Improving the multi-layered medical security system and supporting innovative development in the pharmaceutical industry

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Executive Summary

Innovation is an important driving force for social progress and development, and the capacity to conduct innovative pharmaceutical research and development (R&D) is one of the key indicators of a country's scientific research and innovation capabilities. The Chinese government attaches great importance to pharmaceutical innovation and has for years promoted the advancement of the industry by setting goals for the development of innovative medicines in economic and industrial policy planning documents. Through these development goals, the government has been gradually improving the review and approval process for innovative drugs, pharmaceutical patent protections, and other mechanisms that support innovation.

After the establishment of the National Healthcare Security Administration (NHSA) in 2018, the government implemented a series of payment reforms to strengthen coverage for innovative drugs. By strengthening the management of the National Reimbursement Drug List (NRDL), the period between updates to the NRDL was shortened. National pricing negotiations on innovative drugs are now carried out on an annual basis instead of every few years, bringing into play the strategic purchasing role of China's basic medical insurance (BMI) fund. As a result, an increasing number of innovative drugs are being covered under BMI, helping to expand patient access to innovative therapies. The introduction of new analytical methods, such as health economic evaluation to assess medical insurance payment standards, is expected to better reflect the value of innovative drugs in the NRDL. The structure of the multi-layered medical security system (MLSS) continues to be clarified and improved, which has promoted the rapid nationwide development of city supplementary commercial health insurance (CSCHI) – municipal-level commercial insurance plans that are customized to different regions and that broaden the payment channels for innovative drugs.

Through the support of an array of policies, China has achieved significant progress in pharmaceutical innovation. For example, the speed of getting innovative drugs to market has greatly accelerated. The number of approved

innovative drugs has also significantly increased. In addition, China's R&D capabilities for developing innovative drugs are increasingly recognized by international regulatory authorities. Most importantly, access to many innovative medicines has improved.

Despite all the positive progress, China still faces challenges in pharmaceutical innovation. Challenges in the domestic industry include an increasing homogeneity in products such as "me-too" medicines with only marginal clinical value, and declining innovation in pioneering first-in-class drugs. Based on international practices, the establishment of a comprehensive evaluation and payment system for innovative medicines plays an integral role in industry development. At present, the existing MLSS system in China remains inadequate and requires further refinement. The BMI is only designed to cover basic medical needs, and faces immense financial pressures with limited payment capabilities. These constraints on the BMI inhibit its capacity to empower pharmaceutical innovation. Therefore, this report recommends exploring multi-payment models to better support the development of pharmaceutical innovation:

1. **Improve the price evaluation mechanism of innovative drugs for NRDL.** Fully reflect the value of innovative drugs from multiple angles including the scientific innovation they represent as well as their impacts on patients, the healthcare system and society overall. In addition, considerations of clinical practice and patient outcomes can further inform value. Further clarify evaluation criteria for the safety, effectiveness, economic efficiency, innovation, and equity of innovative drugs. Involve stakeholders with different perspectives and roles in decision-making during the evaluation process for medicines. Finally, determine the evaluation criteria and parameters that are in line with China's national conditions, and make appropriate adjustments for treatments of rare diseases, genetic diseases with a higher prevalence in specific regions, and other special diseases.

2. **Expand pilot trials of commercial health insurance (CHI) and other supplementary funding and insurance mechanisms to support payments for innovative drugs.** Encourage local authorities to implement pilot programs for multi-party co-payment mechanisms, and explore using co-payments combined with risk sharing agreements. In addition, clarify the boundary of coverage between CHI and BMI, such as by establishing and improving the drug reimbursement list for CHI. Encourage data sharing between BMI, medical service institutions, and commercial health insurers to support effective CHI product development, enabling insurers to create products tailored to specific diseases and populations. Broaden financing sources for CHI to include tax preferences, expanded flexibility to use personal BMI accounts to purchase CHI,

and increased support from charitable funds to ensure the insurance system is sustainable in the long term. Concurrently, continue to carry out innovative payment models such as risk sharing agreements based on multi-layered medical security system in local areas.

3. **Strengthen cross-departmental cooperation and improve the synergy mechanism between different layers within the medical security system.** Strengthen collaborative cooperation among all relevant government departments, including between central and local governments, as well as between government and social organizations, to provide organizational and technical support for efficient coordination within the medical security system.

1. Introduction

Bristol-Myers Squibb (BMS) is honored to be invited to participate in the China Development Forum. As a global biopharmaceutical company, BMS has long been committed to discovering, developing and delivering innovative products in immuno-oncology, hematology, immunology, and other fields, to meet the unmet and urgent needs for major diseases in China, helping patients overcome serious diseases, and contributing to the construction of a "Healthy China."

