得到了以下这幅图表，直观展示了不同层级统筹的优缺点。

表 29 不同统筹模式的优缺点

模式 优缺点	省级统筹模式	市级统筹模式	县级统筹模式
优点	·提高医保抗风险能力 ·降低管理成本 ·改善参保机会不公	·符合各地区管理实际水平 ·统一全市的缴费水平和医保待遇，增加医保谈判能力 ·为建立省级调剂金打基础	·考虑当地经济水平与医疗服务水平 ·有利于明确各级政府的执行责任 ·有利于某项社会保障制度的逐步推行
缺点	·各省差异过大，目前管理水平难以适应 ·降低地方或行业筹资积极性，筹资能力不足 ·同标准筹资将扩大基金筹集的公平性问题	·同筹资标准，会因居民支出不同，得到基金补偿不同，出现收入偏低地区结余部分补贴城镇高收入群体的情况 ·省内各市基金难以调节	·医保基金难以调剂使用，降低基金使用效率；基金结余结构性不平衡，赤字与结余现状并存 ·单一地区基金共济能力较差，抗风险能力较弱，难以满足劳动力流动要求

我国目前的统筹层级过低，因此提升统筹层次是必要的。但结合我国目前不同地区的经济实力、收入水平与医疗水准，也不易直接上升至全国这样的高层次模式，不然将造成大规模的浪费以及制度衔接不到位。目前，省级政府的财政主动性最强，从国家的管理幅度来看最为科学，且最大程度地考虑到地方发展差异，因此本文以省级统筹作为提升统筹级别的最优选择。

实际上，并非所有省份都适用于直接进行省级统筹的路径。统筹提升应当分阶段分步骤来进行。在第一阶段，经济较发达的，统筹基金压力不明显、医疗资源配备较为齐全的省份可以积极探索省级统筹的筹资方式。同时，像地域辽阔、人员稀少的，即便实行市级统筹基金压力也较严峻的省份，也可以先一步直接进行省级统筹。其余经济实力较一般或欠发达，但拥有一定人口数量的省份，还是

先将市级统筹落实好，通过经济发展减小不同地区的差距。在完成第一阶段之后，第二阶段的任务就是进一步推广省级统筹。无论在哪个阶段，都应当注意与当地的经济实力与收入水平相衔接，不能因为层级的上升削减参保人的权益。

七、完善药品谈判启动机制

（一）明确药品医保准入启动机制

应当科学设计药品医保准入的启动机制，充分发挥邀请制与申请制的特长。

表 30 邀请制与申请制的比较

动态调整的启动类型	利	弊
邀请制	由专家推荐，监管部门向企业发出参加动态调整评审的邀请，有利于主动选择优秀产品纳入遴选的范围	①部分企业参加医保动态调整的意愿不明确；②企业等待动态调整的启动，对于何时启动动态调整程序无法进行有效预测，主动收集材料积极申报的积极性降低
申请制	由企业申请，专家组和监管部门对材料进行评审，有利于企业提前准备材料并主动申报，形成“申请—受理—评审—动态调整”的常态化机制	①企业提交评审的品种水平层次不齐，需要专家组和监管部门进行大量前期初筛工作以确定入围品种范围，不符合医保准入条件的品种将占用大量审评资源；②企业自行提交数据材料的真实性、完整性和科学性问题可能会干扰评审结果

区别药品类别，采取差异化的医保准入启动方式。对于医保目录内无相似/相同适应症品种的新药，采用邀请制（遴选制），由医保方主动邀请相关品种参与医保准入遴选，并会同临床专家对品种进行评估；对于医保目录内已有相似/相同适应症品种的药品，采用申请制，由申请企业对目录内品种进行“挑战”，证明自身药品的成本-效益优势。

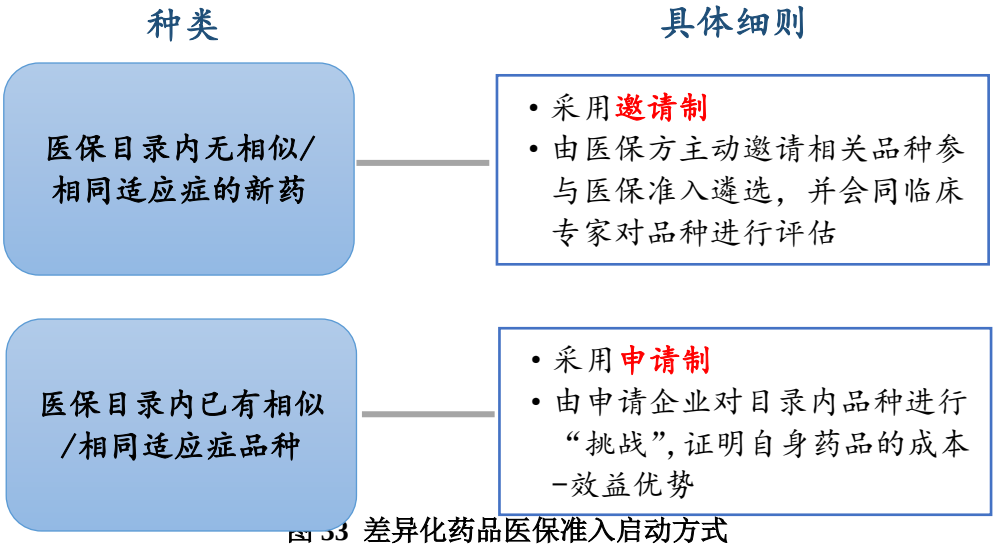


图 33 差异化药品医保准入启动方式

（二）明确常规准入和谈判准入的适用范围

建议从医保目录管理机制的政策层面明确常规准入和谈判准入的适用范围和标准。

表 31 常规准入与谈判准入的比较

医保准入方式	经济性评估结果
常规准入	经济性较好的药品
谈判准入	经济性较差的药品

药品医保准入分为常规准入和谈判准入两种方式。对同类药品按照药物经济学原则进行比较，明确对于满足有效性、安全性等前提，价格（费用）与药品目录内现有品种相当或较低的药品，即经济性较好的药品，采用“常规准入”的方式直接纳入医保目录；对于价格较高或对医保基金影响较大的专利独家药品，即经济性较差的药品，则采用“谈判准入”的方式纳入医保目录。

（三）建立申请制启动流程

由于我国尚未建立起申请制的启动流程，目前课题组对申请制实施的要求、流程和规定构想如下：

1 组建医保准入委员会

实现医保目录动态调整机制的前提是组建医保准入委员会，进行医保目录动态准入审评工作。以澳大利亚和日本为例，澳大利亚设有药品福利咨询委员会（Pharmaceutical Benefits Advisory Committee, PBAC）,该机构由政府独立设置、

主席由总理任命[38]，人员由医学专家、保险专家、卫生经济学家、消费者代表组成，其下设经济学附属委员会（ESC）和药品附属委员会（DUSC），其中 PBAC 负责向卫生和老龄部（MHA）推荐药品和药剂被列入药品补贴计划，ESC 负责对申请的药物进行经济学评价，DUSC 负责收集澳大利亚药品使用的数据并分析，同时与其他国家做比较。PBAC 每年 3 月、7 月、11 月召开评审年会，针对已经上市的药品或针对暂未获得上市许可的新药、新疫苗，或具有新适应症的药品进行审评，决定是否纳入澳大利亚药品福利计划（PBS）。

日本设有中央社会保险医学委员会，由医学专家、牙医学专家、药学专家组成，下设药物算定组，主要负责新上市药物谈判价格的计算；对已经进入医保目录的药品市场扩大重新计算等加算率的研究；进行药物分类研究等其他需要随时进行的工作；提出药价制度的修改意见，并每 2 年向药价专门部门报告等。企业每年有 4 次机会就已获得上市许可的药品提交药品价格谈判申请书。

我国可以此为借鉴，设立医保准入委员会，该委员会由医学专家、药学专家、药物经济学专家、消费者代表组成，涉及国家医疗保障局、国家药品监督管理局、国家卫生健康委员会等相关部门的职能，主要负责拟定与修订申请材料指南与程序指南、审核评估企业申请资料(包括药物经济学材料、药品临床资料、药品上市审评相关批件等)、医保目录准入中的沟通与反馈、讨论审评建议、药品谈判相关工作等，每年定期召开 3-4 次评审会议，决定药品是否纳入医保。

2 提出申请与材料提交

[38] 傅鸿鹏, 杨宏伟, 韩会学. 澳大利亚药品管理体制及政策经验[J]. 中华医院管理杂志, 2013, 29(1):73-76.

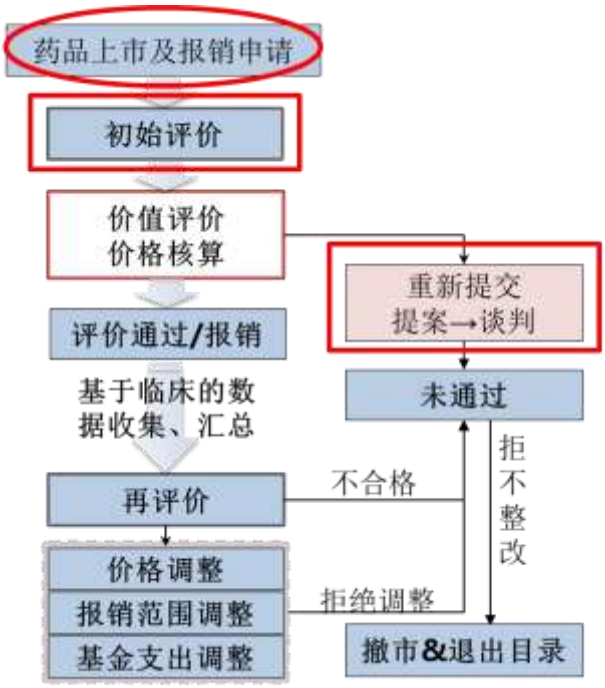


图 34 英国医保准入申请流程

借鉴国外经验，英国由英国国立临床规范研究院（NICE）对企业申请材料进行初始评价与价值评估，作为决定是否需要进行谈判或是否可以直接进入医保目录的决策依据。对于未通过初始评价的药品予以剔除。

澳大利亚 PBS（药物补贴计划）目录有 4 种申请形式——①重大申请；②一般申请；③委员会秘书处申请；④提交现有药品的新品牌。重大申请包括新药或疫苗、新适应症的准入申请。后三种申请文件通常不需要经济建模且 PBAC 可能不参与评估。重大申请材料需要详细说明该药的使用条件（如身体特定部位的肿瘤）和患者特征（如年龄和是否存在某种基因组成）。企业可选择性地同卫生与老龄化部召开会议，由 PBAC（药物补贴咨询委员会）确定是否需要进行预评估。若申请未被批准或驳回，制造商可以保留一次向 DHA 提出间接申请（相当于两次机会）的权利。PBAC 负责对材料完整性和逻辑性进行初审与评价，内容包括背景、临床评估、经济评估、实践中使用药物和其他相关信息的审查，并对 TGA 的建议进行采纳和思考[39]。无论 TGA 审查的临床试验研究类型如何，PBAC 在就临床有效性和安全性进行比较之前，都会考虑许多有关临床研究的其他因素，包括研究数量和设计、研究人数（称为“样本量”）以及研究人员如何衡量健康

[39] Paris V, Belloni A. VALUE IN PHARMACEUTICAL PRICING COUNTRY PROFILE: AUSTRALIA[EB/OL]. https://search.oecd.org/health/Value-in-Pharmaceutical-Pricing-Australia.pdf. 2014-11/2018-10.

结果等等。在考虑了所有类型的信息后，PBAC 开始评价结果——健康产出是否更优、至少相等（不劣于）或更差。决策过程需要 PBAC 进行大量的判断，这使得风险发生率大大减小[40]。

表 32 不同分类药品的提交类型

提交类型	适用对象	涉及材料
主要提交	新药、新疫苗，或具有新适应症的药品	背景材料、临床、经济性、药品使用等
次要提交	目录中已有药品的新剂型或者新规格的生物等效仿制药	背景材料、临床、药品使用等
委员会秘书处提交	同“次要提交”（不需要 PBAC 考虑成本效益、不影响财政、与目录内药品在安全性无差别）	背景材料、临床、药品使用等
现有药品新品牌提交	针对目录中已有的经 TGA 批准的仿制药的新品牌，且患者人群及适应症相同	背景材料、生物等效性、成本信息

表 33 主要提交类型的申请材料项目

项目	主要内容
背景材料	必要的药品基本信息和预期使用说明
临床研究材料	已有最佳的证明药品安全、有效性的临床实验数据
经济性评价材料	成本效果分析材料或者最小成本分析材料
药品使用材料	药品使用情况及市场预期评估；对财政预算的影响分析
补充材料	其他会影响 PBAC 决策的信息

基于澳大利亚的实践经验，我国可以发布申请材料指南，消除企业材料准备的困惑，同时提供相应模板，提高评估效率。在实施阶段，可首先由医保准入委员会根据企业提供的必要信息和素材进行评估，形成模板，起到示范作用，之后企业根据模板进行自主评估，医保委员会负责审核。

综上所述，结合我国情况，第一步，应当由认为自身品种符合医保准入条件的企业提出申请，为防止重蹈注册申请积压的覆辙，要求企业进行材料自查（参照注册申请资料、临床试验数据自查核查形式），若工作人员审评过程中发现材料造假或严重不符合条件的情况将对企业予以严厉处罚。

同时，对非保密性文件实行公示公开，受社会监督。可以参考国外临床试验数据公示公开的部分经验。迄今为止，全球共有超过40个国家都制定了药物临床试验数据公开的相关法律、法规或指南，包括澳大利亚、法国、印度、巴西、日本等。其中，美国的Clinical Trials．gov和欧盟的EU-CTR是2个最具有代表性、且发展最为完善的临床试验注册与结果公开平台，而且都是强制公开。中国可以

[40] GSK. The Pharmaceutical Benefi ts Scheme in Australia[EB/OL]. https://au.gsk.com/media/421635/gsk-viiv-the-pbs-in-australia-feb-2018.pdf. 2018-02/2018-05-01.

通过借鉴其经验和方法，建立企业准入承诺的自评价数据公开机制。

①美国经验总结

随着2005年希乐葆、万络和一些小儿抗抑郁药等药物的一连串研发失败，制药企业不可避免地面临着越来越大的压力，国际性的杂志编辑委员会和美国国立卫生研究院（NIH）的一位高级官员对3个大型制药企业提出了批评，指责他们没有将那些重要临床试验信息公布在美国政府公共数据库中。此后，一些主要医学杂志的编辑们已经达成一致看法，对于在2005年1月1日以后才开始试验的研究结果，除非在公共数据库中登记过才能给予发表；正在进行的临床试验如果想获得发表，也必须在2005年9月中期以前在公共数据库中进行登记。

政府部门正在讨论一项立法，要求企业对外公开临床试验数据，否则将面临每天10,000 美元的罚款。《公平获取临床试验法案》要求试验发起者登记所有由私人或公共资金资助的药物、生物制品或医学设备的研究，表明这些研究具有安全性和有效性。临床试验注册和结果信息提交终极规则（Final Rule）规定药品公开临床试验结果摘要要囊括不良反应事件发生的时间表、搜集方法、全因死亡率、研究计划、统计分析方案等信息，且要每年更新数据内容[41]。

在美国的努力下，世卫组织正在考虑建立一个全球的、自发性的临床试验登记体系，要求临床试验数据至少公开20项主要内容。这20个数据包括试验目标、可行性要求、资金来源、预期时间安排、主要成果和其他重要成果等。

②欧盟经验总结

2011年3月欧盟创建了EU-CTR网站，公众可以通过登录该网站，公开获取EudraCT数据库中的药物临床试验信息进行监督。同时还创建了单一的临床试验数据提交系统，设置了统一的科学和伦理审查标准，并在整个欧盟/欧洲经济体境内具有法律强制力。并明确要求所有在欧盟境内进行的临床试验必须公开临床试验注册信息、临床试验结果摘要和CSR信息。医学领先杂志《英国医学杂志》(British Medical Journal, BMJ) 从2013年1月开始，要求作者在发表论文时，需承诺“基于合理的要求”可以共享“论文中用来分析和得出研究结果和结论的个体患者的所有匿名数据”[42]。

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[41] 张伟. 保证药物安全性受重视 临床试验数据公开成潮流[N]. 中国医药报, 2006-01-24(07).

[42] Tom Robinson, 周仙仕. 英国临床药师支持公开临床试验数据[N]. 医药经济报,

此外，在国家、政府的呼吁下，很多大型企业构建了自己的临床试验数据公开平台。比如，2004 年，葛兰素史克（GSK）开放其临床试验注册库(GlaxoSmith-Kline Register)。开放的数据包括临床试验注册信息和研究结果摘要，并成为第一家公开临床试验数据的医药企业。GSK又进一步宣布，向研究人员系统地提供详细的原始数据[43]。

耶鲁大学的数据开放项目(Yale University Open Data Access，YODA)，起源于2011年，就是出于当时媒体质疑医疗器械公司Medtronic隐瞒了其产品“Infuse”临床试验中的不良反应，并且夸大了有效性结果而设立。

因此，借鉴临床试验数据公开经验，可以尝试进行准入承诺履行证明材料的公开，以加强数据和信息的可信度。可分为强制公开和自愿公开，从纵向上可以分为政府网站、医药学术期刊、企业网站、公共机构、其他社会团体杂志等的多层次公开模式。根据是否触及商业机密或临床试验数据保护法，可以将其分为4大类：准入承诺中涉及的基本信息公开、研究结果摘要公开、临床数据及商业操作数据公开和原始数据公开。如患者个人数据集、患者病例报告表(case report forum，CRF)、解释数据集结构和内容的文档(例如注释CRF、变量定义、数据推导规范、数据集定义文件)、商业报表、公司年报等等。

当然，在公开信息过程中也要格外重视法律问题和商业道德问题，即①数据的公开是否违反了《与贸易有关的知识产权协定》(TRIPS) 第39.3条中有关药品试验数据保护的相关规定；②数据的公开是否侵犯了医药企业的商业秘密和患者的个人隐私；③数据的公开是否会造成数据滥用。所以，对于临床数据，国家应通过“采取必要的措施以保证该数据不被不正当的商业使用”来保证临床试验数据在公开的同时，又不违反TRIPS 39.3的规定，即进行建立在“药品试验数据专有权”基础上的“临床试验数据公开”；对于商业性数据，企业可以将原始数据进行编码或处理、引入编校机制后再进行发布，在不损失数据有效性和真实性的前提下，保护商业机密和个人隐私不受侵害；而对于滥用问题，主要的解决措施有控制准入和条件使用，要求对数据请求者的身份进行验证，并设定相应的资格标准、签署使用协议等方式对公众开放，而且只能用于科研、监督等非商业目的。

2014-09-05(008).

[43] 杨莉，田丽娟，林琳. 药物临床试验数据公开制度研究及启示[J]. 中国新药杂志，2017, 26(09): 990-998.

利用上述企业自评信息公开的方式，促进其他组织、第三方机构等共同参与，发展多种数据公开模式，国家给予一定的资金支持或者设立专门的项目，鼓励医药企业、公共部门、学术机构等以合作或独立的形式建立各种模式的数据公开平台，并通过可控的方式，实现一定程度的原始数据公开，在保护患者隐私、保证药品监管程序的完整性和不损害医药企业的研究创新的积极性的原则下，充分实现数据的透明化，进一步保障公众知情权、维护科学伦理、发挥社会监督作用，使得上交政府部门的企业数据有一定的可信度和科学性，便于有关部门放心使用这些数据进行上市、医保准入后的再评价，以确定药品是否达到预期效果。保证企业材料的真实性、科学性，同时避免申请拥堵和材料积压。

3 明确企业申请资料要求

在进行完上述流程，第二步企业应当上交符合要求的相关材料，材料中应当至少包括药品安全性、有效性、药物经济学、预算影响分析、价格预期等内容。我国目前针对经济性评估方面没有建立统一的标准和指南，同时也没有构建专业、独立、官方、权威的机构进行报告撰写以及材料评估。因此，为保证材料的真实性与科学性，我国应当尽快出版我国的药物经济学评价指南；同时建议由政府委托第三方机构进行药物经济学和预算影响的评估，以及相关材料的出具。

表 34 企业材料提交要求构想

范围	具体项目		谈判准入要求	
安全性	不良反应报告 Ⅳ期临床试验报告		无严重不良反应、临床使用安全性较高	效益>风险
	定期安全性更新报告 新药监测期评价报告		安全性良好、无重大不良事件	
	临床用药跟踪监测		用药合理、无药物滥用及无理由超适应证用药情况	
有效性	新药监测期评价报告		药品疗效良好、临床治愈率达标	
	Ⅳ期临床试验报告		临床治愈率达标、疗效可观	
	临床疗效报告		病人恢复良好、医生反映良好	
经济性	临床价值、药品疗效	药物经济学评价报告、预算影响分析	成本效果良好、与其他类似药品的比较结果可观	性价比高
	药品成本 销售量与价格 基金运算、成本效益			

第三步，由审核部门先进行材料的初始评价，即形式评价，主要考虑材料的格式、完整性、真实性、科学性等，并出具一个入围品种清单。

第四步，对入围品种的企业材料进行详细、规范、封闭式审查。澳大利亚评

估办公室在进行全面的评价回顾时，着重审查药品的安全性、有效性、潜在效益和对现有医疗服务有补充作用的证据；参与专家包括临床医生、临床流行病学专家、健康经济学家、生物统计学家和临床药理学家。

评价过程就是有经验的专家权衡不理想证据的可接受性过程，并产生一个价格预期。此过程完成后，材料没有问题、成本效益符合要求、临床价值高的药品将通过常规准入或谈判准入的方式进入医保准入环节，拟通过谈判准入的药品则正式进入谈判环节。

4 完善谈判内容

进行至下一阶段即第五步，应当进行具体的谈判程序。谈判不应当仅仅局限在价格，还应当兼顾药品供应保障问题。对于临床急需、预估价值高但存在较大风险的药品，还可以就药品签订协议，使药品附条件准入，在后续医保评估过程中，若药品不符合医保准入则经评估后，通过医保退出机制退出目录。

表 35 澳大 35 利亚医保谈判合同细节

谈判类别	具体事件
前言	定义
	解释
	关于这项契约的指南
	致谢
运作流程	初始评估
	再评估
报销规定	折扣情况
	报销情况
	如果库存耗尽或供应不足，则修订报销额度
	新药规定
偿付协定	供应和支持信息
	逾期付款
	数据信息提供
	消费税
保密条款	不披露保密信息
	例外情形
	幸存者原则
总则	公司确认
	争议解决方案
	合并与销售
继续运行与终止	契约的继续运行
	终止契约
注意事项	格式和材料交付

	审核地址
相关方	相关方

第六步，谈判企业拥有一次申诉和重新谈判的机会。同时建立长期沟通的可能和机制，使得双方（谈判双方）信息透明化，企业熟悉谈判流程、谈判要求和审核标准，政府了解企业诉求、药品特性、特殊情形。同时，在后续的目录动态退出机制和支付标准动态调整的过程中，也应当保证与企业的实时沟通与交流，形成持续性的评价、沟通、调整机制。

5 明确医保准入申请程序

按照澳大利亚 PBAC 程序指南，企业应在 PBAC 年会前 17 周及 11 周对不同类型的申请提交相应资料，前 6 周委员会对资料内容进行反馈，企业作出回复，随后进行 DUSC 和 ESC 会议，委员会将 DUSC 和 ESC 初步审评意见反馈给生产企业，企业就问题作出回复，年会上将对所有材料进行审评，给出结论。PBAC 年会后针对推荐与不推荐的产品进行公开，无论是否推荐进入 PBS，均需隐去关键信息公开评估结果，并解释原因。

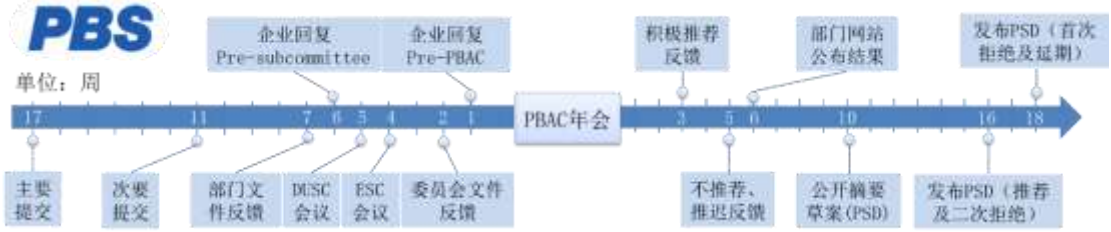

图 35 澳大利亚医保准入流程图

基于澳大利亚的程序指南相关规定，我国制定医保目录准入程序指南，有利于目录准入的规范性，方便企业对目录准入过程作出充分准备建立信息沟通交流机制，减少企业盲目操作，提高企业和委员会的工作效率，秉持公开透明原则，及时公布审评结果，同时做好相关保密工作。

致谢

衷心感谢来自国家卫健委、北京、江苏、山东、安徽等省市卫生部门、医保部门、中国社会保障学会、中国社会科学院、中国劳动和社会保障科学研究院、中国发展研究基金会、青岛市社会保险研究会、北京大学、中国药科大学、沈阳药科大学、天津大学、温州医科大学、南京医科大学、北京协和医院、北京 306 医院、东部战区总医院、江苏省人民医院、南京鼓楼医院、南京明基医院、南通大学附属医院、无锡市人民医院、徐州医学院附属医院、苏州大学附属第一医院、泰州市人民医院、江苏省苏北人民医院、东南大学中大医院、江苏省中医院、江苏省肿瘤医院、东南大学中大医院、合肥市第一人民医院、北京同仁医院以及中国外商投资企业协会药品研制和开发行业委员会（RDPAC）等单位的专家、学者在调研、访谈和研讨过程中对项目研究给予的专业指导！

中国药科大学国家药物政策与医药产业经济研究中心

2019 年 7 月

Research on Local Implementation of National Reimbursement Negotiated Drugs in China

The Research Center of National Drug Policy & Ecosystem

(NDPE)

March 5, 2019

Preface

In 2016 President Xi Jinping pointed out that “health is the incumbent requirement for all-around development of humankind and the fundamental condition for socio-economic development; people’s health and longevity is the key symbol of national prosperity and rejuvenation, and rather the common wish of all nationalities across China.”. The Healthy China 2030 Outline, as one of the priority of national development in the new era, comprised of major tasks that need to be accomplished, including establishment of tiered medical system, universal health coverage, drug supply system, and .etc. The objective is to establish effective, high-quality and sustainable national healthcare system in order to meet the medical needs of people; furthermore, ensure the healthy development of economy and society.

In 2017 Ministry of Human Resource and Social Security implemented the first reimbursement negotiation for innovative drugs, and 36 drugs were successfully negotiated with reimbursement payment standard. It was required by MoHRSS that localities should implement negotiation results, hence 36 drugs to be included into B list of reimbursement drug list and no adjustment to be made to reimbursement payment standard. By end of 2017 all the negotiated drugs have been implemented in 31 provinces and cities across the country, which have been included into the PRDL B lists and are paid by the basic medical insurance fund and patients jointly, and in the meantime, the limits of payment scope required by MOHRSS have been strictly enforced. However, in most regions, there have been a lot of obstacles, in terms of medical reimbursement, local procurement, hospital access and channels, etc., which have negatively affected the result of local implementation of national reimbursement negotiation.

In 2018 the National Health Security Administration included 17 oncology drugs into B list of reimbursement drug list through negotiation, and reimbursement payment standards of these drugs were set. Local medical security, human resource

and social security, and health authorities made work plans accordingly to ensure local implementation, which has significantly improved patient access to oncology drugs.

In 2018 R&D-based Pharmaceutical Association Committee of CAEFI (RDPAC) entrusted China Pharmaceutical University Research Center of National Drug Policy and Ecosystem to conduct a study project – Research on Local Implementation of National Reimbursement Negotiated Drugs in China, which was studied by sorting of policies, institution comparison and other empirical research methods, focusing on the research and analysis of the regions with better and worse negotiation implementation results, summarizing the policy implementation experience of various regions, analyzing the existing problems of various provinces and cities, and proposing relevant improvement and perfection suggestions based on the reflection to the lessons learned and, so as to provide experience for the next round of negotiations.

Subject researchers

Principal Investigator: Shao Rong

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Chapter I Background, Purpose and Significance of Research

I. Research Background

In 2017, the Ministry of Human Resources and Social Security of the People's Republic of China (MOHRSS) implemented the first round of negotiation on the price of innovative drugs covered by the national medical insurance after the release of the new Version of the National Reimbursement Drug List (NRDL). The drugs approved in the negotiation form the standard of medical insurance payment and are incorporated into the management range of Class B medical insurance drugs. In July of the same year, MOHRSS issued the *Notice on Incorporating 36 Drugs into the Class B Scope of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance* (No. 54 Document), which requested all parts of the country to implement the negotiation results and include 36 drugs priced through negotiations in the range of Class B reimbursement without adjusting the limited scope of payment. Meanwhile, all provinces (districts and municipalities) were required to actively explore various ways to strengthen the management of related drugs and promote the rational drug use. The unified provisions on prior review shall be established for drugs requiring "prior review before use" or other drugs requiring strict management; the drugs with large consumption and high cost shall be included in the intelligent monitoring system of basic medical insurance and medical service for key monitoring and their cost analysis shall be conducted properly; effective measures shall be taken to encourage designated retail pharmacies to provide drugs for the insured, and to play an active role in ensuring the supply of covered by medical insurance.

After the release of No. 54 Document, all parts of the country have introduced the corresponding measures to implement the negotiation results. As of the end of December 2017, all the drugs priced through government negotiation have been implemented in 31 provinces and cities across the country, which have been included in the list of Class B drugs and are paid by the basic medical insurance fund and the insured jointly, and in the meantime, the limits of payment scope required by

MOHRSS have been strictly enforced. Zhejiang, Jiangsu, Beijing, Guangdong, Henan and etc. have better implemented the negotiation results. However, in most regions, there have been a lot of obstacles (in trems of medical reimbursement, local procurement, hospital access and channels, etc.) during the implementation of drugs priced through negotiations, such as too low reimbursement ratio, access of the grassroots limited by the National Essential Medicines List, secondary bargaining of hospitals, drug proportion, blocked opening of retail channels and etc. For example, in Chongqing, Shandong, Guizhou, Henan and other regions, more stricter restrictions have been imposed on medical institutions, qualification of medical practitioners, reimbursement ratio, qualification of patients, disease categories and other aspects of drug use; in this context, the coverage of reimbursement policy for varieties priced through negotiations has been greatly reduced, and drug use and reimbursement of patients as well as the landing and implementation effects of drugs priced through negotiations on medical insurance access have not received good feedback.

In this program, the implementation of China's drugs priced through negotiations on medical insurance access will be studied by sorting of policies, institution comparison and other empirical research methods, focusing on the research and analysis of the regions with better and worse negotiation implementation results, summarizing the policy implementation experience of various regions, analyzing the existing problems of various provinces and cities, proposing relevant improvement and perfection suggestions based on the reflection to the lessons learned and promoting them in the regions with relatively-poor policy landing effects, so as to help better benefit patients with the drugs priced through negotiations, improve the affordability of drugs, and clarify the local access barriers and provide experience for the next round of negotiations.

II. Research Purpose and Significance

(1) Research purpose

This project studies the access policies, implementation situation and obstacles faced by the negotiation results in various regions by ways of sorting policies,

literature research and investigation and interview, and, on the basis of field research, draws on the experience of provinces and cities with better implementation effects of landing policies to provide policy suggestions for provinces with poor implementation effects. The goal is to help regions cope with the challenges of implementing the negotiation results of innovative drugs, improve the local access environment of drugs priced through negotiations, and clarify the local access barriers and provide experience for the next round of negotiations. Meanwhile, the following several problems are expected to be solved:

① How about the overall landing of varieties priced through negotiations in various provinces and cities at present?

② What are the experiences and lessons learned from the policy implementation of varieties priced through negotiations in typical regions? Is there anything we can learn from and improve?

③ What are the difficulties in the implementation of medical insurance negotiation policies? How to solve them?

④ How to make suggestions to improve the implementation policy of drugs priced through negotiations?

(2) Research significance

1 Minimize the expense burden of patients and improve the accessibility of drugs priced through negotiations

Based on the policy analysis of drugs priced through negotiations on national medical insurance access and empirical research on the current situation of negotiation landing in various provinces, this research tries to optimize the local access policy of drugs priced through negotiations, establish the new access environment, enable drugs with high clinical value to be implemented rapidly across the country, minimize the medical burden of patients and improve the accessibility of drugs priced through negotiations, so as to optimize the welfare of social medical resources.

2 Promote the optimization and improvement of regulatory policies of drugs priced through negotiations

By investigating the implementation status and effects of the landing and implementation of drugs priced through negotiations in typical provinces of China, the influences of the current negotiation access policies and measures in various regions on the drug use of patients will be feedback, to improve the regulatory policies of drugs priced through negotiations, which is of great significance to the design and optimization of the macro-level systems.

3 Establish new paths for reform and development of access policies of drugs priced through negotiations

Based on the landing and implementation status of the current round of medical insurance access of drugs priced through negotiations in various regions on medical insurance access, the obstacles encountered and the lessons learned are summarized, to improve the medical insurance negotiation mechanism and attempt to put forward new paths for reform and development of access policies of drugs priced through negotiations in the next stage of negotiation.

Chapter II Implementation Effects of National Drug Price Negotiation

I. Background of Drug Price Negotiation

Since 2015, China has carried out three drug price negotiations. The National Health and Family Planning Commission (NHFPC) was mainly responsible for the first negotiation and issued a notice jointly with 7 departments on May 23, 2016, and announced the negotiation results of the first batch of national drug price negotiations. The main body of the second negotiation was the medical insurance department, 36 of the 44 drug varieties were finally included, and the price was decreased considerably, averaging 44%; MOHRSS issued a notice on July 13, 2017, officially marking the entry into implementation phase of the national medical insurance negotiation results. The last negotiation mainly aimed at the anticancer drugs and, on October 10, 2018, 17 varieties were successfully included in the National Reimbursement Drug List after more than 3 months of negotiation, with an average price decrease of 56.7%.

The subjects, mechanisms, price cut and targets of the three negotiations were different, but all the main purposes were to improve the accessibility of high-value and high-price drugs and benefit the majority of patients through government negotiations.

II. General Situation of the Three Negotiations

(I) First round of drug price negotiation

1 Policy background

In February 2015, the General Office of the State Council issued the *Guiding Opinions on Improving the Centralized Medicine Procurement for Public Hospitals*, which proposed the classified procurement of drugs and established an open, transparent and multi-participatory price negotiation mechanism for part of patented drugs and exclusively produced drugs. For the first time, this document clarifies the "national negotiation" at the national level. Hereafter, NHFPC drafted the *Pilot Work Programme for Establishing Drug Price Negotiation Mechanism (Draft for Comments)* (hereinafter referred to as the "Programme"), in which the specific

operation process of the negotiations was provided. In October 2015, with the approval of the State Council, 16 ministries and commissions (bureaus) led by NHFPC jointly established a joint inter-ministerial conference system for drug price negotiation, and the first national drug price negotiation was launched in November. On May 20, 2016, the first batch of negotiation results was released to the public after being reviewed and approved by the joint inter-ministerial conference of the national drug price negotiation.

2 Negotiation effects

(1) Success rate

Five varieties were included in the first batch of national drug price negotiations and three varieties were selected finally, with a success rate of 60%. The five varieties included Gefitinib, Erlotinib and Icotinib for advanced non-small cell lung cancer, Viread for chronic hepatitis B and Lenalidomide for multiple myeloma, manufactured by AstraZeneca, Roche, Betta, GSK and Celgene respectively. Roche's Erlotinib failed to make the list under the "2 out of 3" competition rule for drugs for non-small cell lung cancer, two other drugs with more favorable prices were successfully selected, and the drugs for rare diseases from Celgene were only "not yet announced".

(2) Price cut

Among the three drugs in the pilot negotiations, the average price cut reached 59%, up to 67%. The prices of Viread, Iressa and Conmana were reduced by 67%, 55% and 54% respectively, similar to those of surrounding countries (regions)[1]. The average monthly expenses for the above three drugs were reduced from RMB1,500, RMB12,000 and RMB15,000 to RMB490, RMB5,500 and RMB7,000 respectively. Refer to the table1 below for details.

Table 1. Status of 3 Drugs in the Pilot Negotiations

Generic name (trade name)	Manufacturers	Therapeutic area	Average monthly price cut	Price cut
Tenofovir Disoprox (Viread)	GSK	First-line treatment of chronic hepatitis B	RMB1500→RMB490	67%

1 Description on the national drug price negotiations
http://www.nhfpc.gov.cn/yaozs/s3578/201605/fc76991a7161418ebd2ce093cc1fea02.shtml

Gefitinib (Iressa)	AstraZeneca	Targeted therapy for non-small cell lung cancer	RMB12000→RMB5500	55%
Icotinib(Conmana)	Betta Pharmaceuticals	Targeted therapy for non-small cell lung cancer	RMB15000→RMB7000	54%

3 Negotiation process

(1) Organizational form

The implementation organization for negotiations consisted of "two committees and two databases". According to the *Programme*, the price negotiations were implemented by the following three organizations: ① National Steering Committee for Negotiation of Drug Prices. The negotiation was led by NHFPC and its members include National Development and Reform Commission (NDRC), Ministry of Education, Ministry of Industry and Information Technology (MIIT), Ministry of Finance, MOHRSS, Ministry of Commerce, National Audit Office, General Administration of Customs, P.R China, State Taxation Administration, State Administration for Industry and Commerce, CFDA, National Intellectual Property Administration, China Insurance Regulatory Commission, Medical Department of the General Logistics Department and other ministries and leaders, which were responsible for examining and approving major issues such as varieties of drugs priced through negotiations, negotiation implementation programme and procurement prices. ② National Supervisory Committee for of Drug Price Negotiation. Its members were mainly composed of relevant government departments, Discipline Inspection Office and Supervisory Bureau of NHFPC, representatives of relevant stakeholders, some NPC (the National People's Congress) representatives and members of the CPPCC (Chinese People's Political Consultative Conference), which were responsible for full supervision of the negotiations, and receiving accusation and complaints. ③ The national drug price negotiation expert database and drug price information database were established. Experts participating in the negotiation were randomly selected from the expert database every time and the same expert could only participate in one link of the drug price

negotiation.

(2) Negotiation process

The first batch of pilot national drug price negotiations was organized according to the thought of "one policy for one drug". The negotiation group studied and refined the negotiation strategies and processes for each enterprise and each drug, and the whole negotiation process was recorded or videotaped, and the memorandum was established in order to ensure the standardization and fairness of the negotiation process.

The procedures were composed of formulation of negotiation programme, establishment of negotiation group, selection of drugs priced through negotiations, release of negotiation announcement (issued on the platform of the Integrated Management Information System for the Guarantee for the Supply of National Drugs), submission of relevant technical data and other materials by manufacturers, publishing of negotiation and results (published on the platform of the Integrated Management Information System for the Guarantee for the Supply of National Drugs, provincial centralized medicine procurement platform and designated media), procurement organization (note: military hospitals also purchased drugs according to the negotiation results), distribution and settlement and price monitoring[2].

4 Implementation effects

The purpose of "sacrifice volume for price" was basically realized in the market.

According to Ji Haiwei, head of GSK, sales of Tenofovir Disoprox increased threefold nationwide after the negotiation results of drug price were implemented by provinces in 2016 in succession, and sales increased 4-5 times in cities where the prices for negotiations were implemented. In 2016, sales of Conmana exceeded RMB1 billion for the first time, an increase of 13.4% compared with the same period in 2015, according to data released by Zhejiang Betta. In 2017, Conmana entered the national medical insurance list, its amount of sales declined slightly from 2016, but its sales volume increased by 42% due to landing cohesion and launching of generic

2 Several points and reflections on the mechanism of drug price negotiation http://www.zyzhan.com/news/detail/45851.html

drugs in the market. According to the semi-annual performance forecast of 2018, the company continued to promote the landing of medical insurance policies around the country. In addition to consolidating the major metropolitan markets, the company also tapped into potential markets and expanded to the second- and third-tier cities. The sales of Conmana in the reporting period continued to increase by 28.54% year-on-year.

(2) Second drug price negotiation

1 Policy background

On April 14, 2017, MOHRSS took the lead in the negotiation of incorporating drug varieties into the National Reimbursement Drug List and 44 varieties were identified mainly based on the criteria of clinical necessity, outstanding therapeutic effect, higher price and heavy burden on the masses, and the results of the negotiation were released on July 19, 2017.

2 Negotiation effects

(1) Success rate

The second price negotiation was carried out in 2017, which mainly targeted at clinical drugs with high prices and urgent needs. Promoting the real implementation of drugs priced through negotiations is an important measure to guarantee the supply of drugs for severe cases and to give the masses a practical sense of gain. The negotiation could be divided into traditional Chinese medicine and Western medicine, with the diagnosis and treatment scope covering cardiovascular and cerebrovascular diseases, rare diseases, chronic nephrosis, mental diseases, infections, tumors and other fields. Among the 44 varieties, 36 varieties were finally selected and the success rate reached 81.8%, with details as table2.

Table 2. List of Drugs and Therapeutic Areas in the Second Negotiation

Classification	Specific classification	Therapeutic area	Name of drugs	
Western medicine	Drugs for serious or chronic diseases	Heart and cerebral vessels	Recombinant Human Brain Natriuretic Peptide (Tibet Rhodiola Pharmaceutical)	Recombinant human prourokinase (Tasly)
			Ticagrelor (AstraZeneca)	Allisartan Isoproxil

				(Salubris)
		Anti-infection	Posaconazole (Merck Sharp & Dohme)	Morinidazole and Sodium Chloride (Jiangsu Haosen)
		Eye AMD	Ranibizumab (Novartis)	Conbercept (KangHong Pharmaceutical)
		Chronic nephrosis	Lanthanum carbonate (Shire)	Sevelamer (Sanofi)
		Mental diseases	Quetiapine (AstraZeneca)	Paroxetine (GSK)
		Diabetes	Liraglutide (Novo Nordisk)	
		Others	Tolvaptan (Otsuka Pharmaceutical)	
	Anticancer drugs	Tumour	Rituximab (Roche)	Apatinib (Hengrui Medicine)
			Trastuzumab (Roche)	Chidamide (ChipScreen BioS)
			Bevacizumab (Roche)	Fulvestrant (AstraZeneca)
			Sorafenib (Bayer)	Abiraterone (Johnson & Johnson)
			Bortezomib (Johnson & Johnson)	Everolimus (Novartis)
			Erlotinib(Roche)	Lenalidomide (Celgene)
			Nimotuzumab (Biotech)	Lapatinib (GSK)
			Recombinant Human Endostatin (Shandong Simcere)	
	Drugs for rare diseases	Rare diseases	Recombinant Human Coagulation Factor Ⅶa (Novo Nordisk)	Recombinant Human Interferonβ-1b (Bayer)
Chinese patent medicine	Anticancer drugs	Tumour	Shenyi Capsule (Jilin Yatai)	Compound Realgar Natural Indigo Tablets (Yifan Pharmaceutical)
			Astragalus polysaccharide injection (Tianjin Sainuo)	
	Drugs for serious or chronic diseases	Heart and cerebral vessels	Ginkgolide Injection (Chengdu Baiyu)	Diterpene Ginkgolides Meglumine Injection (Kanion Pharmaceutical)

(2) Price cut

The state expects to realize the availability of clinical drugs with urgent needs and high prices through "sacrifice volume for price". Driven by the negotiation, 36 pilot drug varieties saw an average price cut of 44% and a maximum price cut of 70%.

The payment standard of most imported drugs after negotiation was lower than the price of the surrounding international market, greatly reducing the burden of medical expenses of patients in our country[3]. The price of a large number of drugs was reduced by more than 40%, as shown table3.

Table 3. Price of Drugs in the Second Negotiation

Therapeutic area	Product name/company	Manufacturers	Specifications	Minimum bidding price (RMB)	Payment priced through negotiations (RMB)	Price cut
Heart and cerebral vessels	Recombinant Human Brain Natriuretic Peptide	Tibet Rhodiola Pharmaceutical	0.5mg	1709	585	42.02%
Anti-infection	Posaconazole	Merck Sharp & Dohme	105ml:4.2g	4905	2800	42.9%
Diabetes	Liraglutide	Novo Nordisk	3ml:18mg	723	410	44.3%
Others	Tolvaptan	Otsuka Pharmaceutical	15mg*5 tablets	840	495	41.1%
Tumour	Rituximab	Roche	50ml:0.5g	16041	8289.87	48.3%
	Trastuzumab	Roche	20ml:440mg	21613	7600	64.8%
	Bevacizumab	Roche	4ml:0.1g	5176	1998	61.4%
	Sorafenib	Bayer	200mg	23280	12180	47.7%
	Bortezomib	Johnson & Johnson	1mg*1 bottle	4842.5	2344.26	51.6%
			3.5mg	12512.4	6116	51.1%
	Erlotinib	Roche	150mg	3220	1365	57.6%
	Astragalus polysaccharide injection	Tianjin Sainuo	250mg	494	278	43.72%
	Fulvestrant	AstraZeneca	5ml:250mg	5419.6	2400	55.72%
	Abiraterone	Johnson & Johnson	250mg	36925	17390.4	52.9%
	Lenalidomide	Celgene	25mg*21 pills	58787.2	23141.79	60.6%
			10mg	46170.5	18186	60.6%

3 Negotiation results of Access to National Reimbursement Drug List issued by MOHRSS, http://www.mohrss.gov.cn/SYrlzyhshbzb/dongtaixinwen/buneiyaowen/201707/t20170719_274189.html

	lapatinib	GSK	250mg	8300	4900	41%

Source: combining and sorting based on PDB database and Research Report of TF Securities

3 Negotiation process

(1) Negotiation procedures

In April, MOHRSS released the list of 44 drugs to be negotiated, and then the special working group and supervisory group were established to undertake specific work and carry out the whole-process supervision, and experts were organized to negotiate with relevant enterprises.

