Healthcare

创新药医保降幅长期趋缓，企业谈判具有灵活性

Long-term Price Cut for Innovative Drug in NRDL to Slow Down, More Flexibility for Company in Negotiation

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热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

事件

国家医疗保障局（NHSA）发布《谈判药品续约规则（2023 年版征求意见稿），整体延续 2022 版的框架，亦有部分调整。主要调整包括:

1） 纳入常规目录管理的条件新增“谈判进入目录且连续纳入目录‘协议期内谈判药品部分’超过 8 年的药品”。
2） 简易续约规则区分连续纳入目录“协议内谈判药品部分”4 年及以内、超过 4 年两类。4 年及以内品种计算规则与 2022 年规则相同；超过 4 年的品种，支付标准在计算值基础上减半。
3） 医保基金支出预算从 2025 年续约开始不再按照销售金额 65%计算，而是以纳入医保支付范围的药品费用计算。考虑到参照标准的变化，医保支付节点金额也相应调增。从 2025 年起，谈判药品简易续约的医保支付节点金额从 2 /10/20/40 亿元相应调增为 3 /15 /30 /60 亿元。
4） 按照现行药品注册管理办法及注册分类标准认定的 1 类化学药品、1 类治疗用生物制品、1 类和 3 类中药，续约时如比值 A>110%，企业可申请通过重新谈判确定降幅，重新谈判的降幅可不一定高于按简易续约规则确定的降幅。如谈判失败，调出目录。

点评

老产品降价规则明确、预期长期降幅趋缓。征求意见稿中提到，连续纳入目录内 8 年的药品可进入常规目录管理、连续纳入目录超过 4 年的药品，简易续约时支付标准在计算值基础上减半。我们认为，按 2018 年为医保目录执行首年开始计算，目录内 8 年以上药品可能在 2025 年开始正式进入常规目录，在专利期内价格企稳。对于连续纳入目录超过 4 年的药品，我们理解为按规则降价幅度减半，故药品的销售峰值有边际提升可能。

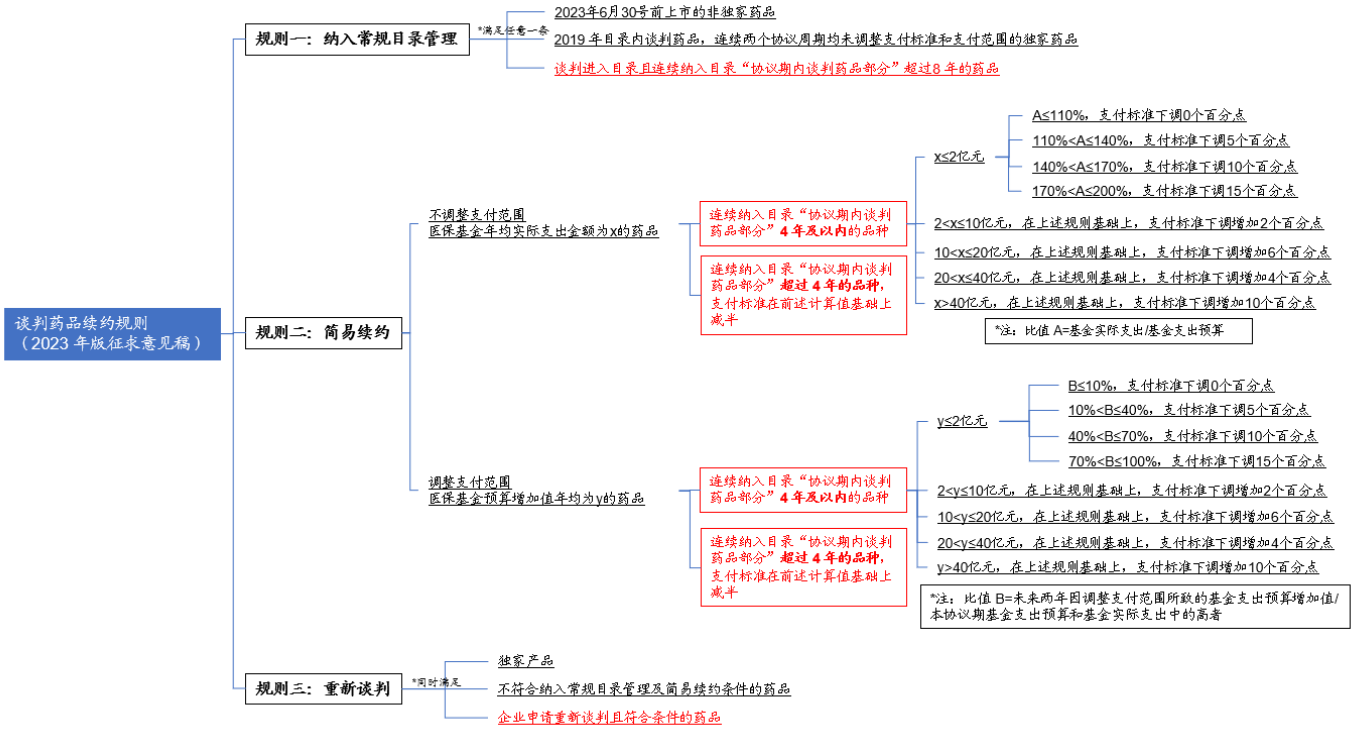
医保基金支出预算口径将变更，数据精确度可能提高。根据征求意见稿，医保基金支出预算自 2025 年续约开始，口径由“销售金额的 65%”更改为“纳入医保支付范围的药品费用”。我们认为，药品费用口径费用在信息化提高的前提下，数据精确度可能更高，较销售额 65%的估算值更有利于医保基金支出和预算的长期管理。此外，我们认为 2025 年起对医保支付节点金额调增至 3/15/30/60 亿元主要系口径变更，按占用医保资金规模分级的逻辑和临界值没有变化。