The Chinese government attaches great importance to pharmaceutical innovation, putting forward goals related to innovative drug development in programmatic documents such as the *Outlines on National Innovation-driven Development Strategy* and the *Guidelines for Pharmaceutical Industry Development Planning*. Measures taken to promote the innovative development of the pharmaceutical industry include improving patent protection, drug review and approval, and other systems. After the establishment of the National Healthcare Security Administration (NHSA) in 2018, by bringing into play the strategic purchasing role of the basic medical insurance (BMI) fund and carrying out national pricing negotiations on innovative drugs on a regular basis, a value assessment framework for innovative drugs has been gradually established in the process of determining BMI payment standards. This has not only effectively improved patient accessibility to innovative drugs, but also further incentivized innovation for the pharmaceutical industry.

It is necessary for the medical security system as the payer to further strengthen support for pharmaceutical innovation through multiple mechanisms, while ensuring sustainability of the BMI fund. This report puts forward relevant recommendations on value evaluation and innovative payment strategies for innovative drugs, with some references taken from international experience, to better promote pharmaceutical innovation and strengthen support for building a "Healthy China."

2. Overview of pharmaceutical innovation development in China

2.1 Significance of pharmaceutical innovation

According to the healthcare industry development plan released as part of the 14th Five-Year Plan by the Ministry of Industry and Information Technology, "The pharmaceutical industry is a strategic industry related to the national economy and people's livelihood, and economic development and national security, which forms an important basis for the construction of Healthy China."[1] Innovative research and development (R&D) capabilities in the pharmaceutical industry are an important indicator of a country's scientific research level and capacity for innovation, which is not only related to the overall well-being of society, but also the key to ensuring national drug safety. Innovative drugs with significant efficacy are often an important and sometimes the only means to relieve suffering and improve the quality of life for patients, which demonstrates their intrinsic clinical value and value for patients. Pharmaceutical innovations strive towards breakthrough treatments that are both high-quality and efficient, with the goal to reduce the prevalence of diseases, diminish overall medical expenditures, improve the efficiency of medical services, and help patients regain their ability to work. As such, pharmaceutical innovations that are able to reduce social and economic burdens, and provide a long-term driving force for social and economic development truly reflects their intrinsic economic and social value.

2.2 Progress and problems of pharmaceutical innovation in China

Pharmaceutical innovation requires a robust healthcare ecosystem. China has made strides in recent years toward expediting the review and approval of innovative drugs and strengthening patent protections for innovative drugs. The number of innovative drugs listed on the market, the number of innovative drug applications submitted, and the number of innovative drugs added to the National Reimbursement Drug List (NRDL) have all increased. However, China's pharmaceutical innovation still faces some obstacles, which can be addressed in part by improving the payment system for innovative drugs.

2.2.1. Progress of pharmaceutical innovation in China

Through the reform of the drug review and approval system and the establishment of a mechanism for early settlement of drug patent disputes, the marketing speed of innovative drugs has accelerated greatly, and the number of approved innovative drugs has increased in China. The annual number of marketed new drugs in Class 1 (innovative drugs that have not been marketed anywhere worldwide) increased 6 times from 4 in 2016, to 25 in 2021 (excluding Chinese

patent medicines). The annual number of Class 1 new drug applications accepted by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) has also increased from 184 in 2016, to 1379 in 2021, with a compound annual growth rate of 40%. [2] Meanwhile, the launch time of imported innovative drugs in China has also accelerated. Prior to 2016, the launch time for imported innovative drugs in China lagged by an average of 7-8 years compared with overseas. This lag time has been shortened to 2-3 years, with a few achieving simultaneous listing worldwide.[3]

By deepening reforms of the medical security system, the role of strategic purchasing of the BMI fund has gradually strengthened and access to certain innovative drugs has improved. Since the establishment of the NHSA in 2018 through the end of 2021, 250 drugs were successively included in the NRDL through national negotiations. [4,5] The annual national negotiation process has shortened the average time that innovative drugs go from market launch to being included in the NRDL. A total of 14 innovative drugs were included in the NRDL immediately after their launch in 2020.[6] In 2021, 26 innovative drugs were included, further improving patients' access to innovative drugs.[7]

Fueled by various factors, China has improved its pharmaceutical innovation capability and has been increasingly recognized by international regulatory authorities. Since 2019, several innovative drugs developed in China have been successively approved by the United States Food and Drug Administration (FDA or USFDA) for market launch.[8,9]

2.2.2. Challenges faced in pharmaceutical innovation in China

Despite the significant progress, China still faces certain challenges in pharmaceutical innovation, such as fierce competition among me-too drugs and limited candidates for first-in-class medicines.