It could be divided into the following links:

① Rigorous and thorough negotiation rules were formulated: the main body and policy conditions of the negotiation were clarified, that is, the drugs selected in the negotiation were incorporated into the list of Class B drugs and the medical insurance payment standards determined in the negotiation were implemented uniformly across the country, the separation of declaration, evaluation and negotiation was clarified, the combination of objective evaluation and expert evaluation was defined, and the specific negotiation procedures were specified.

② Experts were organized to carry out evaluation and calculation: two completely independent evaluation expert groups were set up in MOHRSS to carry out evaluation and calculation from two perspectives of drug economics and affordability of the medical insurance funds. One was the drug economics evaluation group, which mainly made suggestions through drug economics methods and by analyzing clinical value of drugs, international and domestic price comparisons and reference of similar drugs. The other was the medical fund support capacity measurement group, which collected, calculated and analyzed 3.09 million pieces of medical insurance data from 44 drugs priced through negotiations in 68 co-ordinated regions. Finally, the expected payment price of medical insurance was determined by the established rules, which reflected the justice and equity of the negotiation[4].

4 Zhang Miao. Disclosure of National Drug Price Negotiations[J]. Social Security in China, 2017(08): 16-19.

③ The negotiation was carried out according to the specified procedures: the enterprises involved in the negotiation were grouped randomly; the supervision group conducted the supervision on the site and the whole negotiation process was videotaped; the final expected payment price of medical insurance was determined by the working group based on the payment standard estimated by the pharmaceutical group and the medical insurance group, and then the expected payment price was sealed in an envelope and sent to the negotiation site by the specially-assigned person.

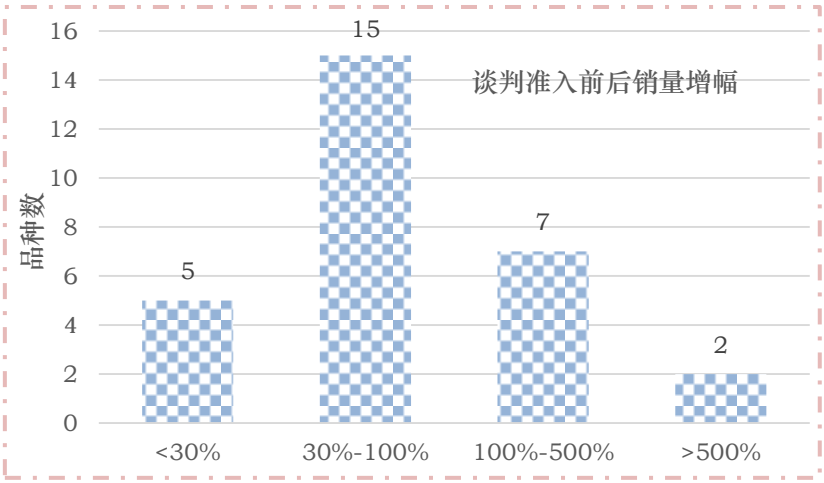
(2) Highlights of the negotiation

Two innovative measures were initiated in this national drug price negotiation: 1. The legal advisers were fully involved in ensuring legal compliance. The authority of the negotiation process was guaranteed by employing legal professionals who were familiar with the medicine field and the medical insurance field to examine the preliminary qualification, control the legality and standardize the follow-up negotiation and agreement signing; 2. The big data of medical insurance was used to assist in the formulation of medical insurance policies for the first time. This measure was also favorable to ensure the sustainability of medical insurance funds.

4 Status of implementation

(1) Drug sales -- from the enterprise's perspective

Based on the summary results, most drugs realized a sales growth of 30%-100%, even increasing by more than 500%. However, the sales of some drugs were not very ideal.



序号	药品名称	序号	药品名称
1	阿帕替尼	16	贝伐珠单抗
2	阿利沙坦酯	17	厄洛替尼
3	康柏西普	18	碳酸司维拉姆
4	重组人尿激酶原	19	泊沙康唑
5	银杏二萜内酯	20	重组人凝血因子VIIa
6	重组人脑利钠肽	21	利拉鲁肽
7	银杏内酯注射液	22	依维莫司
8	氟维司群	23	雷珠单抗
9	替格瑞洛	24	西达苯胺
10	唑吡坦缓释片	25	碳酸镧咀嚼片
11	索拉非尼	26	血管内皮抑制素
12	尼妥珠单抗	27	来那度胺
13	托伐普坦	28	阿比特龙
14	拉帕替尼	29	哪替佐米
15	曲妥珠单抗		

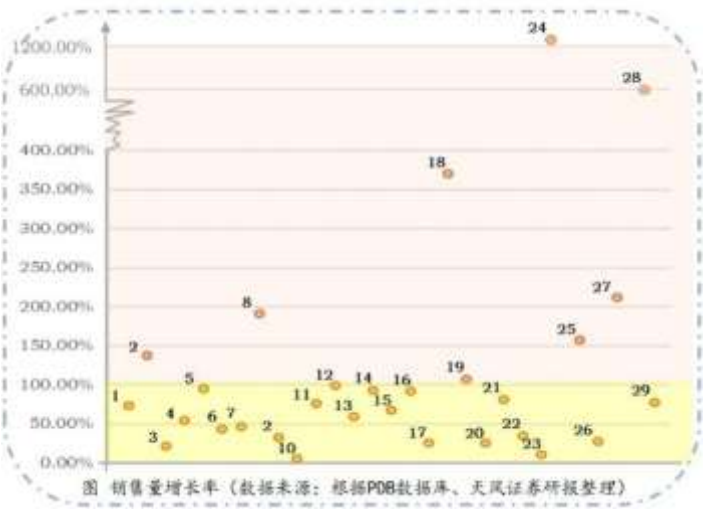


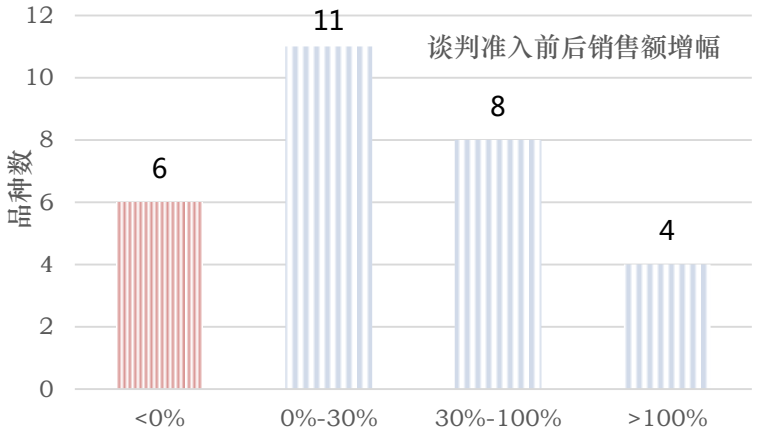
Figure 1. Increase of Drug Sales before and after the Second Access Negotiation

Although documents had been issued by provinces to promote the implementation of policies for drugs priced through negotiations, the problem of "drugs could be incorporated into the range of medical insurance, but could not be used in hospitals" remained intractable. On the one hand, after the release of zero profit policy, drugs were changed from the original profit subject to the current cost subject, and hospitals lacked both motivation and enthusiasm for the access of drugs for negotiation; on the other hand, although some provinces declared that the drugs priced through negotiations would not be included into the calculation of drug proportion indicator, the implementation of this policy was not positive, and in the implementation process of cities and hospitals, there were situations that this policy was not implemented or was difficult to be implemented. Moreover, the long adjustment period of medication catalogue and the few varieties involved in a single adjustment also made it impossible for the drug varieties for negotiations to be timely updated and included into the hospitals' purchase and use catalogue. All of these caused hospitals to fail to achieve the goal of guaranteeing the supply of drugs priced through negotiations, and also fail to make patients enjoy the benefits of health insurance negotiations.

It was generally believed that the investment scale and management difficulty of general hospitals were greater than those of specialized hospitals, while the profitability, availability and replicability of general hospitals were obviously weaker

than those of specialized hospitals; therefore, it was not surprised that specialized hospitals were superior to general hospitals in terms of the implementation effect of negotiation policies. Hu Xin, a pharmacist at the Pharmaceutical Department of Beijing Hospital, stressed that not all drugs included into the health insurance list were available in large general hospitals; this was because no hospital in China could complete all the drugs in the list. Each hospital had its own positioning, and the strength and weakness of various departments shall be taken into consideration[5].

In addition, enterprises also generally reflected that the sales after the negotiation were far from the expectation. The price of drugs was cut by an average of 44% through the negotiation mode; however, the sales volume of enterprises failed to achieve the target of steady growth due to the sluggishness of access to hospitals, and a considerable number of enterprises saw a negative growth rate of sales volume, as shown in the Figure2.



5 The Paper. 17 anticancer drugs included in medical insurance by cutting price in half, barrier breaking required for benefiting patients [EB/OL]. http://news.sina.com.cn/o/2018-10-11/doc-ifxeuwws3204879.shtml. [2018-10-11/2018-11-14].

序号	药品名称	序号	药品名称
1	阿帕替尼	16	贝伐珠单抗
2	阿利沙坦酯	17	厄洛替尼
3	康柏西普	18	碳酸司维拉姆
4	重组人尿激酶原	19	泊沙康唑
5	银杏二萜内酯	20	重组人凝血因子VIIa
6	重组人脑利钠肽	21	利拉鲁肽
7	银杏内酯注射液	22	依维莫司
8	氟维司群	23	雷珠单抗
9	替格瑞洛	24	西达苯胺
10	唑硫平缓释片	25	碳酸钢咀嚼片
11	索拉非尼	26	血管内皮抑制素
12	尼妥珠单抗	27	来那度胺
13	托伐普坦	28	阿比特龙
14	拉帕替尼	29	硼替佐米
15	曲妥珠单抗		

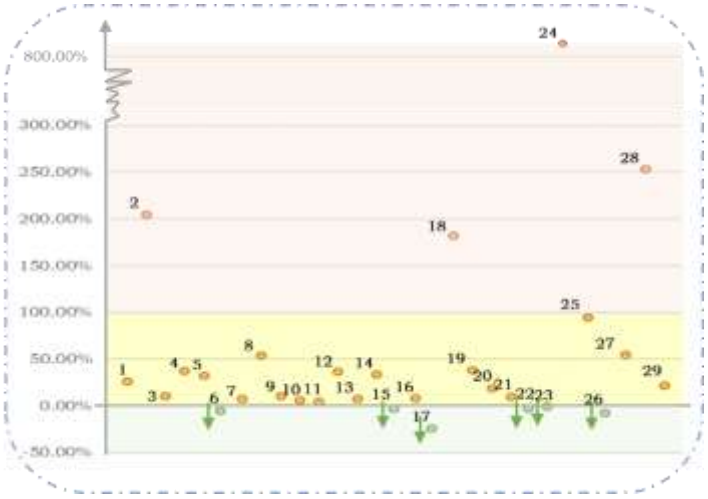


Figure 2. Sales Growth of for Negotiations

Although sales of some drugs kept increasing after the negotiation, their annular growth rate showed a downward trend or ended flat as before, which was undoubtedly a blow to the enthusiasm of enterprises for future negotiations.

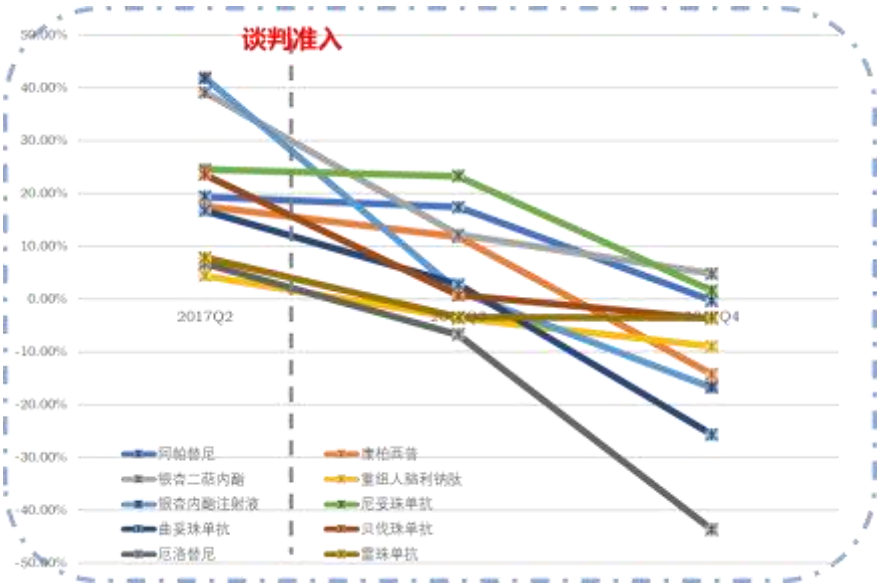


Figure 3. Change in Sales Growth Rate of Partial Drugs Priced through Negotiations
Source: sorting based on PDB database and Research Report of TF Securities

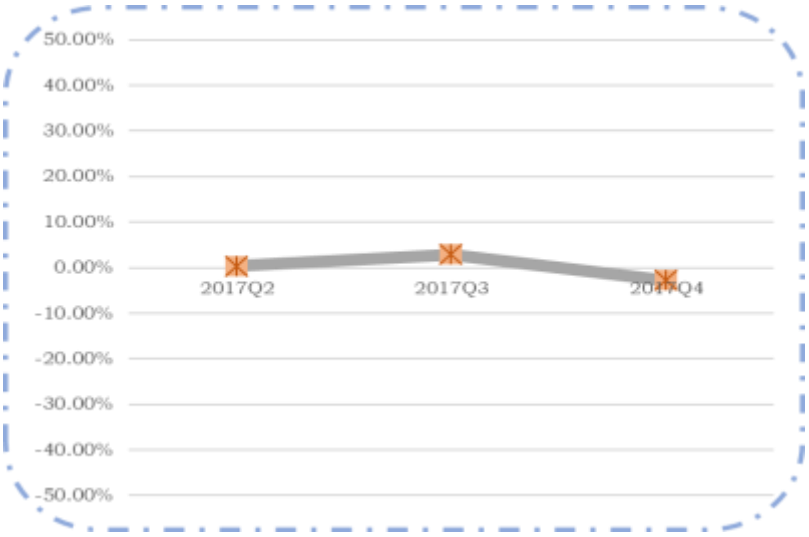


Figure 4. Change in Sales Growth Rate of Recombinant Human Coagulation Factor VIIa
Source: sorting based on PDB database and Research Report of TF Securities

(2) Implementation of policies: from the government's perspective

National negotiation and local implementation were an integral whole, and the first stage of negotiation and the second stage of implementation were equally crucial. From the documents issued by various provinces, all provinces could strictly implement the requirements of No. 54 Document, most provinces encouraged pharmacies to act as channels for supply and reimbursement of drugs priced through negotiations in the range of medical insurance, and some provinces and cities had made effective explorations in drug classification management, drug proportion, general control of medical insurance and other related supporting policies. Moreover, all regions attached great importance to the rational drug use and took effective measures to encourage the rational use of drugs priced through negotiations in hospitals. And certain support and consideration were given to the drugs with limit of medical insurance exceeding the total amount of medical insurance. The main measures to ensure the implementation of drugs priced through negotiations in various regions were as follows:

① Normative implementation documents

By the end of December 2017, all the drugs priced through government negotiation had been implemented in 31 provinces and cities across the country, and all the drugs priced through negotiations had been included in the list of Class B

drugs in 31 provinces and cities, which would be jointly paid by the basic medical insurance fund and the insured, and in the meantime, the payment scope required by MOHRSS had been strictly implemented in all regions.

Table 4. Implementation Policies of Drugs Priced through Negotiations in Various Provinces

Provinces	Release time	Implementation documents	Execution time
Jiangsu	08/02/2017	*Notice of Jiangsu Human Resources and Social Security Department on Incorporating 36 Kinds of Drugs into the Class B Scope of the Catalogue of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance* (No. 265 [2017] of Jiangsu Human Resources and Social Security Department)	09/01/2017
Zhejiang	08/23/2017	*Notice on the Implementation of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance* (2017 Edition) and Other Related Matters (No. 100 [2017] of Zhejiang Province Human Resources and Social Security Department)	09/01/2017
Shanghai	11/15/2017	*Notice of the Catalogue of Drugs for the Shanghai Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance* (2017 Edition) (No. 430 [2017] of Shanghai Municipal Human Resources and Social Security Bureau)	12/01/2017
Shandong	08/21/2017	*Notice of Human Resources and Social Security Department of Shandong Province on the Implementation of the Catalogue of Drugs for the National Basic Medical*	09/01/2017

		Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Edition) (No. 34 [2017] of Human Resources and Social Security Department of Shandong Province)	
	09/01/2017	*Notice of Human Resources and Social Security Department of Shandong Province on Connecting Provincial Medical Insurance with the Adjustment Policy of the Catalogue of Drugs for the National Medical Insurance in 2017* (No. 74 [2017] of Human Resources and Social Security Department of Shandong Province)	
Guangdong	09/25/2017	*Notice on the Implementation of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Edition)* (No. 221 [2017] of Human Resources and Social Security Department of Guangdong Province)	10/01/2017
Gansu	09/25/2017	*Notice of Gansu Province on the Implementation of the National Negotiation Results of 36 Drugs Priced through Negotiations* (No. 32 [2017] of Gansu Provincial Medical Reform Leading Group Office)	11/01/2017
	10/20/2017	*Notice on the Issuance of the the Catalogue of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance for Urban Workers in Gansu Province (2017 Edition)*	

Guizhou	11/22/2017	*Notice for Public Opinions on the Work Programme for Adjustments for the Catalogue of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance in Guizhou Province in 2017 (Draft for Opinions)* (No. 22 [2017] of Human Resources and Social Security Department of Guizhou Province)	12/20/2017
Beijing	08/28/2017	*Notice on the Adjustment and Improvement of Policies on Special Diseases in Outpatient Department of Basic Medical Insurance* (No. 179 [2017] of Beijing Municipal Human Resources and Social Security Bureau)	09/01/2017
	08/28/2017	*Notice on Incorporating Dolasetron Injection and Other Drugs into the Reimbursement Drug List of Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance* (No. 180 [2017] of Beijing Municipal Human Resources and Social Security Bureau)	
	03/01/2018	*Notice on the Issuance of the Reimbursement Scope of the Catalogue of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance of Beijing City* (2017 Edition) (No. 40 [2017] of Beijing Municipal Human Resources and Social Security Bureau)	
Shaanxi	08/23/2017	*Notice of Department of Human Resources and Social Security of Shaanxi Province on the Implementation of the*	09/01/2017

		Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Edition) and the Incorporation of Drugs Priced through Negotiations into the Scope of Payment	
Anhui	05/16/2018	*Notice on the Issuance of the the Catalogue of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance in Anhui Province* (2018 Edition) (No. 24 [2018] of Human Resources and Social Security Department of Anhui Province)	09/01/2017
	08/14/2017	Forwarding the *Notice of the Ministry of Human Resources and Social Security on Incorporating 36 Kinds of Drugs into the Class B Scope of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance*	
Chongqing	12/22/2017	*Notice of Chongqing Municipal Human Resources and Social Security Bureau on Incorporating 36 Kinds of Medicine Priced through Government Negotiation into the Catalogue of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance in Chongqing* (No. 266 [2017] of Chongqing Municipal Human Resources and Social Security Bureau)	09/01/2017
Sichuan	06/21/2018	*Notice on the Issuance of the Catalogue of Drugs for the Basic*	09/01/2017

		Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2018 Edition) in Sichuan Province (No. 29 [2018] of Sichuan Provincial Human Resources and Social Security Department)	
	11/07/2017	Notice on the Implementation of 36 Medicines Priced through Government Negotiation and the *Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Edition)* at the Provincial Level	
Jilin	01/10/2018	*Notice of Jilin Province on the Implementation of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Edition)* (No. 89 [2017] of Jilin Provincial Human Resources and Social Security Department)	09/01/2017
	09/06/2017	*Notice on the Issuance of Provisional Measures for the Administration of Special Drugs for the Basic Medical Insurance of Jilin Province* (No. 58 [2017] of Jilin Provincial Human Resources and Social Security Department)	
Liaoning	08/10/2017	*Forwarding the Notice of the Ministry of Human Resources and Social Security on Incorporating 36 Kinds of Drugs into the Class B Scope of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the*	09/01/2017

		Maternity Insurance (No. 171 [2017] of Liaoning Provincial Department of Human Resources and Social Security)	

② Normative procurement documents

For the procurement of 36 drugs priced through negotiations, the General Office of NHFPC and the General Office of MOHRSS issued the *Notice on Completing the Centralized Procurement of 36 Drugs Priced through Negotiations* (No. 856 [2017] of Administration Letter of Drugs of General Office of NHFPC). To this end, provinces and cities had made corresponding provisions related to the procurement of drugs priced through negotiations during the implementation of documents related to the 36 drugs priced through negotiations. Among them, Jiangsu, Zhejiang, Guangdong, Gansu, Liaoning and etc. clearly stipulated in the documents that these drugs shall be purchased by direct online procurement, Shaanxi and Xinjiang adopted the policy of price-limit online procurement, while other provinces had not yet made clear provisions. Although the drugs priced through negotiations had been incorprated into the payment scope of medical insurance, patients often reported that the hospitals they visit had not purchased these drugs, resulting in patients unable to purchase the required drugs, and directly affecting the implementation of drugs priced through negotiations.

Table 5. Provisions on Procurement of Drugs Priced through Negotiations in Individual Provinces

Provinces	Policy documents	Procurement method
Heilongjiang	*Notice on Completing the Centralized Procurement of 36 Kinds of Medicines Priced through Government Negotiation*	Direct online procurement
Guangdong	*Notice on the Implementation of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Edition)*	Direct online procurement
Shaanxi	*Notice on the Networking of 36 Kinds of Medicines Priced through Government Negotiation*	Price-limit online procurement
Xinjiang	*Notice on Incorporating 36 Kinds of Drugs Priced through Negotiations into the Class B Scope of the Catalogue of Drugs for*	Price-limit online

	the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance	procurement
Jiangsu	*Notice on the Centralized Procurement of 36 Kinds of Drugs Priced through Negotiations*	Direct online procurement
Zhejiang	*Notice on Incorporating Medicine Priced through Government Negotiation into the Online Trading of Zhejiang Drug Purchasing and Trading Platform*	Direct online procurement

③ Operability provisions

A Regulating the conditions of use

In No. 54 Document, provinces (districts and cities) were expected to actively explore various ways to strengthen management of drugs and promote rational drug use. To this end, the provinces had put forward specific requirements for the management of drugs priced through negotiations in the relevant documents. Some provinces had incorporated drugs priced through negotiations into the management of special drugs, such as Gansu, Guizhou, Jiangsu, Shandong, Chongqing and etc.

Among them, Jiangsu and Shandong Provinces also conducted the "three designation" management of these drugs priced through negotiations, that is, designated medical institutions, designated responsible physicians and designated retail pharmacies. The notification document of Jiangsu Province on 36 drugs priced through government negotiation indicated that the negotiation would be organized by NHFPC, and the anticancer molecular targeted drugs in the *Reimbursement Drug List for The National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version)* and No. 54 Document issued by MOHRSS would be incorporated into the management of special drugs. Furthermore, according to the *Notice on the Issuance of the Implementation Scheme for Management of Special Drugs for Urban Medical Insurance in Jiangsu Province* (No. 278 [2013] of Jiangsu Human Resources and Social Security Department), the use of special drugs in treatment shall follow the "three designation" principle, that is, designated medical institutions, designated responsible physicians and designated retail pharmacies. The list of "three designation" of special drugs for medical insurance shall be submitted to the provincial medical insurance agency for the

record. The Notice Issued by Human Resources and Social Security Department of Shandong Province on the Implementation of the Reimbursement Drug List for The National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version) (No. 34 [2017] of Human Resources and Social Security Department of Shandong Province) required that the "three designation" be gradually applied to some drugs priced through negotiations and other related high-value drugs determined by the state and our province in accordance with the management methods of special drugs for critical illness insurance. In the meantime, the positive role of agreement management in guaranteeing the supply for drugs by pharmacies shall be brought into play.

The 36 kinds of drugs priced through negotiations have been incorporated into the management of special drugs by Guizhou Province, and the "five designation" management of designated hospitals, designated physicians, designated patients, and designated drugs and designated dosage has been implemented, and the restricted conditions of use have been strictly executed. The drug registration and record system was established to encourage the regions where conditions permit to explore ways to extend the sale of drugs in designated pharmacies.

Guizhou Province's specific requirements for "five designation" management were as follows:

① For designated hospitals, Guizhou Province required all co-ordinated regions to determine designated medical institutions according to local conditions. In principle, the agencies would entrust tertiary hospitals to handle the medication qualification of special drugs for the insured, but for some regions without tertiary hospitals, secondary hospitals with standardized management could also handle the medication qualification for the insured.

② For designated physicians, Guizhou Province required that designated medical institutions should declare the physicians qualified to prescribe special drugs for the insured and the physicians qualified to handle the medication qualification of special drugs as designated physicians. In principle, the designated physicians should be the associate chief physicians and above, and should only be responsible for

prescribing special drugs and handling qualification corresponding to his/her own professional direction of disease diagnosis and treatment.

③ For designated patients, Guizhou Province required the insured to receive the recognition of medication qualification before using special drugs, and purchase the drugs after receiving the recognition according to the prescriptions issued by the designated physicians in the co-ordinated regions, and then the expenses could be reimbursed. The specific application process of patients was as follows: first, the insured should request a designated physician to fill in the qualification application form for special drugs, and the physician should submit the relevant medical records and data of the insured to the medical insurance department of the hospital for review. After approval, the hospital would enter relevant information (including basic information of the patient, disease information, medication information, information of designated physician, information of designated hospital and special drug pharmacy that may need to be designated) into the medical insurance information system and upload it. Then, the medical insurance information system will automatically associate the patient's information with drugs, hospital, physician and pharmacy. Finally, the patient could settle the account by the social security card and enjoy medical insurance treatment as long as the information was matched.

④ For designated drugs, Guizhou Province required the insured to use only special drugs corresponding to their indications.

⑤ For designated dosage, Human Resources and Social Security Department of Guizhou Province had established the maximum dosage covered in the m scope of payment by the medical insurance institution for each special drug, and no payment would be made for the part exceeding the maximum dosage. Two methods were adopted: one method was to set the dosage according to the course of treatment; the other method was to set the dosage according to the time point. The method of "double restriction" was used in the medical insurance of Guizhou Province: firstly, the total dosage was designed by month. Considering the problem of meditation cohesion, the dosage was generally established by the maximum dosage of the prescribed drug per month plus the dosage for one week. In the meantime, a total

dosage (maximum monthly dosage for one year and three months) was established by year, and the excess part shall be paid by the insured themselves.

Chongqing had established the prior review system of limited hospitals (pharmacies), limited physicians, limited disease categories and strict supervision for 18 drugs in the drugs priced through negotiations. Specifically, these 18 drugs were Trastuzumab, Bevacizumab, Nimotuzumab, Rituximab, Erlotinib, Sorafenib, Lapatinib, Apatinib, Bortezomib, Recombinant Human Endostatin, Chidamide, Abiraterone, Fulvestrant, Recombinant Human Interferon β-1b, Everolimus, Lenalidomide, Conbercept and Ranibizumab.

Relevant notification documents of Shaanxi Province required that cities actively explore the management measures of drugs priced through negotiations, and promote rational drug use by classified management. For drugs requiring "prior review before use" or other drugs requiring strict management, cases filing in real names, centralized supply by designated hospitals or retail pharmacies, designated responsible physicians, designated settlement conditions, designated settlement process and other measures could be adopted to ensure that the circulation and use of drugs were controllable and traceable.

For regulating the conditions of use, some provinces and cities carried out fine management for different varieties of drugs priced through government negotiation. For example, Fujian Province pointed out in the *Notice* that "the drugs priced through government negotiation shall be included into the payment scope for special diseases in the outpatient department according to their categories". The Sevelamer oral sustained-release dosage form and the Lanthanum Carbonate Chewable Tablets were incorporated into the "range of drugs covered by the outpatient dialysis insurance for severe uremia".

For anticancer drugs, Shanxi Province issued the *Notice on Incorporating Trastuzumab Injection and Other 32 Drugs Priced through Negotiations into the Management of Diseases Requiring Large Expense in Outpatient Department of Provincial Direct Medical Insurance*. In the *Notice*, Recombinant Human Coagulation

Factor Ⅶa was incorporated into the scope of drug use for hemophilia, and lanthanum carbonate and Sevelamer were incorporated into the scope of drug use for uremia dialysis.

B Self-payment ratio

The No. 54 Document issued by MOHRSS stipulated that the standards of payment by the medical insurance institution was composed of all the expenses jointly paid by the basic medical insurance funds and the insured, and that the proportion of basic medical insurance funds and the insured shall be determined by the co-ordinated regions. The stipulated standard of payment is valid until December 31, 2019, and will be adjusted according to the relevant provisions of standards of payment for drugs by the medical insurance institution after the expiration of the validity period. Up to the present, the unified payment ratio of the medical insurance institution has been set by 14 provinces and cities with regard to reimbursement ratio. The self-payment ratio of the insured is basically between 20% and 50%. 16 provinces and cities allow each co-ordinated region to determine the payment ratio of the medical insurance institution by themselves[6].

Table 6. Reimbursement Status of Drugs Priced through Negotiations in Provinces and Cities

Provinces	Document release time	Document no.	Document execution time	Reimbursement ratio
Jiangsu	08/02/2017	No. 265 [2017] of of Jiangsu Human Resources and Social Security Department	09/01/2017	According to the provisions of No. 54 Document, the standard of payment was composed of the total expenses paid by basic medical insurance funds and the insured. The payment ratio of basic medical insurance funds shall be determined by all the districts and cities and submitted to the provincial department for the record

6 China Health Insurance: Implementation Situation, Problems and Improvement Opinions for Drugs Priced through Negotiations in National Medical Insurance, https://mp.weixin.qq.com/s/pKgJIF-3weAUDiS7zFsANg.

Zhejiang	08/23/2017	No. 100 [2017] of Zhejiang Province Human Resources and Social Security Department	09/01/2017	Incorporated into the management of class B drugs for medical insurance in Zhejiang Province
Shanghai	11/15/2017	No. 430 [2017] for the medical insurance of Shanghai Municipal Human Resources and Social Security Bureau	12/01/2017	The specific standards of payment by the medical insurance institution were implemented in accordance with Document No. 54 [2017] issued by MOHRSS
Guangdong	09/25/2017	No. 221 [2017] of Human Resources and Social Security Department of Guangdong Province	10/01/2017	Paid according to the provisions of the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance
Shandong	08/21/2017	No. 34 [2017] of Human Resources and Social Security Department of Shandong Province	09/01/2017	The standard of payment was implemented in accordance with the provisions of the state; the self-pay ratio of the insured was uniformly formulated by the municipal human resources and social security department and submitted to the provincial department for the record
Gansu	09/25/2017	No. 32 [2017] of Gansu Provincial Medical Reform Leading Group Office	11/01/2017	Based on the reimbursement ratio of class B drugs in the co-ordinated regions
Guizhou	11/22/2017	No. 22 [2017] of Human Resources and Social Security Department of Guizhou	12/20/2017	A certain proportion was paid by the insured, and the payment was made according to the provisions of the basic medical insurance in each co-ordinated region; the

		Province		beforehand self-pay ratio followed the unified standard in the whole province, and could be adjusted dynamically according to the incidence rate and medical insurance funds
Henan	08/11/2017	No. 68 [2017] of Department of Human Resources and Social Security of Henan Province	09/01/2017	The self-pay ratio of 36 kinds of drugs was tentatively set at 20%; the new edition of *Henan Provincial Catalogue of Drugs* was officially implemented on January 1, 2018. After the new edition of the *Catalogue of Drugs* was released, the self-pay ratio for class B drugs was determined by local authorities according to regulations.
Beijing	08/31/2017	No. 180 [2017] for the medical insurance of Beijing Municipal Human Resources and Social Security Bureau	09/01/2017	The standard of payment by the medical insurance institution was composed of expenses paid jointly by basic medical insurance funds and the insured
Shaanxi	09/11/2017	——	09/11/2017	The specific payment ratio was determined by each co-ordinated region
Anhui	08/16/2017	No. 41 [2017] of Human Resources and Social Security Department of Anhui Province	09/01/2017	Paid according to class B drugs; the limited scope of payment followed the state regulations
Chongqing	12/22/2017	No. 266 [2017] of Chongqing Municipal Human Resources and	09/01/2017	The share proportion of medical insurance and the insured was established by each city (prefecture) according to the principle of classified management

		Social Security Bureau		
Jilin	07/31/2017	No. 55 [2017] of General Office of Jilin Provincial Human Resources and Social Security Department	09/01/2017	Temporarily followed the current payment methods and standards of medical insurance
Liaoning	08/10/2017	No. 171[2017] of Liaoning Provincial Department of Human Resources and Social Security	09/01/2017	The self-payment ratio was 30%

There were some differences in the self-payment ratio among provinces. Henan Province was the first province in the country to determine the self-payment ratio of drugs priced through government negotiation, with self-payment ratio tentatively set at 20%. Liaoning Province followed the price of drugs through government negotiation incorporated into the national price negotiation, without organizing the additional negotiations. Within a medical year, each insured was restricted to purchase drugs at one designated drug supplier, which should not be changed in principle. After the insured paid 30% for the drugs purchased at the designated drug supplier, 80% of the rest shall be paid by the overal planning fund of staff medical insurance and 70% of the rest shall be paid by the overal planning fund of residents' medical insurance. Chongqing Municipality stipulated that the insured should pay 10% for the drugs before being incorporated into the scope of medical insurance reimbursement.

The self-payment ratio for 36 drugs in Sichuan Province was divided into two categories: for the 20 drugs (Recombinant Human Coagulation Factor Ⅶa and etc.) in the drugs priced through negotiations, the deductible was not implemented, the drugs were paid individually by the overal planning fund of basic medical insurance,

and the total expense of drugs paid by the overal planning fund of basic medical insurance would not exceed RMB150,000 for each insured in one year. For example, in Chengdu City, for the 20 drugs, the payment ratio of overal planning fund of urban employees' basic medical insurance was 70%; the payment ratio of overal planning fund of urban and rural basic medical insurance for high-end payers was 60%, and the payment ratio for low-end payers was 55%. For the other 16 drugs (Liraglutide, etc.), the provisions of Class B drugs in Sichuan Province were followed. For example, in Chengdu City, for the other 16 drugs, 10% would be paid by the insured of urban employees' basic medical insurance first; 20% would be paid by the insured of urban and rural residents' basic medical insurance first.

C Link of policies

For implementation of drugs priced through negotiations, it is necessary for local government to introduce practical supporting policies to ensure implementation and provide security, while the all-round policy link is required to solve inconsistency between the original local policy management and the new national policy requirements, including the transformation of the former drugs priced through negotiations for serious diseases in the original serious disease negotiation area to Class B drugs in the list, and how to properly solve the original charitable drug donation model of the drug varieties involved in the negotiation, which requires provinces to release corresponding policies and improve the link of policies. For this purpose, Gansu, Guizhou, Shandong, Sichuan and other provinces had made specific provisions for link of policies.

According to the implementation document of drugs priced through negotiations in Gansu Province, for the related drugs included in the 36 drugs priced through government negotiation in the *Notice on Including Special Drugs for Breast Cancer Patients into the Payment Scope of Basic Medical Insurance* (No. 389 [2016] of the Department for Human Resources and Social Security of Gansu Province) and the *Notice on Including Special Drugs for Leukemia Patients into the Payment Scope of Basic Medical Insurance* (No. 390 [2016] of the Department for Human Resources and Social Security of Gansu Province) issued by the Provincial Department for

Human Resources and Social Security, the price of drugs through government negotiation would be followed since November 1, 2017, and the original negotiation agreement would be terminated naturally. But, patients who had not finished the previous donation cycle as of November 1, 2017 were still subject to the original provisions, and would be subject to the price of drugs through government negotiation after the end of the donation cycle.

According to the *Notice of Guizhou Province on the Work Programme for Adjusting the List of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance in Guizhou Province in 2017 (Draft for Comment)* (No. 22 [2017] of the Department for Human Resources and Social Security of Guizhou Province), the List of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance in Guizhou Province (2017 Version) should be implemented from December 20, 2017. After the list was implemented, the *List of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance in Guizhou Province (2010 Version)* and the relevant supplementary documents, and the *Notice on Fixed Quota Settlement for Outpatient Special Treatment of Chronic Granulocytic (Myeloid) Leukemia* (No. 143 [2016] of the Department for Human Resources and Social Security of Guizhou Province) were abolished.

Shandong Province had made corresponding provisions on the link between the original critical illness insurance and 36 drugs priced through negotiations. The transitional period policy was implemented for the drugs in the payment scope of Shandong Province's critical illness insurance included in the 2017 Version of the *National Reimbursement Drug List* and 36 negotiable drugs determined by the state, and the original provisions expired on December 31, 2017. Cities were required to subsidize the self-pay portion of the insured after critical illness insurance payment through the basic medical insurance funds based on Class B drug policies, so as to ensure that the actual treatment level of the insured would not be decreased. The specific transitional measures were as follows: ① Five drugs, including Decitabine, Dasatinib, Gefitinib, Icotinib and Recombinant Human Coagulation Factor IX were still

subject to the price of grugs through negotiation of Shandong Province; ② The price of drugs through government negotiation was implemented for seven drugs as of September 1, including Bortezomib, Lenalidomide, Erlotinib, Recombinant Human Endostatin, Bevacizumab, Trastuzumab and Apatinib. For the above 12 drugs, the expenses incurred by the insured after September 1, 2017 for the purchase of drugs, and the self-pay portion (including the deductible) after the critical illness insurance payment would be subsidized by 50% through the basic medical insurance funds. After the end of the transitional period, the self-payment ratio for these 12 drugs was determined as 20% from 1 January 2018. Tenofovir Disoproxil was included in the management of Class B drugs of the provincial basic medical insurance and was subject to the basic medical insurance policy. ③ Link of policies related to drug donation scheme: For patients who had used drugs in the charitable donation (drug donation) schemes before September 1, 2017, but had not entered the charitable donation (drug donation) process, drugs would be purchased at the prices of drugs through government negotiation from September 1, 2017, and patients could continue to apply for the charitable donation (drug donation). The specific schemes issued by charitable organizations and drug suppliers would apply.

According to Sichuan Province's document on the implementation of 36 drugs priced through negotiations: prior to the release of the List of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance in Sichuan Province (2017 Version), the *List of Drugs for Basic Medical Insurance, Employment Injury Insurance and Maternity Insurance in Sichuan Province* (2010 Version) and the relevant supplementary documents continued to be implemented (drugs deleted during adjustment of the 2017 Version of the *National Reimbursement Drug List* were no longer implemented). Those provisions inconsistent with the 2007 Version of the *National Reimbursement Drug List* were temporarily implemented in accordance with the current provisions of our province. At the local execution level, Chengdu City transferred 6 varieties in the list of drugs for major and serious diseases that were overlapped with the National Reimbursement Drug List (2017 Version) and 8 varieties overlapped with 36 drugs

priced through government negotiation. The medical insurance agency of Chengdu City formulated the treatment link measures.

④ Privileges

A Not included in the general control of medical insurance and drug proportion

In order to control the increasing medical expenses and promote rational drug use, the state had taken a series of measures, including controlling the drug proportion and controlling the total expenses. *The Guiding Opinions of the General Office of the State Council on Urban Public Hospital Comprehensive Reform Pilot* put forward that "Efforts should be made to reduce the drug proportion (excluding Chinese herbal pieces) in pilot urban public hospitals to about 30% by 2017. The state had restricted the growth rate of the total medical income, requiring that the annual growth of medical income in public hospitals should not exceed 10%. However, due to the high price of some drugs among the 36 drugs priced through negotiations, the incorporation of these drugs in the drug proportion and the calculation of total expenses would hinder the hospital from introducing these drugs and the implementation of these drugs priced through negotiations.

In order to further guarantee the clinical application of drugs priced through government negotiation and improve their accessibility, some provinces and cities, considering that it was still at the initial stage that some drugs were included into medical insurance payment and the number of patients was still uncertain, temporarily did not include the drugs priced through government negotiation into the drug proportion in medical institutions and the assessment of controlled total expenses of medical insurance on the basis of rational drug use, in order to ensure the clinical application of drugs priced through negotiations. For example, on November 15, 2017, the Anhui Provincial Health Planning Commission issued the *Notice on Strengthening the Administration of Drug Purchase and Use*, which proposed that the drugs priced through government negotiation would not be included in the assessment of the drug proportion in medical institutions temporarily, and separate accounting and reasonable regulation and control would be executed. The statistics showed that, as of the first half of 2018, Tianjin, Hainan, Ningxia and

other provinces and cities had made clear that the drugs priced through government negotiation are not included in the drug proportion or have defined the separate accounting requirements, and 22 provinces/cities nationwide have clarified the requirements. Provincial provisions on the proportion of drugs priced through negotiations are shown in the following table 7:

Table 7. Drugs Priced through Government Negotiation not included in the Drug Proportion or Separate Accounting Status of Provinces

Provinces	Specific contents
Jiangsu	The procurement quantity of medical institutions would be separately accounted for and reasonably regulated and controlled during the procurement period
	The Department of Human Resources and Social Security should link up medical insurance policies, guide medical institutions to settle the drugs priced through negotiations properly, safeguard and protect the rights and interests of the insured
Zhejiang	The procurement quantity of medical institutions would be separately accounted for and reasonably regulated and controlled during the procurement period
Shanghai	The municipal administrative departments of medical insurance and health planning would carry out the "three designation" management of designated hospitals, designated physicians and designated indication for the insured, and make a difference between these drugs and other drugs in terms of drug proportion and assessment of the total amount of medical insurance, so as to ensure the rational drug use
	Considering that it was still at the initial stage that some drugs were included into medical insurance payment, and the number of patients was still uncertain, in order to effectively reduce the burden of medical expenses of the insured, these drugs would not be temporarily included in the hospitals' drug proportion and the assessment of general medical insurance control on the basis of rational drug use
Guangdong	For the relevant data of drugs priced through government negotiation purchased by medical institutions during the procurement period, our province would temporarily implement separate accounting and reasonable regulation and control in medical reform and other related assessments on the basis of rational drug use
	Drug proportion = drug income of hospitals (excluding income of Chinese herbal pieces and drugs priced through government negotiation) / total medical income x 100%
Henan	Drugs priced through government negotiation (including their generic drugs) and specific drugs for major and serious diseases would not be included in the

	drug proportion and the control and assessment of total medical insurance amount of medical institutions
Gansu	During the procurement period of 2016-2017, departments would no longer organize the price negotiation, and the procurement volume of medical institutions would be separately accounted and reasonably regulated and controlled for the time being. The first batch of drugs would not be included in the drug proportion
	The drugs priced through government negotiation would be included in the management of special drugs. In the procurement period of the first batch of drugs priced through negotiations, the procurement volume of medical institutions would be separately accounted (not included in the assessment of drug proportion) and reasonably regulated and controlled for the time being, and the expenses would also not be included in the compensation payment limit for hospitalization or outpatient medical insurance
	The drugs priced through government negotiation would be included in the management of special drugs. The drugs priced through negotiations would not be included in the assessment of drug proportion of medical institutions temporarily
Shaanxi	The procurement quantity of medical institutions would be separately accounted for and reasonably regulated and controlled
Anhui	The drugs priced through government negotiation would not be included in the assessment of drug proportion of medical institutions temporarily, and would be separately accounted for and reasonably regulated and controlled
	During the procurement period of 2016-2017, the price negotiation would not be organized additionally, and the procurement volume of medical institutions would be separately accounted and reasonably regulated and controlled for the time being
Chongqing	The municipal health planning commission would implement separate accounting and reasonable regulation and control for drugs priced through government negotiation during the procurement period
	The procurement period of the first batch of drugs priced through negotiations published by the state was 2016-2017. The municipal health planning commission would implement separate accounting for drugs priced through government negotiation during the procurement period. The 3 drugs were not counted in the statistics and drug proportion indicator of medical institutions
Sichuan	The procurement quantity of medical institutions should be separately accounted for and reasonably regulated and controlled during the procurement period
	The 36 drugs priced through negotiations would be implemented from September 1, 2017. Provincial Medical Insurance Bureau would formulate the specific measures for supplementary reimbursement of 36 drugs priced through government negotiation, and strictly review the supplementary reimbursement. The expenses of 36 drugs priced through government negotiation incurred by designated medical institutions in 2017 were not

	included in the total amount control
Jilin	The procurement quantity of medical institutions should be separately accounted for and reasonably regulated and controlled during the procurement period of 2016-2017
	The 36 drugs priced through negotiations would be included in the management scope of special drugs. Considering that it is still at the initial stage that the special drugs are included into medical insurance payment and the number of patients is still uncertain, these drugs would not temporarily be included in the assessment of total amount control of medical insurance of medical institutions on the basis of rational drug use, in order to effectively lighten the burden of medical expenses of the insured
Liaoning	Medical institutions would sign procurement contracts with enterprises, to specify the procurement volume and purchase directly online at prices through negotiation. During the procurement period, the procurement volume of medical institutions would be separately accounted and reasonably regulated and controlled for the time being
	During the procurement period, the procurement volume of drugs priced through government negotiation of medical institutions would be separately accounted for the time being, that is, the medical institutions would separately account the drugs priced through government negotiation when counting the dosage and amount proportion of these drugs
	Medical and health institutions should correctly understand the relevant provisions of the state and the province, and the procurement volume of medical institutions during the procurement period should be separately accounted

B Supply at designated pharmacies

The No. 54 Document of MOHRSS required provinces to take effective measures to encourage designated retail pharmacies to provide drugs for the insured and play an active role in ensuring the supply of medical insurance drugs. To this end, the implementation documents of 36 drugs priced through negotiations issued by provinces encouraged the designated retail drug sales to negotiate drugs, strengthened the protocol management of designated pharmacies, established a "double channel" for supply of drugs priced through negotiations and improved the accessibility of drugs priced through negotiations.