医保谈判给予企业一定的灵活性。征求意见稿提出，对于 1 类化学药、1 类治疗用生物制品等，若建议续约时如比值 A>110%，企业可申请重新谈判，降幅不一定高于简易续约规定的降幅。我们认为，本条规定，尤其是在医保支出或比值在规则的临界值时，给予企业在医保谈判中一定的灵活度，对创新药亦是一定程度上的政策支持。

风险

行业监管政策风险。

Fig 1. 《谈判药品续约规则（2023 年征求意见稿）》中，医保协议期内时间较长药品的降价幅度放缓、药品支付节点金额提高



Source: NHSA, HTI
Note: 红色文字为 2023 年版征求意见稿较 2022 年版的新增内容

APPENDIX 1

Summary

Event. The National Health Security Administration (NHSA) issued the Rules for Negotiating Drug Renewals (Draft for Comments 2023), which continues the framework of the 2022 version as a whole, with some adjustments. Key adjustments include:

1) The conditions for inclusion in the regular catalogue management are added: "drugs that have been included in the 'negotiated drug part' of the catalogue for more than 8 consecutive years."

2) The simplified renewal rules distinguish between two categories: those that have been included in the catalogue for ≤ 4 consecutive years and > 4 years. The rules for drugs included for ≤ 4 years are the same as those for 2022 version. For those included > 4 years, the payment standard is halved on the basis of the calculated value.

3) The medical insurance fund expenditure budget will be calculated based on the cost of drugs covered by medical insurance instead of 65% of the sales from the renewal of the contract in 2025. Taking into account the change in the reference standard, the amount of medical insurance payment nodes has also been increased from 0.2/1/2/4 bn RMB to 0.3/1.5/3/6 bn RMB from 2025.

4) For Class 1 chemicals, Class 1 therapeutic biological products, Class 1 and Class 3 traditional Chinese medicines, if ratio A >110% at the time of renewal, the company can apply for renegotiation, and the price cut in renegotiation may not necessarily be higher than the price cut determined according to the simplified renewal rules. If renegotiations fail, the drug will be removed from the catalogue.

Comments.