According to data from CDE, in 2020, a total of 694 Class 1 innovative chemical drugs have been approved as Investigational New Drugs (IND), with 80.69% of all applications concentrated in oncology, anti-infection, circulatory system, and four other therapeutic areas. The same trend has also been observed in biological medicines.[10] The reason behind this is the high concentration of therapeutic targets and insufficient breakthroughs and innovations in the mechanism of drug action. Between 2016 and 2021, CDE accepted a total of 1649 Class 1 new drugs applications, with 520 targets, among which the top 6% of targets accounted for 41% of new drug applications.[2] In recent years, studies have frequently reported on the "clustering effect" of innovative drugs in China.[11,12] In 2021, the CDE also released a report suggesting a high concentration and lack of diversity in the distribution of therapeutic targets and indications for new drug clinical trials.[13]

To some degree, high homogeneity reflects still insufficient research and development (R&D) capabilities in China. From 2018 to 2020, only 2 first-in-class (FIC) new drugs (drugs with brand-new and unique mechanism of action to treat a disease) was approved in China, compared with 21 FIC new drugs approved in the U.S. over just one year. [14] [15]

The reason behind this remaining disparity may lie in part with several key aspects of payment system. At present, China's payment system mainly relies on BMI and individual out-of-pocket payments, which provides a limited payment capacity for innovative medicines, and therefore weakens support for pharmaceutical innovation.

2.3 Importance of the payment system for pharmaceutical innovation and international practice

Research and development (R&D) for innovative drugs is a long-term and complex process, requiring large investments and varying levels of risk. The ability for companies to recoup the investments that were necessary to the develop those medicines is an important driving force for pharmaceutical innovation. Innovative drugs are often more highly priced because they reflect the level of R&D investment and scientific research that was required to go into their development. A comprehensive payment system for innovative drugs could offer a more stable environment for the purchase and use of medicines following their market launch, ensuring commercial viability for innovative drugs while improving patient accessibility. For rare diseases and regional genetic diseases, due to the smaller size of the patient group, the corresponding development of innovative drugs is more difficult and less commercially viable, despite their significant social value and benefit to patients and healthcare systems. Without the support of a fully developed medical payment system, it is difficult to maintain a sustainable level of funding resources to invest in the R&D of innovative drugs for such diseases. A robust payment system for innovative drugs would also benefit the development of the domestic pharmaceutical industry by providing support for domestic companies, increasing their motivation and capacity to innovate, and accelerating their growth to better compete on the international stage.

Looking at the experience of major developed economies, the medical security payment systems in these countries cover innovative drugs, and have synced their health insurance systems so that innovative drugs are able to be reimbursed at the same time that they are launched in the market. These measures allow innovative drugs to be commercially viable for pharmaceutical companies, and help

pharmaceutical companies acquire the resources they need to pursue the next round of innovation, thereby forming a reinforcing cycle of innovation.[16]

Payment for innovative drugs in developed countries mainly includes the following aspects:

1. **Reimbursement list management**. Developed countries usually initiate interim policies or special tracks for innovative drugs that meet certain criteria to be included in their national reimbursement lists for therapies, which is also the main path to support payment for innovative drugs. With slight differences in eligibility criteria for innovative drugs in different countries, the main focuses for inclusion are clinical efficacy, drug prices, and clinical unmet needs. In addition, reimbursement policies in developed economies have generally adopted list management policies based on drug classifications and link to different determination methods for payment standards. The most innovative countries also do not place caps on the maximum annual cost per patient that they will reimburse for medicines, which allows a value-based pricing assessment system to thrive and support innovation.

2. **Determination of payment standards**. There are significant differences in the forms of medical insurance around the world. However, in determining payment criteria, payment standards are applied according to the efficacy or degree of scientific innovation that the drugs represent, and there is a higher willingness to pay for drugs that present a higher degree of innovation. In the process of evaluating the value of therapies, different groups such as healthcare professionals (HCPs), pharmacists, health economists, patient advocacy groups, enterprises, and industry associations are also involved in the process.

3. **Comprehensive value assessment**. When evaluating the value of drugs, economic factors that could impact a healthcare systems' capacity are included as much as possible, such as the direct, potential, and social costs of treatments. Potential costs that are taken under consideration include if the drug could reduce public service expenditures, and the burden of care for implementing the therapy. The social costs and benefits that drugs are also assessed on include potential benefits to the employment rate or labor market, and future medical insurance expenditures.