Table 8.Distribution Channels of Drugs Priced through Government Negotiation of Provinces

Provinces	Description of policy documents
Gansu	Encourage the designated retail drug sales to negotiate drugs
Jiangsu	All regions are required to take effective measures to encourage retail pharmacies

	to provide drugs for the insured and play an active role in ensuring the supply of medical insurance drugs; for drugs priced through negotiations sold in designated retail pharmacies, the protocol management of designated retail pharmacies should be conscientiously strengthened
Guizhou	Establish the record and registration system for drug use, and extend the sale of drugs to designated pharmacies in areas where conditions permitted
Shandong	Take effective measures to encourage retail pharmacies to provide drugs for the insured and play an active role in ensuring the supply of medical insurance drugs
Liaoning	Encourage designated retail pharmacies to provide drugs for the insured
Jilin	Establish the management mechanism of designated retail pharmacies for special drugs and gradually create conditions to take effective measures to encourage designated retail pharmacies to provide special drug services for the insured
Shaanxi	For drugs requiring "prior review before use" or other drugs requiring strict management, real-name registration of cases, centralized supply in designated hospitals or retail pharmacies could be adopted
Qinghai	The insured who use drugs priced through negotiations can purchase them in outpatient departments (designated retail pharmacies)

The reimbursement policies for drugs priced through negotiations in the outpatient departments (designated retail pharmacies) in some prefectures and municipalities are also gradually expanding. For example, outpatients in Zhuhai City, Guangdong Province can purchase drugs at their own expense at the pharmacies with the outsourcing prescription from hospitals, and then reimburse at Zhuhai Medical Insurance Center by invoice according to the hospitalization treatment. Patients in Ningbo City and Taizhou City, Zhejiang Province can directly settle the expenses by the system and should only pay the self-pay portion.

When evaluating the implementation of drugs priced through negotiations in 31 provinces in China, this study evaluates the implementation situation of drugs priced through negotiations in 31 provinces in China, by taking the provincial implementation policies and procurement policies as policy guarantee, and considering the operability provisions at the time of implementation and the special treatment of drugs priced through negotiations as important reference factors.

The implementation policies and procurement policies are included into policy guarantee. The scoring is based on whether the normative documents are available to standardize both implementation policies and procurement policies at the provincial level; specific implementation provisions mainly include operation rules,

standardized conditions of use, self-payment ratio, drug proportion, control of total amount of medical insurance and supply of community pharmacies. The evaluation criteria for scoring include the provisions on policy operability in the provincial implementation policies, whether the provincial-level government stipulates the use of drugs, such as "three designations" and "five designations", whether the provincial-level government unifies the self-payment ratio at provincial level, whether the provincial-level government indicates that the drugs priced through negotiations are not included in the assessment of drug proportion, whether the provincial-level government includes the drugs priced through negotiations in the total controlled amount of medical insurance of medical institutions, and whether the provincial level opens the community pharmacies to supply the drugs priced through negotiations and etc.

Table 9. Evaluation Basis and Criteria of Implementation Status

Indicators	Evaluation basis	Scoring criteria	Score
Policy guarantee			
Implementation policy	Does the provincial-level government have normative documents to regulate the implementation	√: documents are formulated	√: 11 —: 0
Procurement policies	Does the provincial-level government have normative documents to regulate the procurement of drugs priced through negotiations	√: documents are formulated	√: 11 —: 0
Specific provisions			
Operation rules	The provincial implementation policies have provided the provisions related to policy operability	√: provisions are formulated	√: 13 —: 0
Standardized conditions of use	Does the provincial-level government stipulates the use of drugs, such as "three designations" and "five designations", refines the classified management of drugs in the list and formulates the detailed management requirements	√: provisions are formulated	√: 5, 3, 3, 2 —: 0
Self-payment ratio	Whether the self-payment ratio is unified at the provincial level	√: provincial provisions are formulated; ○: provincial	√: 13 ○: 6.5 —: 0

		provisions are not formulated, but municipal provisions are formulated	
Drug proportion	Is it indicated that the drugs priced through negotiations are not included in the assessment of drug proportion the provincial level	√: not included	√: 13 —: 0
Control of total amount of medical insurance	Whether the drugs priced through negotiations are included in the total controlled amount of medical insurance of medical institutions at the provincial level	√: not included	√: 13 —: 0
Supply at community pharmacies	Whether the community pharmacies are opened for drugs priced through negotiations at the provincial level	√: opened	√: 13 —: 0

With a full score of 100 points, both implementation policies and procurement policies are regarded as the basic elements to evaluate the implementation, and the statistics show that almost all provinces in China have introduced relevant policy documents, so the score of policy documents is set lower than the item of specific provisions, and the province will obtain 11 points if it has introduced the documents. In the item of specific provisions, the score of 6 specific provisions is unified (13 points). In some provinces and cities, no clear self-payment ratio is stipulated in the provincial-level documents, but the municipal-/district-level government under the provincial level stipulates the self-payment ratio. In this case, when evaluating the province, the self-payment ratio is determined as 6.5 points and as 13 points if the self-payment ratio has been defined at the provincial level.

For standardized conditions of use, the province will get 5 points if it has made provisions with regard to the use of drugs priced through negotiations. The province will get 3 points if it has refined the classified management of drugs priced through negotiations and made a distinction between drugs for chronic diseases and drugs for tumours. The province will get 2 points if it has specified the “three designations” and “five designations” in the standardized conditions of use. A total of 13 points is

given for standardized conditions of use.

Table 10. Summary of Overall Implementation of Health Insurance Negotiation Policies in 31 Provinces of China

Provinces	Implementation policy 11	Procurement policy 11	Operation rules 13	Standardized conditions of use 13				Self-payment ratio	Drug proportion	Total controlled amount of medical insurance	Supply at community pharmacies	Total points
				Yes/no (5)	Drugs for chronic diseases (3)	Drugs for tumours (3)	Refined or not (2)	13	13	13	13	
Tibet	√	√	—	—	—	—	—	—	—	—	—	22
Qinghai	√	√	—	√	—	√	—	√	√	—	√	69
Hebei	√	√	√	—	—	—	—	√	√	—	—	61
Guangxi	√	√	—	—	—	—	—	—	—	—	—	22
Hainan	√	√	—	—	—	—	—	√	√	—	—	48
Inner Mongolia	√	√	—	—	—	—	—	—	√	—	—	35
Shanxi	√	√	—	√	—	√	√	—	√	—	—	45
Beijing	√	√	√	√	—	√	√	—	—	—	√	58
Jiangsu	√	√	√	√	—	√	√	○	√	—	√	77.5
Zhejiang	√	√	√	√	—	—	—	—	√	—	√	66
Shanghai	√	√	√	√	√	√	√	√	√	√	—	87
Shandong	√	√	√	√	—	√	√	√	—	—	√	71
Gansu	√	√	—	√	—	√	—	—	√	—	√	56
Guizhou	√	√	√	√	—	√	—	√	—	—	√	69
Guangdong	√	√	√	√	—	—	—	√	√	—	—	66

Shaanxi	√	√	—	√	—	—	—	○	√	—	√	59.5
Anhui	√	√	—	√	—	—	—	√	√	—	√	66
Chongqing	√	√	√	√	—	√	√	√	√	—	√	84
Sichuan	√	√	√	√	—	—	—	√	√	√	√	92
Jilin	√	√	—	√	—	—	√	√	√	√	√	81
Liaoning	√	√	—	—	—	—	—	√	√	—	√	61
Henan	√	—	√	√	√	√	√	√	√	√	—	76
Yunnan	√	√	—	√	—	—	—	√	√	—	—	53
Fujian	√	√	√	√	√	—	—	√	—	—	—	56
Heilongjiang	√	√	—	√	—	√	—	○	√	—	√	62.5
Hunan	√	√	—	√	—	√	—	○	√	—	√	62.5
Jiangxi	√	√	—	—	—	—	—	—	√	—	—	35
Hubei	√	√	√	√	—	√	√	○	—	—	√	64.5
Tianjin	√	√	√	—	—	—	—	√	√	√	√	87
Xinjiang	√	√	—	√	—	—	—	○	—	—	—	33.5
Ningxia	√	√	√	—	—	—	—	—	√	—	—	48

As shown in the table above, after scoring and counting based on the above 8 indicators, the provinces with 6 or more indicators (≥75) are those with better implementation effects, the provinces with 4 or more indicators (50-74) are those with good implementation effects, the provinces with 3 or more indicators (26-49) are those with poor implementation effects, and the provinces with 2 or less indicators (≤25) are those with worse land implementation effects.

The implementation of drugs in specific provinces is as follows:

① Provinces with better implementation effects: Jiangsu, Shanghai, Sichuan, Chongqing, Jilin, Henan and Tianjin;

② Provinces with good implementation effects: Beijing, Shandong, Guangdong, Zhejiang, Qinghai, Hebei, Gansu, Guizhou, Shaanxi, Anhui, Liaoning, Hunan, Yunnan, Hubei, Fujian and Heilongjiang;

③ Provinces with poor implementation effects: Hainan, Shanxi, Jiangxi, Ningxia,

Xinjiang and Inner Mongolia;

④ Provinces with worse implementation effects: Tibet and Guangxi

⑤ Analysis of implementation of drugs priced through negotiations in typical areas

After the introduction of a series of policies by the state, whether the local government can really implement them is the decisive factor to ensure the implementation of drugs priced through negotiations. During implementation, the provinces show mixed results and some provinces have better implemented the drugs priced through negotiations, such as Henan Province and Jiangsu Province, which are worthy of reference by other provinces and cities.

A. Implementation of drugs priced through negotiations,in Henan Province

On August 11, 2017, Henan Province became the first province in China to specify the individual self-payment ratio (20%) of 36 drugs priced through negotiations,. As of July 3, 2018, , all 39 drugs priced through negotiations, had been included in the payment scope of Henan provincial medical insurance, including the three drugs priced through negotiations in 2015. In September 2018, the state conducted special negotiations on anticancer drugs, including 17 anticancer drugs into the Class B Scope of the *Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version)*, and determined the payment standard of medical insurance, requiring provinces to ensure the implementation before the end of November. Before November 30, 2018, 17 anticancer drugs were included in the list of Class B drugs in Henan Province in accordance with the requirements of national policies.

a. Implementation policies

Henan Province had issued a series of policies in order to ensure the implementation of drugs priced through negotiations,.

Table 11. Implementation Policies for Drugs Priced through Negotiations, in Henan Province

Policy provisions	Document name	Release date	Specific contents
Self-payment ratio	Notice of Henan Provincial Department	08/08/2017	The self-payment ratio of Class B drugs (including 36 drugs priced through

	of Human Resources and Social Security on the Implementation of the List of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version)		negotiations,) was added and tentatively set at 20% in the whole province; after the publication of the new Version of the *Drug List*, the self-payment ratio of Class B drugs was determined in accordance with the regulations
Standard management	Notice of Health Commission of Henan Province on Including Drugs Priced through Negotiations, into the Reimbursement Scope of New Rural Cooperative Medical System (NRCMS)	08/26/2016	Carry out necessary examination and evaluation regularly for NRCMS patients, and prescribe specific drugs reasonably according to the evaluation; the prescribed dose of a specific drug should not exceed the demand for **3 months** at a time Implement the **packaging and recycling** system for specific drugs: designated medical institutions should establish strict specific drug management and registration system, and set up specific drug counters
	Notice of Henan Provincial Department of Human Resources and Social Security on the Printing and Distribution of the List of Drugs for the Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance in Henan Province (2017 Version)	12/29/2017	Include 36 drugs priced through government negotiation into the scope of Class B of the *Drug List*, and implement the **unified management** of cancer-targeting drugs such as Icotinib, Dasatinib, Gefitinib and Imatinib in the *Drug List* as **special drugs**
	Notice of Henan Provincial Department of Human Resources and Social Security and Health Commission of Henan Province on Guaranteeing the Clinical Application of Drugs Priced through Government	07/03/2018	Strengthen the management of drugs priced through negotiations,: drugs with large dosage and high cost should be included in the intelligent monitoring system of basic medical insurance service for **key monitoring** and analysis of expenses

	Negotiation		
Assessment indicators	Notice of Henan Provincial Department of Human Resources and Social Security and Health Commission of Henan Province on Guaranteeing the Clinical Application of Drugs Priced through Government Negotiation	07/03/2018	Guarantee the clinical application of drugs priced through negotiations: drugs priced through government negotiation (including their generic drugs) and specific drugs for major and serious diseases were not included in the **assessment of drug proportion in medical institutions** and **the total controlled amount of medical insurance temporarily**

In order to effectively reduce the drug burden of cancer patients, Henan Provincial Department of Human Resources and Social Security issued the *Notice on Forwarding the Notice of the Bureau of Medical Administration of NHFPC on the Preparation and Use of 17 Anti-cancer Drugs Priced through Government Medical Insurance Negotiation* on November 2, 2018, requiring the provincial third-level hospitals with registered oncology department and tumor hospitals at all levels prepare the drugs priced through negotiations in time according to clinical needs and diagnostic and therapeutic capabilities, and that the preparation of drugs priced through negotiations, be implemented by November 30, 2018. In addition, the Notice stressed that all local units should earnestly implement the relevant requirements of the *Notice on Guaranteeing the Clinical Application of Drugs Priced through Government Negotiation* issued by the Henan Provincial Department of Human Resources and Social Security and Health Commission of Henan Province, and should not affect the supply and use of drugs on the grounds of total control of medical expenses, total control of medical insurance expenses and "drug proportion", and should include drugs in the formulary and the list of basic drugs, so as to meet the needs of patients for medication.

b. Link of policies

The *Notice of Henan Province on Guaranteeing the Clinical Application of Drugs Priced through Government Negotiation* (No. 225 [2018] of Department of Human

Resources and Socail Security of Henan Province) proposed that the proper link between medical security for major and serious diseases and the use of drugs priced through negotiations shall be ensured. Based on the scope of clinical indications of drugs priced through negotiations, the following adjustments and standardization were made to the names of some newly added outpatient disease categories in the medical security for major and serious diseases in the *Notice of Henan Provincial Department of Human Resources and Social Security on Increasing the Outpatient Disease Categories in the Medical Security for Major and Serious Diseases* (No.19 [2018] of Department of Human Resources and Socail Security of Henan Province):

(1) “HER2 positive breast cancer” was changed to “breast cancer”.

(2) “Late gastric cancer” was changed to “gastric cancer”.

(3) “Stage III/IV nasopharynx cancer” was changed to “nasopharynx cancer”.

(4) “Advanced renal cell carcinoma” was changed to “kidney cancer”.

Table 12. Link between Medical Security for Major and Serious Diseases and the Use of Drugs Priced through Negotiations

Original outpatient disease categories for major and serious diseases	**Newly added drugs priced through negotiations**	**Scope of outpatient disease categories for major and serious diseases after adjustment**
HER2 positive breast cancer	✧ HER2 positive metastatic breast cancer ✧ Advanced or metastatic breast cancer with HER2 overexpression and previous treatment with anthracycline, paclitaxel and trastuzumab ✧ Treatment of advanced, hormone receptor (ER/PR) positive breast cancer after failure of treatment with aromatase inhibitor	Mammary cancer
Stage III/IV nasopharynx cancer	✧ Stage III/IV nasopharynx cancer, combined with radiotherapy treatment of positive expression of epidermal growth factor receptor (EGFR)	Nasopharynx cancer
Late gastric cancer	✧ HER2 positive advanced metastatic gastric cancer ✧ Only for patients with progressive or recurrent advanced gastric adenocarcinoma or adenocarcinoma of esophagogastric junction who have had at least two types of systemic	Gastric cancer

	chemotherapy	
Advanced renal cell carcinoma	✧ Inoperable renal cell carcinoma ✧ Adult patients with advanced renal cell carcinoma who have failed treatment with sunitinib or sorafenib ✧ Adult patients with renal angiomyolipoma (TSC-AML) related to tuberous sclerosis, immediate surgical treatment not required	Renal carcinoma

B Implementation of Drugs Priced through Negotiations in Jiangsu Province

a. Implementation policies

Jiangsu Province has earnestly implemented the national drug price negotiation policies, and local cities have actively issued documents to ensure the smooth implementation of drugs priced through negotiations.

Table 13. Implementation Status of Drugs Priced through Negotiations in Various Cities of Jiangsu Province

Type of policies	Requirements of provincial-level documents	Local policies	Specific contents of local policies
Procurement policy	*Notice on the Centralized Procurement of 36 Drugs Priced through Negotiations* (No. 8 [2017] of Administration of Office of Suzhou Health and Family Planning Commission): upload the 36 drugs priced through negotiations of MOHRSS onto the Centralized Online Procurement and Supervision Platform for Drugs (Consumables) in Provincial Medical Institutions for direct procurement	*Notice of Nanjing City on the Concentrated Procurement of 36 Drugs Priced through Negotiations* (No. 17 [2017] of Ningxia Provincial Medical Reform Leading Group Office)	Direct online procurement of 36 drugs priced through negotiations
Self-payment ratio	*Notice on Including 36 Drugs in the Class B Scope of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance* (No. 265 [2017] of Suzhou Municipal Department of	*Notice of Wuxi City on Forwarding Related Documents for the List of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the*	The self-payment ratio of drugs priced through negotiations (except for Trastuzumab Injection) is tentatively set at 50%

	Human Resources and Social Security): the payment ratio of basic medical insurance fund should be determined by all cities and districts uniformly and submitted to the provincial department for record	*Maternity Insurance (2017 Version)* (No. 251 [2017] of Bureau of Human Resources and Social Security of Wuxi)	
Standardized management	*Notice on Including Relevant Drugs into the Management of Special Medicare Insurance Drugs* (No. 346 [2017] of Suzhou Municipal Department of Human Resources and Social Security): implement the "three designations" for special medical insurance drugs	Wuxi City: *Forwarding the Notice of Provincial Department of Human Resources and Social Security on Including Related Drugs into the Management of Special Medicare Insurance Drugs* (No. 365 [2017] of Bureau of Human Resources and Social Security of Wuxi)	Implement the strict management of "three designations" for special drugs, i.e. designated medical institutions, designated physicians and designated pharmacies
Rational drug use	*Notice on Including 36 Drugs in the Class B Scope of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance* (No. 265 [2017] of Suzhou Municipal Department of Human Resources and Social Security): various regions should actively explore various forms to strengthen the management of drugs priced through negotiations and promote rational drug use	*Notice of Nanjing City on the Concentrated Procurement of 36 Drugs Priced through Negotiations* (No. 17 [2017] of Ningxia Provincial Medical Reform Leading Group Office)	Medical institutions should rationally use the drugs priced through negotiations, timely adjust their list of drugs for cancer treatment and clinical application grade management record, and submit them to the municipal and district health and family planning administrative departments for record
Assessment indicators	*Notice on Centralized Procurement of Drugs Priced through Government Negotiation* (No. 7 [2016] of Administration for Drugs of Suzhou Health and Family Planning Commission):	Nanjing City forwards the *Notice of Provincial Health Planning Commission on Centralized Procurement of Drugs*	During the procurement period, the purchased drugs should be separately

	the centralized procurement of drugs priced through government negotiation should be standardized. During the procurement period, the procurement volume of medical institutions should be separately accounted and rationally regulated and controlled	*Priced through Government Negotiation* (No. 3 [2016] of Affairs for Ningxia Health and Family Planning Commission)	accounted and rationally regulated and controlled

b. Link of policies

The *Notice of Jiangsu Provincial Department of Human Resources and Social Security on Including Related Drugs into the Management of Special Medical Insurance Drugs* required that all districts and cities should link the treatment policies of new and old special drugs and design the payment policies for the anti-cancer molecular targeted drugs in 36 drugs priced through negotiations. To this end, Wuxi Municipal Department of Human Resources and Social Security issued the *Notice on Forwarding Related Documents for the List of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version)* (No. 251 [2017] of Bureau of Human Resources and Social Security of Wuxi), and Suzhou Municipal Department of Human Resources and Social Security issued the *Notice on Forwarding Related Documents for the List of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version)* (No. 19 [2017] of Suzhou Municipal Department of Human Resources and Social Security for Management Measures of Designated Medical Institutions of Social Medical Insurance), both of which required Trastuzumab injection (National Catalog No.: TX10) and Imatinib oral sustained-release dosage form (National Catalog No.: 801), as well as the former Gefitinib oral sustained-release dosage form (National Catalog No.: 800) for medical insurance cooperation project in Wuxi City should be temporarily implemented in accordance with the provisions of the original special drugs, and Herceptin (Trastuzumab for Injection) could be used for the treatment of indications of HER2 positive advanced metastatic gastric carcinoma.

(3) Drug use – patients' perspective

After being included in the list of drugs priced through negotiations, drugs can enjoy the reimbursement according to Class B of the medical insurance list, which will greatly reduce the economic pressure on patients. However, many drugs had been incorporated in the Patient Assistance Program (PAP) before being included into the list priced through negotiations, and their prices had been decreased through preference and assistance program. In order to reduce the impact of lower prices on enterprises, most drugs were withdrawn from the original assistance programs and were subjected to the price of drugs through government negotiation.

The statistics show that 21 of the 64 drugs priced through negotiations in 2016, 2017 and 2018 had been incorporated in the Patient Assistance Program before being included into the list priced through negotiations. After being included in the national health insurance list through negotiation, 20 assistance programs (see table 14) chose to cancel the original assistance and implement the price of drugs through government negotiation.

Table 14. Original Patient Assistance Programs of Drugs Priced through Negotiations

Drug name (trade name)	Manufacturers	Program name	Status after negotiation
Trastuzumab (Herceptin)	Roche	Herceptin Patient Assistance Program (Cancer Foundation of China)	Stop
Bevacizumab (Avastin)	Roche	Avastin Patient Assistance Program (China Charity Foundation)	Stop
Erlotinib (Tarceva)	Roche	Tarceva (Erlotinib) Charity Medicine Donation Program (China Charity Foundation)	Stop
Ranibizumab (Lucentis)	Novartis	Lucentis Charity Assistance Program (China Primay Health Care Foundation)	Stop
Nilotinib (Tasigna)	Novartis	Glivec Global Patient Assistance Program (China Charity Foundation)	Stop
Pazopanib (Votrient)	Novartis	Votrient Patient Assistance	Stop

		Program (China Charity Foundation)	
Sorafenib (Nexavar)	Bayer	Nexavar Patient Assistance Program (China Charity Foundation)	Stop
Recombinant Human Interferonβ-1b (Betaseron)	Bayer	Betaseron Patient Assistance Program (China Charity Foundation)	Stop
Crizotinib (Xalkori)	Pfizer	Xalkori Patient Assistance Program (Cancer Foundation of China)	Stop
Sunitinib (Sutent)	Pfizer	Sutent Patient Assistance Program (Cancer Foundation of China)	Stop
Fulvestrant (Faslodex)	AstraZeneca	Faslodex Charity Assistance Program (China Women's Development Foundation)	Stop
Gefitinib (Iressa)	AstraZeneca	Iressa Charity Assistance Program (China Charity Foundation)	Stop
Bortezomib (Velcade)	Johnson & Johnson	Velcade Patient Assistance Program (Cancer Foundation of China)	Stop
Nimotuzumab (Taixinsheng)	Biotech	Taixinsheng Nasopharyngeal Carcinoma Special Patient Assistance Program (Qingdao Special Program)	Continue
Apatinib (AiTan)	Hengrui	AiTan Patient Assistance Program (China Pharmaceutical Innovation and Research Development Association)	Stop
Chidamide (Epidaza)	ChipScreen BioS	Chidamide (Epidaza) Charity Assistance Program (Beijing Renze Foundation)	Stop
Cetuximab (Erbitux)	Merck	Erbitux Assistance Program (China Charity Foundation)	Stop
Anlotinib (Fukewei)	Chia-tai Tianqing	Fukewei - Lung Cancer Patient Assistance Program (China Primay Health Care Foundation)	Stop
Ibrutinib (Yike)	Xi'an Janssen	New Born - Lymphoma Patient Assistance Program	Stop

		(China Primay Health Care Foundation)	
Ixazomib (Ninlaro)	Takeda Pharmaceutical	Ninlaro Patient Assistance Program (Cancer Foundation of China)	Stop
Icotinib (Conmana)	Zhejiang Beida	Conmana Free Medicine Donation Charity Program (Betta Pharmaceuticals & China Pharmaceutical industry Research and Development Association)	Stop

The following problems were exposed during implementation of price of drugs through government negotiation: ① the price cut was not obvious when comparing the price of drugs in the charity assistance programs with the price of drugs through government negotiation; ② after drugs were withdrawn from the charity assistance programs and were included in the list priced through negotiations, the drug price was increased instead of decreased.

① Not obvious price cut

Most of the drugs priced through government negotiation had been incorporated into the Patient Assistance Program (PAP) before being included in the national negotiation list. After national negotiation, many projects had hedged the impact of price cut by canceling the drug donation policies. When the policies of drug donation were available, the price of drugs had been cut to a certain extent. However, after the drugs were included in the list priced through negotiations, the original price of drugs was negotiated by the enterprises with the medical insurance department, the final price of drugs had been greatly reduced compared with the original price, but there was no significant price cut compared with the original preferential policies.

Anlotinib, a domestic drug variety, was taken as an example for analysis. When the drug donation policies were provided before price cut, non-subsistence insurance patients could get a lifelong drug donation after purchasing 16 boxes of drugs totaling RMB99,200. When the drug donation was cancelled after price cut, the annual drug expenses based on mOS was RMB92140. The potential real price cut was

only 7.11% compared with 45% apparent price cut. So the price of many drugs after being included in the list priced through negotiations had not changed a lot for patients.

Table 15. Comparison of Anlotinib Price Cut before and after Cancellation of Drug Donation Policies[7]

Items	Values
Specifications	12mg/pill
Medicare payment standard	RMB487
Daily dose	12mg/pill
Dosage per course of treatment (21 days) (stop for 1 week every 2 weeks)	14 pills
Median overall survival (mOS)	9.46 months
Drug donation	
Annual drug expenses of patients	RMB99200
Drug donation cancelled	
Annual drug expenses of patients	RMB92140
Apparent price cut	45%
Potential real price cut	7.11%

② Drug price increased instead of decreased

Currently, a very prominent problem was found during the implementation of drugs priced through negotiations, that is, drugs could enjoy both medical insurance and price of drugs through government negotiation, but they could not be used in hospitals, while most of the final places for patients to use drugs were hospitals. In this context, many drugs priced through negotiations could still be used in the hospitals before negotiation, and could be sold in the form of free drugs, and patients could buy the required drugs priced through negotiations at a favorable price. But after negotiation, because of fixed drug price and restrictions on the drug proportion and the total expense control of medical insurance, the drugs priced through negotiations that could have been purchased in hospitals could not be sold in hospitals any longer, and the patients could not buy the drugs at the price of drugs through government negotiation, but could only buy them at their own expense, which made the price of drugs increasing instead of decreasing for patients.

7 Source: Drug Package Inserts, Medical Insurance Bureau, www.yaozh.com, TF Securities

Furthermore, some provincial/municipal regulations stipulated that only inpatients could reimburse the drugs in the list priced through negotiations, patients needed to be admitted to hospital in order to obtain drugs, and additional hospitalization expenses also greatly increased their financial pressure.

Take Betaferon, a drug for multiple sclerosis, for example. Betaferon has been repeatedly exposed as unavailable in medical institutions. Betaferon was included the national medical insurance list as early as July 2017, but Betaferon was still rejected by hospitals in Beijing, Inner Mongolia, Gansu, Shaanxi, Jiangsu and other provinces more than a year later. In addition, as the state has included the drug into the scope of medical insurance, and some patient assistance programs set up by charity organizations and pharmaceutical companies have been suspended accordingly, forcing patients to buy the drug in pharmacies at full cost.

During implementation of the second negotiation, the directions for improvement are summarized as follows: ① Some provinces failed to issue the official workable documents related to the use and management of drug varieties priced through negotiations in the medical insurance list (only the procurement documents provided the regulations related to the instructions, bidding and procurement of 36 drugs) - Tibet, etc.; ② Some provinces devolved the powers of self-payment ratio and qualification provisions to the cities, without follow-up implementation or relevant provisions at the provincial level - Heilongjiang, Tibet, Hebei and Guangxi, etc.; ③ Some provinces failed to provide separate stipulations on drug proportion of drugs priced through negotiations and controlled cost of medical insurance, etc. - Xinjiang, Hubei, Gansu and Guizhou, etc.; ④ After the implementation of zero profit margin in some provinces, hospitals were not highly motivated to purchase drugs, and eligible patients were not able to buy drugs -- common phenomenon; ⑤ Most of the drugs priced through negotiations had a too low reimbursement rate – Suzhou and Fujian etc. On the whole, the operability of provincial and municipal policies was not ideal, and too many limitations were imposed in the process of implementation, leading to patients' low sense of gain.

(3) Third drug price negotiation

1 Policy background

On October 10, 2018, the National Healthcare Security Administration issued the *Notice on the Inclusion of 17 Anticancer Drugs into the List of Class B Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance*, releasing the results of the third round of national medical insurance access negotiation that lasted three months.

2 Negotiation effects

(1) Success rate

The special access negotiation of anticancer drugs included 18 varieties, and except for Ruxolitinib tablets (Jakavi) of Novartis Pharmaceuticals, 17 varieties were successfully incorporated in the medical insurance list with a success rate of up to 94.1%. Of the 17 varieties, 11 varieties were new products approved for marketing after 2017. In particular, the domestic innovative drug Anlotinib was approved for marketing in May 2018, and was included in the national medical insurance reimbursement list at the end of September, with a medical insurance access cycle of only 4 months, realizing efficiency much higher than the average 15 months in developed countries.

(2) Price cut

17 drugs were included in the negotiation, with an average price cut of 56.7% and a maximum price cut of 71%. The payment standard for most imported drugs after negotiation was lower than the market price of surrounding countries or regions, about 36% lower on average. The situation of some drugs is as shown in table16.

Table 16. 8 Drugs with Price Cut over 65% in the Drugs Priced through Negotiations

Name of drugs	Manufacturers	Specifications	Price before negotiation	Medical insurance payment standard	Price cut
Cetuximab	Merck	100mg (20ml)/bottle	RMB4240	RMB1295	69.46%
Axitinib	Pfizer	5mg/tablet 1mg/tablet	RMB708 RMB207	RMB207 RMB60.4	70.76%

Osimertinib	AstraZeneca	80mg/tablet 40mg/tablet	RMB1760 RMB1035	RMB510 RMB300	71.02%
Crizotinib	Pfizer	250mg/pill 200mg/pill	RMB892 RMB752	RMB260 RMB219.2	70.85%
Nilotinib	Novartis	200mg/pill 150mg/pill	RMB300 RMB241	RMB94.7 RMB76	68.46%
Pazopanib	Novartis	400mg/tablet 200mg/tablet	RMB782 RMB460	RMB272 RMB160	65.22%
Sunitinib	Pfizer	50mg/pill 37.5mg/pill 25mg/pill 12.5mg/pill	RMB1353 RMB1085 RMB796 RMB468	RMB448 RMB359.4 RMB263.5 RMB155	66.88%
Ibrutinib	Xi'an Janssen	140mg/pill	RMB540	RMB189	65.00%

3 Negotiation process

(1) Negotiation procedures

More than 70 experts from 20 provinces in China had earnestly and efficiently completed the key links of variety selection, clinical efficacy evaluation, economic evaluation, and impact analysis of future fund use forecast and budget, as well as final negotiation on the spot.

① Enterprises submitted materials: enterprises submitted basic information, efficacy and price of drugs as required.

② Expert evaluation: the National Healthcare Security Administration evaluated the drugs priced through negotiations in terms of drug economy and fund support capacity through two groups of parallel assessment. One was the fund calculation group, which, on the basis of fully utilizing the medical insurance data retrieved and collected during the last round of drug price negotiation in 2017, supplemented the latest data of 21 co-ordinated regions in a short period of time, covering 68 co-ordinated regions in 26 provinces, totaling 170 million basic data. The internationally accepted evaluation methods were also adopted in the negotiation, which measured the expected payment standards of drugs after being included in the national list, and made quantitative predictions on the increase in sales by cost-effectiveness and other pharmacoeconomic methods.

③ Price negotiation: medical insurance agencies organized negotiation experts

to carry out negotiation with enterprises separately.

(2) Highlights of the negotiation

The negotiation strengthened the new value orientation for drug suppliers, that is, the research and development of new drugs should be guided by its clinical value, economic efficiency (cost-effectiveness) value and affordable value of basic medical insurance funds, so as to realize the policy linkage, administrative function linkage and stakeholder linkage under the role positioning of medical insurance as a service purchaser.

(4) Comparison and reflection of the three negotiations

1 Comparison of the three negotiations

The comparison of the three negotiations is shown in table17.

Table 17. Comparison of Overall Situation of the Three Negotiations

Time	Main body of negotiation	Success rate	Average price cut	Negotiation process
2015	NHFPC	60% (3/5)	59%	① NHFPC led the establishment of the steering committee for negotiation of drug prices, and the establishment of the national expert database for negotiation of drug prices and the drug price information base ② Procedures were composed of formulation of negotiation plan, establishment of negotiation teams, selection of drugs priced through negotiations, release of negotiation announcements, submission of relevant technical data and other materials by manufacturers, negotiation, publication of results, organization of procurement, distribution and settlement as well as price monitoring
2017	MOHRSS	81.8% (36/44)	44%	① MOHRSS set up special working team and supervision team to undertake specific work and carry out overall supervision, and organized experts to negotiate with relevant enterprises ② Procedures were composed of formulation of rigorous and thorough negotiation rules: clarified the inclusion of successfully drugs priced through negotiations into the list of Class B drugs and unified the implementation of medical insurance payment standards determined during negotiation across the country ③ Organized experts to carry out evaluation and calculation: two completely independent evaluation expert groups were organized to carry out evaluation and calculation in terms of

				drug economy and affordability of medical insurance funds respectively ④ Negotiated in accordance with the prescribed procedures: negotiation enterprises were randomly grouped; supervision group supervised and videotaped the whole negotiation process; working group determined the final expected payment price of medical insurance according to the estimated payment standard of pharmaceutical group and medical insurance group on the spot, and sent to the negotiation site by special person after sealing with envelopes
2018	National Healthcare Security Administration	94.1% (16/17)	56.7%	① More than 70 experts from 20 provinces in China had earnestly and efficiently completed the key links of variety selection, clinical efficacy evaluation, economic evaluation, and impact analysis of future fund use forecast and budget, as well as final negotiation on the spot ② "Enterprises submitted materials": enterprises submitted basic information, efficacy and price of drugs as required → "Expert evaluation": expert team evaluated in terms of drug economy and fund support capacity, and provided evaluation opinions → "Price negotiation": medical insurance agencies organized negotiation experts to carry out negotiation with enterprises separately

2 Drugs Priced through Negotiations have achieved good results in price cut and gradually play its linkage role

The variety of drugs in the first round of negotiation was very limited, making it difficult to influence the price cut of similar drugs. The number of varieties in the second round of negotiation increased sharply. After the third round of negotiation, "4+7" drug procurement with target quantity was introduced and implemented immediately, and the linkage role was gradually brought into play.

Because of limited energy, the medical insurance management department could not negotiate with many manufacturers one by one, but to select some of the urgently needed and representative varieties for negotiation, and then guide the market competition mechanism through the linkage role of drugs priced through negotiations, so as to drive the innovation of the whole drug price and straighten out the existing drug price system.

3 Governments and enterprises have accumulated good negotiation experience in

the three negotiations

(1) Change of leading main body

The first round of national drug price negotiation was led by NHFPC, with its advantages in the control of sales channels and drug proportion in public hospitals. The second round of negotiation was led and organized by MOHRSS and its negotiation strength lied in medical insurance access and reimbursement[8]. The third round of negotiation was organized by National Healthcare Security Administration that was newly established in the new round of institutional reform. It was provided with greater strategic purchasing power and stronger bargaining power because it integrated three functions, including supervising medical insurance-related medical behavior, managing the payment functions of the three major medical insurances, setting the price and charging standards of drugs and medical services, and pricing functions of bidding policies.

The comparison of the three rounds of negotiation showed that the differences of negotiation leading main body affected the negotiation situation to a certain extent. From NHFPC, MOHRSS to National Healthcare Security Administration, the negotiation main body and execution main body in the first two negotiations were not unified, that is, the final rights to purchase and prescribe drugs were mainly in the medical institutions, instead of in the negotiation leading main body, and these factors, like asymmetric status and information asymmetry, led to the ineffective integration of government's negotiation advantages. The next two rounds of negotiation were led by the competent department of medical insurance, which was more conducive to carry out work and implement the drugs priced through negotiations than the first round of negotiation. It was thus found that the third special negotiation on access of anticancer drugs organized by National Healthcare Security Administration had a more significant effect due to the more authoritative and persuasive implementation security.

8 Ding Jinxi, Chen Ye, Li Wei, Zheng Cuiwei, Dong Rui. Analysis on the Implementation of Patent Drugs Priced through Government Negotiations [J]. Chinese Journal of Pharmaceuticals, 2017, 48(06): 910-917.

(2) Negotiation main body is becoming more engaged and drugs priced through negotiations usher in opportunities for development

With the improvement of the universal health insurance system, the integration of urban and rural medical insurance has been accelerated, and health insurance agencies also have more leverage in negotiations and are more confident in negotiations. As for pharmaceutical enterprises, the gradual expansion of types and varieties of drugs priced through negotiations and the generally substantial increase in sales also make them more and more positive. Experts generally believe that national policies have played an obvious supporting role in the negotiation of medical insurance drugs[9]. In recent years, the state has repeatedly advocated and encouraged in major medical reform documents that the co-payment mechanism between local medical insurance agencies and drug suppliers should be established through negotiation, which has promoted the exploration and practice of medical insurance negotiation in various regions. The drugs priced through negotiations see an opportunity for development with the implementation of many new medical reform policies, such as national implementation of critical illness insurance program, gradual development of national drug price negotiations, and reform of medical insurance payment mode.

4 Negotiation system and procedure are constantly standardized, and problems are found and efforts are made to solve them in negotiation practices

(1) National drug price negotiation rules are becoming more standardized

The first round of negotiation lacks transparency compared with the last two rounds of negotiation. Little information was revealed about the pricing principles of the joint committee of 16 ministries and commissions, documents and data submitted by pharmaceutical enterprises during negotiation, situation of evaluation experts, evaluation criteria and opinions, and specific negotiation process between joint committee and pharmaceutical enterprises[10]. In addition, the implementation

9 Zhang Zhan, Yang Jianwei, Liang Yongqing, Chen Wei, Xia Sujian. PEST-SWOT Analysis on Current Negotiation Mechanism of Medical Insurance Drugs in China[J]. Medicine and Society, 2017, 30(06): 30-33.

10 Yang Qian, Wang Baoyun, Wang Shiyu. Study on Negotiation Mechanism of Drug Price in

guarantee for operability was not clear, so the link with the medical insurance was not close, which led to the uneven implementation of the negotiation results in various regions in the later period. Some provinces were worried that the huge burden of medical insurance payment would hinder the medical insurance incorporation process of drugs priced through negotiations.

The practice of the three rounds of negotiation shows that the determinate, reasonable and appropriate negotiation rules are conducive to ensuring the efficient and orderly development of the negotiation, and ensuring the participation enthusiasm of all parties and fully communicating their demands.

(2) The basis for negotiation decisions is becoming more scientific

In 2017, the HTA method was initiated in the negotiation of health insurance drugs led by MOHRSS, which encouraged enterprises to calculate the expected payment standard of drugs after being included in the national list by pharmacoeconomic methods and make quantitative prediction on the increase of sales[11]. The evaluation process of medical insurance payment standard for anti-cancer drugs in 2018 was more scientific. On the basis of making full use of the medical insurance data retrieved and collected in the last round of drug price negotiation, the latest data of 21 co-ordinated regions were supplemented in a very short time. Furthermore, the internationally accepted evaluation methods were also adopted in the negotiation, which measured the expected payment standards of drugs after being included in the national list, and made quantitative predictions on the increase in sales by cost-effectiveness and other pharmacoeconomic methods.

5 Analysis of existing problems during the implementation of drugs priced through negotiations

(1) Laws and regulations involved in all links

① Drug market access

China[J]. Pharmacy and Clinics of Chinese Materia Medica, 2017, 8(04): 53-56+52.

11 Wu Lin, Chen Jiani, Lei Yuan, Li Qinhui, Chen Yongfa. Path Choice for Constructing Interest Balance Mechanism in Negotiation of Patent Drug Price - Enlightenment from Drug Price Negotiation Mechanism in Typical Countries including Germany, Britain and Korea[J]. Price: Theory & Practice, 2018(03): 83-86.

In 2013, the former State Food and Drug Administration (SFDA) issued the *Opinions of the State Food and Drug Administration on Deepening the Reform of Drug Evaluation, Review and Approval and Further Encouraging Drug Innovation*, indicating that it was necessary to optimize the allocation of evaluation and review resources, improve the evaluation and review environment of innovative drugs and adjust the attitudes toward generic drug review resources.

In 2015, the State Council issued the *Opinions of the State Council on Reform of the System of Evaluation, Review and Approval of Drugs and Medical Devices*, proposing to simplify the procedures of drug examination and approval, improve the examination and approval of drug clinical trials, speed up the evaluation, review and approval of innovative drugs, solve the backlog of registration applications and carry out the pilot work of the system of the holders of drug marketing licenses.

In 2015, the former State Food and Drug Administration issued the *Announcement on Self-inspection & Verification of Drug Clinical Trial Data*, requiring applicants to conduct self-inspection of clinical trials for pending registration drugs declared for production or import, so as to ensure the quality of marketed drugs.

In 2015, the former State Food and Drug Administration issued the *Notice of the State Food and Drug Administration on Further Standardizing the Acceptance of Drug Registration*, requiring that formal examination and on-site inspection should be strictly carried out to ensure the drug quality of listed pharmaceutical enterprises.

In 2016, the State Council issued the *Notice on Issuing the Plan for the Pilot Program of the System of the Holders of Drug Marketing Licenses*, and in 2017, the former State Food and Drug Administration issued the *Notice of the State Food and Drug Administration on Improving the Pilot Work of the System of the Holders of Drug Marketing Licenses*, which required to carry out the pilot work of the system of the holders of drug marketing licenses in 10 provinces and municipalities directly under the central government, stipulate the conditions and obligations of applicants and holders, and the conditions and obligations of entrusted manufacturing enterprises, further liberalize the sub-contract production, allow the transfer of approval number and simplify the review and approval process.

In 2016, the State Council issued the *Opinions on the Generic Drug Quality and Therapeutic Effect Consistency Assessments*, clarifying the selection objects and reference preparations and strengthening the management of consistency assessments, so as to ensure the quality of marketed generic drugs.

In 2017, the former State Food and Drug Administration issued the *Opinions of the State Food and Drug Administration on Encouraging the Implementation of Priority Examination and Approval for Innovative Drugs*, which included the registration application of 7 drugs with obvious clinical value in the scope of priority examination and approval, and included the registration of drugs with obvious clinical advantages for preventing and treating rare diseases and multiple diseases in the scope of priority examination and approval. In addition, the procedures of priority examination and approval were stipulated in detail, a clear time limit was provided for each link, and specific operation guidelines were provided for accelerating the marketing of drugs.

In 2018, the State Council issued the *Notice of the State Council on Promoting the Reform of "Separating Operating Permits and Business Licenses"*, and the State Food and Drug Administration also issued the *Circular on Implementing the Requirements of the State Council for the Reform of "Separating Operating Permits and Business Licenses" and Working Effectively on the Examination and Approval concerning Drug Regulation*, which made it clear to simplify the process, optimize the examination and approval services, promote the register system, strengthen the interim and ex-post supervision and speed up the marketing of drugs.

In 2018, the State Council issued the *Notice of the General Office of the State Council on the Issuance of the Key Work of Deepening the Reform of the Medical and Health Sectors for the Second Half of the Year of 2018*, which called for accelerating the examination and approval of domestic marketing of new drugs that were marketed abroad.

② Medical insurance access of drugs

In 2016, NHFPC issued the *Notice of the General Office of the National Health and Family Planning Commission on the Publication of the Results of National Drug*

Price Negotiations, which called for encouraging the preferential procurement and use of drugs priced through negotiations, and local governments to further consolidate and improve the health insurance system and payment methods, and link up with relevant health insurance policies properly.

In 2017, the State Council issued the Notice on the *13th Five-Year Plan for Deepening the Medical and Health System Reform*, which called for an increase in the number of drugs involved in the national price negotiation and proper link between price negotiation and health insurance policies.