The price-cut rules for mature products are clear, and the long-term decline is expected to slow down. As mentioned in the Draft for Comments, drugs that have been included in the catalogue for 8 consecutive years can enter the regular catalogue management, and drugs that have been included in the catalogue for more than 4 consecutive years will be halved on the basis of the calculated value at the time of simplified renewal. We believe that based on the calculation of 2018 as the first year of implementation of the medical insurance catalogue, drugs more than 8 years in the catalogue may officially enter the regular catalogue in 2025, and the price will stabilize within the patent protection window. For drugs that have been included in the catalogue for more than 4 consecutive years, we understand that the price reduction is halved according to the rules, so the peak sales of drugs may be marginally increased.

The calibre for budget for medical insurance fund spending will change, and the accuracy of the data may be improved. According to the consultation draft, the medical insurance fund expenditure budget will be changed from "65% of the sales amount" to "drug expenses included in the scope of medical insurance payment" starting from the renewal of the contract in 2025. We believe that under the premise of improving informatization, the accuracy of data may be higher, which is more conducive to the long-term management of medical insurance fund expenditure and budget than the estimate of 65% of sales. In addition, we believe that the increase in the amount of medical insurance payment nodes to 0.3/1.5/3/6 billion RMB from 2025 is mainly due to the change in calibre, and the logic and cut-off value of grading according to the scale of medical insurance funds occupied have not changed.

Companies are given some flexibility in health insurance negotiations. The Draft proposes that for Class 1 chemical drugs and Class 1 therapeutic biological products, if the ratio is proposed to be A >110% at the time of renewal, the enterprise can apply for renegotiation, and the reduction is not necessarily higher than the reduction stipulated in the simplified renewal. We believe that this provision, especially when the medical insurance expenditure or ratio is at the threshold of the rules, gives companies a certain degree of flexibility in medical insurance negotiations, and is also a certain degree of policy support for innovative drugs.

Risks. Risks of industry regulatory policy.

附录 APPENDIX

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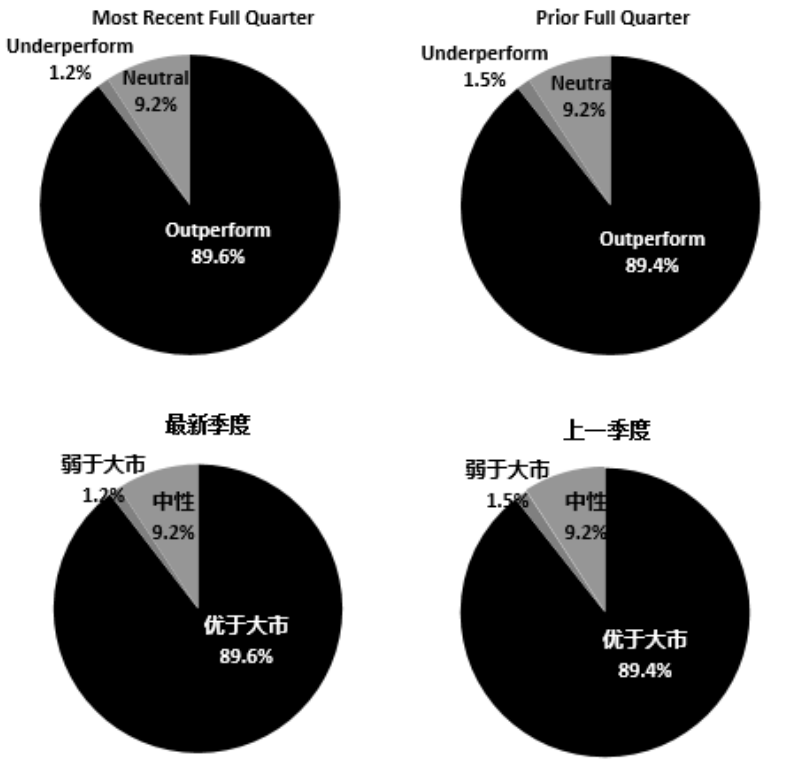

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