4. **Multi-payer co-payment**. As multiple parties frequently participate in the payment of innovative medicines, they are often paid for in different proportions by multiple forms of medical insurance. In some countries, payments can be financed through funds established by the government or by charitable organizations.

3. Payment for innovative drugs under the multi-layered medical security system

3.1 The positioning of the multi-layered medical security system

In 2020, the central government officially set the development goals of China's multi-layered medical security system, proposing that "by 2030, a comprehensive medical security system should be established featuring BMI as the backbone, medical assistance as the underpinning, and supplementary medical insurance, CHI, charitable donations, and medical assistance flourishing together...to achieve better access to healthcare." The goal also emphasized "enabling the BMI fund to play a role in strategic purchasing to promote high-quality and collaborative development of medical security and healthcare services." With the principle of "covering basic needs," BMI as the backbone of the medical security system should "appropriately determine its scope and payment standards based on its capacity."[17] In addition, the 14th Five-Year Plan encouraged CHI to incorporate innovative drugs into its coverage to support pharmaceutical innovation.[18]

3.2 Progress of payment system reform for innovative drugs

For a long time, social medical insurance has been the pillar of healthcare security in China. Beginning in the 1990s, several of the main payment mechanisms for innovative drugs were formed through a series of policy developments, including the NRDL, the national negotiation mechanism, and the payment standards that formed based on these mechanisms.

The NRDL is the basic policy standard for drugs covered by the BMI. In 2000, China formulated the first version of the NRDL, but only three adjustments were made prior to 2017.[19] The adjustment period was long, and support for innovative drugs was very limited. In 2017, the Ministry of Human Resources and Social Security of the PRC launched a new round of negotiations and included 36 drugs on the NRDL. After the establishment of the NHSA in 2018, special negotiations with a focus on cancer drugs were organized and 17 innovative drugs were included in the NRDL.[20] Since then, the national negotiations for innovative drugs have been carried out annually, and guiding principles have been provided for the exclusion of drugs from the NRDL. In recent years, some drugs have been removed from the NRDL, leading to the greater inclusion of innovative drugs. The purpose of establishing the national negotiation mechanism is to enable the BMI fund to play a more strategic purchasing role. Specifically, this mechanism enables the providers to negotiate with pharmaceutical companies based on "actual BMI expenditures," improve fund use efficiency, reduce the burden on

patients, maximize drug coverage within the limited BMI fund, and support the pharmaceutical industry to embark on new innovative development. The BMI payment standards for innovative drugs are determined in the process of price negotiation and consultation.[21] The BMI fund makes payments to designated providers and retail pharmacies according to the prescribed proportion provided by BMI payment standards.

After several years of practice, the process and mechanism for national negotiations of innovative drugs has been gradually clarified, including for the preparation, application, expert review, negotiation, and the announcement of the results. At the review stage, experts in clinical practice, pharmaceuticals, pharmacoeconomics, BMI management, and other fields are gathered together to evaluate every therapy's safety, clinical efficacy, economic efficiency, innovativeness, and equity.[22]

The therapeutic areas covered by negotiated innovative drugs includes not only different cancers, but also brings a new focus to rare diseases. According to NHSA data, by the end of 2021, there were more than 60 rare disease drugs that were approved in China and more than 40 of them were included in the NRDL.[23] In the 2021 NRDL, cancer drugs and drugs for rare diseases were two key focuses of the national negotiation.

In recent years, the emerging city supplementary commercial health insurance (CSCHI) has expanded coverage for some innovative drugs, including for cancer therapies and treatments of rare diseases, providing a new channel for innovative drug payment.

3.3 Current challenges faced by innovative drug payments

At present, the supplementary layers of the medical security system are still under development, such as CHI and charitable donations. BMI may remain one of the most important payment channels for innovative drugs for a long time. Therefore, for drugs that cannot be included in the NRDL, their access to patients will be low. Given that at the present time there are not enough other potential payers that could defray the cost of these important therapies for patients, this jeopardizes the commercial viability of breakthrough medicines in China, and leads to insufficient funding to support future innovation.

The operating principle of the BMI is to "cover basic needs," while ensuring fund sustainability. Therefore, it would not be realistic for BMI to include all innovative drugs in the NRDL. Although the therapeutic areas covered by the BMI are gradually expanding, the focus is mainly on cancer and rare diseases.

With the implementation of the system of BMI formulary, the NRDL is unified across the country, and local governments do not have the authority to adjust it. This has a tremendous impact on treatments for diseases that have a higher prevalence in only certain regions, but remain relatively uncommon on a national scale. If drugs for such diseases cannot be included in the NRDL, it will inevitably have a great impact on patients suffering from these regional diseases.