In 2017, MOHRSS issued the *Notice on Including 36 Drugs into the Class B Scope of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance*, which included Liraglutide Injection and other 36 drugs into the scope of Class B of the medical insurance list, and required all provinces and cities to properly implement the requirements.

In 2018, the State Council issued the *Notice of the General Office of the State Council on the Issuance of the Key Work of Deepening the Reform of the Medical and Health Sectors for the Second Half of the Year of 2018*, requiring that the exclusive anticancer drugs outside the medical insurance list should be included in the negotiations on medical insurance access.

In 2018, the National Healthcare Security Administration issued the *Circular on Issuing the Scope of Anti-Cancer Drugs for Special Negotiations on Medical Insurance Access in 2018*, which made it clear that 18 varieties from 12 companies should be included in the special negotiation on medical insurance access of anti-cancer drugs.

In 2018, the National Healthcare Security Administration issued the *Notice on Incorporating 17 Drugs into the Class B Scope of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance*, which included 17 anticancer drugs priced through negotiation in the National Reimbursement Drug List, so as to reduce the economic burden of cancer patients, and required all provinces to properly implement the Notice.

③ Drug distribution and procurement

In 2015, the State Council issued the *Guiding Opinions of the General Office of*

the State Council on Improving Centralized Procurement of Drugs for Public Hospitals, requiring that classified procurement shall be carried out according to the situation of drug supply guarantee, different drugs shall be implemented by open tender in double-envelope system, procurement through price negotiation, direct hospital procurement and fixed-point production, and the functions of provincial-level drug centralized procurement platform shall be expanded, so as to break down the mechanism of covering hospital expenses with drug revenue, reduce the artificially high price of drugs and lighten the drug use burden of patients.

In 2016, 8 departments of the State Council jointly issued the *Opinions on Implementing "Two-invoices System" in Drug Procurement of Public Medical Institutions (for Trial Implementation)*, clarifying the definition of the two-invoices system, and requiring public medical institutions to strictly implement the regulations on the management of drug procurement and sale invoices, promote the implementation of the two-invoices system and strengthen supervision, so as to reduce the artificially high price of drugs.

In 2016, the General Office of the State Council issued the *Notice on the Key Work of Deepening the Reform of the Medical and Health Sectors for the Year of 2016*, which required to fully promote centralized drug procurement in public hospitals, popularize local experience and practices, encourage and guide inter-provincial and inter-regional joint procurement, and encourage joint volume-based procurement among certain regions in the pilot provinces of comprehensive medical reform, so as to reduce the cost of drugs, device and consumables through centralized procurement.

In 2016, NHFPC, NDRC, MIIT, MOHRSS and other ministries and commissions jointly issued the *Notice on Centralized Procurement of Drugs Priced through Government Negotiation*, which required to carry out the proper centralized procurement of drugs priced through government negotiation, expand the pilot scope of drugs priced through negotiations, reduce the artificially high price of drugs, reduce the economic burden of drug use for the public, and publicly post the results of national drug price negotiations on the provincial-level centralized drug

procurement platform and specify the procurement volume.

In 2017, the State Council issued the *Notice on the 13th Five-Year Plan for Deepening the Medical and Health System Reform*, which required to adhere to the principle of centralized volume-based procurement, promote the implementation of classified procurement of drugs in public hospitals, cultivate centralized procurement entities, encourage cross-regional joint procurement and joint procurement of drugs and high-value medical consumables in specialized hospitals, and requested pilot provinces and medical institutions to implement the two-invoices system to reduce the artificially high high price of drugs.

In 2018, the National Healthcare Security Administration issued the *Notice on Convening the Symposium on Centralized Drug Procurement*, to convey the trend of implementing provincial-level special procurement of anticancer drugs in the medical insurance list and the pilot work of centralized drug procurement organized by the state.

In 2018, the National Healthcare Security Administration and the National Health Commission of the People's Republic of China issued the *Notice on Centralized Procurement of Anticancer Drugs at Provincial Level*, which required to carry out the special centralized procurement of drugs for critical diseases, with focus on anti-cancer drugs, and to reduce prices through centralized volume-based procurement and to alleviate the economic burden of drug use for the public.

In 2018, Sunshine Medical Procurement All-In-One (www.smpaa.cn), with the consent of the National Healthcare Security Administration, issued the *4+7 Cities Document for Pharmaceutical Centralized Procurement*, indicating that the state organized the centralized procurement pilot of drugs, taking 4 municipalities directly under the central government and 7 capital cities as pilot, purchasing 31 varieties of drugs in an agreed volume, so as to further promote the operation of centralized volume-based procurement across the country, require medical institutions to give priority to the centralized procurement of selected varieties, and ensure the completion of procurement volume agreed in the 4+7 cities document for pharmaceutical centralized procurement.

④ Clinical access of drugs

In 2011, MOHRSS issued the *Opinions on Further Promoting the Reform of Medical Insurance Payment Mode*, which required local governments to determine the total amount control indicators for each payment mode according to the total fund expenditure, implement it in each designated medical institution according to the level, category, characteristics and the amount of services undertaken of different designated medical institutions, and strengthen the control of total payment amount in combination with fund budget management.

In 2012, MOHRSS issued the *Opinions on Controlling the Total Payment of Basic Medical Insurance*, requiring carrying out the control of total payment of basic medical insurance, strengthening and improving the fund budget management and rationally determining the control target of total payment in co-ordinated regions in accordance with the comprehensive implementation of budget management of basic medical insurance funds.

In 2015, the State Council issued the *Guiding Opinions on Urban Public Hospital Comprehensive Reform Pilot*, which required the use of various methods to break down the mechanism of covering hospital expenses with drug revenue, strictly control the unreasonable increase of medical expenses, and strive to reduce the drug proportion in pilot urban public hospitals to about 30% by 2017.

In 2015, NHFPC, NDRC and MOHRSS issued *Some Opinions on Controlling the Unreasonable Increase of Medical Expenses in Public Hospitals*, requiring effective control of the unreasonable increase of medical expenses in public hospitals, lightening the economic burden of drug use for the public, strengthening the supervision of medical expenses, strengthening the internal control of medical institutions, and reducing the artificially high price of drugs and consumables.

In 2016, the General Office of the State Council issued the *Notice on the Key Work of Deepening the Reform of the Medical and Health Sectors for the Year of 2016*, which required to consolidate the achievements of the reform of abolishing drug price additions in public hospitals and abolish drug price additions in all public hospitals in new pilot cities. It was necessary to reduce the cost of drugs, devices and

consumables through control of medical insurance expenses and strictly control the unreasonable inspection and testing expenses, so as to make room for adjusting the price of medical services. The unreasonable increase of medical expenses should be strictly controlled, key monitoring of unreasonable use of high-priced supplementary and nutritional drugs should be carried out to initially curb the trend of unreasonable increase of medical expenses.

In 2016, NHFPC issued the *Notice on Quickly Determining the Increase Rate of Medical Expenses*, requiring provinces and cities to determine the annual increase rate of medical expenses in the region according to the local medical level, to rank the increase of medical expenses in hospitals in the region based on the monitoring results of expense indicators, and to dynamically manage and annually adjust the expense control target, so as to strive to reduce the increase rate of national medical expenses to below 10% by the end of 2017.

In 2017, the State Council issued the *Notice on the 13th Five-Year Plan for Deepening the Medical and Health System Reform*, requiring provinces to set annual control targets for the increase of medical expenses, to control the average increase rate of medical expenses in public hospitals nationwide below 10% in 2017, to implement the prescription review system and guide local governments to list high-priced supplementary and nutritional drugs for key monitoring. The comprehensive reform of public hospitals shall be carried out by the end of September 2017 and the drug price addition in all public hospitals shall be cancelled.

In 2018, MOHRSS issued the *Notice on the Publication of the Recommended Catalogue of Medical Insurance Paid by Disease Categories*, which required that hospitals should control the expenses by taking the initiative to control the cost and assuming a substantial burden of supplementary drugs according to the disease categories, and reasonably formulate payment standards for disease categories in the medical insurance and properly carry out the cost settlement.

In 2018, the National Health Commission issued the *Notice on the Preparation and Use of 17 Medical Insurance Anticancer Drugs Priced through Government Negotiation*, requiring hospitals not to influence the supply guarantee and demand

for rational use of drugs priced through negotiations on the grounds of control of total medical expenses, control of total medical insurance expenses, drug proportion and restrictions on the number of drug varieties. Meanwhile, hospitals should rationally use the drugs priced through negotiations in accordance with the relevant diagnosis and treatment norms and guidelines, and improve the level of rational drug use. 17 anticancer drugs priced through negotiations shall not be limited by drug proportion and control of total medical insurance expenses.

In 2018, the National Health Commission issued the *Notice on the Implementation of 17 Anticancer Drugs Priced through Government Medical Insurance Negotiations*, which required to guarantee the normal supply of drugs priced through negotiations and ensure patients accessible to the varieties priced through negotiations included in the National Reimbursement Drug List; the supply and demand for rational drug use of drugs priced through negotiations shall not be affected by the control of total expenses, drug proportion and basic drug list of medical institutions, and the supply of drugs priced through negotiations shall be guaranteed well.

(2) Empirical study on implementation

① Empirical legal study

The empirical study is to verify a hypothesis or another fact through objectively obtained facts. It focuses more on what actually happens than on what should happen or what will happen in theory. For empirical legal study, the effect that legislators hope to achieve through law sometimes deviates from the real effect in reality. Therefore, it is necessary to keep the actual effect close to the desired effect through empirical study, so as to prevent the legislators from having the mentality of "solipsism" in legislation. From a certain point of view, law is an independent variable, and society is a dependent variable, and legislation is tantamount to a legal experiment. It is necessary to summarize and analyze the dependent variable, and then analyze the scientificity of the independent variable. In this report, the scientificity of laws and regulations will be analyzed by summarizing the actual implementation effect of the above laws and regulations.

② Drug marketing

For marketing of drugs, MAH system was firstly carried out on a pilot basis in 10 provinces and cities, including Beijing, Tianjin, Hebei, Shanghai and Jiangsu. As of October 2017, 560 applications have been accepted by the pilot provinces and cities for various pilot drugs, 128 of which have been examined and approved, accounting for 23%; 428 of which have been accepted, and are being examined and approved, accounting for 77%. The period of drug marketing shall be shortened and the repeated construction shall be reduced. Although there are still some problems, such as the transfer of responsibilities between entrusting party and entrusted party and the need to further improve the enthusiasm of scientific research, the pilot work has achieved preliminary results and it is necessary to improve the supporting laws and regulations.

Generic drug consistency assessments and self-inspection and verification of clinical data are mainly aimed to ensure the quality of marketed drugs. As of November 2018, only 105 out of 289 varieties had passed the consistency assessment, and the results were not satisfactory, proving that there was still much room for improvement in the quality of marketed drugs. The latest 4+7 volume-based procurement takes the consistency indicator as a mandatory indicator. It can be seen that in the future, quality will become an important part of drug marketing. For verification of clinical data, the number of accepted self-inspection of Qilu Pharmaceutical, Chia-tai Tianqing, CSPC Pharmaceutical Group, Zhejiang Huahai Pharmaceutical, Hengrui Medicine and Jiangsu Hausen was more than 10. Up to now, out of 105 drugs that have passed the consistency assessment or have been deemed as passing the consistency assessment of generic drugs, there are 6 generic drugs that passed the consistency assessments of 3 enterprises and more, such as Zhejiang Huahai. It can be seen that some pharmaceutical enterprises do pay attention to their own quality and stand out under the policies of consistency assessments and self-inspection and verification of clinical data.

In terms of review, according to the drug review report of 2017, the Drug Evaluation Center had included 25 batches of 423 applications for registration into

the preferential review process by the end of 2017, and the average time used for the first round of review of IND application, NDA and ANDA was 39 working days, 59 working days and 81 working days, respectively. The time required for review and approval of various registration applications for chemical drugs had been decreased significantly, which basically solved the problem of backlog of generic drug registration applications. In April 2018, additional 24 varieties were included in the preferential review list, including HPV vaccines. It could be seen that the national laws and regulations were effective in speeding up the review process, and their procedure setting was scientific to a certain extent. To sum up, governments expect that the marketing of drugs can be accelerated and their quality can be guaranteed. The legal policies on the marketing of drugs have certain effects, proving that they are scientific.

③ Incorporation into the national medical insurance

In terms of the effect of incorporation of drug varieties priced through negotiations into medical insurance, from the national point of view, 3 of 5 varieties priced through negotiation for procurement were carried out in 2016, 36 of 44 varieties priced through negotiation were successfully included into the list in 2017, and 17 of 18 varieties were included into the list in 2018, which greatly expanded the categories and scope of drugs in the medical insurance list, and also ensured a certain price cut. The main indicator of the promotion effect in each province is the implementation situation in each province. For the 36 varieties that were included in the list through negotiation in 2017, the implementation of 36 varieties priced through negotiation was accelerated across the country since the national publication of the inclusion of 36 varieties into the scope of medical insurance. As of September 2017, 19 provinces, including Anhui, Beijing, Henan, Fujian and Hubei, have clarified the ways to incorporate the varieties priced through negotiations into the medical insurance list of each province. Four provinces, including Anhui, Hebei, Henan and Fujian, have defined the self-payment ratio of 36 varieties, and Heilongjiang has been working on the networking procurement of varieties priced through negotiation. In October 2017, 36 varieties were implemented in all provinces

across China. For the 17 varieties included in the national medical insurance in 2018, Fujian, Sichuan, Xinjiang, Zhejiang, Hunan, Tianjin, Inner Mongolia and Liaoning had all started to incorporate 17 varieties in the local list as of November 7, 2018, and moreover, 13 provinces including Jiangsu, Beijing and Henan had set specific implementation dates. Therefore, it is feasible to incorporate the varieties priced through negotiations into the medical insurance and to require provinces to incorporate them into their own medical insurance list.

④ Procurement of drugs

Throughout the procurement policies issued by the state in recent years, it is undoubtedly that they all expect to carry out centralized procurement, ensure the volume of purchased drugs and reduce artificially high drug prices, so as to achieve the effect of increasing in volume and decreasing in price. Furthermore, the implementation of the two-invoices system is to streamline the circulation links and reduce the artificially high drug prices. The 4+7 document required the proper consistency assessments, and the previous double-envelope bidding also emphasized that the "quality bidding" should be provided. Hence, the aim of the state is to ensure the quality of drugs while minimizing the price. However, one of the problems caused by the double-envelope is "Anhui Model", that is, only pursuit of low prices, which resulted in various drug quality risks. As a result, one of the major advantages of volume-based procurement is to take consistency assessment as a threshold to ensure the quality of generic drugs participating in the bidding. It is expected not to overstep the bottom line of quality under the premise of low price. In this centralized procurement, the average price of selected drugs was cut by 52%, with the maximum price cut of up to 96%. The price of the originator Gefitinib Tablets was cut by 76%, of Fosinopril Sodium Tablets was cut by 68%, of Entecavir was cut by 90% and of Hengrui Irbesartan was cut by 60%. The price of Amlodipine of Jingxin Pharmaceutical was reduced to RMB0.14 and the price of Entecavir Dispersible Tablets of Chia-tai Tianqing was reduced to RMB0.62, respectively. In terms of price cut, the drug prices indeed saw a significant decline in 11 cities through centralized procurement, such as Beijing, Shanghai, Tianjin, Chongqing, Guangzhou, Shenzhen,

Shenyang, Dalian, Xi'an, Chengdu and Xiamen. However, the price cut was achieved at the expense of the premium of consistency assessments, which further depressed the profit margin of pharmaceutical enterprises. In addition, the clinical dosage of drugs depends on the specific situation, so the dosage is not necessarily the actual dosage required. Since the implementation of volume-based procurement, pharmaceutical stocks have fallen sharply. Although the volume-based procurement can achieve both price cut and quality assurance to a certain extent, it is not conducive to the survival of pharmaceutical enterprises in the long run. Therefore, the implementation of policies should be adjusted to make it more scientific.

⑤ Clinical application in hospitals

The state has adopted a series of policies to control the unreasonable increase of medical expenses, such as zero price difference, control of total expenses and indicators of drug proportion, etc. The control of total expenses has suppressed the excessive growth of medical expenses, and the growth rate of medical insurance fund expenditure has continued to drop sharply. Data show that the drug proportion in hospitals dropped from 50% in 2008 to 39% in 2016. In Jiangsu Province, the drug proportion declined gradually from 2004 to 2016, but the total medical expenses kept increasing. The control of total mediccal insurance expenses was actually ineffective. Based on the report of the Department of Healthcare Reform of NHFPC, the average growth rate of the total medical expenses of public hospitals in Sichuan Province was 13.15% in 2017, which was far from the required target of 10%, ranking the last place in the whole country. In addition, the control of total expenses has also led to some hospitals to shuffle patients, and for the drug proportion, some "magic Chinese drugs" occupied the medical insurance funds, resulting in failure to control the expenses. Furthermore, the drug proportion will restrict the allocation of some high-priced drugs in hospitals, such as Betaseron, which is contrary to the original intention of expense control, proving that the policies should be more scientifically to guarantee control of medical expenses.

In order to prevent the drug varieties priced through negotiations from being affected by the drug proportion and other expense control polies, many provinces

issued documents requesting the drug proportion to be released, and the state also issued documents requesting that the expense of 17 drugs priced through negotiations not be included in the scope of total expense control. As of July 2018, 23 provinces had explicitly issued documents proposing to implement the separate accounting for drugs priced through government negotiation and not included in the statistics of drug proportion. In the meantime, in July 2018, the Hunan Provincial Medical Reform Group issued a notice to implement the "two-channel" procurement mode of agreed designated medical institutions and designated special drug retail pharmacies for drugs included in the payment of basic medical insurance through government price negotiation and drugs included in the provincial major diseases insurance through price negotiation. In many provinces where documents had been issued, there were provincial-level documents indicating that drugs priced through negotiations would not account for the drug proportion, but cities had not specifically implemented the documents or encountered many difficulties in the process. Among 16 cities in Anhui Province, Wuhu and Fuyang had indicated on public websites that they would implement the provincial-level regulations on the drug proportion, while the rest of the cities had not released any documents. Among 19 cities in Guangdong Province, Foshan had indicated on public websites that it would implement the provincial-level regulations on the drug proportion, while the rest of the cities had not released any documents. Therefore, the implementation at the municipal level was ineffective. Empirical analysis based on this fact shows that it is necessary for the state to further formulate supporting policies to ensure local implementation and strengthen intermediate supervision for not including in the drug proportion and total expenses.

To sum up, the existing problems in the three rounds of drug price negotiations can be summarized as shown in figure5.

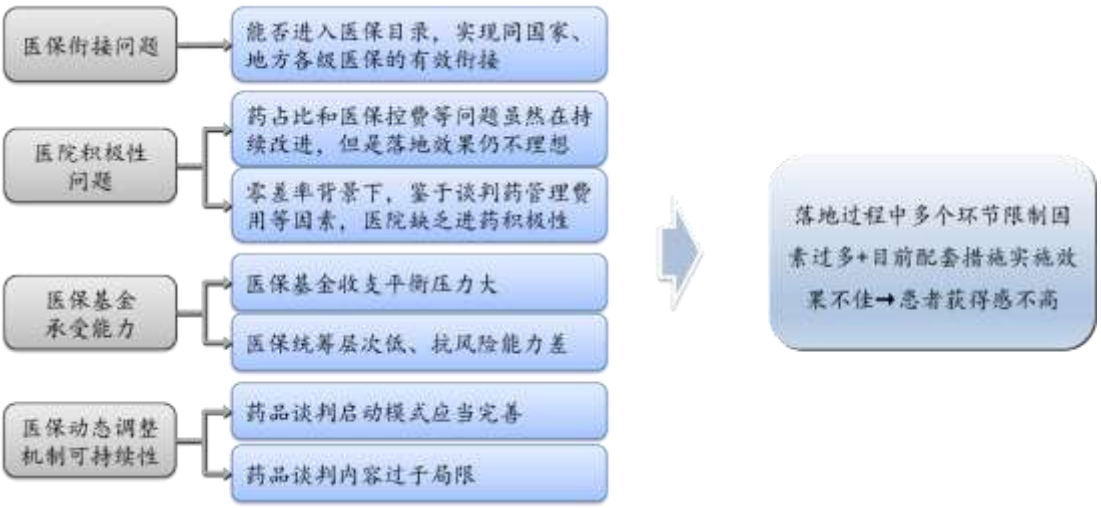


Figure 5. Core Problems in Three Rounds of Drug Price Negotiations

Chapter III Analysis of Core Problems in Three Rounds of Drug Price Negotiations

I. Hospitals are Less Motivated

In the implementation of drugs priced through negotiations, the core problem we had to confront first was that the enthusiasm of hospitals was not high. Drugs priced through negotiations were unavailable to patients in hospitals, mainly because: ① Drug zero price addition policy made the pharmacy a cost department and increased the warehouse management costs; ② Evaluation indicators such as drug proportion and control of total expenses restricted hospitals from prescribing the drugs priced through negotiations; ③ The number of annual meetings of the hospital pharmaceutical management committee was limited, and a waiting period was required for drugs to be included in hospitals. Moreover, fewer varieties were adjusted in each meeting, in particular for anti-cancer drugs.

In response to the above problems, the "three factor" theory was applied by the research group.

For the problem of low enthusiasm, American psychologist Herzberg put forward the two factor theory in 1959, also known as the "motivator-hygiene theory". He divided the related factors in the enterprise into two types, namely satisfaction factor and dissatisfaction factor. Satisfaction factor referred to the factor that could satisfy and motivate people, that is, motivator. Motivators were related to the work itself or the job content, including achievement, appreciation, meaning and challenge of the work itself, sense of responsibility, promotion and development etc. Dissatisfaction factor referred to the factor that prone to produce opinions and negative behaviors, namely hygiene factors, which included company policy and management, supervision, salary, relationship between colleagues and working conditions.

On the basis of Herzberg's theory, Professor Yu Wenzhao, a famous psychologist in China, put forward a three-factor theory which was more suitable for cultural motivation in China, also known as motivation and de-motivation continuous

zone model, including motivation, hygiene and de-motivation theory. He believed that motivation and de-motivation factors existed at two continuous endpoints, with many motivation forms of different strengths and weaknesses in-between, all of which constituted a continuous zone. Hygiene factor was located in the middle transition zone of motivation and de-motivation continuous zone.

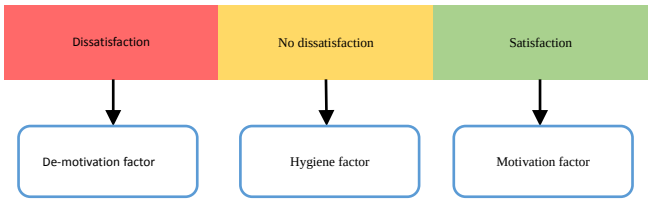


Figure 6. Reciprocal Diagram of Satisfaction and Three Factors

In the three-factor theory, these three factors could be uniformly distinguished. Motivation factor resulted in strong or stronger motivation, and psychological satisfaction of employees; hygiene factor resulted in weak or weaker motivation, and psychological no-dissatisfaction of employees; de-motivation factor resulted in dissatisfaction of employees. Hygiene factor was not an isolated factor and was located in the middle transition zone of motivation and de-motivation continuous zone.

Table 18. Connotation of Three-factor Theory

Motivation factor	Hygiene factor	De-motivation factor
Cause satisfaction	Cause no-dissatisfaction	Cause dissatisfaction
Increase enthusiasm	Protect enthusiasm	Decrease enthusiasm
Increase work efficiency	Will not increase work efficiency	Decrease work efficiency

Based on the three-factor theory, the drug proportion, control of total expense, warehouse cost and other factors could be regarded as de-motivation factors for hospitals with insufficient enthusiasm during implementation of drugs priced through negotiations; hospital grade, level, department development, doctor's salary and treatment could be regarded as hygiene factors. Maintaining the current situation would not make hospitals more active, nor would it produce negative emotions; no motivation factors were available now.

II. Affordability of Medical Insurance Fund

(1) Great pressure of fiscal balance of medical insurance fund

Although the balance rate of the national medical insurance fund had maintained a stable growth level, the cumulative balance of the basic medical insurance fund had continued to show negative growth in recent years, and risks had gradually emerged. The medical insurance funds for urban employees in Shanghai and Beijing had been unable to cover their expenses in 2011. A relevant calculation by the Chinese Academy of Social Sciences (CASS) also showed that the medical insurance for urban employees saw a general deficit in 2017, that is, the medical insurance funds for urban employees in second-tier and above cities failed to achieve balance[12]. According to data from HealthcareReport, irrational drug use in China was a serious waste of medical insurance funds.

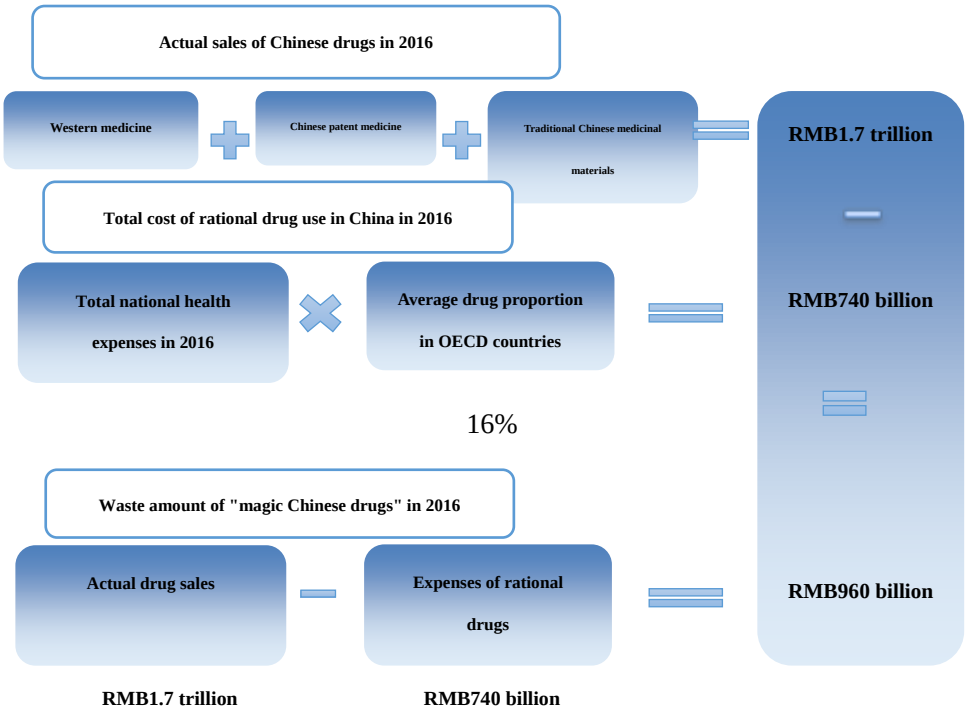


Figure 7. Irrational drug use in China caused serious waste of medical insurance funds

The fund management and use of 28 provinces, 166 cities and 569 counties (cities and districts) in 2015 and the first half of 2016 were sampled, and 3715

12 Luo Jian, Fang Yibing. Anti-risk Capability and Influencing Factors of Basic Medical Insurance Fund in China[J]. Seeker, 2013(03): 264-266.

designated medical institutions, 2002 designated retail pharmacies and other relevant units were investigated. The specific situation of random inspection was as figure8:

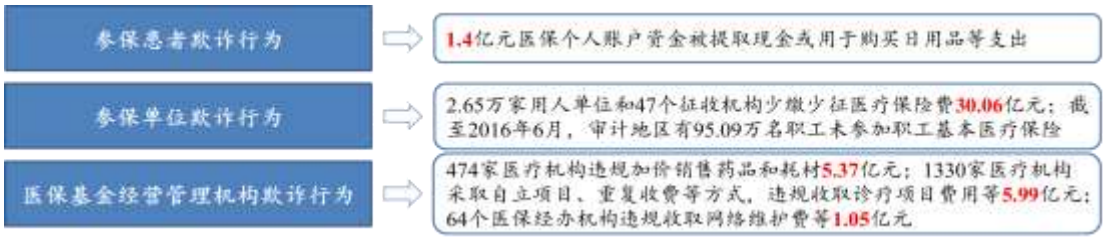


Figure 8. Statistics of Medical Fund Fraud

(2) Low level of overall planning of medical insurance

1 Overview

The basic medical insurance is a social insurance system used to compensate workers for economic losses caused by disease risks. Its connotation is that the state or society provides medical services or economic compensation to the national citizen after they are suffered from diseases and injuries. In 1998, China issued the *Decision on Setting up Basic Medical Insurance System for Staff Members and Workers in Cities and Towns*, and began to establish the basic medical insurance system for urban workers. At present, the main basic medical insurance system in China is composed of the basic medical insurance system for urban workers, the new-type rural cooperative medical care system and the basic medical insurance system for urban residents. According to the report of MOHRSS, the number of people covered in the basic medical insurance in China has exceeded 1.3 billion as of October 2017. The implementation of basic medical insurance system can not only adjust income differences, maintain social stability, promote social civilization and progress, but also indirectly improve labor productivity and promote the development of production.

In principle, the overall planning at the prefectural and municipal levels is implemented for the basic medical insurance fund, covering all employers and their employees in cities and towns, and some provinces are exploring ways of overall planning at the provincial level. The sign of overall planning of medical insurance in a certain region is to achieve the unification of payment and treatment policies,

conjunctive use of medical insurance fund, service network and handling process. Currently, the three basic medical insurances in China are planned at the district or county level as a whole, and are gradually improved to the overall planning at the municipal level or even provincial level in recent years. However, the speed is slow, progress is different in various regions, and the insurance categories are also not unified. In this regard, the state issued the *Opinions of the CPC Central Committee and the State Council on Deepening the Reform of the Medical and Health Care System* in 2009, which required that the basic medical insurance shall "gradually increase the level of financing and overall planning, narrow the gap in the guarantee level, and ultimately achieve the basic unity of the institutional framework along with social economy development".

2 Problems arising from low level of overall planning

(1) Limited labor mobility

Along with the rapid development of urbanization in China, the flow of population and labor force is growing frequently. The corresponding basic medical insurance, especially the employee's medical insurance, is characterized by administrative localization, which leads to great resistance to the transfer and continuation of medical insurance of high-mobility labor force across the regions, thus restricting the free flow of labor force. In the long run, the low level of overall planning and fragmentation model will significantly reduce the willingness of some highly mobile labor force (such as migrant workers) to participate in the medical insurance, and even hinder the rational flow of some talents. This will greatly reduce the effect of social welfare, which is not conducive to the smooth operation and harmonious development of the medical insurance system, or to the balanced development of regional economy.

(2) Restrict the mutual aid effect of medical insurance, making it difficult for conjunctive use of medical insurance funds

China has a vast territory, and provinces, cities and counties have different development speed and level, including economic level, population structure, supply of medical and health resources and etc. From these differences, various financing

levels and contribution burdens of medical insurance funds will arise in different regions, which seriously violate the fairness principle in medical insurance financing and exacerbate the gap of income distribution in different regions. Similarly, the low level of overal planning will reduce the scale of funds in different regions and decrease the anti-risk capabilities, and most people cannot achieve their goal of resisting small risks, which will weaken the function of adjusting income distribution, and go against the realization of the goal of equalization of public services in different regions and hinder the quality improvement of urbanization.

The overal planning of medical insurance fund is based on the "law of large numbers", that is, to raise funds uniformly in certain range and to organize in an overall manner, share and coordinate risks and medical burdens through the social force of the public. Therefore, the capabilities to withstand risks will become stronger with the increase of the overal planning level and the scope. Because of low level of overal planning and small scope, the capabilities to withstand risks and the mutual aid effect of the fund will be severely weakened. The study shows that fund balances in some regions cannot be used as a whole under the low level of overal planning in China, and the accumulative fund balance rate in some co-ordinated regions is relatively high, while in other regions, the accumulative fund balance rate is relatively low, even in deficits. The efficiency of fund utilization is decreased due to the structural imbalance of fund balance. For example, in 2011, Yunxiao County and Pinghe County in Zhangzhou City overspent RMB2.63 million and RMB0.37 million respectively, while the balance rates at the municipal level, of Changtai County and Changshan County all exceeded 25%. The funds could not be regulated each other, thus reducing the utilization rate and risk prevention capability of the funds. In 2014, besides Minqing County, Yongtai County and Fuzhou City, which lost about RMB10 million, other counties (cities) had saw a surplus, Fuqing County, Mawei County, Minhou County and Changle County made a surplus of RMB104.673 million, RMB107.66 million, RMB70 million and RMB34.56 million, respectively. Yunnan Province achieved mixed results before the implementation of municipal-level overal planning. Take Dali Prefecture in 2010 as an example, the accumulated balance of

Eryuan County's overal planning fund can afford the payment for 5.22 months and Jianchuan County for 5 months. 53.7% of the insured in Dali City and Dali Prefecture accounted for 73.27% of the balance of the overal planning fund in the entire prefecture; in Nanjian County, Eryuan County and Jianchuan County, 13.5% of the insured accounted for only 2.82% of the balance of the overal planning fund in the entire prefecture; in Yangbi County, Weishan County and Yongping County, 11.79% of the insured accounted for only 5.14% of the balance of the overal planning fund in the entire prefecture. Thus it can be seen that the balanced development of different regions will be affected, the efficiency of fund utilization will be reduced, and the social inequity will be aggravated due to the low level of overal planning.

(3) Difficulties in site-off medical treatment

With the gradual increase of population mobility, medical service in another place will also arise more frequently. At present, besides the basic problems of high medical expenses and low reimbursement ratio, there are also problems such as complex reimbursement procedures, different treatment and audit time in different regions to be solved for site-off medical treatment. Due to the different local conditions in different regions, the medical insurance policies differ in payment base, deductible, ceiling line, payment ratio, medical insurance list, and the corresponding settlement methods and operating system are also different. And information is not unified and cannot be shared at the low level of overal planning, such as at the county level. At the county level of overal planning, if patients need to see a doctor in another hospital instead of in the county-level co-ordinated hospital, they must handle the process of site-off medical treatment, which is not only necessary for the county-level hospital to issue referral applications, but also need to wait for the approval from the county-level medical insurance agencies. In addition, patients seeking medical service in superior hospitals will often encounter increased referral expense, reduced payment amount of medical insurance and other situations arising from inconsistent fund overal planning policies. These tedious procedures and inconsistency between regions will greatly increase the difficulties in getting medical service and economic burden of the insured. More seriously, the low level of overal

planning leads to the inconsistency of reimbursement conditions and ratio as well as different management systems in different regions, resulting in information asymmetry. This has spawned the idea that some people collaborate with physicians from off-site hospitals to defraud medical insurance funds, posing a threat to the unnecessary loss of medical insurance funds.

(4) Others

At present, most of China's medical insurance funds are coordinated at the prefectural and municipal levels, but there are still many funds coordinated at the district and county levels. The lower the level of overal planning is, the greater the gap between regions and the worse the fairness will be. Different medical insurance systems are available in different regions, for example, designated hospitals in different counties and districts of the same city, deductible standard and reimbursement ratio are different, which will result in different treatment, and in turn will inevitably lead to imbalance in people's minds, contrary to the original intention of medical insurance to achieve harmonious social development. From a rational point of view, low-level overal planning will lead to an increase in the number of regulatory targets, and the more the number is, the greater the difficulty of supervision and the higher the cost will be. In the meantime, on the premise of maintaining a low level of overal planning, the development of medical insurance will only result in the constant modification or even reestablishment of the medical insurance management system, which will waste a large amount of human resources and funds, increase the economic costs and personnel management costs, and in turn increase the difficulties in improving the level of overal planning and create a vicious circle.

III. Sustainability of Dynamic Adjustment Mechanism of Medical Insurance

(1) Starting mechanism of medical insurance negotiation access

The starting mechanism of medical insurance access in China is the selection system at the present stage.

For the determination of drug varieties of medical insurance priced through government negotiation in China in 2017, selection channels was set up by the

medical insurance departments to select drugs that conformed to the concept or scope of special medical insurance drugs. Then, experts from clinical medicine, pharmacology, health economics, medical insurance and other fields were invited by the medical insurance departments to form an independent expert group. Finally, based on the principles of drug value evaluation and pharmacoeconomic evaluation, independent evaluation for the clinical efficacy, safety and use cost of drugs was carried out by the experts, and targets priced through negotiations were determined through voting and scoring of experts. It could be seen from this that the current starting mode of medical insurance access in China was the expert selection mode, that is, the final access drugs were selected from a large number of varieties by ballot according to different regions, different backgrounds and different opinions of professional experts.

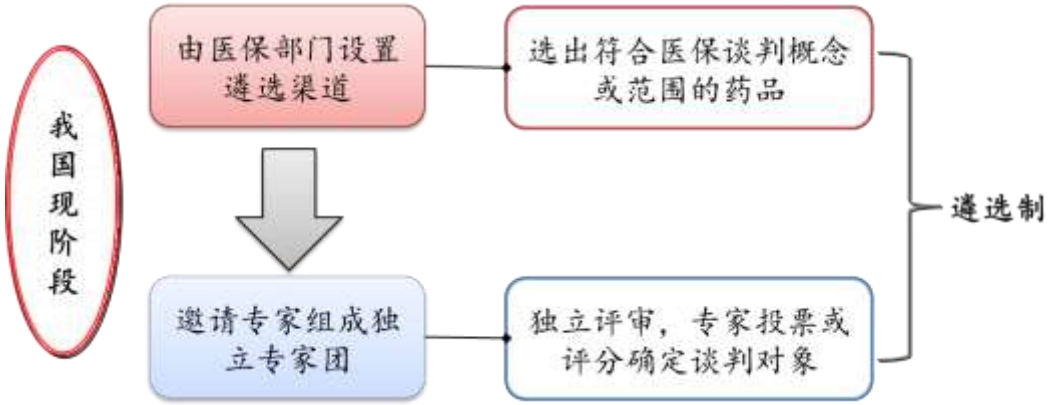


Figure 9. Starting Mechanism of Medical Insurance Negotiation Access in China at the Present Stage

The advantages of this model were: ① the access process was simple and practicable and took a short time; ② the congestion of declaring enterprises was eliminated; ③ the results were clear, which was conducive to the active selection of excellent drugs into the scope of selection.

But this mode also faced some problems in operation: ① No compulsory requirements were provided for R&D firms to provide relevant data on drug economic assessments and evidence-based medicine of corresponding varieties[13],

13 Chang Jinghua, Sun Lihua, Dong Hao. Centralized Review Mechanism of Selection of Medical Insurance Drugs in Australia and its Enlightenment[J]. Chinese Journal of New Drugs, 2008, 17(17): 1465-1467.

and the selection was mainly based on expert experience and group discussion, which would undoubtedly increase the subjectivity of the evaluation results to a certain extent; ② Every update of the list is "motion-type" and every adjustment would involve major actions. The evaluation group and organizations were temporary and abnormal, and the system was featured with volatility and uncertainty; ③ The selection criteria were blurred, prone to result in unfair appeals; ④ It was difficult for enterprises to prepare materials adequately within a short time from invitation of negotiation to submission of materials; ⑤ The negotiation entity is the national medical insurance institutions, but the actual payer is the local medical insurance fund, resulting in low engagement of local medical insurance institutions.

The declaration system refers to that the pharmaceutical enterprise submits an application for access to the relevant departments according to its own situation, prepares drug materials by themselves according to negotiation criteria and material review regulations, and submits the materials at the same time.

Compared with the selection system, the declaration system has the following advantages: ① both system and materials are standardized; enterprises can prepare materials in advance, and the results and processes are predictable; ② the establishment of review standards, review institutions and declaration process enables the system form a long-term mechanism; ③ the rules are clear and enterprises have the initiative in hands, which is conductive to enhance enterprises' enthusiasm in negotiation access; ④ the declaration system is procedural, normalized and transparent, which is conducive to the establishment of dynamic adjustment mechanism.

However, the implementation of the application system also has the following problems: ① the level of varieties submitted by enterprises for review is not even, which requires performing a lot of preliminary screening work by expert groups and regulatory departments to determine the scope of selected varieties. Varieties inconsistent with the requirements of negotiation access will take up a lot of review resources; ② the authenticity, completeness and scientificity of data materials submitted by enterprises themselves may interfere with the review results. To

guarantee the authenticity and scientificity of enterprise data, information and materials, the establishment of good restriction and supervisory mechanism is required.

(2) Too limited content of medical insurance negotiation

In the current stage, the content of medical insurance negotiation in China is mainly limited to price. The bidding, procurement, market supply and benefit commitment have not been paid enough attention (for example, the "Herceptin" outage occurred frequently after the price cut of drugs priced through negotiations last year); the negotiation process is too short to realize sufficient communication and consensus, as shown below.

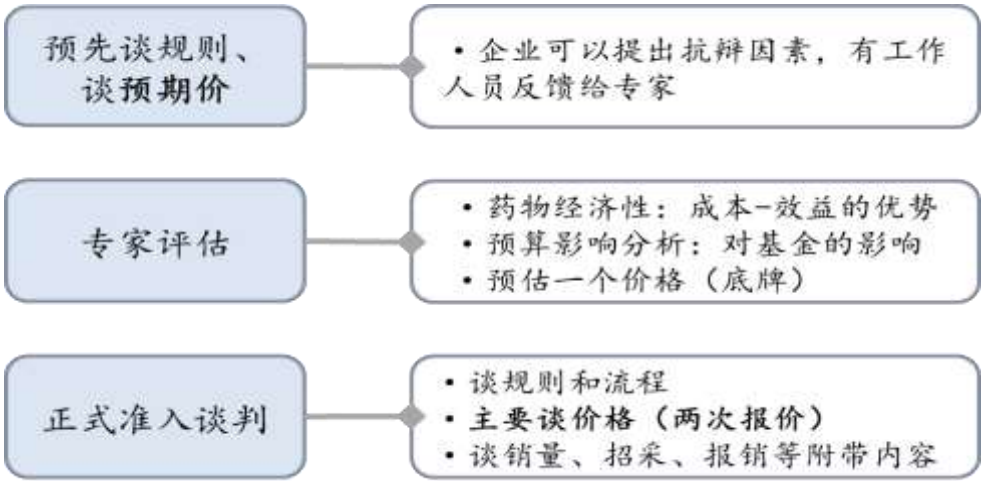


Figure 10. Current Status of Contents of Medical Insurance Negotiation in China

IV. Problems in Implementation, Use and Management of Drugs Priced through Negotiations

(1) Outpatient and inpatient reimbursement

1 Background analysis of outpatient reimbursement policy

In the first place, the insured seeking outpatient medical treatment shall confirm whether they are entitled to the outpatient reimbursement, whether they are seeking medical treatment in the designated hospital, and whether their medical treatment items are covered by the reimbursement scope. Finally, they shall determine whether the amount of medical treatment exceeds the deductible of outpatient medical insurance reimbursement. The deductible for outpatient

reimbursement of social security and medical insurance is generally fixed at RMB1,800, with a maximum limit of RMB20,000, depending on different regions

Besides the above general types of outpatient reimbursement (overal planning of outpatient), several reimbursement models and regulations are provided for outpatient chronic diseases, outpatient special diseases, outpatient mental diseases, outpatient AIDs, outpatient serious diseases, etc.

With regard to chronic diseases, special diseases and serious diseases, the provisions will be formulated by different provinces and cities on specific disease categories (a list will be typically provided), and the corresponding patients can submit application and reimburse after the disease categories in the list have been reviewed.

For the place of reimbursement, the diagnosis and treatment, medication and medical services of the individual designated hospital are generally eligible for application for outpatient reimbursement. Taking Nanjing City as an example, the overal planning of outpatient, reimbursement ratio of other outpatient reimbursement items, deductible and ceiling, etc. are summarized and analyzed.

Table 19. Outpatient Reimbursement Policy of Nanjing City[14]

Benefits of outpatient overal planning				
Personnel category		Employee	Retiree	Veteran worker before the founding of the PRC
Deductible		RMB1,200	RMB1,000	RMB200
Ratio of allowance	Community medical institutions	70%	75%	100%
	Other medical institutions	60%	65%	95%
Ceiling		RMB2,000	RMB3,000	RMB4,000
Outpatient chronic diseases				
The specific diseases are divided into three categories: Category I includes hypertension stage II, hypertension stage III, angina, myocardial infarction, epilepsy, active tuberculosis, chronic atrophic gastritis and myasthenia gravis, etc. Category II includes chronic hepatitis B, chronic hepatitis D, chronic nephritis, chronic renal				

[14] Website of Nanjing Municipal Human Resources and Social Security Bureau. Summary of Reimbursement Ratio/Scope of Medical Insurance for Urban Employees in Nanjing [EB/OL]. http://nj.bendibao.com/live/20141113/48096.shtm. [07/13/2018/11-15/2018].

insufficiency (nondialytic treatment), etc. Category III includes systemic lupus erythematosus, chronic aplastic anemia and motor neuron disease, etc.					
		Employee	Retiree	Retiree over the age of 70	Veteran worker before the founding of the PRC
Deductible		RMB1,000	RMB800	RMB600	None
Allowance		Community hospitals: 70%	Community hospitals: 85%	Community hospitals: 95%	Community hospitals: 100%
		Non-community hospitals: 60%	Non-community hospitals: 75%	Non-community hospitals: 85%	Non-community hospitals: 95%
Limit of allowance	Category I	RMB2,000	RMB3,000	RMB3,500	RMB4,000
	Category II	RMB4,000	RMB5,000	RMB5,500	RMB6,000
	Category III	RMB10,000	RMB10,000	RMB10,000	RMB10,000
	For patients who suffer from two or more chronic diseases (based on the number of disease category) simultaneously, the original maximum allowance limit will be increased by RMB2,000				

Allowance of expense quota for outpatient treatment of chronic hepatitis C with interferon α				
Requirements	Deductible	Payment ratio	Ceiling limit	Remarks
Patients with chronic hepatitis C	No deductible is set for the allowance	70%	RMB3,200 per month	The monthly expense quota is only valid for the current month, without accumulating
Outpatient antiviral therapy				During the treatment with interferon α, the "outpatient chronic diseases" allowance of Hepatitis C can also be provided
Use of interferon α (common and long-lasting)				The allowance of outpatient expense quota will not be provided simultaneously during hospitalization

Specific outpatient items						
Outpatient dialysis of chronic renal	**Expenses and allowance of related items**		**Self-payment ratio**			
	Item name	Limit of	Employee	Retiree	Retiree over the age	Veteran worker

failure		allowance			of 70	participated in revolutionary work before the founding of the PRC
	Dialysis expense	RMB63,000 per year	8%	5%	4%	None
	Expenses for auxiliary examination and medication	RMB12,000 per year	10%	7%	5%	None
	Remarks	① Maximum payment limit: the dialysis expense is the limit of dialysis medical expense; the auxiliary treatment expense is the payment limit of medical insurance fund				
		② The insured available to the outpatient dialysis treatment of chronic renal failure will not be entitled to the quota allowance of outpatient chronic diseases of chronic nephritis and chronic renal insufficiency (nondialytic treatment)				
		③ Drugs and items with self-payment ratio shall be paid by the insured according to the proportion and then paid according to the individual sharing proportion stipulated in this table				

	Expenses and allowance of related items			**Self-payment ratio**			
	Item name	Time	Maximum payment limit of medical insurance fund	Employee	Retiree	Retiree over the age of 70	Veteran worker before the founding of the PRC
Outpatient anti-rejection treatment after human organ transplantation	Treatment with anti-rejection drugs	The year of transplantation	RMB80,000	8%	5%	4%	None
		The first year after transplantation	RMB80,000	8%	5%	4%	None
		The second year after transplantation	RMB75,000	8%	5%	4%	None
		The third year after transplantation	RMB70,000	8%	5%	4%	None
		The fourth year after transplantation and later	RMB65,000	8%	5%	4%	None
	Auxiliary examination and medication	The year of transplantation	RMB10,000	10%	7%	5%	None
		The first year after transplantation	RMB10,000	10%	7%	5%	None
		The second year after transplantation	RMB8,000	10%	7%	5%	None
		The third year after transplantation	RMB6,000	10%	7%	5%	None
		The fourth year after	RMB4,000 per	10%	7%	5%	None

		transplantation and later	year				
	Remarks	① "CellCept" is included into the scope of the limit of treatment with anti-rejection drugs by the generic name of "Mycophenolate Mofetil" for unified management					
		② Drugs and items with self-payment ratio shall be paid by the insured according to the proportion and then paid according to the individual sharing proportion stipulated this table					

Outpatient anti-rejection treatment after hematopoietic stem cell (allograft) transplantation	**Expenses and allowance of related items**			**Self-payment ratio**			
	Item name	Time	Maximum payment limit of medical insurance fund	Employee	Retiree	Retiree over the age of 70	Veteran worker before the founding of the PRC
	Treatment with anti-rejection drugs	The year of transplantation	RMB80,000	8%	5%	4%	None
		The first year after transplantation	RMB80,000	8%	5%	4%	None
	Auxiliary examination and medication	The year of transplantation	RMB10,000	10%	7%	5%	None
		The first year after transplantation	RMB10,000	10%	7%	5%	None
	Remarks	① The allowance for outpatient anti-rejection treatment after hematopoietic stem cell (allograft) transplantation will be stopped at the end of the first year after transplantation; for those patients requiring further treatment, they should be evaluated by the designated hospital, and handle the review and registration formalities at the medical insurance department of the municipal social security center, and the medical insurance fund will pay according to the allowance standard of the corresponding year of anti-rejection treatment after organ transplantation					
		② Drugs and items with self-payment ratio should be paid by the insured according to the proportion and then paid according to the individual sharing proportion stipulated this table					

Outpatient treatment of malignant tumor	**Expenses and allowance of related items**			**Self-payment ratio**			
	Item name	Time after definite diagnosis	Maximum payment limit of medical insurance fund	Employee	Retiree	Retiree over the age of 70	Veteran worker participated in revolutionary work before the founding of the PRC
	Outpatient chemoradiotherapy (apply for at designated hospitals)	Yearly	RMB150,000	8%	5%	4%	None
	Directed drug treatment (apply for at designated hospitals)	Yearly	RMB100,000	8%	5%	4%	None

	Auxiliary examination and medication (seek medical treatment at designated hospitals. No further application is required)	The year of definite diagnosis	RMB20,000	10%	7%	5%	None
		1-3 years after definite diagnosis	RMB20,000 per year	10%	7%	5%	None
		4-5 years after definite diagnosis	RMB10,000 per year	10%	7%	5%	None
		6 years after definite diagnosis and later	RMB4,000 per year	10%	7%	5%	None
	Remarks	Drugs and items with self-payment ratio should be paid by the insured according to the proportion and then paid according to the individual sharing proportion stipulated this table					

Guangzhou Municipal Human Resources and Society Security Bureau issued the *Notice of Guangzhou Municipal Human Resources and Society Security Bureau on Incorporating Liraglutide and Other Drugs into the Catalogue of Drugs for General Outpatient, Specific Outpatient Items and Designated Outpatient Chronic Diseases*, which required incorporating 32 drugs priced through government negotiation in the catalogue of drugs for general outpatient, 6 drugs in the catalogue of drugs for outpatient chronic diseases and 7 drugs in the catalogue of specific outpatient drugs from June 1, 2018. These 32 drugs were composed of 3 drugs successfully priced through negotiations in the first batch in July 2016 (Tenofovir Disoproxil, Gefitinib and Icotinib), and 29 of the 36 varieties priced through negotiations in July 2017.

According to the Notice of Guangzhou Municipal Human Resources and Society Security Bureau, the above policies shall be valid for 5 years in terms of implementation. After the implementation of policies, for the drugs newly added in the catalogue, the proportion of individual out-of-pocket expenses shall be fixed at 5% for employees' social medical insurance and at 15% for social medical insurance for urban and rural residents; if the actual price of drugs was lower than the medical insurance payment standards, the actual price shall prevail.

Media statistics showed that patients shall spend RMB10,000-20,000 per month before targeted drugs were included in the scope of medical insurance reimbursement, and their actual expenditure could be controlled at about RMB1,000-2,000 after targeted drugs were included. Taking liraglutide (3ml:18mg/piece, pre-filled stylus) as an example, the original price was RMB771.93/piece and the payment standard was RMB410/piece after being included in the medical insurance, drop by 46%. The insured could reimburse proportionally at the price of RMB410/piece and the employees participating in the medical insurance might only pay RMB100-200/piece.

But some drugs were not included in the outpatient medical insurance. It was reported that the types of drugs priced through government negotiations not in the outpatient medical insurance list of Guangdong Province included: Recombinant Human Prourokinase (chemical drug class), Recombinant Human Coagulation Factor VIIa, Recombinant Human Brain Natriuretic Peptide, Rituximab, Diterpene Ginkgolides Meglumine Injection (traditional Chinese medicine class), Ginkgolide Injection and Astragalus Polysaccharide Injection.

2 Analysis of outpatient reimbursement impact of drugs priced through negotiations

(1) The effects of outpatient reimbursement are relatively small, affecting the implementation and use of drugs

For treatment of some diseases, it may be not necessary for patients to be hospitalized, but the injection by professional physicians is required, so patients need to buy drugs in the outpatient department. However, the reimbursement ratio and amount are limited in accordance with the outpatient reimbursement process and regulations, and this may result in patients being unwilling to take medication or being forced to buy drugs in hospital, which will greatly affect the implementation and use of drugs priced through negotiations.

Taking Ranibizumab of Novartis and Conbercept of Kanghong Pharmaceutical as an example, they are suitable for the treatment of eye diseases, and it is generally not necessary for patients to be hospitalized, and patients may only be necessary to

be injected with medication at a prescribed time. Then patients are forced to buy drugs and get injections in the outpatient department, and the outpatient overal planning reimbursement has both deductible and maximum payment limit, resulting in very limited amount of reimbursement. Even if Conbercept could be included in the scope of outpatient serious disease reimbursement of Shanxi Province, its amount of reimbursement is much less than that of inpatient reimbursement. The sales volume of Conbercept is only increased by about 20% and its growth of sales is only about 5%. As for its competitor Ranibizumab, their treatment indications are similar, so one of them will inevitably be unable to obtain benefits from preferential policies with regard to the reimbursement of outpatient serious diseases, and its sales and use will suffer from great impact.

As a result, further discussion is required as to whether attention shall be paid to the link between medical insurance and high-value drugs, and whether the limit of outpatient reimbursement shall be lifted.

(2) Some drugs are not included in outpatient medical insurance, and the approach of buying drugs in outpatient department is limited

The outpatient reimbursement of various provinces is different, in particular, the policies and regulations related to outpatient chronic diseases and outpatient serious diseases have their own characteristics. Although the drugs priced through negotiations are included into the national medical insurance, it does not mean that they can be reimbursed in the outpatient department at will. If these drugs cannot be incorporated into the reimbursement scope of outpatient serious diseases and outpatient chronic diseases at the provincial or municipal level, the reimbursement limit and guarantee strength will be very limited.

For example, after Guangzhou Municipal Human Resources and Society Security Bureau issued the *Notice of Guangzhou Municipal Human Resources and Society Security Bureau on Incorporating Liraglutide and Other Drugs into the Catalogue of Drugs for General Outpatient, Specific Outpatient Items and Designated Outpatient Chronic Diseases*, the analysis showed that several types of drugs priced through negotiations were not included in the scope of outpatient reimbursement, including

Recombinant Human Prourokinase (chemical drug class), Recombinant Human Coagulation Factor VIIa, Recombinant Human Brain Natriuretic Peptide, Rituximab, Diterpene Ginkgolides Meglumine Injection (traditional Chinese medicine class), Ginkgolide Injection and Astragalus polysaccharide injection. As mentioned above, the treatment indications of Ranibizumab and Conbercept are similar, so one of them will inevitably be unable to obtain benefits from preferential policies with regard to the outpatient reimbursement, and the drug eligible for reimbursement will be favored by most patients, and thus the sales and use of the other drug will suffer from impact.

As a result, the link between drugs priced through negotiations and outpatient guarantee shall be properly improved, for example, provinces and cities are expected to actively incorporate the corresponding drugs into the category of outpatient specific diseases, outpatient chronic diseases and outpatient serious diseases, and to appropriately increase the reimbursement ratio.

(2) Variety differentiation management

1 Variety differentiation management of chronic diseases and serious diseases

The varieties of drugs priced through negotiations, especially the varieties for cancer and other serious diseases, chronic diseases and rare diseases priced in the second negotiation, were uniformly managed according to the national and local documents, lacking the idea of classification management and scientific design. If in the process of implementing the "three designation" management, some local policies set the "three designation" restriction on hospitals, physicians and patients without distinguishing the drugs for chronic diseases from the drugs for serious diseases, which is not conducive to the implementation of reimbursement and reducing the medication accessibility of patients with chronic diseases, it is because that the reimbursement of drugs for chronic diseases is inconsistent with the reimbursement of drugs for chronic diseases included in the original medical insurance list.

2 Management of drugs for rare diseases

On May 22, 2018, five departments including the National Health Commission

of the People's Republic of China, the Ministry of Science and Technology of the People's Republic of China, the Ministry of Industry and Information Technology of the People's Republic of China, the National Medical Products Administration and the National Administration of Traditional Chinese Medicine of People's Republic of China jointly issued the *First List of Rare Diseases*, covering 121 diseases. According to the *Investigation Report on Survival Status of Groups with Rare Diseases in China*, the greatest difficulties of patients with rare diseases encountered during the treatment mainly include too high cost of treatment, lack of medical technology and inability to buy appropriate drugs or high drug prices. Due to various reasons, the number of varieties of drugs for rare diseases in our medical insurance list is relatively small at present. Only Recombinant Human Coagulation Factor Ⅶa for treatment of hemophilia and Recombinant Human Interferon β-1b for treatment of multiple sclerosis in the second round of negotiation are incorporated into the scope of drugs for rare diseases accessed through negotiation, which is inconsistent with the diseases covered by the rare diseases list, and the health rights and interests of patients with rare diseases cannot be guaranteed.

Moreover, even if the price of drugs has been cut through negotiation, this portion of patients is still unable to obtain medical security as they cannot afford the self-payment part of drug expenses.

Chapter IV Learn from the Experience of Typical Countries

I. Study on Anti-risk Capabilities of Medical Insurance Funds in Typical Countries

(1) The United States

1 Allow full play to the expense control role of medical insurance payment system

The public medical insurance department in the United States has designed and implemented the control measures on medical insurance expenses for the three main bodies, that is, demand side, supply side and payment side.

For the demand side, the United States has designed differentiated insurance plans based on differences of the population, and the expense control is mainly restricted to the elderly, children, soldiers and other special groups. For example, for hospitalization insurance payment of the elderly and other vulnerable groups in the United States, the standards of medical insurance payment and patient's self-payment are determined according to the length of stay. Most hospitalization expenses within 90 days of stay are covered by the hospitalization insurance, and the remaining portion shall be paid by the beneficiaries themselves, with specific standards as follows: beneficiaries shall pay $1,260 for the 1st to 60th days of hospitalization, pay $315 daily for the 61st to 90th days of hospitalization, and pay $630 daily for the portion of days of hospitalization over 90. The cumulative extension is up to 60 days, and all the expenses for the portion of days of hospitalization over 150 shall be paid by patients[15]. Unlike this design, the medical insurance settlement in China is based on the social wage level and the deductible of medical insurance, while the medical insurance payment model in the United States has really shortened the length of stay and the hospitalization expenses for patients. In addition, the hospitalization insurance in the United States also covers the professional nursing expenses of beneficiaries after discharge, which is more beneficial to reducing the occupancy of medical resources and increasing the service efficiency of medical resources, and has brought some reference and inspiration to the design of medical insurance payment mode in China. The U.S. government has

15 Liu Ping, Hu Caixia. Study on the Design of Public Health Insurance System in United States [J]. Medicine & Philosophy (A), 2018, 39(11): 60-62.

also encouraged consumers to establish regional health insurance alliances by legislation, in a bid to strengthen forces of the demand side.

The United States has adopted a series of control measures on medical insurance expenses for the supply side: physicians and hospitals are mutually independent in the design of organizational system; the development of Health Maintenance Organization (HMO) and other private controlled medical organizations is encouraged so as to provide more choices for the public and share the financial pressure of public medical insurance expenditure; the establishment of responsible medical organizations is promoted, and the quality and efficiency of medical services are combined as the payment standard; the price of drugs, consumables and devices of medical device enterprises is controlled.

On the payment side, the United States has been actively exploring the application of DRGs for control of medical insurance expenses. After implementation, the growth rate of per capita medical expenses has been put under control obviously, as shown in Figure 11.

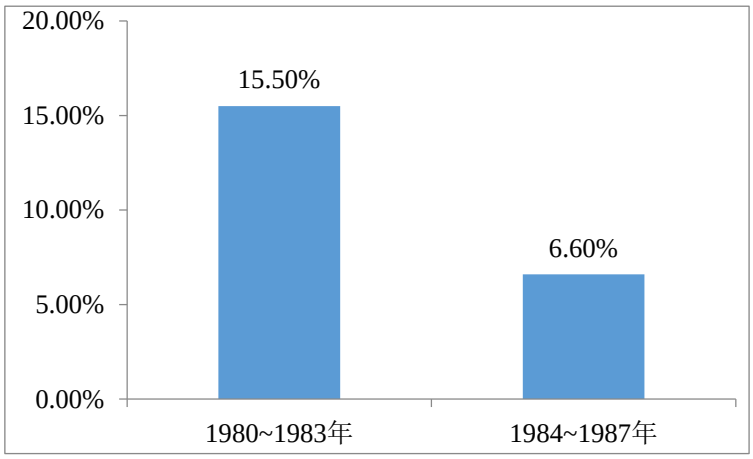


Figure 11. Growth Rate of Per Capita Medical Expenses in the United States Declined Obviously after Implementation of DRGs

(Source: CN.healthcare.com, collated by Dr. Zhang Ziran)

2 Control of medical insurance expenditure through supervision of medical insurance physicians

For expenditure of medical insurance funds, the supervision mechanism of medical insurance physicians in the United States is divided into three stages: advanced, present and subsequent supervision and the corresponding systems are

service supervision system, fraud inspection system and payment audit system[16].

The service supervision system refers to that professionals supervise the process of medical services provided by licensed physicians, to put an end to false cases, excessive examination and false number of patients and other illegal behaviors. In order to control the supervision cost and ensure the supervision effectiveness, the medical insurance department divides the supervision into general supervision, direct supervision and personal supervision according to the degree of correlation. For “general supervision”, it is not necessary for the supervision physician to be present at the scene of medical services. “Direct supervision” requires the supervision physician to wear overalls and stay in the same medical institution as patients receiving medical services. "Personal supervision", as the most stringent form, requires the supervision physician to appear on the scene of medical services. Among the three levels of supervision, physicians responsible for supervision must be always available for guidance and assistance.

The fraud inspection system is suitable at the scenario before the medical insurance payment is carried out. When the medical insurance physician lodges a claim, the relevant inspection department analyzes the data on the claim statement, so as to identify the waste and fraud behavior of medical insurance fund in advance and prevent them at the first sign, as shown in Figure 12. Remarkable results have been achieved with operation of the system. The loss of funds was reduced by about $115 million in 2012.

16 Wu Yushan, Shen Shuguang, Mu Gong. References on Supervision of Foreign Medical Insurance Physicians[J]. China Social Security, 2013(05): 29-31.

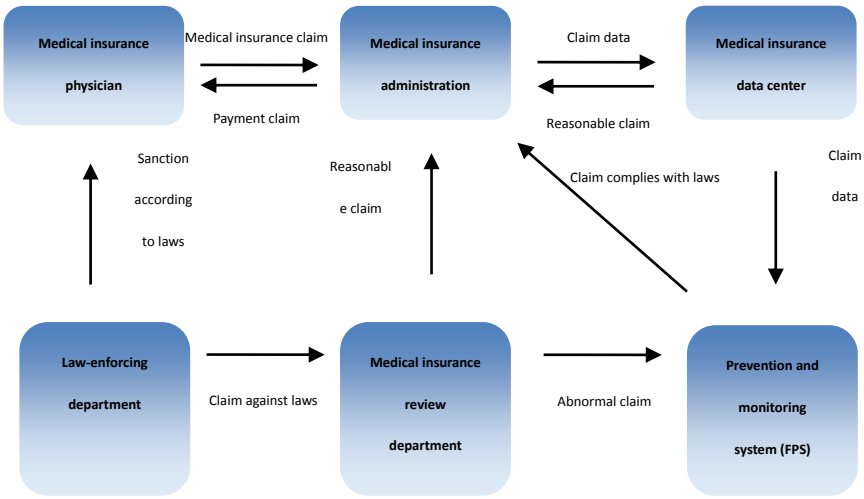


Figure 12. Operation Process of Fraud Inspection System

The payment audit system is suitable at the scenario after the medical insurance payment is carried out. The system is aimed at discovering the violation records and recovering the losses by examining the claims records of physicians in the last three years. The system, as the last line of defense to detect waste and fraud of medical insurance, will strictly review the medical insurance payment records of medical insurance physicians in the past three years. Once fraud or waste behavior is detected, physicians will be requested to pay back the expenses immediately so as to save the medical insurance losses.

As a matter of fact, although the supervision mechanism for medical insurance physicians is relatively sound, there is almost no phenomenon of excessive diagnosis and treatment by medical staff in the United States. On the one hand, except for independent legal person contractual relationship, no employment relationship exists between hospitals and physicians, so hospitals cannot exert influence on physicians' diagnosis and treatment behavior from an economical point of view; on the other hand, physicians themselves have a reasonable high level of medical service income, so it is not necessary for them to acquire other wealth through excessive medical treatment and other means. But the United States also saw the phenomenon of blind expansion of medical institutions and upgrading of equipment. To strengthen control over such expenditures, the U.S. government effectively

prevents the abuse of medical devices through access to medical institutions, facilities and equipment and medical staff and the establishment of peer review mechanism (evaluate the professional level of organizations according to the professional standards approved by the government, and reduce administrative costs unrelated to clinical diagnosis and treatment)[17].

3 Crack down on medical insurance fraud behavior

The United States attaches great importance to the anti-fraud of medical insurance. Medical insurance fraud is first reflected in judicial practice and is a federal felony. Once found, the Federal Bureau of Investigation (FBI) will assume the direct responsibility of fraud investigation, and the United States Department of Health and Human Services (HHS) and the Department of Justice will jointly enforce the law to impose "criminal charges, three times compensation, penalties and kick-outs" on all illegal brokerages. And, the U.S. government also strengthens the anti-fraud power of medical insurance from other levels. Except for the subjects involved in the above judicial acts, the Centers for Medicare and Medicaid Services (CMS) has also established the Center for Public Integrity (CPI) to monitor the fraud, abuse and waste of Medicare, Medicaid and CHIP. Moreover, CMS detects fraud through data modeling, mining and visualization tools based on massive data provided by various medical information databases and electronic health records. The anti-fraud software of three stages of prepayment prevention, prepayment investigation and retrospective recovery has been developed to identify suspicious compensation and fraud behavior of medical service providers and beneficiaries[18].

(2) United Kingdom

The UK government released on its official website that unnecessary waste in the UK medical process in 2015 amounted to billions of pounds, and the economic burden would undoubtedly impute to patients and the society. Although the statistical data on medical waste and fraud is not available in China, it can be shown

17 Yan Guang. From Theory to Practice: Reflection and Regulation of Control of Medical Expenses[J]. China Health Law, 2017, 25(01): 26-32+59.

18 Li Chengzhi. Several Enlightenments of American Medical Insurance System on Current Medical Reform[J]. China Medical Insurance, 2018(05): 68-71.

in the population base estimation and cases exposed on the network.

The United Kingdom adopts the theory of "government procurement of services" in the supervision of medical expenses, which means that the government acts as the "buyer" for the entire citizen to negotiate with medical institutions on behalf of the majority of patients, so as to enhance the negotiation ability of the buyer[19]. The government health department, as a third-party buyer, implements different payment modes for different medical service providers, and for large urban hospitals, the mode of lump-sum budget + government subsidies is adopted. In such a way, the responsibility of controlling medical expenses falls on the hospital, empowering the medical service provider to control the growth of medical expenses consciously. The possible excess medical expenses are offset by the government subsidies appropriately, providing guarantee to the operation of hospitals. For providers of primary health care or services, the efficiency can be improved by procurement of services. Only the content and quality of purchased services concern, irrespective of the "public" or "private" identify of providers[20].

The United Kingdom has implemented strict law enforcement for supervision of drug price and medical expenses. Monitor, NHS TDA and NHS England under the UK Department of Health are responsible for supervising the corresponding medical service institutions. If medical and health institutions fail to implement national or local expense standards, Monitor and other supervision institutions are entitled to order them to rectify within a time limit or even take severe measures such as cancellation of administrative licenses. Good supervision and law enforcement effects have been achieved by the division of responsibilities among medical insurance supervision institutions.

(3) Germany

On the one hand, Germany has formulated various control systems for medical insurance expenses through legislative institutions, such as drug reference pricing

19 Yan Guang. From Theory to Practice: Reflection and Regulation of Control of Medical Expenses[J]. China Health Law, 2017, 25(01): 26-32+59.
20 Zhu Ji. Research on Control of Third-party Medical Expenses[D]. Zhejiang Finance and Economics College, 2012.

system, medical insurance drug expense sharing system and medical expense payment limit system. On the other hand, the cooperation between government and social organizations is established, in which the government is mainly in charge of formulation and supervision of policies and programmes, and social management organizations (including insurance agencies and physician organizations) implement the autonomous management through the council and play an important role in the supervision of medical insurance funds[21].

1 Drug reference pricing system

The use of reference price is the essence of Germany's medical insurance payment system. In Germany, the drugs in the reimbursement scope are divided into three categories according to the composition and effect of drugs, namely, drugs of same composition, drugs of similar composition and drugs of same efficacy[22]. Each category is divided into several sub-categories, and then the reimbursement price applicable to each sub-category of the same category is determined, namely, the reference price. For drugs that are applicable to the reference price, drugs whose price is lower than the reference price, as well as drugs that are not applicable to the reference price, their expenses are shared by the patients according to the proportion stipulated by law, and the expenses of the portion higher than the reference price are fully borne by patients[23]. With this system, consumers' expense awareness is stimulated and the drug demand is reduced. The medical insurance in Germany is based on the principles of material benefit and reimbursement, that is, the insured can directly receive medical services without necessity to pay for them, the medical expenses of which are assumed by the medical insurance bureau. Guided by the principle of material benefit, physicians will be motivated to prescribe low-price drugs, and the prepayment system will restrain their impulse to make

21 Wu Yajuan. Study on the Improvement Measures for Supervision of Medical Insurance Funds in China Based on the Experience of Foreign Medical Insurance Fund Supervision[J]. Guide to Business, 2016(19): 87.

22 Shen Tuanjie, Huang Taikang. Thought on the Importance of Reform of Medical Insurance Payment System during Medical Improvement [J]. Chinese Health Economics, 2014, 33(06): 8-10.

23 Sun Zhaoquan, Xiao Hang. Overview of Expense Payment Management of Overseas Medical Insurance Drugs[J]. China Medical Insurance, 2011(10): 68-69.

extraordinary prescription. Plus strict supervision and review system, physicians will also make choices that are in their interest[24]. Due to the close connection between pricing and compensation mechanisms, drugs manufacturers have to price cautiously according to the reference price of similar drugs as long as they expect to increase the sales volume of drugs[25]. The related OECD data on the drop in the ratio of drug expenses to total health expenditures in Germany show that the drug expenses in Germany have been greatly controlled benefiting from reference price system, copayment mechanism and other supporting mechanisms[26].

2 Drug expense payment limit system

For payment limit system, Germany stipulates that patients must pay 10% of the drug price each time they visit a doctor and buy drugs, and the total amount paid is limited (minimum: €5, maximum: €10. Free of charge for special population)[27]. Moreover, Germany's statutory medical insurance fund assumes limited liability for the expenses of medical insurance drugs, and does not assume responsibilities for the expenses that exceed the budget limit. In terms of physicians, they will be warned when the amount of prescription exceeds the budget, and will be placed under financial supervision and required to make appropriate written reviews when the amount of budget exceeds 115%. Physicians must make a detailed description and explanation in case of exceeding 125%. If their reply is not satisfactory and convincing, physicians will have to bear the expenses in excess of the budget. This system regulates the behavior of physicians and properly controls the medical expenses[28].

3 Autonomous management of medical insurance physicians through the council

24 Zhu Ji. Research on Control of Third-party Medical Expenses[D]. Zhejiang Finance and Economics College, 2012.
25 Xiang Guochun. Payment Standards of Medical Insurance Drugs from the Perspective of German Practices[J]. China Social Security, 2018(01): 80-81.
26 Changfeng, Cui Penglei, Xia Qiang, Zhang Jianyun. Enlightenment of Germany's Drug Reference Price System on the Establishment of Medical Insurance Payment Standard in China[J]. Chinese Journal of Health Policy, 2015, 8(07): 55-60.
27 Xiang Guochun. Payment Standards of Medical Insurance Drugs from the Perspective of German Practices [J]. China Social Security, 2018(01): 80-81.
28 Zhu Ji. Research on Control of Third-party Medical Expenses[D]. Zhejiang Finance and Economics College, 2012.

In Germany, the medical insurance institutions settle the outpatient expenses through the Association of Insurance Physicians (KVB), instead of directly settling the expenses with physicians. KVB is responsible for establishing a supervisory executive committee specialized in the supervision and management of physicians in the Association. Physicians should diagnose and treat the medical patients according to the "List of Diagnosis and Treatment Services" formulated by the Association. The review of physicians by the supervisory executive committee is divided into "abnormal bill review" and "contingency review". Specifically, the committee audits the service item bills in the process of diagnosis and treatment of physicians, and compares them with the original average data. If physicians' medical expenses far exceed the average level, the supervisory executive committee will inquire physicians on behalf of KVB and request them to provide relevant evidence. If the evidence shows that the drugs prescribed by physicians are unreasonable, they should bear part of the drug expenses[10,29].

(4) Singapore

As a typical country of saving-type provident fund system in the world, Singapore takes the national social insurance as the core of medical system and establishes the reasonable sharing mechanism between government and individual responsibilities, which is conducive to the efficient utilization of medical resources. The Singapore government, at the beginning of designing the medical security system, has established the consciousness that the citizen must be responsible for their own health. In the three-level medical insurance system of Singapore, one of the most important components is the establishment of personal medical savings account. The government guarantees that the citizen is responsible for their own health by this kind of compulsory savings. This design can effectively prevent excessive consumption and avoid waste of medical resources[30]. Facts prove that Singapore's medical insurance has been structurally sound and shows good trend

29 Wu Yushan, Shen Shuguang, Mu Gong. References on Supervision of Foreign Medical Insurance Physicians[J]. China Social Security, 2013(05): 29-31.

30 Yi Longfei. Operation and Enlightenment of Universal Health Care in Britain, Singapore and Hong Kong, China[J]. Chinese Journal of Health Policy, 2014, 7(05): 49-55.

since the introduction of the medical savings account in 1984.

Singapore also stipulates that the personal account activation and the payment scope are subjected to the "medium cost segment", so small amount of medical expenses shall be paid by patients in cash, which can effectively ensure the accumulation continuity of personal accounts[31]. Although China has also set up the personal accounts, the activation restriction and the scope of medical expense payment are too loose, resulting in difficulties in making surplus of personal account in front of large amount of medical expenses, and reducing the anti-risk capabilities. To make matters worse, the effective restrictions on the illegal use of personal account funds are not available in China, which results in many abuses of medical insurance funds, and the original intention of restricting medical consumption fails to be realized with personal accounts.

In order to eliminate the moral hazards of unnecessary withdrawal and over-treatment of minor illness caused by excessive deposits in the account, the Singapore government has also set a limit on the total amount of medical savings accounts. The funds exceeding the limit will be automatically transferred to the general account of the central provident fund to be used for other purposes, such as house purchase and investment.

II. Medical Insurance Financing Pattern of Canada

The medical insurance system of Canada is one of the most perfect in the world. Although China and Canada differ greatly in terms of national nature, political system and economic strength, we can still select the methods to improve the level of medical insurance financing by drawing lessons from Canadian medical insurance financing.

In the first place, the model of universal free medical insurance in Canada is implemented at specific provinces, and then the corresponding policies are formulated by the national government. This free medical insurance system originated from the SSSP program released by Saskatchewan in 1947, which declared

31 Chu Tingyong. Study on the Development of China's Medical Security System[D]. Dongbei University of Finance and Economics, 2012.

that the residents in the province could enjoy free hospitalization services. After that, many provinces in Canada began to implement similar programs. It was not until 1957 that the Parliament of Canada stipulated that the medical expenses of citizens in each province should be composed of hospitalization expense and diagnostic expense, and should be paid by the provincial government and the federal government at the ratio of 1:1 respectively. Later, the appropriation of transfer payment mode was adopted instead.

In 1977, in order to encourage the provinces to increase their medical consumption to adjust the total medical expenses, the federal government required the provinces to increase the payment of other medical services by way of changing protocol, such as physical therapy, bonesetting, massage, appropriate medical subsidies for the elderly and dental care for children. In order to prevent provinces from charging patients high extra diagnosis and treatment expenses for additional items, the federal government deducted the expenses from the appropriation of transfer payment so as to protect patients' rights and interests.

In Canada, the medical insurance funds are jointly collected by the federal government and the provincial government, usually from corporate income tax and personal income tax. In addition to this, the provincial government can also raise medical insurance funds from consumption tax and payroll tax levied at a certain proportion based on the actual situation of the provinces. At the national level, the federal government also withdraws the national medical insurance funds at a certain proportion through the taxes levied by provinces, mainly used for transfer payment for the provinces with insufficient funds (adjustment fund, actually).

In fact, the perfection of Canadian medical insurance system is also supported by its high tax, which is not suitable for our national conditions, as we must consider the domestic economic level. The success of this overal planning mode in Canada depends on the fact that small gap exists between medical and health facilities in different regions, and the vertical management system from the national government to the provincial government is relatively clear and easy to manage. Moreover, the legislative executive power of Canadian provinces is different from

that of China's provinces, as Canada empowers its provinces with greater independent legislative power, enabling local provinces to adjust the amount of medical insurance funds based on the situation of their own provinces. If China implements the provincial-level overal planning, it is necessary to improve the vertical supervision force of local institutions, and to understand the actual situation of various local medical institutions, and meanwhile guarantee the economic level of the provinces matching with the medical and health resources prior to the implementation of provincial-level overal planning.

Chapter V Empirical Analysis of Use of Drugs Priced through Negotiations

This study included 563 analysis objects, including 3 drugs priced through negotiations in 2016, 36 drugs priced through negotiations in 2017 (the anti-cancer drugs priced through negotiations in 2018 are not covered in the analysis as their negotiation time is too close), and typical adjuvant drugs selected according to the list of provincial adjuvant drugs, with names of specific varieties as follows. The drugs could be divided into adjuvant drugs, drugs priced through negotiations and their generic drugs as well as other drugs (including drugs suitable for the same diseases as drugs priced through negotiations). The medical insurance list in China is based on generic name access and compensation, so the sales and cost expenditure of generic drugs of the drugs priced through negotiations are included in the calculation of the drugs priced through negotiations.

Table 20. Summary List of Study Objects

Classification	Specific classification		Name of drugs
Adjuvant drugs	Immune class		Deproteinised Calf Blood Serum
			Calf Spleen Extraction
	Angiocarpy		Hemocoagulase
	Nervous system		Oxiracetam, Pidotimod, Cerebroprotein Hydrolysate
			Monosialotetera-hexosyl Ganglioside
	Traditional Chinese medicine injection		Shenmai Injection, Shenqi Fuzheng Injection, Honghua Injection
			Danhong Injection, Dengzhan Xixin Injection, Mailuoning Injection
			Xingnaojing Injection, Shenfu Injection, Aidi Injection
			Shuxuetong Injection, Breviscapine Injection, Xueshuantong Injection
			Safflower Yellow for Injection
Drugs priced through negotiations	Drugs priced through negotiations in 2016	Tenofovir Disoproxil Fumarate	Viread (GSK)
			Qingzhong (Chia-tai Tianqing)
			Beixin (Chengdu Brilliant)
			Naxinde (Qilu Pharmaceutical)
			Zhengwen (Anhui Biochem)
		Icotinib Hydrochloride	Conmana (Betta Pharmaceuticals)

		Gefitinib	Iressa (AstraZeneca)
			Yiruike (Qilu Pharmaceutical)
	Drugs priced through negotiations in 2017	lapatinib, Apatinib, Erlotinib, Sorafenib, Liraglutide	
		Ticagrelor	Brilinta (AstraZeneca)
			Salubris (Taiyi)
		Recombinant Human Prourokinase, Recombinant Human Coagulation Factor Ⅶa, Recombinant Human Brain Natriuretic Peptide	
		Tolvaptan, Allisartan Isoproxil, Morinidazole and Sodium Chloride, Posaconazole, Fulvestrant	
		Trastuzumab, Bevacizumab, Nimotuzumab, Rituximab, Recombinant Human Interferonβ-1b	
		Bortezomib	Wanke (Janssen)
			Qianping (Chia-tai Tianqing)
			Xintai (Haosen)
			Qipule (Qilu Pharmaceutical)
		Recombinant Human Endostatin, Chidamide, Abiraterone, Everolimus	
		Lenalidomide	Ruifumei (Celgene)
			Lisheng (Beijing SL)
		Quetiapine, Paroxetine, Conbercept, Ranibizumab, Sevelamer, Lanthanum Carbonate, Shenyi Capsule	
		Diterpene Ginkgolides Meglumine Injection, Ginkgolide Injection, Compound Realgar Natural Indigo Tablets, Astragalus Polysaccharide Injection	

I. Use and Sales of Drugs Priced through Negotiations

Since the conclusion of the negotiations in 2017, 36 drugs priced through negotiations had been included in the medical insurance list and could be entitled to the official reimbursement of the state. Considering the lag of the negotiation effects, the data of 15 months before and after the release of the negotiation results in July 2017 was selected for statistics, as follows Figure 13.

The figure below showed that the sales of most of the drugs priced through negotiations had risen since the release of the negotiation results in July 2017, and the sales were increased significantly after the negotiations (the slope of the line segment increased obviously), and the lag effect of about 4-5 months could be observed (the red line was the release node of the negotiation results).

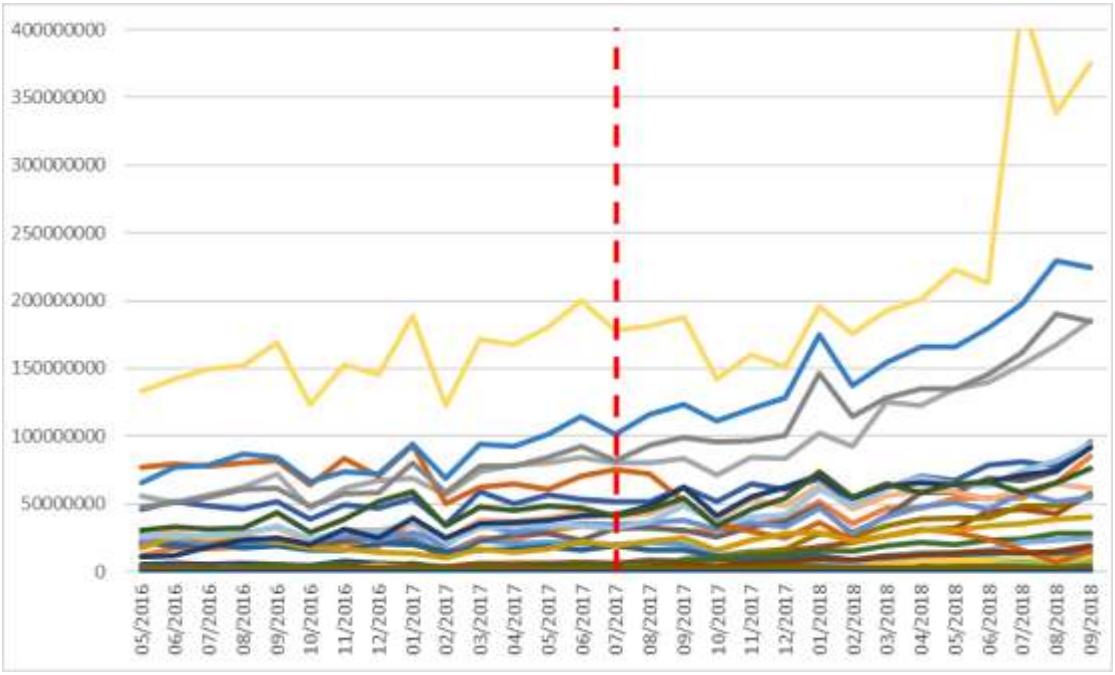


Figure 13. Sales of Drugs Priced through Negotiations before and after Medical Insurance Access in 2017 (unit: RMB)

The growth rate of sales of 36 drugs priced through negotiations was further analyzed in the study. From the figure 14, it could be seen that although the sales of drugs priced through negotiations increased significantly, the growth rate of sales did not show a significant growth trend. These drugs were exclusive varieties and enterprises might expect more from their marketing, but enterprises were still far from meeting the goal of “sacrifice price for volume”.

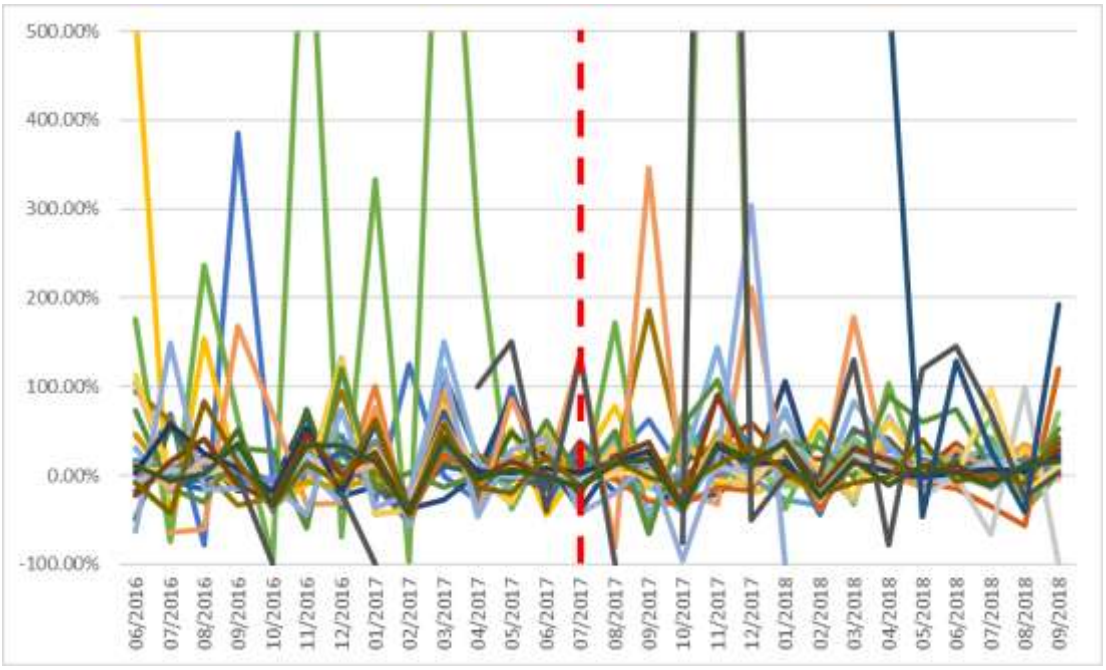


Figure 14. Growth Rate of Sales of Drugs Priced through Negotiations before and after Medical Insurance Access in 2017

The negotiation effects in 2016 were similar to those in 2017 (15 months before and after the release of negotiation results were selected as the scope of the study). Three varieties of Tenofovir Disoprox, Icotinib and Gefitinib were mainly included in the negotiations in 2016, and their sales increased significantly due to the sharp decrease in prices, as shown below. After release of the negotiation results (the red line in the figure 15), the sales of the three varieties saw great increase, and a lag effect could be observed. The figure showed that the lag period lasted about 4-5 months.

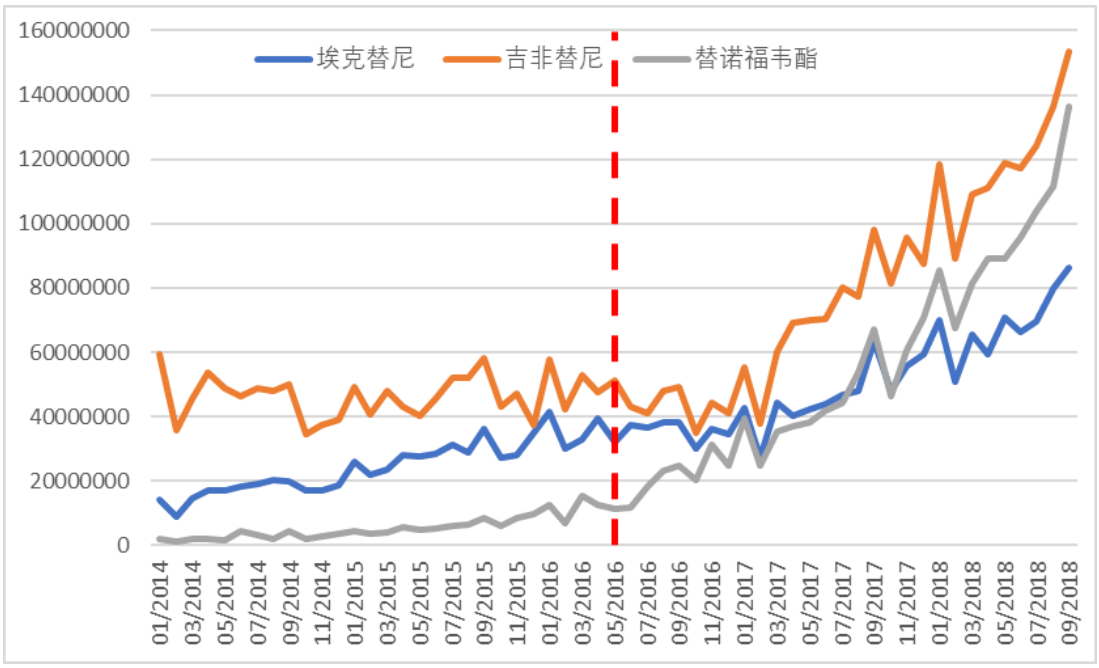


Figure 15. Sales of Drugs Priced through Negotiations before and after Medical Insurance Access in 2016 (unit: RMB)

Similarly, the calculation and analysis of the growth rate of sales of the three drugs priced through negotiations in 2016 showed similar growth rate to that in 2017, the growth rate of sales of the drugs priced through negotiations in the first round of negotiations hadn't saw any sign of growth and showed an irregular trend of change (as shown in the figure 16).

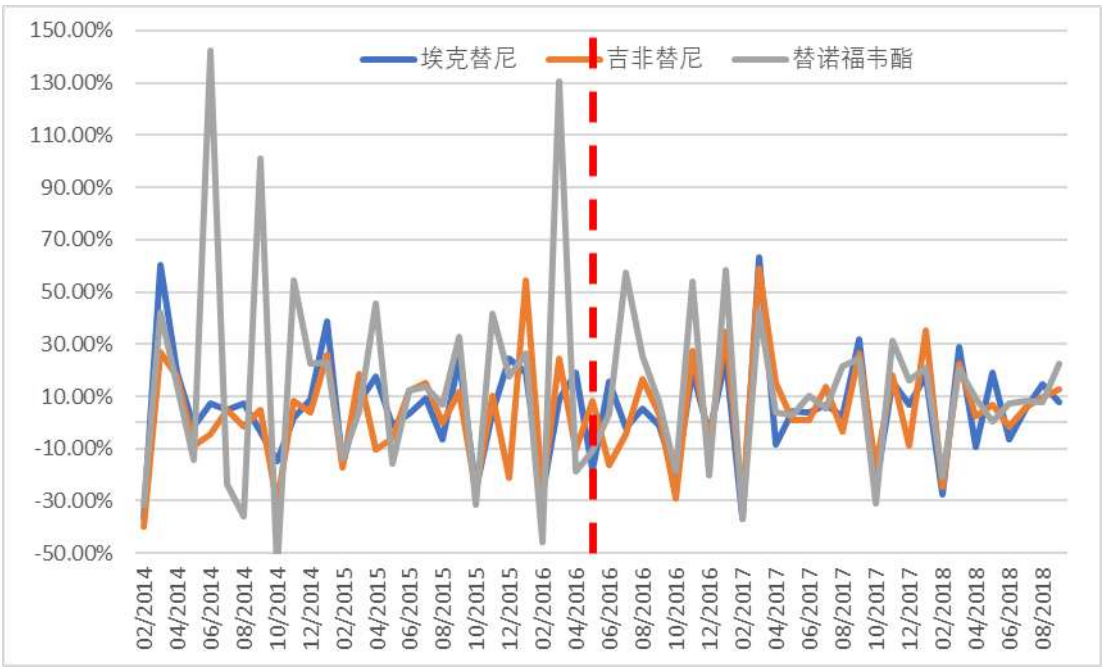
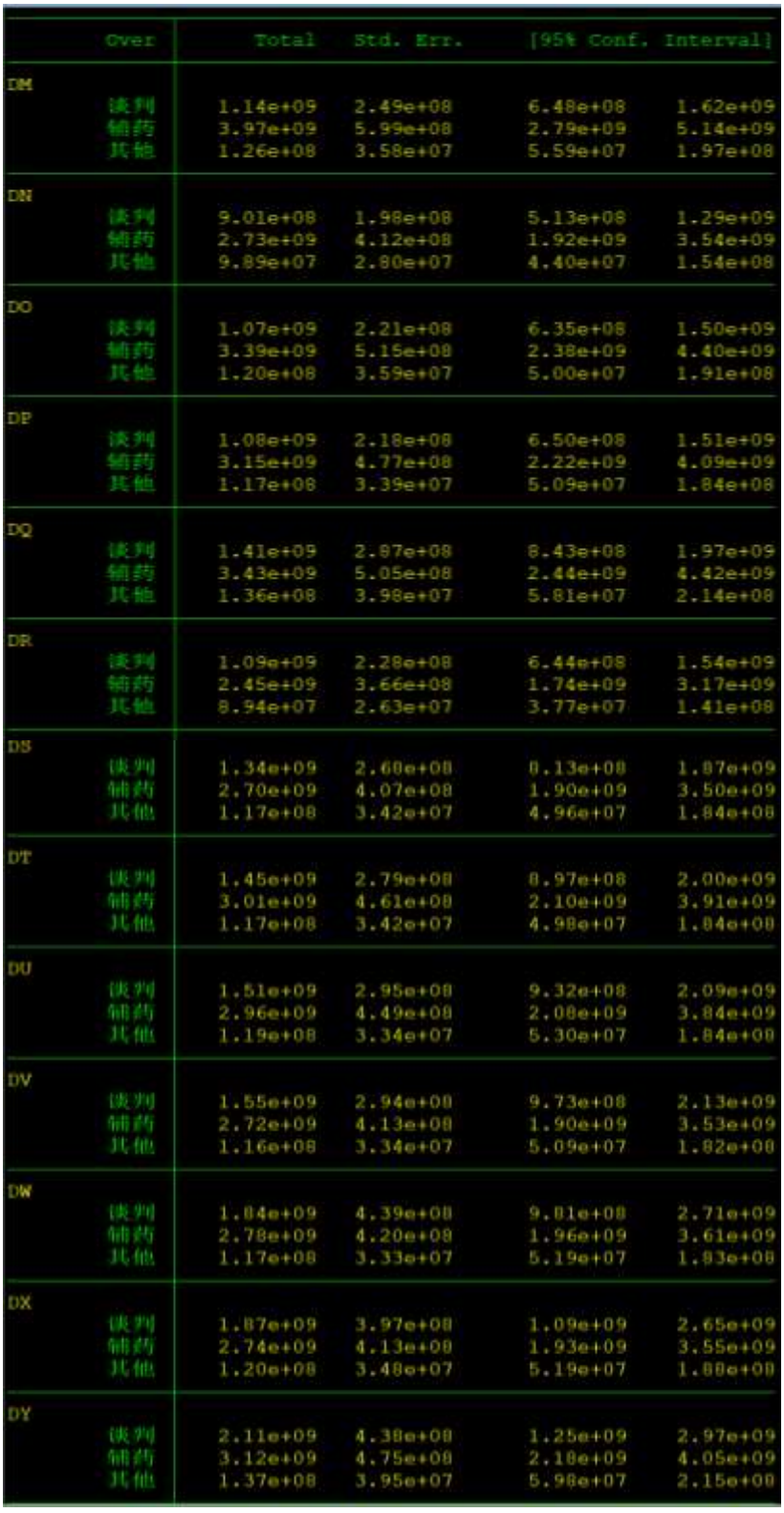


Figure 16. Growth Rate of Sales of Drugs Priced through Negotiations before and after Medical

II. Comparison of Expenses between Drugs Priced through Negotiations and Adjuvant Drugs

Based on screening and list of adjuvant drugs in the table above, the expenses of adjuvant drugs and drugs priced through negotiations were specifically calculated and compared. The period from September 2017 to September 2018 was chosen as the study period, and the total sales of adjuvant drugs listed in this period were compared with those of drugs priced through negotiations. The specific comparison results for each month were shown in the figure below. The calculation showed that, in the period from September 2017 to September 2018 (after access of 36 drugs priced through negotiations), 39 varieties priced through negotiation (39 drugs) occupied RMB18.36 billion of sales space, while adjuvant drugs occupied RMB39.15 billion of sales space, and RMB39.15 billion was far more than RMB18.36 billion. It indicated that some clinically useless, abusive and redundant adjuvant drugs could set aside considerable expense space for clinically urgently needed, high-value and high-priced drugs. So it follows from that attention shall be paid to the rational use of drugs to ensure the implementation of drugs priced through negotiations, in addition to the policies such as "cancellation of drug proportion" and "not accounting for the total expense control indicator".



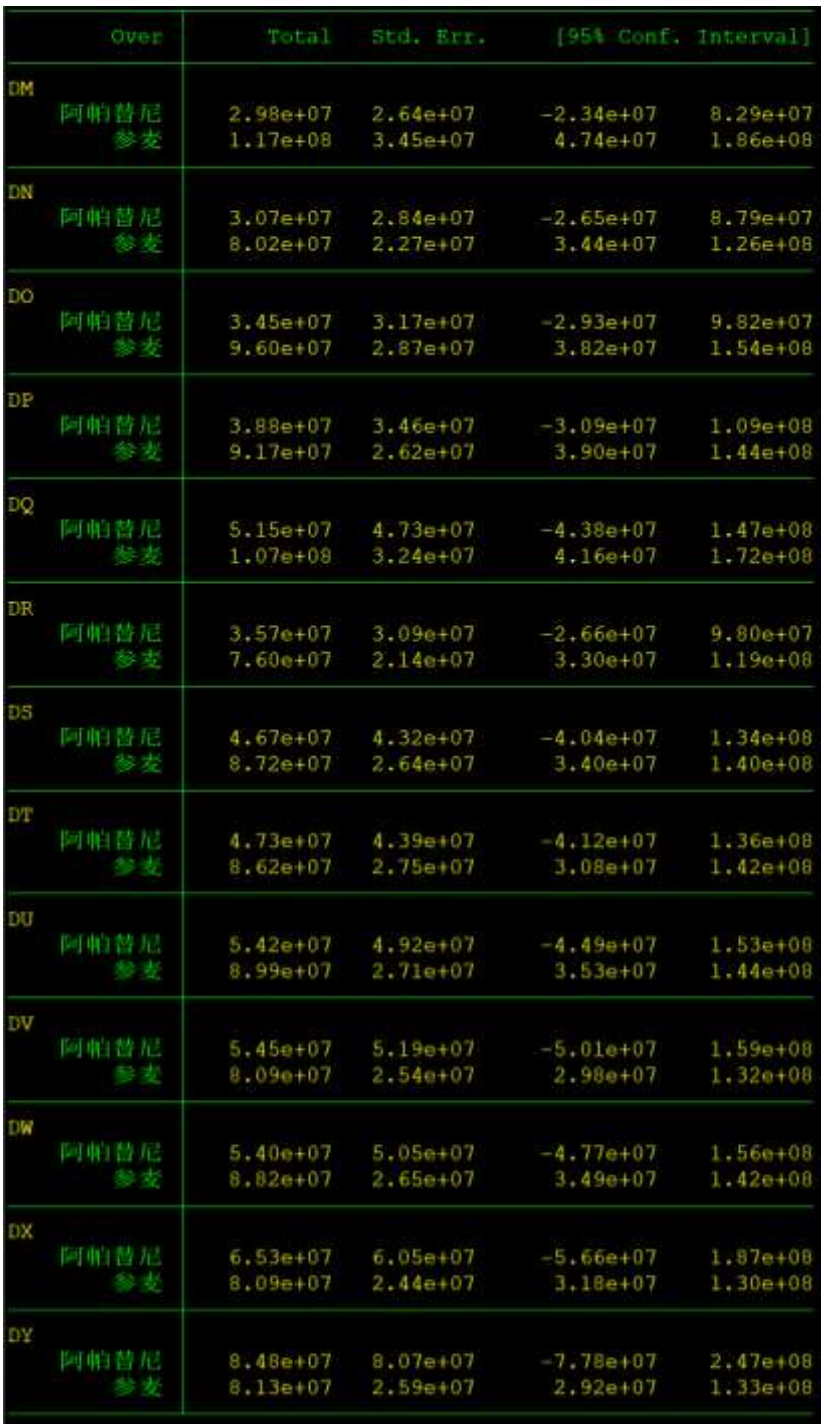
Over		Total	Std. Err.	[95% Conf.	Interval]
DM					
	谈判	1.14e+09	2.49e+08	6.48e+08	1.62e+09
	辅药	3.97e+09	5.99e+08	2.79e+09	5.14e+09
	其他	1.26e+08	3.58e+07	5.59e+07	1.97e+08
DN					
	谈判	9.01e+08	1.98e+08	5.13e+08	1.29e+09
	辅药	2.73e+09	4.12e+08	1.92e+09	3.54e+09
	其他	9.89e+07	2.80e+07	4.40e+07	1.54e+08
DO					
	谈判	1.07e+09	2.21e+08	6.35e+08	1.50e+09
	辅药	3.39e+09	5.15e+08	2.38e+09	4.40e+09
	其他	1.20e+08	3.59e+07	5.00e+07	1.91e+08
DP					
	谈判	1.08e+09	2.18e+08	6.50e+08	1.51e+09
	辅药	3.15e+09	4.77e+08	2.22e+09	4.09e+09
	其他	1.17e+08	3.39e+07	5.09e+07	1.84e+08
DQ					
	谈判	1.41e+09	2.87e+08	8.43e+08	1.97e+09
	辅药	3.43e+09	5.05e+08	2.44e+09	4.42e+09
	其他	1.36e+08	3.98e+07	5.81e+07	2.14e+08
DR					
	谈判	1.09e+09	2.28e+08	6.44e+08	1.54e+09
	辅药	2.45e+09	3.66e+08	1.74e+09	3.17e+09
	其他	8.94e+07	2.63e+07	3.77e+07	1.41e+08
DS					
	谈判	1.34e+09	2.68e+08	8.13e+08	1.87e+09
	辅药	2.70e+09	4.07e+08	1.90e+09	3.50e+09
	其他	1.17e+08	3.42e+07	4.96e+07	1.84e+08
DT					
	谈判	1.45e+09	2.79e+08	8.97e+08	2.00e+09
	辅药	3.01e+09	4.61e+08	2.10e+09	3.91e+09
	其他	1.17e+08	3.42e+07	4.98e+07	1.84e+08
DU					
	谈判	1.51e+09	2.95e+08	9.32e+08	2.09e+09
	辅药	2.96e+09	4.49e+08	2.08e+09	3.84e+09
	其他	1.19e+08	3.34e+07	5.30e+07	1.84e+08
DV					
	谈判	1.55e+09	2.94e+08	9.73e+08	2.13e+09
	辅药	2.72e+09	4.13e+08	1.90e+09	3.53e+09
	其他	1.16e+08	3.34e+07	5.09e+07	1.82e+08
DW					
	谈判	1.84e+09	4.39e+08	9.81e+08	2.71e+09
	辅药	2.78e+09	4.20e+08	1.96e+09	3.61e+09
	其他	1.17e+08	3.33e+07	5.19e+07	1.83e+08
DX					
	谈判	1.87e+09	3.97e+08	1.09e+09	2.65e+09
	辅药	2.74e+09	4.13e+08	1.93e+09	3.55e+09
	其他	1.20e+08	3.48e+07	5.19e+07	1.88e+08
DY					
	谈判	2.11e+09	4.38e+08	1.25e+09	2.97e+09
	辅药	3.12e+09	4.75e+08	2.18e+09	4.05e+09
	其他	1.37e+08	3.95e+07	5.98e+07	2.15e+08

Figure 17. Comparison of Sales of Drugs Priced through Negotiations and Adjuvant Drugs from 09/2017 to 09/2018

(Unit: RMB; where, e+n denotes $\times 10^n$; for example, 2.11e+09 denotes 2.11×10^9)

Taking Apatinib (a drug priced through negotiation) and Shenmai (an adjuvant drug) as examples, the sales of Apatinib (anti-cancer drug) amounted to RMB627.80

million between September 2017 and September 2018, while the sales of Shenmai (oral liquid and injection) amounted to RMB1.163 billion in the same period, which was much higher than the sales of Apatinib (the comparison of the specific monthly sales were as figure 18).



Over		Total	Std. Err.	[95% Conf.	Interval]
DM					
	阿帕替尼	2.98e+07	2.64e+07	-2.34e+07	8.29e+07
	参麦	1.17e+08	3.45e+07	4.74e+07	1.86e+08
DN					
	阿帕替尼	3.07e+07	2.84e+07	-2.65e+07	8.79e+07
	参麦	8.02e+07	2.27e+07	3.44e+07	1.26e+08
DO					
	阿帕替尼	3.45e+07	3.17e+07	-2.93e+07	9.82e+07
	参麦	9.60e+07	2.87e+07	3.82e+07	1.54e+08
DP					
	阿帕替尼	3.88e+07	3.46e+07	-3.09e+07	1.09e+08
	参麦	9.17e+07	2.62e+07	3.90e+07	1.44e+08
DQ					
	阿帕替尼	5.15e+07	4.73e+07	-4.38e+07	1.47e+08
	参麦	1.07e+08	3.24e+07	4.16e+07	1.72e+08
DR					
	阿帕替尼	3.57e+07	3.09e+07	-2.66e+07	9.80e+07
	参麦	7.60e+07	2.14e+07	3.30e+07	1.19e+08
DS					
	阿帕替尼	4.67e+07	4.32e+07	-4.04e+07	1.34e+08
	参麦	8.72e+07	2.64e+07	3.40e+07	1.40e+08
DT					
	阿帕替尼	4.73e+07	4.39e+07	-4.12e+07	1.36e+08
	参麦	8.62e+07	2.75e+07	3.08e+07	1.42e+08
DU					
	阿帕替尼	5.42e+07	4.92e+07	-4.49e+07	1.53e+08
	参麦	8.99e+07	2.71e+07	3.53e+07	1.44e+08
DV					
	阿帕替尼	5.45e+07	5.19e+07	-5.01e+07	1.59e+08
	参麦	8.09e+07	2.54e+07	2.98e+07	1.32e+08
DW					
	阿帕替尼	5.40e+07	5.05e+07	-4.77e+07	1.56e+08
	参麦	8.82e+07	2.65e+07	3.49e+07	1.42e+08
DX					
	阿帕替尼	6.53e+07	6.05e+07	-5.66e+07	1.87e+08
	参麦	8.09e+07	2.44e+07	3.18e+07	1.30e+08
DY					
	阿帕替尼	8.48e+07	8.07e+07	-7.78e+07	2.47e+08
	参麦	8.13e+07	2.59e+07	2.92e+07	1.33e+08

Figure 18. Comparison of Sales of Apatinib and Shenmai from 09/2017 to 09/2018

(Unit: RMB; where, e+n denotes $\times 10^n$; for example, 8.48e+07 denotes 8.48×10^7)

III. Comparison of Implementation of Drugs Priced through Negotiations among Cities

In this study, 41 cities and regions were selected to be analyzed for the implementation situation of drugs priced through negotiations in various provinces and cities, mainly covering the drugs priced through negotiations in 2017. The provincial overal planning of medical insurance hasn't been realized in the state, so the study took "city" as the main unit in the analysis.

As shown in the figure 19, after the conclusion of negotiations in 2017, the month-on-month growth rate of the drugs priced through negotiations (after negotiation VS before negotiation; 14 months before and after negotiation) was 1241.55% on average in 41 sample cities and regions, with minimum rate and maximum rate of -100.00% and 91053.89% respectively (a single drug with definite specification was regarded as an entry).

Variable	Obs	Mean	Std. Dev.	Min	Max
环比增速	947	12.41554	63.40593	-1	910.5389

Figure 19. Overall Situation of Month-on-month Sales Growth before and after Negotiations

The statistical analysis showed that the month-on-month growth rate of different cities and regions had statistically significant difference (P=0.000<0.05, confidence interval 95%), that is, various cities and regions differed in the use and sales growth rate of drugs priced through negotiations due to the differences of environment, political and economic development, policy implementation, drug use practices and other factors (as shown in figure 20).

Analysis of Variance

Source	SS	df	MS	F	Prob > F
Between groups	218901.318	40	5472.53295	1.38	0.0593
Within groups	3584313.48	906	3956.19589		
Total	3803214.8	946	4020.31163		

Bartlett's test for equal variances: chi2(40) = 2.5e+03 Prob>chi2 = 0.000

Figure 20. Comparison of Sales Growth Rate of Drugs Priced through Negotiations in Different Regions before and after Negotiation

The specific figures of the month-on-month sales growth rate of drugs priced

through negotiations in different cities and regions were provided below. For example, the month-on-month sales growth rate in Shanghai, Shenzhen, Guangzhou, Yangzhou and etc. was great, basically more than 3000%; Linyi, Weifang and etc. saw the lowest month-on-month sales growth rate (negative); Changchun, Wuxi, Xi'an and etc. showed a slower growth rate, below 100% (as shown in figure 21).

市名	Summary of 环比增速 Mean	Std. Dev.	Freq.
上海	32.862665	144.69821	35
临沂	-.10355436	1.015897	16
乌鲁木齐	7.7857176	24.108433	26
北京	3.8127692	7.3644035	41
南京	5.8071945	11.145906	32
南宁	2.4426671	3.3671996	19
南昌	10.591834	22.419673	24
合肥	4.8417116	11.382466	26
哈尔滨	5.9823732	23.665187	30
大连	1.6170024	3.9743336	21
天津	22.689565	83.454496	32
太原	2.3919056	6.9041072	19
宁波	10.415589	14.169693	6
常州	9.9459775	23.754249	15
广州	40.989915	119.86336	37
徐州	19.011475	44.571749	17
成都	4.4600153	10.921382	21
扬州	97.739078	201.20965	8
无锡	.27060489	.73977822	6
昆明	6.6554514	11.349485	20
杭州	21.692488	46.505897	18
武汉	2.02891	6.7771169	32
沈阳	2.1170005	5.3133564	30
济南	7.8969215	29.620499	31
济宁	3.6787185	4.1716553	19
浙江城市集群	44.209135	79.891562	11
深圳	47.459205	172.20373	24
温州	19.461679	53.906014	17
潍坊	-.2733873	.7597044	20
烟台	2.1365502	5.4281521	23
珠三角	2.3986254	3.0631106	22
石家庄	10.409783	29.645791	31
福厦泉	39.070664	165.11241	30
苏州	9.5956784	17.060289	17
西安	1.5181992	2.7487052	26
贵阳	7.9537668	16.527674	19
郑州	12.634604	22.531074	30
重庆	1.3021751	2.2215621	29
长春	.83250661	1.8443244	25
长沙	12.267529	45.950452	26
青岛	6.2386312	16.492047	16
Total	12.415538	63.405927	947

Figure 21. Month-on-month Sales Growth Rate of Drugs Priced through Negotiations in Different Regions

Then, 7 cities were selected from all sample cities according to 4 different

intervals of scoring results for the implementation of the above policies and systems (2 cities were selected for each interval, and 7 cities were selected finally for lack of data in Tibet). In addition, because the agreement on the provincial overal planning in China had not been yet reached, the typical cities were selected to represent provinces, and the results were only for reference. After negotiations, the sales of related drugs increased significantly in 7 cities including Beijing, Nanning, Shijiazhuang, Nanchang, Shanghai, Tianjin and Urumqi, as shown below (with about 4-5 months of lag effect) ; and, certain gap existed in the growth rate of different cities.

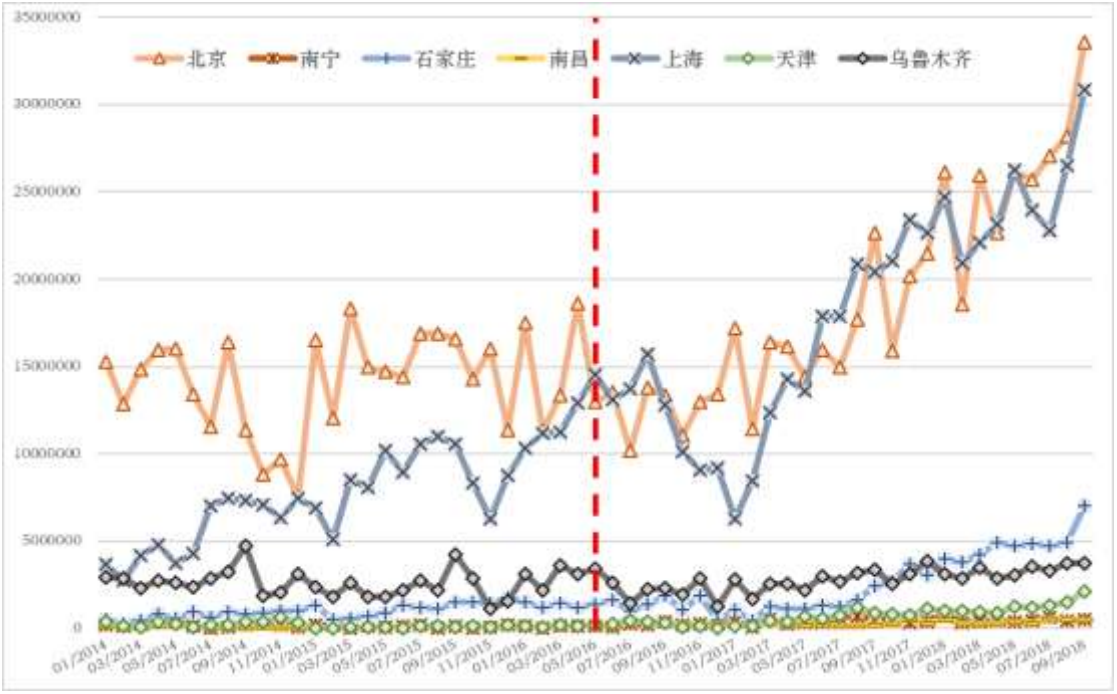


Figure 22. Sales of Drugs Priced through Negotiations in Sample Cities before and after Medical Insurance Access in 2016 (Unit: RMB)

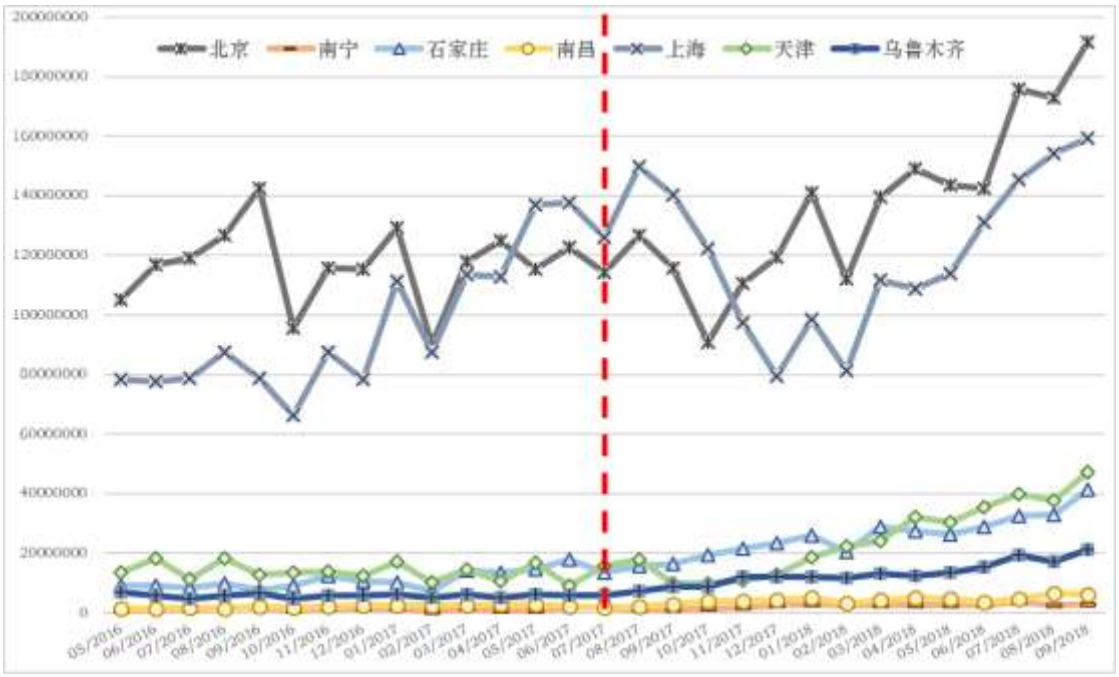


Figure 23. Sales of Drugs Priced through Negotiations in Sample Cities before and after Medical Insurance Access in 2017 (Unit: RMB)

The fluctuation of drug growth rate showed that no obvious rules were observed in the monthly fluctuation of drug growth rate, whether for drugs priced through negotiations in 2016 or drugs priced through negotiations in 2017, and no obvious difference were observed between provinces and cities (as shown in figure 24 and figure 25).

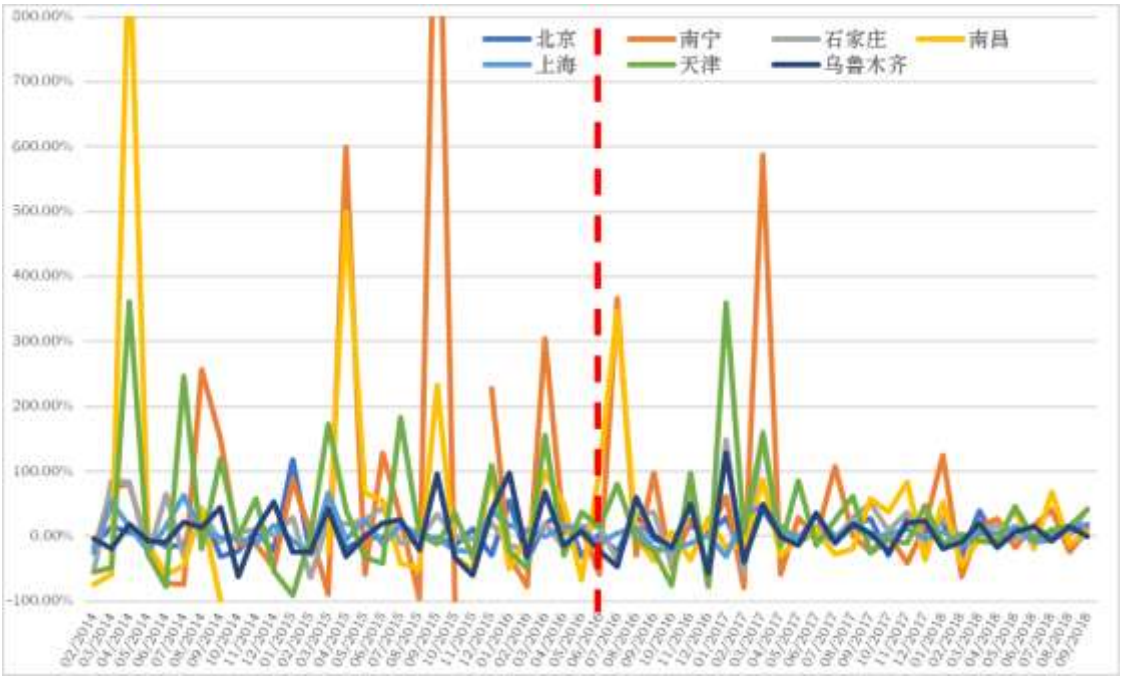


Figure 24. Sales Growth Rate of Drugs Priced through Negotiations in Sample Cities in 2016 before and after Medical Insurance Access

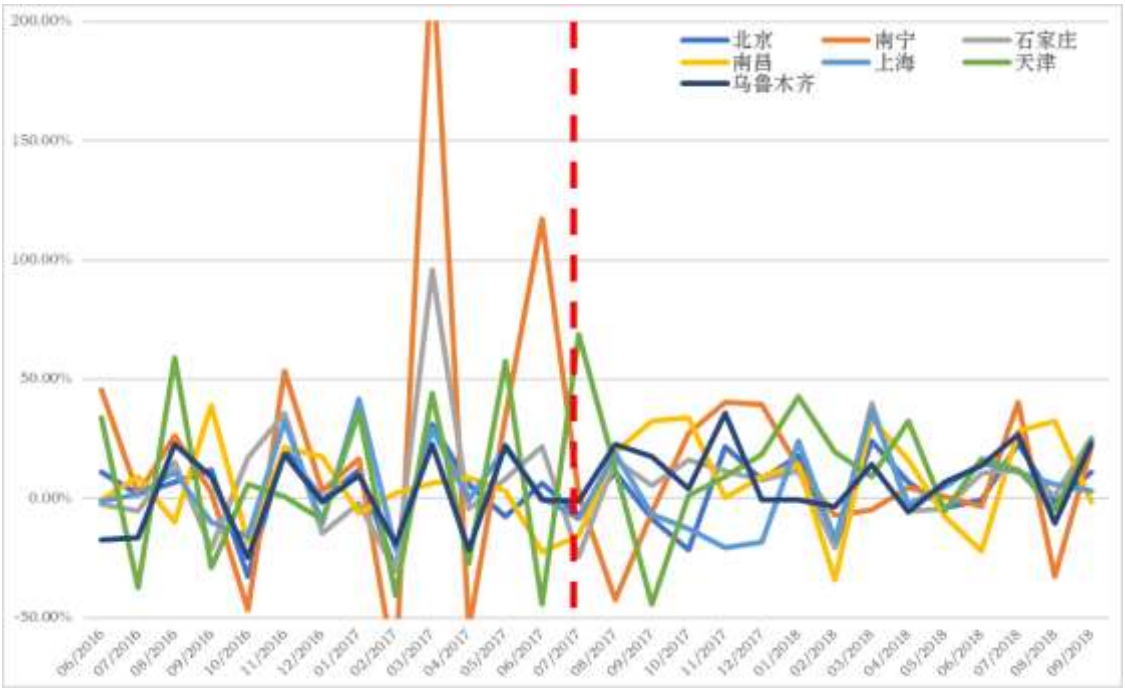


Figure 25. Sales Growth Rate of Drugs Priced through Negotiations in Sample Cities in 2017 before and after Medical Insurance Access

Chapter VI Reflections on Core Recommendations

I. Improving the Motivation Environment of Medical Institutions – Solving the Problem of “Difficulties in Access Hospitals”

(1) Eliminating "de-motivation factor" for the implementation of Drugs Priced through Negotiations

For drug proportion and total expense control of hospitals, 22 provinces/cities in China have clearly demanded that the drugs priced through negotiations will not be included in the evaluation of drug proportion; in order to promote the accessibility of drugs priced through negotiations and improve patients' sense of gain, some provinces have stipulated that the drugs priced through negotiations shall not be included in the lump-sum budget of medical insurance in hospitals, as shown in figure 26.

图 各省国家谈判药品不纳入药占比或单独核算情况　　图 各省国家谈判药品不纳入总额控费情况

Figure 26. Policies and Regulations on Drug Proportion and Total Expense Control of Drugs Priced through Negotiations in Provinces

No great results were achieved after the policies were released. The main bodies for policy release and institutional implementation were clearly differentiated, the initiative and decision-making power of concrete implementation were held by the municipal-level government and even at the district- and county-level government. After the provincial-level documents were released, fewer documents at the municipal level and county level were introduced. Taking Anhui Province and Sichuan Province as examples, of the 16 cities in Anhui Province, only Wuhu City and Fuyang City indicated on public websites that the drugs priced through negotiations

would not be included in the evaluation of drug proportion, accounting for 12.5%; of the 21 cities/prefectures in Sichuan Province, only Luzhou City, Zigong City and Nanchong City indicated on public websites that the drugs priced through negotiations would not be included in the evaluation of drug proportion at the provincial level, accounting for only 14.3%, as shown in figure 27.

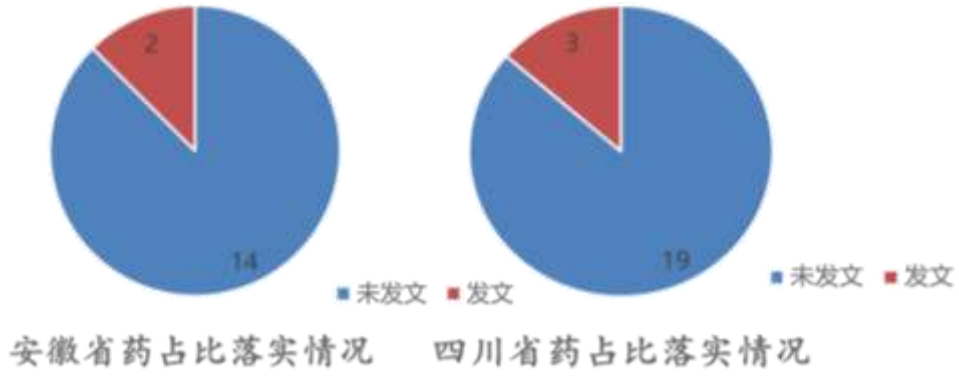


Figure 27. Implementation of Drug Proportion Policies on Drugs Priced through Negotiations in Specific Cities and Counties of Sichuan and Anhui Provinces

The *Notice on Strengthening the Management of Drug Purchase and Use* (No. 526 [2017] of the Secretariat of Drugs Administration of the Health and Family Planning Commission of Anhui) issued by the Health and Family Planning Commission of Anhui Province indicated that "the drugs priced through government negotiation would temporarily not be included in the evaluation of drug proportion of medical institutions, and would be separately accounted and reasonably regulated." After related documents were released in Anhui Province, we searched whether 16 cities in the province responded to the provincial-level call to introduce the document on not including the drugs priced through negotiations into the evaluation of drug proportion. The search showed that, of the 16 cities in Anhui Province, only Fuyang City and Wuhu City (refer to the table 21) had forwarded the related documents.

Table 21. Documents on not Including the Drugs Priced through Negotiations into the Drug Proportion Released by the Cities in Anhui Province

Cities	Documents	Date
Fuyang	Forwarding the *Notice on Strengthening the Management of Drug Purchase and Use*	12/05/2017

Wuhu	Notice on Forwarding the *Notice on Strengthening the Management of Drug Purchase and Use*	11/22/2017

In the Notice on *Implementing 36 Drugs Priced through Government Negotiation and the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version)* at the Provincial Level and Related Issues (No. 958 [2017] of Office of Sichuan Provincial Human Resources and Social Security Department), Sichuan Province indicated that the expenses of 36 drugs priced through government negotiation incurred in the designated medical institutions in 2017 would not be included into the control of total expenses. We searched the documents of 21 cities/prefectures in Sichuan Province about not including the drugs priced through negotiations into the evaluation of drug proportion, the results of which indicated that only Luzhou, Nanchong and Zigong (refer to the table 22) forwarded or issued the related documents amongst 21 cities/prefectures in Sichuan Province, and the other cities did not release relevant documents to respond to the call of the provincial-level document.

Table 22. Documents on not Including the Drugs Priced through Negotiations into the Drug Proportion Released by the Cities in Sichuan Province

Cities	Documents	Date
Luzhou	Notice on Forwarding the *Notice on Implementing the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version) and 36 Drugs Priced through Government Negotiation and Related Issues*	12/06/2017
Nanchong	Notice on Implementing the *Notice on the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version) and 36 Drugs Priced through Government Negotiation and Related Issues*	02/28/2018
Zigong	Notice on Implementing the *Notice on the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance (2017 Version) and 36 Drugs Priced through Government Negotiation and Related Issues* (No. 1 [2018] of Human Resources and Social Security Bureau of Zigong City)	01/31/2018

Based on the three-factor theory, it is necessary to eliminate the de-motivation

factors in the first place, that is, cancellation of drug proportion, total expense control and other evaluation indicators. In comparison with the price negotiations of anti-cancer drugs in 2018, after the release of the *Notice of National Healthcare Security Administration on Incorporating 17 Anti-cancer Drugs into the Class B Scope of the Catalogue of Drugs for the National Basic Medical Insurance, the Employment Injury Insurance and the Maternity Insurance* on October 10, 2018, the Department of Health issued the document of *Notice of the Bureau of Medical Reform and Administration of NHFPC on the Preparation and Use of 17 Anti-cancer Drugs Priced through Government Medical Insurance Negotiation*, emphasizing that hospitals should not influence the supply guarantee and rational use demand of drugs priced through negotiations on the grounds of control of total medical expenses, control of total medical insurance expenses, "drug proportion" and restriction of drug varieties and etc., so as to eliminate the problem of inactive procurement and use in hospitals. The penalty provisions were introduced at the same time -- for hospitals failed to provide drugs priced through negotiations timely and influenced the patients' drug use demand, measures should be taken to reduce their scale of oncology, limit the volume of business, reduce the grade of hospitals, decrease the level of hospitals, and disqualify the assessment and evaluation until proper rectification were made, so as to urge medical institutions to actively and rationally use anticancer drugs priced through negotiations and ensure meeting the supply and patient demand.

In order to solve the problem of "difficulties in access hospital", the state, provinces and cities shall implement the contents and spirit of the above documents, actively implement the de-motivation measures of cancellation of "drug proportion and control of total medical insurance expenses", and extend the spirit of the documents to other varieties priced through negotiations.

(2) Maintaining the "hygiene factor"

Motivation factors and de-motivation factors are at the two endpoints of a continuum, representing two extreme scenarios. Many different forms of motivation should exist between these two extreme scenarios, forming a continuous zone; in fact, there are many intermediate transition zones without strong de-motivation

factors or strong motivation factors, and the hygiene factor is put forward in this context.

Encouraging hospitals to purchase and use the drugs priced through negotiations, and to implement relevant measures including maintaining the grade and level development of hospital departments and physician salary should belong to the category of "hygiene factor". If hospitals can purchase and use the drugs priced through negotiations actively and reasonably based on the requirements and actual situation, the grade and level development of hospital departments and the physician salary will be maintained; if hospitals don't purchase and use or passively purchase and use the drugs priced through negotiations without reason, measures including decreasing the hospital level, deducting the score of department evaluation and deducting physician salary will be taken.

For motivation factors, where appropriate subsidies or remuneration are given based on the prescription dosage of drugs priced through negotiations, the enthusiasm of hospitals to purchase and use the drugs priced through negotiations can be fully motivated, so as to achieve the implementation of drugs priced through negotiations, complete "the last mile" of the drugs priced through negotiations, and enable patients to truly receive the bonus; in addition, physicians are prone to cause potential dangers of irrational drug use, waste and abuse the medical resources, and put a lot of pressure on the medical insurance fund. As a result, further considerations are required on whether to increase the motivation factors.

II. Variety Differentiation Management

Different management strategies shall be formulated for the use of drugs for chronic diseases, serious diseases and rare diseases in hospitals according to the idea of classified management. For example, the restrictions on "three designation" management of drugs for chronic diseases shall be cancelled to improve the medication convenience for patients, and their reimbursement ratio is recommended keeping in line with drugs in the Class B scope of the basic medical insurance, so as to reduce the economic burden of drug use for patients.

For varieties priced through negotiations for the treatment of rare diseases,

authoritative bodies and society of rare diseases, etc. can recommend drugs for rare diseases to be included in the negotiation list, and the rare disease expert group can actively initiate negotiations after demonstration, thus forming the normalization mechanism for the price negotiation of drugs for rare diseases. In the process of drug selection, drugs consistent with the *First List of Rare Diseases* shall be preferentially included in the negotiation list, so as to ease the urgency of drug demand for patients with rare diseases.

Meantime, more attention shall be paid to the patients with rare diseases with lower affordability than the common population, and the state is expected to raise special funds to further increase the reimbursement ratio of medical insurance and establish the self-payment capping mechanism of patients, to ensure the drugs accessibility for these vulnerable patients.

III. Straightening out the Implementation Path of "Dual-channel" - Opening the Channel of Purchasing Drugs in Designated Pharmacies

Drug proportion is an important evaluation indicator for public hospitals. The medical insurance expenditure will be significantly increased due to the inclusion of high-price anticancer drugs in the Class B scope of medical insurance, resulting in that some hospitals are afraid to make a prescription, and increasing the difficulties in implementing the drugs priced through negotiations in hospitals. Due to the difficulty of using the drugs priced through negotiations in hospitals, difficulty of drug use for patients will be increased, and it is also hard for pharmaceutical enterprises to sell these drugs in hospitals or to significantly increase the market share and increase the sales by decreasing price, which will finally affect the enthusiasm of enterprises to participate in subsequent negotiations.

To address the problem, 23 provinces and cities including Tianjin, Zhejiang, Henan and Anhui clearly stipulated that the drugs priced through government negotiation would not be included in the drug proportion or separate accounting, but most provinces stipulated that these drugs would "not be included temporarily". However, it remains to be seen whether this periodical solution can be implemented in the long run and further unified throughout the country.

Therefore, in order to promote the implementation of drugs priced through negotiations and enable the bonus of medical reform benefit more patients, it is recommended to open the dual-channel model of drugs priced through negotiations, and implement the policy of “buying drugs outside with a prescription”, so that the medical insurance expenses of patients can be reimbursed through designated pharmacies. Through the dual-channel model of drugs priced through negotiations, the difficulties of including these drugs into hospitals and failure of the insured to buy drugs will be effectively solved, and meanwhile the initiative of enterprises to participate in the follow-up negotiations of high-price drugs will be increased, realizing win-win for more parties.

For drugs priced through government medical insurance negotiation, the designated pharmacy supply mode has been adopted by 16 provinces in China, including Heilongjiang, Jilin, Liaoning, Tianjin, Shandong, Shaanxi, Qinghai, Gansu, Sichuan, Chongqing, Hubei, Guizhou, Hunan, Jiangsu, Zhejiang and Anhui.

(1) Background for introduction of measures

Taking Betaferon (Recombinant Human Interferon β-1b) as an example, most patients, enterprises and physicians reflected that the drugs priced through negotiations could be included into the scope of the medical insurance, but could not be used in hospitals. However, some patients succeeded in buying Betaferon in hospitals by roundabout routes. Zhao Lei, a 29-year-old native of Inner Mongolia, has suffered from multiple sclerosis for more than 8 years. In August 2018, he was admitted in a local hospital for 15 days and the hospital prescribed Betaferon for him. What’s unusual was that he was nominally “hospitalized”, but he never spent a day in the ward. He went to the hospital every other day and got injection of Betaferon. The secret that Zhao Lei could use Betaferon was precisely the "hospitalization". Based on the local provisions on medical insurance, Betaferon could only be reimbursed in hospitals and hospitalization could decrease the drug proportion - the bill was RMB12,800, including RMB7,080 of Betaferon cost and the rest for nursing fees and accommodation fees, etc., so that the drug proportion was only 55%, nearly half

lower than the 100% expense of purchasing drugs alone. But the thousands of RMB spent on hospitalization were still paid by the health insurance.

The similar examples were not in the minority. For example, outpatients in Zhuhai City, Guangdong Province could purchase drugs in pharmacies at their own expenses with hospital prescriptions, and then enjoy reimbursement as per hospitalization treatment at Zhuhai Medical Insurance Center by invoice.

Designated pharmacies are an important channel for circulation of drugs for patients with chronic diseases. According to the agreed standard of medical insurance payment, both hospitals and pharmacies are covered by patients' medicine taking and medical insurance payment in terms of channels, which can better guarantee the access to drugs and promote the separation of medical treatment and drug sales, namely, the currently hot topic of "dual-channel". Liaoning Province, Jilin Province, Shaanxi Province, Gansu Province, Shandong Province, Qinghai Province and etc. have made clear in the documents the tendency of channels of hospitals/pharmacies for drugs priced through negotiations.

Table 23. Circulation Channels of Drugs Priced through Negotiations in Provinces and Cities in China (Examples)

Provincial regions	Description of policy documents
Liaoning	Designated retail pharmacies are encouraged to provide drugs for the insured
Jilin	The management mechanism of designated retail pharmacies for special drugs is established, conditions are created step by step, and effective measures are taken to encourage designated retail pharmacies to provide special drug services for the insured
Shaanxi	For drugs requiring "prior review before use" or other drugs requiring strict management, real-name registration of cases, centralized supply in designated hospitals or retail pharmacies could be adopted
Gansu	Designated retail pharmacies are encouraged to sell the drugs priced through negotiations at a price not higher than that for online procurement. These drugs should be included in the scope of outpatient overal planning, outpatient subsidies for special diseases or reimbursement of personal accounts by medical insurance departments
Shandong	Effective measures are taken to encourage designated retail pharmacies to provide drugs for the insured and play an active role in ensuring the supply of medical insurance drugs.

Qinghai	The drugs priced through negotiations can be purchased by the insured in the outpatient department (designated retail pharmacies)

In order to eliminate the constraints of drug proportion and control of total medical insurance expenses, broaden the channels for use of drugs priced through negotiations and further promote the separation of medical treatment and drug sales, the mode of supply at designated pharmacies has been adopted by 16 provinces in China, including Jiangsu, Zhejiang, Shandong and Hunan, in view of the drugs priced through government medical insurance negotiation.

Figure 28. Distribution of Mode of Supply at Designated Pharmacies in Some Provinces/Cities

(2) Feasibility analysis of "dual-channel" for specific varieties

The statistics of dosage form and administration route of 36+17 varieties priced through negotiations in 2017 and 2018 are firstly made in this study, and then the feasibility and supporting measures of the "dual-channel" model are expected to be studied through in-depth analysis of drug property and administration route.

Table 24. Summary of Dosage Form and Administration Route of 36 Drugs Priced through Negotiations in 2017

Varieties	Therapeutic area	Name of drugs	Dosage form	Administration route
Drugs for serious or chronic diseases	Heart and cerebral vessels	Recombinant Human Brain Natriuretic Peptide (Tibet Rhodiola Pharmaceutical)	Injection (freeze-dry powder)	Intravenously injected at the loading dose, followed by intravenous drip at the maintenance dose
		Ticagrelor (AstraZeneca)	Round,	Take orally, before or after

			bi-convex, yellow coated tablet	a meal
		Recombinant Human Prourokinase (Tasly)	Injection (white, loose, clear, colourless transparent liquid after redissolving)	50 mg at a time: dissolve 20 mg in 10 ml saline, complete intravenous infusion within 3 minutes, dissolve the remaining 30 mg in 90 mL saline, complete intravenous drip within 30 minutes
		Allisartan Isoproxil (Salubris)	Tablet: white film-coated tablets	Take orally, not to be taken with food
	Anti-infection	Posaconazole (Merck Sharp & Dohme)	Oral suspension	Take orally
		Morinidazole and Sodium Chloride (Jiangsu Haosen)	Injection: light yellow-green to yellow-green clear liquid	Intravenous drip
	Eye AMD	Ranibizumab (Novartis)	Ophthalmic injection: transparent to milky white liquid	Administered by qualified hospitals and ophthalmologists through intravitreal injection under aseptic conditions
		Conbercept (KangHong Pharmaceutical)	Ophthalmic injection	Administered by intravitreal injection
	Chronic nephrosis	Lanthanum carbonate (Shire)	Chewable tablets	Take orally; chew thoroughly before swallowing, take with or immediately after a meal
		Sevelamer (Sanofi)	Tablet: white to off-white elliptical film-coated tablets	Take orally; swallow the tablets completely, without crushing, chewing or breaking into pieces before taking; take with a meal
	Mental diseases	Quetiapine (AstraZeneca)	Tablet	Take orally
		Paroxetine (GSK)	Tablet	Take orally
	Diabetes	Liraglutide (Novo Nordisk)	Injection:	Administered by

			colourless or almost colourless clear isotonic fluid	subcutaneous injection. The injection site may be abdomen, thigh or upper arm. Intravenous or intramuscular injection not allowed
	Others	Tolvaptan (Otsuka Pharmaceutical)	Tablet: blue tablets	Take orally
Other Western medicines	Tumour	Rituximab (Roche)	Injection	Dilute and administer by intravenous drip through an independent infusion tube that is not mixed with other medicines, in the ward with complete reanimation equipment, under the direct supervision of an experienced oncologist or hematologist
		Trastuzumab (Roche)	Injection	Intravenous administration. Intravenous injection or rapid intravenous injection not allowed
		Bevacizumab (Roche)	Aseptic solution for intravenous injection	Before infusion, dilute by health professionals with aseptic technique
		Sorafenib (Bayer)	Tablet	Take orally on an empty stomach or with low-fat or medium-fat food, swallow with a cup of warm water
		Bortezomib (Johnson & Johnson)	Injection	For intravenous administration only. Intrathecal injection can cause death
		Recombinant Human Endostatin (Shandong Simcere)	Injection	Intravenous drip at constant speed
		Nimotuzumab (Biotech Pharma)	Injection	Venous transfusion. The condition of the patient should be closely monitored
		Erlotinib (Roche)	Tablet: round,	Take orally under the instruction of a physician

			bi-convex, yellow coated tablet	with experience in the use of such drugs, at least one hour before a meal or two hours after a meal
		Apatinib (Hengrui Medicine)	Tablet	Take orally under the instruction of an experienced physician
		Chidamide (ChipScreen BioS)	Tablet: off-white tablet	Take orally under the instruction of an experienced physician. Blood routine should be regularly tested during medication (typically, once a week)
		Fulvestrant (AstraZeneca)	Injection, white powder	Intramuscular injection at a slow speed
		Abiraterone (Johnson & Johnson)	Tablet: oval tablets, recess on one side, AA250	Take orally
		Everolimus (Novartis)	Tablet, white or yellowish tablet	Take orally
		Lenalidomide (Celgene)	Capsule	Take orally. Start and provide therapeutic drugs under the supervision of physicians with experience in multiple myeloma treatment
		Lapatinib (GSK)	Yellow tablet	Take orally
	Rare diseases	Recombinant Human Coagulation Factor Ⅶa (Novo Nordisk)	Freeze-dried preparation	Intravenous injection. The whole preparation process of the injection should be completed in sterile conditions
		Recombinant Human Interferonβ-1b (Bayer)	White, massive, loose; colorless or yellowish clear	Subcutaneous injection and dosage titration, under the guidance of a physician with experience in the treatment of the

			liquid after dissolved in the accompanied solvent	disease
Chinese patent medicine	Tumour	Shenyi Capsule (Jilin Yatai)	Capsule	Take before a meal with an empty belly
		Astragalus polysaccharide injection (Tianjin Sainuo)	Injection	Intravenous drip. Skin test should be carried out prior to use. It is only suitable for patients with positive results
		Compound Realgar Natural Indigo Tablets (Yifan Pharmaceutical)	Veneer coated sugar tablet	Take orally
	Heart and cerebral vessels	Ginkgolide Injection (Chengdu Baiyu)	Injection	Intravenous drip. The infusion rate should be strictly controlled
		Diterpene Ginkgolides Meglumine Injection (Kanion Pharmaceutical)	Injection	Intravenous drip

Table Summary of Dosage Form and Administration Route of 17 Drugs Priced through Negotiations in 2018

Varieties	Name of drugs	Dosage form	Administration route
Anticancer drugs	Nilotinib (Novartis)	Regular oral dosage form, capsule	Take orally. Initial treatment should be directed by a physician with experience in treating CML patients and it should not be taken with food -- no food should be taken at least 2 hours before taking medicine and at least 1 hour after taking medicine
	Pazopanib (Novartis)	Regular oral dosage form, tablet	Take orally, not taken with food. Take medicine at least 1 hour before a meal or at least 2 hours after a meal
	Ceritinib (Novartis)	Regular oral dosage form, capsule	It is recommended to take medicine in medical institutions with experience and under the direction of specific professionals, and to carry out ALK gene evaluation, so as to obtain the fully confirmed ALK positive evaluation results
	Octreotide (Novartis)	Mincrosphere	Subcutaneous injection

		injection	
	Axitinib (Pfizer)	Regular oral dosage form, tablet	Take orally. The treatment with Axitinib should be performed by the physicians with oncotherapy experience. The dosage should be increased or decreased depending on individual differences in patients' safety and tolerability
	Crizotinib (Pfizer)	Regular oral dosage form, capsule	Take orally. It is recommended to take medicine in medical institutions with experience and under the direction of specific professionals. The ALK positive evaluation results confirmed by the fully verified testing method must be obtained before taking medicine
	Sunitinib (Pfizer)	Regular oral dosage form, capsule	Take orally with food or without food
	Osimertinib (AstraZeneca)	Oral sustained-release dosage form, beige film-coated tablets	Take orally with water and with the prescription provided by the physicians with rich experience in antineoplaston
	Regorafenib (Bayer)	Regular oral dosage form, tablet	Take orally
	Afatinib (Boehringer Ingelheim)	Oral sustained-release dosage form, dark blue and circular film-coated tablets, raised on both sides, with sloping edges	Take orally under the guidance of experienced physician. Mutation status of EGFR should be determined by a fully validated test method before starting treatment
	Pegaspargase (Jiangsu Hengrui)	Injection	Intramuscular injection; intravenous drip
	Vemurafenib (Roche)	Regular oral dosage form, tablet	Take orally
	Cetuximab (Merck)	Injection	Intravenous drip. Preventive medication of antihistamines and corticosteroids should be carried out

			before first use. The patient's condition should be closely monitored during medication and within 1 hour after medication, and the reanimation equipment must be provided
	Ixazomib (Takeda)	Regular oral dosage form, capsule	Take orally
	Ibrutinib (Xi'an Janssen)	Regular oral dosage form, capsule	Take orally
	Azacitidine (Celgene)	Injection	Intravenous injection or intravenous drip
	Anlotinib (Chia-tai Tianqing)	Regular oral dosage form, capsule	Take orally under the instruction of physicians with experience in the use of antineoplastic drugs

(3) Implementation method of "dual-channel" for specific varieties

Five main bodies are involved in the implementation of dual channel, including medical insurance departments, medical institutions, designated pharmacies, circulation enterprises and patients. The following several points shall be ensured in order to ensure the smooth implementation of dual channel of drugs priced through negotiations:

① The qualification of designated pharmacies shall be specified

For implementation of the dual channel, it is necessary to select the designated pharmacies in the first place, to ensure the supply and the use safety of drugs priced through negotiations. Compared with generic drugs, the drugs priced through negotiations have higher requirements for storage management, prescription audit and professional services. Therefore, in order to ensure the supply of drugs priced through negotiations, designated pharmacies shall be provided with appropriate facilities and equipment, pharmaceutical service personnel and information system.

A. Requirements for operation qualification. The designated pharmacies shall be the designated retail pharmacies of the social medical insurance, strictly implement the social medical insurance policies and has not been subjected to the disposal by the food and drug supervision, industrial and commercial administration, human

resources and social security departments within three years before the date of application (including matters which are under investigation and have not been concluded); the chain store headquarters to which the social pharmacies selling the drugs priced through negotiations are affiliated to shall obtain the *Certificate of Quality Management Practices for Pharmaceutical Trading*, with a registered capital of more than RMB5 million.

B. Requirements for facilities and equipment. The designated pharmacies shall have an independent place for operating the purchased drugs priced through negotiations and its own drug distribution center, so as to deploy the drugs priced through negotiations in the prescribed range within two hours. The chain store headquarters shall have the storage and use area and equipment that conform to the cold chain requirements, and have the perfect cold chain quality management system. The software and hardware conditions for access to the medical insurance information system shall be met, the normal operation of the medical insurance information system shall be ensured, and the "purchase-sale-stock" situation of the stipulated drugs can be correctly reflected. The inspection and accept of pharmacies shall be carried out by the manufacturing enterprises of drugs priced through negotiations, requiring that the storage temperature of pharmacies not exceed 20℃, and the operation process of drugs not exceed 15 minutes. The transport vehicles and drivers shall also be recorded. The arrival temperature and quantity of drugs delivered to the pharmacies shall be checked. Drugs shall be stored in the medical refrigerators equipped with 24-hour temperature and humidity monitor, and the storage temperature shall be controlled in the equilibrium temperature range of biological agents from 2℃ to 8℃. The pharmacies shall also be provided with short-message alarm. Medical refrigerators shall be equipped with standby batteries, so that the power demand of 4 refrigerators for at least 3 hours can be guaranteed and power failure can be prevented. In addition, the chain store headquarters of designated pharmacies shall have not less than two refrigerated trucks for cold-chain transportation to ensure the supply of drugs.

C. Requirements for pharmaceutical service personnel. At least one licensed

pharmacist shall be on duty in the business place of designated pharmacies to provide pharmaceutical services. Prior to the preparation of drugs priced through negotiations, patients' qualifications and proof materials shall be reviewed, and professional medication guidance shall be provided by designated pharmacies. The patients shall be registered and visited at least once a month to focus on their medication and adverse reactions at any time. In addition, professional managers shall be arranged by designated pharmacies to inspect the storage and delivery of drugs priced through negotiations and to manage the warehouse, so as to ensure the safety of the drugs priced through negotiations.

② Straightening out the dual-channel flow

The flow for patients to purchase the drugs at the determined designated pharmacies is as shown in figure 29:

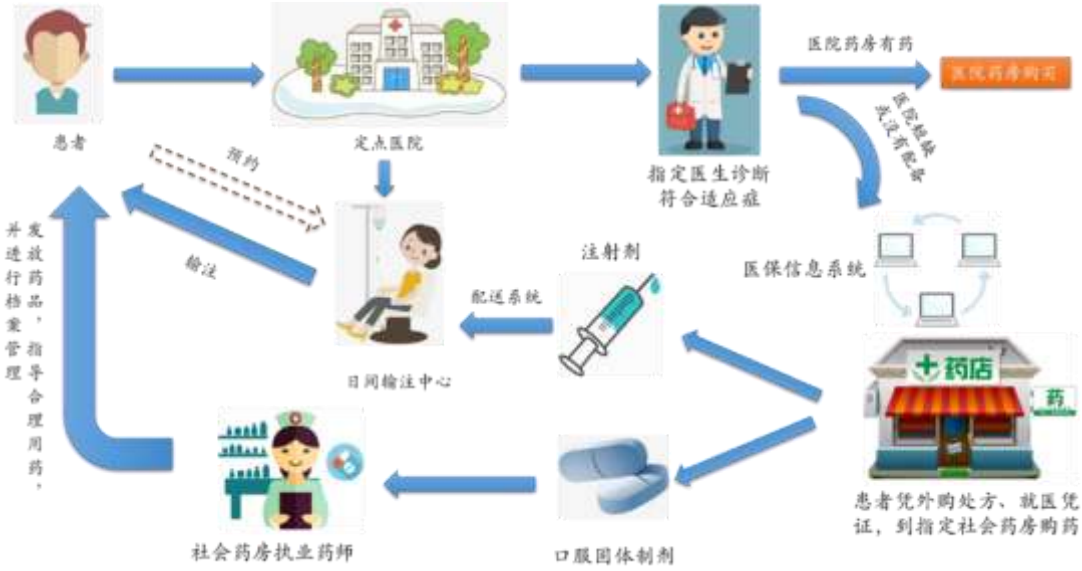


Figure 29. Flow of Patients' Access to Drugs Priced through Negotiations

A. The patient obtains the purchasing qualification at the designated hospital. Firstly, the patient seeks treatment at the designated hospital according to the provisions and is diagnosed by the qualified designated physician. After diagnosing that the patient has the indications of the drugs priced through negotiations, the physician provides the prescription to buy drugs outside the hospital, and determine the dosage of the prescription under the premise of meeting the diagnosis and treatment specifications and the medical necessity of the patient.

B. The physician provides the prescription to buy drugs outside the hospital. The designated hospital in which the patient seeks treatment uploads the prescription to the pharmacy department of the hospital according to the requirements, for the pharmacy department to examine the prescription for the first time. After review, the pharmacy department uploads the prescription to the medical insurance information system established by the medical insurance department, the hospital and the social pharmacy, and the prescription will be reviewed by the medical insurance information system platform again.

C. The patient buys the drugs at the designated pharmacy. After checking the prescription again, the medical insurance information system sends a short message to inform the patients of dispensary, amount of drugs and code of drugs. The patient pays the drug fee and obtains the drugs at the designated pharmacy within the validity period of the prescription (e.g. within 3 days) by drug code, medical certificate and ID card.

D. Release or distribution of drugs. The oral solid preparations purchased by patients do not need to be taken in the hospitals, the hospitals can directly distribute them to the patients and register the patients through professional licensed pharmacists, so as to facilitate the follow-up of patients and provide the guidance of reasonable drug use to the patients. The injections or drugs purchased by patients that must be taken in the hospitals shall be delivered to the hospitals. The designated pharmacies distribute drugs to the designated hospitals through the distribution system, which will send short messages to the patients (including distribution hospitals, expected arrival time and drug code), allowing patients to pay close attention to the status of drug distribution in real time.

E. Patients make an appointment for infusion. After purchasing drugs in the designated pharmacies, patients can make an appointment for infusion at the day infusion center of designated hospitals, and upload the infusion time and drug distribution code to the infusion center appointment system.

F. Patients get injected at the day infusion center of designated hospitals. Patients handle the infusion procedures at the hospital infusion center at the

appointed time to receive the infusion treatment.

③ Standardizing the overal planning reimbursement

Patients will encounter the reimbursement problem of drugs priced through negotiations during procurement and use, which is mainly composed of two ways: direct reimbursement at pharmacies and reimbursement at hospitals.

The reimbursement ways shall depend on different situations in the process of actual reimbursement. If, during hospitalization, there is a shortage of the drugs priced through negotiations in the hospitals or the hospitals do not provide the drugs priced through negotiations, the eligible insured personnel may purchase the drugs at the approved designated pharmacies by the "prescription to buy drugs outside" provided by the designated physician of the designated hospitals. The drug expenses incurred by inpatients in purchasing the drugs priced through negotiations shall be paid in full by the inpatients first, and then reimbursed at the designated medical institutions with the invoice of purchased drugs (on the day of purchasing drugs or the next day), and the expenses of the purchased drugs (excluding the self-payment portion) shall be included in the medical expenses covered by the current hospitalization policies, and the designated medical institutions shall apply to the social security administration department for settlement of the expenses.

The eligible insured personnel may apply for the treatment of outpatient special diseases and outpatient chronic diseases. If it is clear that the use of "outsourced drugs priced through negotiations" is necessary, the treatment cycle shall be calculated from the month on which the approval is obtained (calculate according to the treatment cycle determined in the treatment specification, including the month on which the approval is obtained). In the outpatient treatment cycle, the insured shall purchase drugs at the “designated pharmacies” within 3 days with the “prescription of outsourced drugs” (once a month or every treatment course) provided by the physician of the local designated medical institution, and shall only assume the self-payment portion. At the end of each treatment cycle, the insured who need to sequentially use the "outsourced drugs priced through negotiations" according to the diagnosis shall continue to comply with this provision.

④ Removing obstacles of prescription outflow

On February 9, 2017, the General Office of the State Council issued the *Opinions of the General Office of the State Council on Further Reform and Improvement of Drug Production*, *Circulation and Use Policies*. In order to implement these opinions, relevant policies have been introduced by more than 20 provinces and cities to improve the quality and therapeutic effects of drugs, standardize the circulation and use of drugs, and require medical institutions to prescribe drugs according to the generic names and actively provide the prescriptions, thus allowing patients to purchase drugs in medical institutions or retail pharmacies on their own. Outpatients shall not be restricted by medical institutions from purchasing drugs in retail pharmacies with prescription.

The prescription outflow is aimed to "break down the mechanism of covering hospital expenses with drug revenue", let hospitals return to the essence of medical treatment and weaken the "exclusivity" of prescriptions. In practice, the outflow of prescriptions is faced with a series of obstacles, including source of prescriptions, overal planning of medical insurance, use management and other factors.

A prescription information sharing platform is expected to be established jointly by hospitals, medical insurance departments and designated pharmacies to realize the outflow of hospital prescriptions. On the one hand, patients can purchase the drugs priced through negotiations in pharmacies, which can increase the accessibility of drugs priced through negotiations to patients and improve the operating revenue of social pharmacies; on the other hand, it means that hospitals and physicians waive the exclusive right of prescriptions, thus affecting the enthusiasm of hospital physicians. The interests of physicians shall also be taken into account in the process of prescription outflow, so it is necessary to formulate appropriate policies to establish a reasonable salary for physicians, so as to ensure that the labour reward of physicians won’t be affected by outflow of prescriptions.

Physicians may be reluctant to outflow the prescriptions if they fail to benefit them. Therefore, the service expense of a certain amount shall be provided for each outflow of prescription to compensate the physicians, and the expenses shall be

borne by the social pharmacy. The remuneration paid to physicians due to outflow of prescriptions reflects the value of physicians' labor service and improves the enthusiasm of physicians in making the external prescriptions.

⑤ Improving the ability of infusion and other supporting services

Among the 53 drugs successfully priced through negotiations in 2017 and 2018, injection accounted for 42%. However, the outpatient infusion services are being phased out in various regions, and patients who buy drugs in designated pharmacies are in urgent need of regular infusion channels.

All parts of the country are also exploring the establishment of designated pharmacies for special drugs. In May 2016, the first day ward infusion center in China was put into service in Nantong Tumor Hospital under the joint promotion of Nantong Tumor Hospital, Roche Group and Sinopharm Holdings Nantong Limited. Nantong Tumor Hospital integrated the resources of Sinopharm Holdings Nantong Limited and the infusion center of the hospital was linked with the designated pharmacies, allowing patients to get injected with the special drugs purchased at the designated pharmacies, without the need for going through the hospitalization procedures. The infusion center was provided with professional medical care personnel and equipment to ensure the safety of preparation and use of special drugs.

Therefore, through summarization and consultation of the implementation methods of drugs through negotiations at designated pharmacies in different regions, the infusion centers are recommended with the following three modes: establishing infusion centers at designated pharmacies, completing infusion near designated pharmacies, and establishing infusion centers under the cooperation between designated pharmacies and hospitals. For the establishment of these three infusion modes, the following issues shall be considered: it is necessary to provide professional physicians and pharmacists as well as sterile operation room for infusion and dosing to set up the infusion centers at designated pharmacies; as for infusion near the designated pharmacies, the transportation risks of drugs will be increased, especially some drugs requiring full-process cold chain; the establishment of infusion

centers under the cooperation between designated pharmacies and hospitals will lead to the sharing of responsibilities between designated pharmacies and hospitals, so the sharing of responsibilities and risks shall be properly handled. Patients can choose the above 3 infusion modes after purchasing injection drugs at designated pharmacies with the outsourcing prescription and appointing infusion at medical institutions that make the prescription.

For settlement of infusion expenses, it is necessary to establish the charging standards to separate infusion and payment. When patients pay for drugs at designated pharmacies, the infusion costs shall be settled simultaneously by the designated pharmacies and the infusion center. Patients only need to get infusion directly at the infusion center, which can minimize the handling of infusion cost payment procedures.

The infusion centers shall be provided by designated pharmacies for drugs priced through negotiations, from which the accessibility of drugs priced through negotiations to patients can be improved, the safety of drug use can be increased, hospitalization expenses can be saved, the expenditure of medical insurance funds can be reduced, and the utilization efficiency of medical insurance funds can be enhanced. By providing infusion services, the revenue for related cooperative hospitals and the enthusiasm of their medical staff can also be increased.

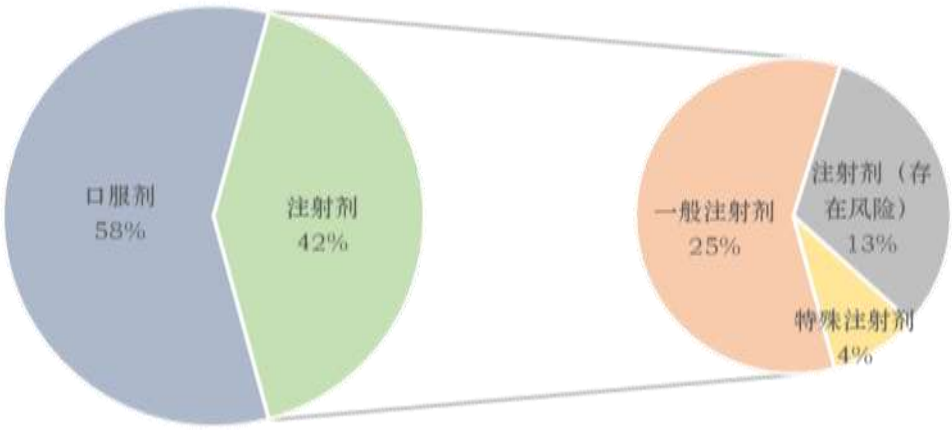


Figure 30. Distribution of Dosage Form of 36+17 Drugs Priced through Negotiations

For a total of 53 varieties priced through negotiations in 2017 and 2018, some drugs can be purchased out of hospital and taken orally at home; some varieties can

be purchased out of hospital or injected out of hospital (general day infusion center), or be purchased out of hospital or injected out of hospital (grade III day infusion center); some varieties can only be injected by experienced and qualified physicians that understand the disease (consult with patients on whether to purchase the drugs out of hospital). Details are as follows:

① For most oral drugs (white shading), outpatients (except for inpatients) can obtain the drugs out of hospital according to physicians' prescription and advice, and get reexamination at any time. For patients with complex diseases, the register system shall be established or the online medication services shall be opened, allowing physicians to monitor and manage the diagnosis, treatment and medication of patients in real time.

② Intravenous or intramuscular drip of injections shall be accompanied and supervised by physicians. For injections (grey shading) with mild adverse reactions, general illness and easy operation, patients can obtain the drugs out of hospital according to physicians' prescription and advice, and get infusion at the day infusion centers, primary medical institutions or community clinics near their residence. Nursing staff or physicians shall observe the patients' condition at any time after injection, and report any unexpected event to the on-site physicians at the first time, allowing physicians to deal with the emergency or send the patients to the nearby hospital.

③ For injections with serious adverse reactions, urgent conditions and easy operation (green shading), patients can obtain the drugs out of hospital according to physicians' prescription and advice, but they shall get injected at the day infusion center in the hospital where they seek medical treatment or the day infusion center of the higher-level hospital near their residence, and shall be provided with emergency equipment such as breathing machine, cardiaopulmonary resuscitation and drugs, as well as experienced clinicists with high level of diagnosis and treatment, so as to observe patients at any time.

④ For Ranibizumab, Conbercept and other special drugs (red shading) requiring intravitreal injection, it is required to be get injected under the supervision

of ophthalmologists at the qualified hospitals and under sterile conditions; Therefore, the implementation of the "dual-channel" initiative will face great difficulties. As a result, they shall be get injected by qualified and experienced physicians in hospitals (appropriate medication service fees shall be charged) in order to maximize the efficacy of medication and ensure patients' safety; if, after full consultation with patients, patients express their understanding and consent, they can also purchase drugs at designated pharmacies out of hospital and get injected by the qualified and experienced physicians at the designated hospitals, and the separation mode shall be adopted.

Table 26. Feasibility Analysis of "Dual-channel" Measures for Drugs Priced through Negotiations

Form	Features of drug use	Specific drugs			
Purchasing at designated pharmcies	·Take orally, no need for injection ·The licensed pharmacists of pharmacies shall provide the education services of drug use requirements, adverse reactions and precautions for patients	Ticagrelor	Lanthanum carbonate	Sorafenib	Compound Realgar Natural Indigo Tablets
		Pazopanib	Sevelamer	Erlotinib	Nilotinib
		Posaconazole	Quetiapine	Apatinib	Allisartan Isoproxil
		Tolvaptan	Paroxetine	Chidamide	Ceritinib
		Abiraterone	Shenyi Capsule	Regorafenib	Axitinib
		Everolimus	Ixazomib	Afatinib	Crizotinib
		Lenalidomide	Ibrutinib	Vemurafenib	Sunitinib
		Iapatinib	Anlotinib	Osimertinib	
Designated pharmcies + general daytime infusion center	·Injections with less risk of use ·Medical staff shall observe the patient's physical condition at any time	Liraglutide	Bortezomib	Fulvestrant	Recombinant Human Brain Natriuretic Peptide
		Octreotide	Pegaspargase	Astragalus polysaccharide injection	Diterpene Ginkgolides Meglumine Injection
		Azacitidine		Ginkgolide Injection	Recombinant Human Endostatin
				Morinidazole and Sodium Chloride	Recombinant Human Interferonβ-1b
Designated pharmcies +	·Injections with high risk of	Cetuximab	Trastuzumab	Recombinant Human	Recombinant Human Coagulation Factor

special daytime infusion center	injection ·Professional pharmacists and nurses shall be available to understand the patient's condition sufficiently and handle the emergencies			Prourokinase	Ⅶa
		Nimotuzumab	Bevacizumab	Rituximab	
Purchase the drugs and get injected in the hospital	·Injections with special operation requirements. The qualified and experienced physicians with professional background shall be available	Ranibizumab	Conbercept		

The following shall be ensured in the process of obtaining drugs out of hospital:

① The designated medical insurance pharmacies shall have an appropriate number of licensed pharmacists. The sale of special drugs -- high-end professional prescription drug -- is different from that of OTC drugs and general prescription drugs. The relatively complex and demanding diagnosis of drug use requires the clear diagnosis by physicians and the evidence by relevant examination data, and sometimes the conclusion of gene detection; for patients' drug use, the physiological indicators of various diseases shall be definite, distinct and specific. Therefore, licensed pharmacists shall not only have general pharmacy knowledge and skills, but also shall master sufficient specific professional information about drugs, including information on treatment of diseases, drugs themselves, competitive products, therapeutic scheme and development; only in this way can the prescription of drugs be reviewed professionally and reasonably, and correct dispensing services and medication guidance can be provided to patients. Generally speaking, the professional management of DTC pharmacies requires the pharmacies to introduce the service support of clinical pharmacy, which can be realized by inviting clinical

pharmacy experts from large general hospitals or specialized hospitals to provide diagnosis and treatment regularly, or train licensed pharmacists and other pharmacy service personnel in pharmacies and impart the latest clinical pharmacy knowledge of related special diseases, so as to serve patients more professionally.

② When reviewing prescriptions, licensed pharmacists in pharmacies shall not only check the prescriptions provided by patients repeatedly, but also pay special attention to whether the hospitals and physicians are those designated hospitals and physicians specified in the policy documents; if not, the cost of patients' drugs may not be reimbursed; special attention shall be paid to No. 54 Document issued by MOHRSS in 2017 and the relevant detailed "restrictive provisions" in the policies of specific provinces or co-ordinated regions. In addition, the original prescription shall be kept for more than 3 years (typically 5 years, stipulated in the DTP pharmacy management requirements), and it is better to keep both electronic and paper versions for verification by relevant departments and, in particular, audit by some special drug enterprises. Of course, attention shall be paid to the login of prescriptions, login audit, prescription information privacy management, use information management of prescriptions and refined compliance management of other links.

③ Open up the information systems of hospitals and designated pharmacies, to connect prescriptions with phycisians' advice. Pharmacists of the pharmacies are expected to understand patients' basic information, disease development, medication precautions and reimbursement access qualification and etc.; and connect the designated pharmacy information system with the medical insurance reimbursement system: define the reimbursement ratio of patients, reimbursement limit, self-payment ratio and etc.

(4) Analysis of specific implementation risks of "dual-channel"

1 Precautions for taking oral drugs

Compared with injections, taking medicine orally is less risky, but patients' medication environment, requirements and conditions are different depending on varieties and indications. For example, ALK positive evaluation results confirmed

through fully verified testing methods shall be obtained before taking Crizotinib of Pfizer. If patients purchase the drugs blindly, and physicians fail to carry out the gene inspection or take it for granted to make decisions, it may lead to ineffective medication, delay the best treatment period and miss the best treatment methods, thus affecting the recovery and life safety of patients. In addition, Lanthanum Carbonate of Shire shall be swallowed after complete chewing, and be taken with a meal or immediately after a meal. Sorafenib of Bayer shall be taken on an empty stomach or taken with low-fat or medium-fat food. Patients can purchase drugs out of hospital with the prescription provided by physicians. If pharmacist do not have sufficient qualification, experience and level, and cannot provide correct pharmaceutical services and medication reminders, or fail to explain the precautions and requirements for taking medicine to the patients, resulting in patients not taking medicine according to the instructions, it will affect the therapeutic effect of drugs to a certain extent, reduce patients' compliance, cannot maximize the treatment benefits of drugs, delay the recovery time of patients and even delay the course of disease.

Table 27. Classification of Medication Precautions for 36+17 Oral Drugs Priced through Negotiations

Classification	Specific precautions
Provisions on time for taking medicine	1 hour before a meal/2 hours after a meal
	On an empty stomach/with low-fat and medium-fat food
	With a meal
	Before a meal
	After a meal
	Before/after a meal
	Not to be taken with food
Provisions on form for taking medicine	Fully chew and then swallow
	Swallow completely, without crushing, chewing or breaking into pieces
Provisions on auxiliary conditions	Warm water
Provisions on prescription physician	Under the guidance of experienced physician
Special provinces	Test the blood routine regularly
	Confirm the clear gene detection results before taking medicine

	Adjust the medication according to patients' safety/tolerance timely

2 Improving the standard of preservation and preparation of injection

Generally, injections require lyophilized agents or small-dose packaging, which require preparation by specific injection agencies before infusion. In this process, pharmacies are vulnerable to storage risks for lyophilizing agents or small-dose original products, and many varieties require aseptic operation in the preparation process of injections, which is also prone to risks. In either case, injections dripped into the human body may be contaminated, resulting in unnecessary casualties and adverse reactions. For example, the aseptic conditions shall be ensured for the preparation of Roche's Bevacizumab and Novo Nordisk's Recombinant Human Coagulation Factor VIIa.

Therefore, pharmacies shall be provided with refrigeration equipment for cold storage of some varieties requiring cold chain management, and constant track and monitoring of storage room temperature, so as to ensure cold chain in the whole process. For day infusion centers of some hospitals and primary medical institutions, the hardware standard of drug preparation room shall be enhanced, with aseptic operation table and increased software standard, and the operation training shall be provided to the preparation personnel so as to meet the aseptic preparation requirements of special varieties.

3 Improving the medical knowledge level of injection nurses

The injection requirements of some injections are rather tedious, as follows:

(1) Different injection methods correspond to different time periods. For example, the Recombinant Human Brain Natriuretic Peptide of Tibet Pharmaceutical shall be injected through intravenous infusion at the loading dosage, followed by intravenous drip at the maintenance dosage; it is emphasized that intrathecal injection of Bortezomib of Johnson & Johnson will result in death;

(2) Different time periods correspond to different dripping speed. For example, the Recombinant Human Prourokinase of Tasly shall be injected by 50 mg at a time: dissolve 20 mg in 10 ml saline, complete intravenous infusion within 3 minutes,

dissolve the remaining 30 mg in 90 mL saline and complete intravenous drip within 30 minutes; Trastuzumab of Roche shall be injected through non-intravenous injection or rapid intravenous injection;

(3) Liraglutide of Novo Nordisk and other drugs with special requirements for injection sites shall be administered by subcutaneous injection at abdomen, thighs or upper arms, and intravenous or intramuscular injection is not allowed;

(4) Rituximab of Roche and other drugs requiring independent injection equipment shall be diluted and administered by intravenous drip with independent infusion tube that does not mix with other drugs;

(5) Some drugs are required to meet the injection conditions according to the results of allergic test, for example, Astragalus Polysaccharide Injection of Tianjin Sainuo shall only be suitable for the patients with negative skin test results; Merck's Cetuximab also requires allergy test to be carried out prior to use, as some infusion reactions occur at the subsequent medication phase.

Drugs priced through negotiations are mostly aimed at diseases with high risk and complicated course, and the condition of most patients is both complex and serious, so if injection nurses and local physicians do not understand enough about the infusion precautions of related drugs, and fail to carry out allergy test, use independent syringes, control the infusion rate and use incorrect injection mode or injection site, which may can lead to very serious allergic reactions and even casualties. As a result, nurses and physicians at the day infusion centers are expected to improve their medical knowledge level, carefully read and study the instructions and research literature of related drugs to ensure the safety and effectiveness of drug use.

4 Improving the first aid ability level of injection center

Although some drugs can save lives and alleviate patients' pain, they also indeed have uncertain side effects or adverse reactions, or produce different medication effects because of the different tolerance capacity of different patients. For example, Rituximab of Roche shall be injected in wards with complete resuscitation equipment; it is necessary to closely monitor the condition of patients injected with

Nimotuzumab manufactured by Biotech Pharma. These are special provisions suitable for adverse drug reactions or exceptional events for special patient groups. Therefore, the institutions responsible for infusion of such drugs shall be provided with first-aid devices and resources including cardiopulmonary resuscitation equipment, and with first-aid personnel to ensure the smooth and effective implementation of emergency prevention and treatment measures, and to protect the patients' life safety and health rights and interests to the greatest extent.

IV. ”Increasing Income” of Medical Insurance Fund

For unsatisfactory balance of the medical insurance fund, the sources of funds can be expanded through differentiated financing and dynamic adjustment of medical insurance financing, so as to increase the income of the funds.

(1) Differentiated financing

The differentiated financing is based on the combination of medical insurance for urban workers, medical insurance for urban residents and new rural cooperative medical system, and is divided into package A and package B on this basis. Package A is the current basic medical insurance level and financing level. Package B is divided into several levels, to cover the scope of reimbursed drugs at different levels with different levels of financing standards, meet the medical insurance needs of different groups of people, and achieve the differentiated financing, in a bid to achieve the goal of increasing income of the medical insurance funds.

Table 28. Financing and Reimbursement System at All Levels

Packages		Scope of reimbursed drugs	Features	Financing level
Package A		Drugs in the medical insurance list	Maintain the current security level	Maintain the status quo
Package B	Level B1	Expand reimbursement scope of drugs for patients with heavy economic burden on the basis of A	Exchange higher funding standards for greater coverage	Higher than the level of package A
	Level B2	Expand reimbursement scope of drugs for patients with heavy economic burden on the basis of level B1		Higher than level B1
	Level B3	Expand reimbursement scope of drugs for		Higher than level B2

		patients with heavy economic burden on the basis of level B2		

(2) Dynamic adjustment of health insurance financing

On January 12, 2016, the *Opinions of the State Council on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents* (No. 3 [2016] of the State Council) (hereinafter referred to as the "Opinion") was released, requesting the integration of urban residents' medical insurance and new rural cooperative medical system, and the establishment of a unified basic medical insurance system for urban and rural residents. The core problem encountered during the integration of urban and rural health insurance lies in the raising of funds. The stable and sustainable development of medical insurance system will be affected by the lack of institutionalized and standardized financing adjustment mechanism and short-term and random adjustment of health insurance financing.

The dynamic adjustment mechanism of medical insurance financing shall be based on the principles of stability, sustainability and actuarial balance, and specialized agencies shall be set up to determine the financing standards. Regular assessment of population structure, disease spectrum and variation in medical demand behavior shall be carried out, and daily supervision of security effectiveness and fund risk shall be performed to dynamically adjust the financing standards on this basis, so as to minimize the randomness of financing standards. The mechanism shall be dynamically adjusted through medical insurance financing, to practically ensure that the adjustment is scientific and that the medical insurance fund is sustainable[32].

32 Li Yaqing. Establishment of Dynamic Adjustment Mechanism for Financing of the Basic Medical Insurance for Urban and Rural Residents[J]. Journal of Northwest AF University (Social Science Edition), 2018(5).

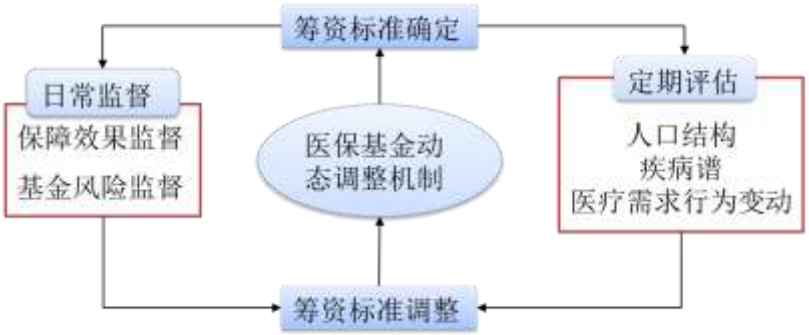


Figure 31. Dynamic Adjustment Mechanism of Medical Insurance Financing

(3) Expand the sources of funds

The sources for raising funds shall be expanded while strengthening the payment of expenses by governments, units and individuals. The following sources may be feasible: (1) Financial and tax support. Part of tobacco and alcohol tax and environmental tax can be used to supplement the medical insurance fund yearly. (2) Adjustment for the structure of fiscal expenditure. A certain proportion of increased amount of annual fiscal revenue can be used to establish the fund similar to that of the national social insurance fund council and establish the basic medical insurance risk reserve fund. (3) Land revenue and income. Part of the compensation revenue and income from land expropriation or transfer can be taken as an important source of funds for the new rural cooperative medical system (medical insurance for urban and rural residents). (4) Issuance of long-term medical security bonds. The central government can input part of large-scale funds originally for economic construction into the social security, so as to deal with the risk of payment of population aging. (5) The commercial state-owned assets and their revenue, and part of the profit bonus of state-owned enterprises can be transferred to the medical insurance fund[33].

V. "Reducing Expenditure" of Medical Insurance Fund

The New England Healthcare Institute (NEHI) once expressed that the medical waste was a kind of medical expense that would not decrease the medical quality even if it was cut. According to People's Daily, medical institutions in our state wasted 20% to 30% of medical resources due to excessive prescription and excessive

33 Tan Zhonghe. Reflections on Improving the Financing Mechanism of Employees' Medical Insurance[J]. China Health Insurance, 2016(5): 13-17.

examination etc., and the proportion of medical insurance fund waste and loss reached as high as 50% caused by drug rebate, artificially high price of drugs and arbitrary charge， etc. According to the statistics in the analysis of Ye Jingyun relating to the medical service utilization of the insured in the national disease medical insurance (2013), the number of cases subjected to repeated examination among the unreasonable examination was as high as 21.1%.

(1) Solve problems of fund waste and low utilization rate

The medication guideline and clinical pathway should be followed to minimize the medical wastes. The report showed that significant benefits were obtained by complying with the standardized treatment guideline -- improve 50% of the medical service quality and save 70% of the medical resource cost[34,35].

The reform of medical insurance payment should be improved and the allocation of medical resources should be optimized, which can be divided into three stages: the total budget management should be implemented at the first stage based on the budget management of the medical insurance fund, but the gradual adjustment from the relatively extensive direct division method to the point method should be made. The diversified factors should be taken into consideration to establish the reasonable indicators and formulas for measuring the total expenses; the system of social co-governance in the pharmaceutical industry should be established, and the consultation and decision-making mechanism considering the interests of all parties should be set up under the legal framework; the multiple payment system should also be gradually built. Secondly, the classification and weight of disease categories should be constantly optimized and adjusted during implementation of the point method in the second stage, to create conditions for progressive implementation of DRGs. Finally, the multi-component medical insurance payment mode should be fully implemented, which should mainly focus the payment based on disease categories and develop into an elaborative payment and

34 WHO: Pharmaceuticals and Health Sector Reform in the Americas: An Economics Perspective, 1998.

35 Ford, Earl S., et al. Explaining the Decrease in US Deaths from Coronary Disease, 1980-2000. New England Journal of Medicine, 2007, 356(23): 2388-2398.

management mode.

(2) Enhance the ani-risk capability of medical insurance fund

1 Perfect the welfare system for the elderly and spread the medical risks

According to foreign experiences, the effective way to relieve the pressure of medical expenses is to establish the elderly medical system and the care insurance system, to share part of the nursing and rehabilitation costs by the care insurance or the elderly welfare funds. The elderly care insurance is not available in China yet, and the commercial elderly care insurance is also scarce, so the elderly care and rehabilitation are mainly borne by the medical insurance fund, in particular, the medical expenses of retired veterans can be completely reimbursed, and some of them are subjected to counterfeit hospitalization for most of the year, bringing a great pressure on the medical insurance fund. Meanwhile, the medical insurance premium rate (8%) in China is relatively low, and the medical insurance premium rate in Germany (entering a super-elderly society) is 14.9% and in Japan is 8.2%. The balance of income and expenditure of medical insurance funds has met severe challenges, so the increase of expenses caused by population aging should not be dealt with by the medical insurance funds[36]. Therefore, the state is expected to speed up the building of care insurance system and elderly welfare system.

2 Change the concept of medical security system

Convert the “negative medical insurance concept of treating diseases when they occur” into the “positive health insurance concept of disease prevention”, and finally realize the ultimate goal of "health for all, die without any illness", which is of critical importance for reducing the pressure of medical insurance payment and improving the anti-risk capability of medical insurance fund from the source. For this purpose, the government should incorporate both prevention and health care as important medical insurance contents, and increase the investment and publicity in prevention and health care. In the meantime, the role of personal accounts should

36 Yang Yansui, Yu Miao. Analysis of Impact of Population Aging on Medical Insurance Funds[J]. China Health Insurance, 2014(10): 12-15.

be effectively gave into fully play, and should be extended to prevention and health care in the existing medical consumption field. The scope of application of personal medical account should be specified, and its use functions should be gradually expanded to physical examination, immunization and other health care services.

(3) Improve the dynamic withdrawal mechanism, “vacating the cage to change birds”

According to incomplete statistics, the medical insurance reimbursement amount of special drugs in W city totaled RMB150 million from 2013 to the first half of 2018, while the purchase amount of monosialotetera-hexosyl ganglioside (monosialotetera-hexosyl ganglioside is an adjuvant drug for the treatment of cerebral ischemia, ischemia of spinal cord and hemorrhagic diseases after central nervous system injury) reached RMB650 million in S province in 2016. As a result, it can be inferred that it is feasible to withdraw drugs with large occupation proportion of medical insurance funds and low clinical value from the medical insurance list and provide space for drugs with high clinical demand and value.

In order to achieve the goal of "vacating the cage to change birds", it is necessary to increase the monitoring efforts of the use of medical insurance funds and strengthen the evaluation of the use of funds, continuously optimize the medical insurance list and payment standard through summary and analysis of the "medical insurance data" and the data of "comprehensive evaluation of clinical drug use", dynamically withdraw the varieties in the list and adjust the payment standards, so as to eliminate the waste of funds.

1 Strengthen information construction, perfect data evaluation and analysis

Drug procurement data system, medical insurance information system and hospital prescription system should be unified, so as to integrate the data, combine the procurement information, use and reimbursement of drugs into a complete chain, and fully analyze the drug varieties through drug dosage, prescription rationality and occupancy of medical insurance fund.

Firstly, the drug procurement system should be effectively connected with the hospital drug use information system to carry out the prior control of the medical

insurance funds. Taking Jiangsu Province as an example, the interview and investigation showed that the pharmaceutical administration department of Jiangsu Province had commenced the pilot work of connecting the drug procurement system with the in-hospital prescription system, which was expected to be applied in all tertiary hospitals by the end of 2018 and achieve the complete coverage in 2019, in a bid to discover the out-of-standard procurement and fund wastes and control the risks through summarization of procurement information and prescription information.

Secondly, the hospital internal intelligent prescription review system should be improved, and the data-based prescription comment system should be implemented. Currently, most hospitals are unable to meet the requirements of timely and comprehensive monitoring and analysis, affected by the large amount of daily prescription information, complexity of clinical medication, inefficiency of artificial prescription comment, limited coverage, weak sampling randomness and insufficient representation. The intelligent hospital prescription comment system based on business intelligence technologies will play a positive role in enhancing the efficiency and effect of hospital prescription comment and dynamic monitoring of medication[37]. The intelligent prescription review systems of Chinese PLA General Hospital, the Second Affiliated Hospital of Nanchang University and Qingdao Municipal Hospital are all typical and worthy of reference. As an important part of hospital information system, the intelligent prescription review system is closely related to other application systems of the hospital and need to be connected with HIS and other systems to share data. Furthermore, the intelligent prescription review system is a part of clinical information, and cannot exist independently from the framework of hospital information system. In order to meet the requirements of hospital information management, the intelligent prescription review system must be integrated with the existing hospital information system to achieve seamless

37 Xu Mengdan, Chen Wenge. Design and Application of Hospital Prescription Comment and Dynamic Medication Monitoring System Architecture based on Business Intelligence Technologies[J]. Journal of Medical Informatics, 2014, 35(5): 33-37.

connection. The medical insurance department should link with the hospital's intelligent prescription review system to realize data sharing and real-time monitoring and ensure the utilization efficiency of medical insurance funds, focusing on drugs with high price, large dosage, non-conforming prescription comment and serious abuse.

Finally, the occupancy of medical insurance funds should be analyzed by combining with procurement information, prescription monitoring and comment results. The physicians and enterprises concerned should be inquired and warned of the varieties that occupy a large proportion of medical insurance funds, and varieties that have unsatisfactory prescription comment results and are not clinically necessary on the basis of procurement information. For physicians and enterprises who still fail to meet the requirements after the inquiry, the following medical insurance withdrawal mechanism should be applied to instruct relevant drug varieties to be removed from the medical insurance list, so as to maximize and optimize the benefit output from the limited medical insurance fund resources.

2 Improve the dynamic withdrawal mechanism of medical insurance list

The physicians and enterprises concerned should be inquired and warned of the varieties that occupy a large proportion of medical insurance funds, and varieties that have unsatisfactory prescription comment results and are not clinically necessary on the basis of the above-mentioned data monitoring results. For physicians and enterprises who still fail to meet the requirements after the inquiry, the evaluation process in the drug re-evaluation system should be applied to evaluate the withdrawal from the medical insurance list. The physicians and enterprises should be notified of the varieties that should be removed from the medical insurance list after evaluation and should be dynamically withdrawn from the list.

In Korea, a large-scale special evaluation of the drug list was carried out from 2006 to 2011, aiming at establishing a model of drug withdrawal mechanism, namely, the drugs without clinical and economic value according to the comprehensive evaluation results should be deleted from the list. Unlike many other countries, the

economy of drugs was preferentially considered on the withdrawal of drugs in Korea, prior to the use of the following indicators: safety, clinical effectiveness, cost-effectiveness indicator, impact on budget, availability of alternative drugs, severity of appropriate diseases as well as price and reimbursement of the same kinds of drugs in other countries. In order to ensure the openness and transparency of decisions, the evaluation criteria, details of the evaluation process and the final evaluation report were posted on the official website of Korea. Drug manufacturers could propose their different opinions at the meeting of the drug welfare security evaluation committee, and could appeal for re-evaluation where they disagreed with the results of the evaluation. The access and withdrawal of the French medical insurance list was based on agreements signed between drug price committee and pharmaceutical companies, with a four-year validity period. If the drugs received good evaluation results and the relationship between sales volume and price was in line with the original agreement, the agreement could be renewed after the four-year validity period, and if the above indicators were not up to standard, the drugs would be automatically removed from the medical insurance list after the four-year validity period, and the agreement would be terminated. The re-evaluation mechanism of Japan was also featured with proper timeliness. Once the drugs in the list seriously deviated from the relevant indicators in the process of quality re-evaluation, price review or routine re-evaluation, they would be withdrawn from the reimbursement list and evaluated on whether they would be eligible for being included in the list again through the re-evaluation system after rectification or price adjustment.

Drawing lessons from the advanced experience of the above-mentioned countries and combining with the current situation of our country, the drugs with serious clinical abuse, repeatedly non-conforming prescription comment results, occupation of a large amount of medical insurance funds and still with prominent problems after being reminded and warned should be dynamically removed from the medical insurance list, on the basis of data monitoring and comprehensive analysis of drug procurement, hospital prescription information, prescription comment results

and fund occupancy ratio. Enterprises should be entitled to appeal and could raise objections to the evaluation results of drug use with sufficient evidences submitted to the experts for review. The review results are related to the withdrawal of drugs or not. The dynamic medical insurance withdrawal mechanism aims at removing the drugs that occupy the medical insurance funds and are not clinically necessary through data-based evaluation and process-based review conclusion, so as to save the medical insurance funds to the maximum extent and realize the rational allocation of effective resources.

3 Realize the dynamic adjustment of medical insurance payment standard

The drug procurement, prescription comment and fund occupancy should be comprehensively evaluated according to the sharing, summarization and analysis results of the data of pharmacy, hospital and medical insurance departments, and the dynamic adjustment of medical insurance payment standard should be realized on this basis, so as to increase the allocation rationalization of medical insurance fund and maximize the value of fund expenditures.

Firstly, based on the summary of procurement data, clinical use data, prescription comment data and medical insurance reimbursement data, the original medical insurance payment standard (price) can be maintained for drugs with standardized procurement behavior, standardized clinical use and good value evaluation results, and the medical insurance payment standard (price) can be increased appropriately for drugs with particularly obvious clinical output benefits; secondly, the medical insurance payment standard (price) can be dynamically lowered for drugs with compliant procurement behavior, occasional defects in clinical use (but corrected in time) and good value evaluation results, and the original standard (price) can be resumed after the procurement behavior is adjusted and reviewed; thirdly, the drugs with compliant procurement behavior, serious clinical abuse or serious non-compliant prescription comment results or value evaluation results not consistent the initial evaluation expectation, they should be eliminated from the medical insurance list, that is, the medical insurance payment standard (price) should be adjusted to zero, and the dynamic access of drugs should be

decided according to the enterprises' access re-application and rectification; finally, for drugs with serious adverse reactions and serious safety problems detected during clinical monitoring, the drug regulatory department should be timely communicated to make the evaluation and decision of withdrawal from the market.

The medical insurance payment standard (price) is expected to be adjusted dynamically by integrating the drug procurement and clinical use information of the hygiene department, the drug re-evaulation information of the drug supervision department as well as the fund reimbursement information and hospital internal prescription comment results of the medical insurance department, so as to optimize the reimbursement ratio of drugs and the distribution of medical insurance funds, realize the implementation and use of high-value and clinically necessary varieties and eliminate the waste of resources.

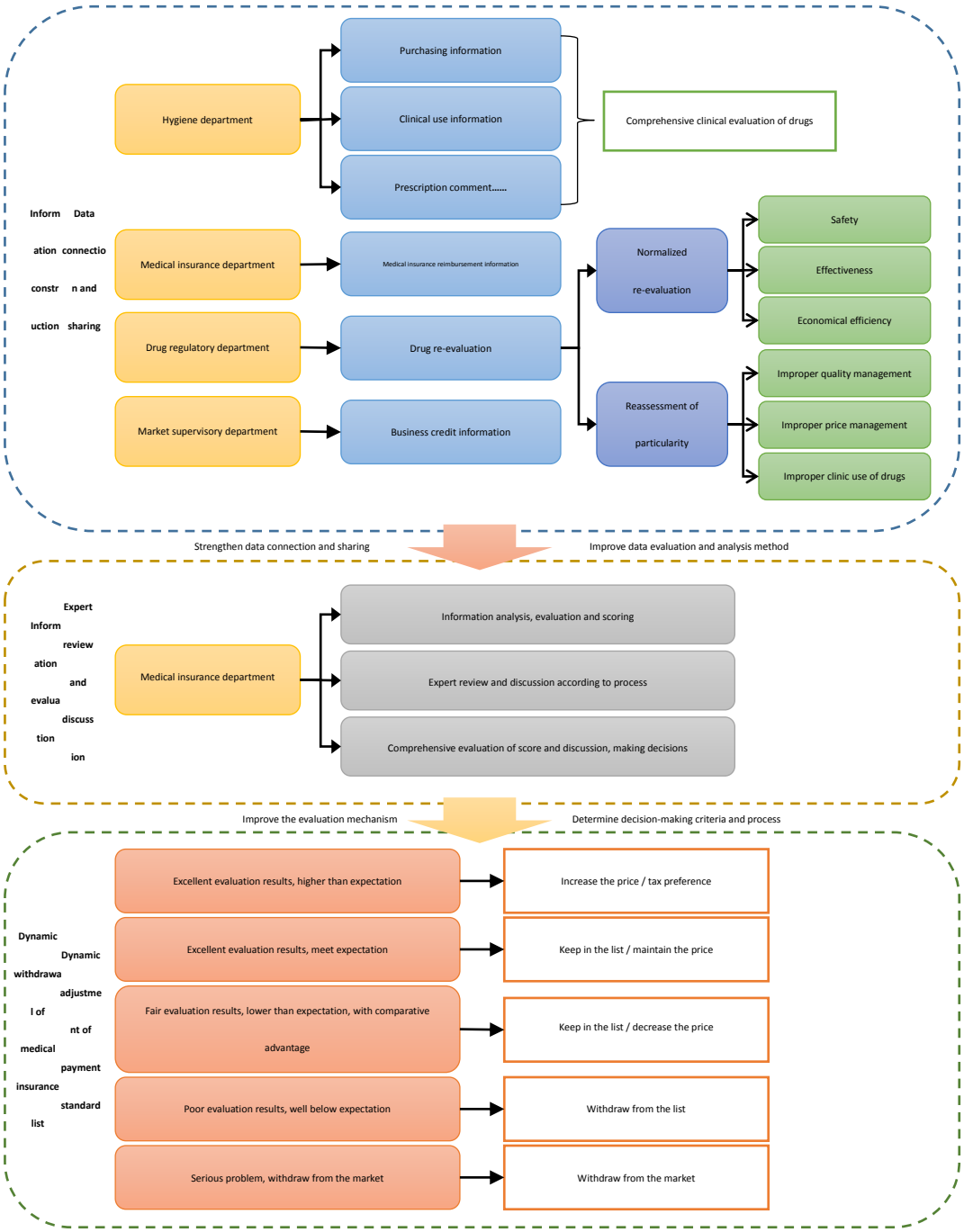


Figure 32. Chart of Optimizing Medical Insurance Fund Operation Mechanism and Realizing the "Reducing Expenditure" Goal

VI. "Mutual Assistance" – Appropriately Increase the Overal planning Level of Medical Insurance

(1) Difficulties and risks in improving the level of overal planning

1 Many obstacles to employee medical insurance reform

The reform of the three basic medical insurance systems at the overal planning

level will face great difficulties, especially the employee's medical insurance, because it is involved with the most economic interests due to its highest contribution ratio and best security effects. In addition, the new rural cooperative medical system and residents' medical insurance are financed by individual payment and government subsidies, while the employee's medical insurance is financed by the joint contribution of units and employees. Therefore, the uplifting of the overal planning level will exert an impact on many units and increase the labor cost of units, not conducive to local economic development.

2 Increased pressure on medical expenditure, prone to cause over-treatment

For improvement of the medical insurance overal planning, another major risk is that it may greatly enhance the pressure on medical expenses, thereby increasing the operational risk of the health insurance fund. Objectively, the medical level and resources in the jurisdiction of a city may not differ greatly, but if the overal planning level is improved to the provincial level or even the national level, the medical level in different regions will vary greatly under the influence of differences in economic development in various regions. Patients will be provided with more choices when seeking medical advice. With the elimination of policy differences and the convenience of medical reimbursement, patients are prone to access the high-quality medical resources of provincial and even domestic Grade III Hospitals, which will not only waste the primary medical resources and result in extreme shortage of top-level medical resources, but also likely to cause severe over-treatment and greatly increase the pressure of medical expenditure. Therefore, the matching and connection of local insured personnel, level of medical security and health expenditure should be ensured and improved step by step while increasing the overal planning level of medical insurance. The government responsibility should be strengthened in the areas with low medical level, the allocation of financial support and medical services should be improved, and the level of medical security should be reduced among different regions. The principle that the rights and interests of the insured should not be impaired in the process of improving the overal planning level should be always adhered to truly realize the fairness and mutual assistance of

medical insurance.

3 Impacts of local protectionism on implementation

In the process of increasing the overal planning level, local protectionism will also bring risks, especially for adjustment fund system. Based on the original idea, the surplus of the funds of each city should be turned over to the provincial accounts after proper implementation of provincial overal planning and adjustment, and the collected adjustment funds should be used for allocation in case of overexpenditure of the medical insurance funds. But in fact, local governments, because of regional protectionism, are unwilling to turn over the funds or are willing to turn over only part of the surplus, which decreases the scale of provincial-level medical insurance funds and renders the system of adjustment funds ineffective, resulting in failure to play its original intention of risk resistance and mutual assistance. Meantime, the fund balance at the municipal level and county level has been depreciating, and the large-scale operation of the provincial social insurance fund cannot be realized through professional institutions, thus increasing the difficulties of maintaining and increasing the value of the funds. The low management level of primary departments has also increased the difficulty of provincial-level overal planning. From the experience of Gansu Province, if the provincial-level fund is of a smaller scale, the pressure of both funds and finance will be increased sharply once the funds of two or three regions realize a surplus. In this case, the provincial government is expected to bear a portion of the payment and then the municipal and county governments should pay a portion. However, this method will either lead to a decline in the credibility of medical insurance or arouse contradictions, or will foster the trend of self-financing of local medical insurance funds, contrary to the original intention of provincial overal planning. In addition, affected by the upward shift of management authorities brought about by the rising overal planning level, the high-level medical insurance agencies cannot feel the pain of the local medical institutions, thus increasing the difficulties of fund supervision and prejudicing the negotiation of reasonable payment prices with local medical institutions.

(2) Improve the overal planning level of medical insurance

1 Ways to improve the overal planning level of medical insurance

Our government also plays a leading role in uplifting the level of overal planning. The state proposed “the central government should unitarily formulate the framework and policies of the basic medical insurance system, while local governments should take the responsibility of organizing the implementation and management, create conditions for gradually uplifting the level of overal planning. Efforts should be made to effectively integrate the resources handling the basic medical insurance, and progressively achieve unified administration of urban and rural basic medical insurance” in the Opinions of the CPC Central Committee and the State Council on Deepening the Reform of the Medical and Health Care System released in 2009. It clearly stated national attitude in uplifting the overal planning level of medical insurance, and emphasized the leading role of central government in establishing and formulating medical insurance policies, as well as the tasks and orientation of local governments.

As for the specific ways to realize policy unification at high overal planning level, firstly, it is required to ensure that a unified medical insurance system of which the source could be a normative document issued by government at the same level or government at higher level is implemented in the region, but it must be ensured that it is unified in the region. The specific performance is that the payment base and ratio in the region is unified in the same project, the deductible must be the same and so as the reimbursement ratio, the designated hospitals should be established and the operation system should be standardized to realize information symmetry and sharing. Generally, it means that the standard of treatment and the standard of payment should be consistent in the same co-ordinated area. Besides, the intra-regional adjustment fund system should be established and improved and the adjustment fund transfer should also be unified.

In the Guiding Opinions on Further Strengthening Medical Insurance Funds Management and the Notice of the State Council on Issuing the Plan on Recent Priorities in Carrying out the Reform of Health Care System (2009-2011), the state proposed that “Each region should speed up the work of uplifting the overal planning

level of basic medical insurance according to the actual situation in the local area, and basically realize the city-level and prefecture-level overal planning. In areas where the city-level and prefecture-level fund collection and reception were indeed difficult, it was possible to establish a city-level and prefecture-level fund risk adjustment system and then gradually realize the transition. In areas where they were possible, it could explore the implementation of provincial-level overal planning". It provides a good path and direction for upgrade of our overal planning level. Details of path are described in the paragraphs below, so it won't be covered again here. The key point extracted here is that it should be clear that during development and implementation process of uplifting overal planning level, our goal is to reduce unnecessary cost and mitigate the conflict brought by low overal planning level, which requires us to pay attention to the development of local economy and properly ensure the convergence of policies step by step, so as to ensure that the medical service level accepted by the people will not decline during uplifting process. Besides, in the aspect of adjustment and overal planning, the responsibilities of each region in the co-ordinated area must be defined, the budget system of overal planning management must be improved, and the limit setting, collecting, managing and using of adjustment fund must be implemented in place.

2 Selection of path

Before selecting path, we should analyze the advantages and disadvantages of each overal planning method at first, in order to select proper path to uplift the level. For this purpose, we have the table below visually showing the advantages and disadvantages of overal planning at different levels.

Table 29. Advantages and disadvantages of different overal planning modes

Modes / Advantages and disadvantages	Provincial-level overal planning	City-level overal planning pooling	Prefecture-level overal planning
Advantages	·Improving risk resistance capacity of medical insurance ·Reducing management cost	·In accordance with actual management level of each region ·Unifying the level of contribution and health	·Considering local economy level and medical service level ·In favor of clarifying the execution responsibilities

	·Improving unfairness of insurance opportunities	care treatment in the whole city, increasing medical insurance negotiation capacity ·Laying a foundation for establishing provincial-level adjustment fund	of government at all levels ·In favor of gradually pushing a certain social security system
Disadvantages	·Provincial differences are too large, the current management level is difficult to adapt ·Reducing local or industrial fund raising initiative, inadequate fund raising capacity ·Fund raising at the same standard will enlarge the fairness problem of fund raising	·For fund raising at the same standard, it will bring out the situation that the balance from low income area subsidizes urban high income group since the different household expenditures cause different fund compensation ·The fund of each city in the province is difficult to adjust	·The medical insurance fund is difficult to adjust and use, thus reducing the utilization efficiency of fund; the fund balance is structurally imbalance, deficit and balance coexist ·Single regional fund has poor mutual aid capacity, and risk resistance capacity, which is difficult to meet labor mobility requirement

The current overal planning level in our country is too low, thus, it is necessary to improve it. However, combining with the economic strength, income level and medical standard in different regions in our country, it is not easy to uplift to the national level directly; otherwise, it will cause massive waste and system convergence not in place. At present, the financial initiative of provincial government is the strongest, it is the most scientific from the span of national management and considers local development differences to the full extent, thus, the provincial-level overal planning is considered as the optimal choice for uplifting overal planning level in this article.

In fact, not all provinces are applicable to the path of directly implementing provincial-level overal planning. The overal planning level should be uplifted step by step according to different stages. At the first stage, the provinces which are economically developed with not obvious overal planning fund pressure and adequately equipped medical resources can actively explore the fund raising mode of provincial-level overal planning. Meanwhile, for provinces which have a vast territory

and is sparsely populated, the fund pressure may be severe even if city-level overal planning is implemented, they can directly implement provincial-level overal planning in one step. For rest provinces with relatively average or underdeveloped economic strength but with a certain population, it would be better to implement city-level overal planning in place at first, and reduce difference between different areas through economic development. After completing the first stage, the task for the second stage is further promoting provincial-level overal planning. No matter at which stage, attention should be paid to linking with local economic strength and income level, and the rights and interests of the insured should not be impaired due to level uplifting.

VII. Improve the Starting Mechanism of Drug Price Negotiation

(1) Define the starting mechanism of medical insurance access for drugs

The starting mechanism of medical insurance access for drugs should be designed scientifically to exert strengths of invitation system and application system.

Table 30. Comparison between Invitation System and Application System

Starting type of dynamic regulation	Advantages	Disadvantages
Invitation system	Recommended by experts, the supervising department sends invitation on attending dynamic regulation review, which is good for actively selecting good products to include in the scope of selection	① The intention of some enterprises on dynamic regulation of medical insurance is not clear; ② Enterprises wait for starting of dynamic regulation, but they cannot predict effectively the time when the dynamic regulation procedure is started, which reduce their enthusiasm on collecting materials and applying actively
Application system	Applied by enterprises, the expert panel and the supervising department review the materials, which is good for enterprises preparing materials in advance and applying initiatively, so that normalized mechanism of "apply-receive-review-dynamic regulation" is formed	① The varieties and levels submitted by enterprises for review are uneven, which requires the expert panel and supervising department to carry out a lot of preliminary screening work in earlier stage to determine the finalists, those varieties not complying with medical insurance access condition will occupy plenty of review resources; ② The authenticity, completeness and scientificity of data and materials submitted by enterprises themselves may interfere with review results

The drug varieties should be distinguished and starting mechanism of differentiated medical insurance access should be adopted. For new drugs with no variety of similar/same indication in the medical insurance list, invitation system (selection system) should be adopted, the medical insurance party should actively invite relevant varieties to participate in medical insurance selection, and evaluate the varieties with clinical experts; for drugs with variety of similar/same indication in the medical insurance list, the application system should be adopted, the applying enterprise should “challenge” the varieties in the List and prove the cost-benefit advantage of their drugs.

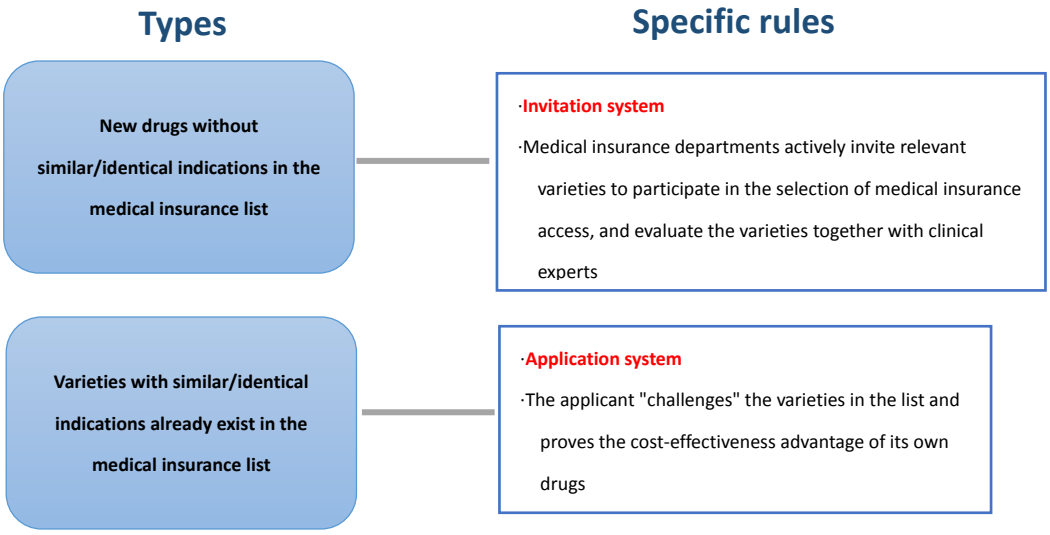


Figure 33. Starting Mode of Differentiated Medical Insurance Access of Drugs

(2) Define the application scope of routine access and negotiation access

It is suggested to define the application scope and standard of routine access and negotiation access from the policy level of medical insurance list management mechanism.

Table 31. Comparison between Routine Access and Negotiation Access

Medical insurance access mode	Economic evaluation results
Routine access	Drugs with better economical efficiency
Negotiation access	Drugs with poor economical efficiency

Medical insurance access for drugs is divided into two modes: routine access and negotiation access. Compared the drugs of the same kind according to the

principle of pharmacoeconomics, the drugs which are defined with prices (charges) equivalent to or lower than those of the existing varieties in the medical insurance list with the premises that the efficiency and safety are satisfied, i.e. economically sound drugs, “routine access” will be adopted to include them in the medical insurance list directly; for patent exclusive drugs with high prices or great influence on medical insurance fund, i.e. poorly economical drugs, “negotiation access” will be adopted to include them in the medical insurance list.

(3) Establish the starting process of application system

Since the starting process of application system hasn’t been established yet in our country, the research group has the following conception on implementation requirements, process and regulations of application system:

1 Establish the medical insurance access committee

The precondition for realizing dynamic regulation mechanism of the medical insurance list is establishing the medical insurance access committee, to carry out review work of dynamic access of the medical insurance list. Taking Australia and Japan as examples, Pharmaceutical Benefits Advisory Committee (PBAC) is established in Australia, which is set up by the government independently and the chairman is appointed by the prime minister[38], and it is composed of medical specialists, insurance professionals, health economists and consumer representatives, with Economics Sub-committee (ESC) and Drug Utilization Sub-committee (DUSC) affiliated to it, in which PBAC is responsible for recommending medicines and medicaments to Management of Health and Aging (MHA) to include them in Pharmaceutical Benefits Scheme (PBS), ESC is responsible for performing economic evaluation on applied drugs, DUSC is responsible for collecting drug utilization data in Australia and analyzing, and also comparing with other countries. PBAC hold annual review conference in March, July and November every year, and review the drugs already on the market or new drugs, new vaccines which have not obtained marketing authorization temporarily or drugs with new indications, to determine

[38] Fu Hongpeng, Yang Hongwei, Han Huixue. Drug Management System and Policy Experience in Australia[J]. Chinese Journal of Hospital Administration, 2013, 29(1):73-76.

whether include them in Pharmaceutical Benefits Scheme (PBS).

Central Social Insurance Medical Council is established in Japan, which is composed of medical specialists, expertus dentalis, and pharmacy specialists with drug pricing group affiliated to it which is mainly responsible for calculating the negotiation price of drugs which are newly on the market; for drugs already in National Reimbursement Drug List, re-calculating the expansion of market and do research on addition rate; carrying out drug classification research and other works which would be carried out at any time as needed; putting forward revision suggestions on drug pricing system, and reporting to specialized department of drug pricing every 2 years and so on. Enterprises have 4 opportunities every year to submit drug price negotiation application for drugs which have already obtained marketing authorization.

Our country can use this as a reference to establish medical insurance committee which is composed of medical specialists, pharmacy specialists, pharmacoeconomics specialists, consumer representatives and involves functions of National Healthcare Security Administration, National Medical Products Administration, National Health Commission of the People's Republic of China and other relevant departments, mainly responsible for formulating and revising guidelines of application materials and guidelines of procedures, reviewing and evaluating application materials from enterprises (including pharmacoeconomics materials, clinical materials of drugs, approval documents for drug marketing authorization review etc.), communication and feedback in medical insurance access, discussion of comments and suggestions, drug price negotiation etc., it hold 3-4 review meetings every year regularly to determine whether the drugs are included in the medical insurance.

2 Application and submission of materials

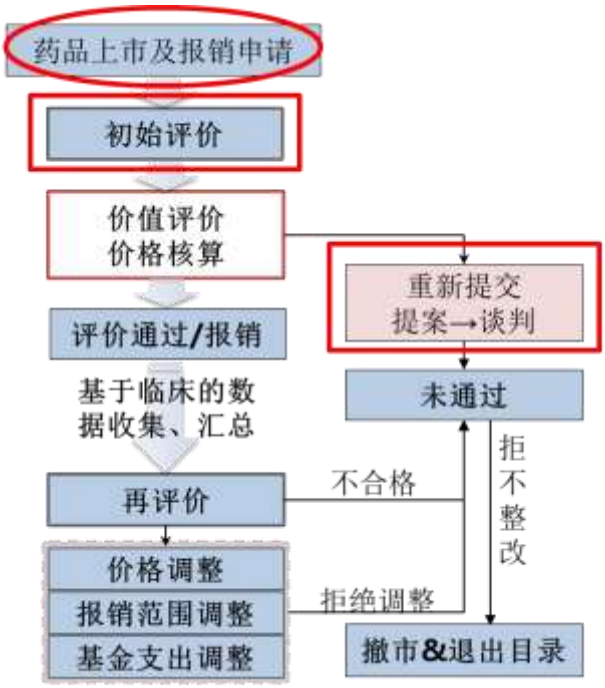


Figure 34. Application Process of Medical Insurance Access in UK

Using foreign experience for reference, the National Institute for Health and Clinical Excellence (NICE) in UK performs initial evaluation and value assessment of application materials from enterprises as the decision-making basis for determining whether negotiation is necessary or whether it can be included in the medical insurance list directly. The drugs which do not pass initial evaluation should be rejected.

There are four application forms for Pharmaceutical Benefits Scheme (PBS) in Australia -- ① Major application; ② General application; ③ Application of committee secretariat; ④ Submitting new brand of existing drugs. Major application includes access application of new drugs or vaccines, new indications. The later three applications documents normally do not need economic modeling, and PBAC may not participate in evaluation. The materials of major application need to specify the utilization conditions for this drug (such as tumor in specific part of body) and patient characteristics (such as age and is there any genetic constitution). Enterprises can hold meetings with Management of Health and Aging (MHA) selectively and PBAC (Pharmaceutical Benefits Advisory Committee) determines whether pre-evaluation is required. If the application is not approved or rejected, the manufacturer can reserve

the right to submit an indirect application to DHA (equivalent to two opportunities). PBAC is responsible for performing pre-evaluation and evaluation on the completeness and logicality of materials, which includes background, clinical evaluation, and economic evaluation, review of drugs used in practice and other relevant information, as well as adopting and thinking the suggestions of TGA[39]. Regardless of the clinical trial study type reviewed by TGA, PBAC may consider plenty of other factors relative to clinical study before comparing clinical validity and safety, including number of studies and design, number of studied personnel (called "Sample size") and how researchers measure health results and so on. After taking into all types of information, PBAC will start to evaluate the results – whether health outcomes are better, at least equal (not worse than) or worse. The decision-making process needs plenty of judgments from PBAC, which greatly reduce the risk occurrence[40].

Table 32. Submission Types of Drugs of Different Drugs

Type of submission	Applicable objects	Materials involved
Primary submission	New drugs, new vaccines, or drugs with new indications	Background materials, clinical materials, economical efficiency, drug use, etc.
Secondary submission	New dosage forms of existing drugs in the list or bioequivalent generic drugs with new specifications	Background materials, clinical materials, drug use, etc.
Submission by the committee secretariat	Same as "secondary application" (no need for PBAC to consider the cost-effectiveness, no impact on finance, and no difference in safety from the drugs in the list)	Background materials, clinical materials, drug use, etc.
Submission of new brands of existing drugs	New brands of generic drugs already in the list approved by TGA, with the same patient population and indications	Background materials, bioequivalence, cost information

Table 33. Items of Application Materials of Main Submission Types

Items	Main contents
Background material	Necessary basic drug information and directions for expected use
Clinical research materials	Best clinical experimental data available to prove the safety and effectiveness of drugs

[39] Paris V, Belloni A. VALUE IN PHARMACEUTICAL PRICING COUNTRY PROFILE: AUSTRALIA[EB/OL]. https://search.oecd.org/health/Value-in-Pharmaceutical-Pricing-Australia.pdf. 2014-11/2018-10.

[40] GSK. The Pharmaceutical Benefi ts Scheme in Australia [EB/OL]. https://au.gsk.com/media/421635/gsk-viiv-the-pbs-in-australia-feb-2018.pdf. 2018-02/2018-05-01.

Economic evaluation materials	Cost effectiveness analysis materials or cost minimization analysis materials
Drug use materials	Drug use situation and market expectation assessment; impact analysis on financial budget
Supplementary materials	Other information affecting PBAC decision-making

Based on Australia practical experience, our country can release guidelines of application materials to eliminate confusion of enterprises on materials preparation, and also provide corresponding templates to improve evaluation efficiency. During implementation phase, medical insurance access committee can perform evaluation on necessary information and materials provided by enterprises at first, and form template to play a demonstration role, thereafter enterprises perform evaluation themselves according to templates and the medical insurance committee is responsible for reviewing.

To sum up and combine with China's national conditions, firstly, enterprise which considers its variety complying with medical insurance access conditions submits application, and it is required to perform self-check on materials (refer to self-inspection form of registration and application materials, clinical trial data) to avoid reoccurrence of overstock of registration and application, the enterprise will be severely punished if the staff find any material fraud or serious non-compliance during review process.

Meanwhile, disclose non-classified documents for public supervision. Some foreign clinical trial data disclosure experience can be referred to. Till now, over 40 countries in the world have formulated relevant laws, regulations or guidelines on clinical trial data disclosure of drugs, including Australia, France, India, Brazil, Japan etc. in which, Clinical Trials.gov from the United States and EU-CTR from EU are 2 clinical trial registration and result disclosure platforms which are the most representative and most developed, and the disclosure is mandatory. China can establish self-evaluation data disclosure mechanism of enterprise access commitment by drawing on their experience and methods.

① Summary of U.S. experience

With a series of research and development failures in drugs such as Celebrex,

Vioxx and some pediatric antidepressant in 2005, pharmaceutical companies inevitably faced increasing pressure, a high-ranking official from international magazine editorial committee and National Institutes of Health (NIH) criticized 3 big pharmaceutical companies that they didn't disclose the important clinical trial information in the public database of U.S. government. Thereafter, the editors from some major medical journals reached an agreement that the research results of trials started from January 1st, 2005 could be published only if they were registered in public database; ongoing clinical trials must also registered in public database before mid-September, 2005 if they wanted to get published.

The government is discussing a legislation which requires pharmaceutical companies disclose clinical trial data; otherwise they will face a fine of $10,000 per day. Fair Access to Clinical Trial Act requires the trial initiator to register all studies of Pharmaceuticals, biological products or medical equipment which are sponsored by private or public fund, indicating that these studies are safe and valid. The Final Rule of Submission of Clinical Trial Register and Result Information stipulates the disclosed summary of clinical trial results of drugs should include information such as time table, collecting method, all-cause mortality, research program, statistical analysis scheme of adverse events, and the data should be updated every year[41].

Under the efforts of the United States, World Health Organization is considering to establish an international spontaneous clinical trial register system, requiring at least 20 main contents to be disclosed in clinical trial data. These 20 data include trial objective, feasibility requirement, funding source, expected time schedule, main achievements and other important achievements.

② Summary of EU experience

EU created EU-CTR website in March, 2011, by which the public can log in and open access clinical trial information of drugs in EudraCT database for supervision. Meanwhile, a single clinical trial data submission system was also established setting up a unified scientific and ethical review standard, which had legal force in the whole

[41] Zhang Wei. Attention Paid to Ensure Safety of Drugs Trends in the Disclosure of Clinical Trial Data[N]. China Pharmaceutical News, 2006-01-24(07).

EU/European Economic Community. It was also expressly required that all clinical trials conducted within EU must disclose clinical trial registration information, clinical trial result summary and CSR information. Since January, 2013, a leading medical journal British Medical Journal (BMJ) had required the authors to make the commitment that "All anonymised data of individual patient which are used for analyzing and drawing study results and conclusions in the paper" could be shared "based on reasonable requirements".[42]

Besides, under the appeal of state and government, many large enterprises created their own clinical trial data disclosure platform. For example, GlaxoSmithKline (GSK) opened its clinical trial register (GlaxoSmith- Kline Register) to public in 2014. The open data included clinical trial registration information and study result summary, and it became the first pharmaceutical company which disclosed clinical trial data. Then GSK further announced that it would provide detailed raw data to researchers systematically[43].

Yale University Open Data Access (YODA) originated from 2011, which was established based on the situation that the media had a question whether the medical device company Medtronic hided the adverse reactions of its product "Infuse" in clinical trial and exaggerated the validity results.

Therefore, use the experience of clinical trial data disclosure for reference, disclosure of proof materials of access commitment fulfillment can be tried to strengthen the credibility of data and information. It can be divided into compulsory disclosure and voluntary disclosure, vertically multi-level disclosure mode can be adopted which is divided into government website, medical journal, enterprise website, public institution, and other social group magazines. Based on whether it touches trade secrets or clinical trial data protection act, it can be divided into 4 categories: disclosure of basic information involved in access commitment, disclosure of study result summary, disclosure of clinical data and business operation

[42] Tom Robinson, Zhou Xianshi. U.K. Clinical Pharmacists Support the Disclosure of Clinical Trial Data[N]. Medicine Economic News, 2014-09-05(008).

[43] Yang Li, Tian Lijuan, Lin Lin. Study and Enlightenment on Disclosure System of Drug Clinical Trial Data[J]. Chinese Journal of New Drugs, 2017, 26(09): 990-998.

data and disclosure of raw material. For example, personal data set of patient, case report forum (CRF) of patient, documents interpreting data set structure and contents (such as comment CRF, variable definition, data derivation specification, data set definition documents), business report and corporate annual report and so on.

Certainly, special attention should be paid to laws and business ethics during information disclosure, i.e. ① whether data disclosure breaches relevant regulations on trial data protection of drugs in clause 39.3 of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); ② whether data disclosure infringes on trade secrets of pharmaceutical companies and personal privacy of patients; ③ whether data disclosure will cause data abuse. Thus, for clinical data, the state should ensure that the regulations of TRIPS 39.3 will not be breached while the clinical trial data is disclosed by “taking necessary measures to ensure the data will not be used improperly for commercial purpose” that is, carry out the "disclosure of clinical trial data" based on "exclusive right of dru g trial data"; for commercial data, the enterprises can encode or treat the raw data and release after introducing redaction mechanism, to protect trade secrets and personal privacy from infringement without losing the validity and authenticity of the data; for abuse problem, the main solutions include access control and conditional use which require identification authentication of data requestor and open to public by setting up corresponding qualification standard and signing agreement of usage etc., and the data can only be used for non-commercial purposes such as scientific research and supervision.

By the above method of enterprise self-evaluation information disclosure, other organizations and the third party organizations are promoted to participate in jointly, and various data disclosure modes are developed. The state will provide certain financial support or establish a specialized program, to encourage the pharmaceutical companies, public departments, academic institutions etc. to establish data disclosure platform in various modes cooperatively or independently, and to achieve a certain degree of raw data disclosure in a controlled way, in order to fully realize data transparency under principle of protecting patient privacy, ensuring the integrity of drug regulatory procedures, and not damaging the enthusiasm of research and innovation in pharmaceutical companies, to further safeguard public right to know, maintain scientific ethics, play a social supervision role, so that the enterprise data submitted to government department are credible and scientific to a certain degree, facilitating relevant departments to use these data

for revaluation after marketing and medical insurance access to determine whether the drugs achieve the desired effect. The authenticity and scientificity of enterprise materials are ensured while application lodgement and material overstocking are avoided.

3 Clarify the requirements of enterprises' application materials

After the above process is completed, enterprises should submit relevant materials in compliance with requirements which should at least include contents such as drug safety, validity, pharmacoeconomics, budget impact analysis, price expectation. Our country has not established unified standards and guidelines for economic evaluation, or established professional, independent, official, authoritative organization for report writing or material evaluation. Therefore, in order to ensure the authenticity and scientificity of materials, our country should publish our national guidelines on pharmacoeconomics evaluation as soon as possible; meanwhile, it is suggested that the government should entrust a third party organization to perform pharmacoeconomics and budget impact evaluation, as well as issue relevant materials.

Table 34. Conception of Requirements for Materials Submitted by Enterprises

Scope	Specific items		Negotiation access requirements	
Safety	Adverse reaction report Phase IV clinical trial report		No serious adverse reactions, higher clinical use safety	Benefits > risks
	Periodic safety update report Evaluation report on monitoring period of new drugs		Good safety, without major adverse events	
	Follow-up monitoring of clinical drug use		Rational drug use, without drug abuse and unreasonable off-label use of drugs	
Effectiveness	Evaluation report on monitoring period of new drugs		Good drug efficacy, clinical cure rate up to standard	
	Phase IV clinical trial report		Clinical cure rate up to standard, good therapeutic effect	
	Clinical efficacy report		Good recovery of patients, good feedback from physicians	
Economical efficienc	Clinical value, drug efficacy	Pharmacoeconomic evaluation	Good cost effectiveness, considerable results of comparison with other similar	High cost perf
	Drug cost			

y	Sales volume and price Fund operation, cost effectiveness	report, budget impact analysis	drugs	orma nce

Thirdly, the review department should perform initial evaluation on materials, i.e. formative evaluation which mainly considers the format, completeness, authenticity and scientificity of materials, and issue a shortlist of varieties.

Fourthly, detailed, normative and closed review should be performed on the materials provided by enterprises which have varieties in the shortlist. Australia Valuation Office focused on the safety, validity, potential benefits of drugs and evidences supplementing existing medical service when performing comprehensive evaluation and review; the experts participating in evaluation and review included clinicians, specialists in clinical epidemiology, specialists in health economics, biostatisticians and specialists in clinical pharmacology.

The evaluation process is a process in which the experienced experts measure the acceptability of non-ideal evidence and generate a price expectation. After this process is completed, the drugs of which the materials and cost benefit comply with requirements and the clinical value is high will enter medical insurance segment through routine access or negotiation access, and the drugs are proposed to pass negotiation access will enter negotiation segment formally.

4 Improve negotiation contents

Specific negotiation procedures should be carried out in the next stage, i.e. step 5. Negotiation should not be limited to price, guarantee of pharmaceutical supply should also be included. For drugs which are urgently needed in clinical settings and have high estimated price and high risk, agreement can also be signed on the drugs to make the drugs conditional access, if the drugs do not comply with medical insurance access requirements during the subsequent medical insurance evaluation process, they can be withdrew from the list by medical insurance withdrawal mechanism.

Table 35. Details of Medical Insurance Negotiation Contract in Australia

Negotiation category	Specific events
Preface	Definition
	Explanation
	Guidelines of this contract
	Acknowledges
Operating process	Initial evaluation
	Reevaluation
Reimbursement provisions	Discount
	Reimbursement
	Revise the reimbursement limit in case of out of stock or in short supply
	Provisions on new drugs
Repayment agreement	Supply and support information
	Overdue payment
	Provision of data and information
	Consumption tax
Confidentiality clause	Non-disclosure of confidential information
	Exceptional cases
	Survival principle
General rules	Company confirmation
	Dispute resolution
	Merger and sale
Continuous operation and termination	Continuous operation of the contract
	Termination of the contract
Precautions	Format and material delivery
	Review address
Related parties	Related parties

And sixthly, the negotiation enterprise has one appeal and renegotiation opportunity. At the same time, the possibility and mechanism of long-term communication should be established to make the information of both parties (Both parties of negotiation) transparent, and enterprise familiar with negotiation process, negotiation requirements and review standards, make the government get acquainted with the appeal, drug characteristics, and special situations of enterprise. Meanwhile, real-time communication with enterprise should be guaranteed during subsequent dynamic withdrawal mechanism of List and dynamic withdrawal mechanism of payment standard process to establish continuous evaluation, communication and regulation mechanism.

5 Define application procedures for medical insurance access

According to guidelines on PBAC procedures in Australia, enterprises should submit corresponding materials for different kind of applications 17 weeks and 11 weeks before PBAC annual meeting. In the first 6 weeks, the Committee will provide feedback on the contents of materials, and the enterprise gives reply, and thereafter DUSC and ESC meeting should be held, the Committee will provide feedback of preliminary review comments of DUSC and ESC to the manufacturing enterprise which should give reply on the problems. All materials will be reviewed during annual meeting to draw conclusions. PBAC will disclose recommended and non-recommended products after annual meeting, no matter whether the product is recommended to enter PBS or not, the evaluation results should be disclosed with key information hidden and the reason for this should be explained.

Figure 35. Flowchart of Medical Insurance Access in Australia

Based on relevant regulations of guidelines on procedures in Australia, our country formulates guidelines on medical insurance access procedures to facilitate normalization of medical insurance access and make convenience for enterprises fully prepared for medical insurance access process and establishing information communication mechanism, to avoid blind operation of the enterprises and improve the efficiency of enterprises and the Committee. The principle of openness and transparency is adhered to and the review results will be disclosed promptly, and meantime, the relevant confidential work should be properly carried out.

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