At the same time, for innovative drugs that have been included in the NRDL through national negotiations, the *Interim Measures for the Administration of Use of Drugs Covered by the BMI* stipulates that "in principle, the negotiated drugs will be directly procured online according to the payment standards during the agreement period." [21] Therefore, the price determined during negotiations is very likely to become the price of the drug, placing mounting price reduction pressures on pharmaceutical companies, which could greatly dampen enthusiasm and the impetus for pharmaceutical innovation. [22]

In the short term, substantial price reductions for innovative drugs via NRDL negotiations has improved patient affordability. However, from the long-term perspective, low prices will make it difficult for innovative pharmaceutical companies to recoup high R&D costs, and affect their pricing strategies in the global market. Under-valued prices, therefore, impact the sustainability of innovative development in the industry, and ultimately lower patient access to innovative treatments.

4. Concluding recommendations to improve the multi-layered medical security system and support innovation in the pharmaceutical industry

Experiences from developed economies have shown that payment standards and co-payment mechanisms for innovative drugs have significantly advanced pharmaceutical innovation, and expanded healthcare system capacity to provide long-term sustainable patient access to breakthrough therapies. Therefore, in addition to improving the policies and mechanisms for each stage of the drug development process, this report recommends strengthening the payment standards and payment mechanisms for innovative drugs based on China's multi-layered medical security system.

Innovative and cost-effective drugs should be included in the NRDL, expanding patient access to life-changing high-value treatments. Concurrently, expanding inclusion would expand commercial viability for innovative drugs, which further encourages innovation. That being said, the inclusion of more innovative drugs will inevitably increase expenditure pressures on the BMI fund. As such, to support and encourage innovation while still ensuring BMI fund sustainability, it is critical to determine BMI payment standards through a more scientific and comprehensive evaluation mechanism. Based on payment standards, more payers should be involved to alleviate financial pressures on the BMI fund, better support pharmaceutical innovation, and improve patient access. We provide greater detail and context to these actionable measures in the concluding recommendations below.

4.1 How to improve the pricing evaluation mechanism for innovative drugs under the BMI system

4.1.1 Clarify multi-dimensional value evaluation criteria

The value of innovative drugs is broad and multi-dimensional, which is not only reflected in the improvement of patients' health, but also in the reduction of disease burden and the resulting benefits to the healthcare system, the economy, and society overall. As such, when assessing value and setting payment standards for innovative drugs, the multi-dimensional value of treatments to the healthcare system, patient outcomes, innovation, the economy, and society should be fully reflected.[24] These dimensions are also prioritized in international practice. At present, although the dimensions for drug evaluation such as safety, clinical efficacy, economic efficiency, scientific innovation, and equity are proposed in

the *Application Guidelines for the 2021 National Reimbursement Drug List Adjustment*, opinions on the connotation of the value of innovative drugs are not aligned. For example, the NRDL price negotiation mechanism currently anchors negotiating innovative medicines to prices of alternative comparator products that are often off-patent medicines that do not deliver the same value to patients, the healthcare system, or society overall. This report recommends that evaluation standards should be more detailed and clearly defined, and the evaluation criteria and rules for safety, clinical-efficacy, economic efficiency, innovation, and equity be further clarified and made publicly available to allow companies to fairly and comprehensively demonstrate the value of their innovative treatments. In addition, existing guidelines for pharmacoeconomic evaluation suggest that "all pharmacoeconomic evaluations applied to public decision-making should take social perspectives into consideration." Costs, such as all direct medical costs, direct non-medical costs and indirect costs, should also be taken into account. However, in practice, only direct medical costs are considered from the payers' perspective. Thus, it is recommended to further improve and clarify all evaluation dimensions.

Take β-thalassemia, a genetic disease with a higher prevalence in southern provinces such as Guangdong, Guangxi, and Hainan, as an example. The current treatment requires long-term blood transfusion and iron chelation therapy. The iron chelation therapy requires continuous subcutaneous injection for more than 8 hours a day, 5-7 days per week. For patients, in addition to the direct cost of treatment, they also have other indirect non-medical costs, such as travel. Additionally, patients may face loss of income due to the demanding treatment process, which further increases the economic burden on patients and their families. From a societal point of view, patients with β-thalassemia often lose the opportunity to get an education due to the long treatment process during childhood, and are more likely to fall into poverty in adulthood due to insufficient knowledge and skills, increasing the burden on social assistance. In contrast, a new treatment mechanism, such as erythropoiesis-stimulating agents (ESAs), can significantly reduce patients' need for regular transfusion and iron chelation therapies. This innovative treatment offers patients an opportunity to return to normalcy, reducing social and public service costs, and creating social value. In this regard, all relevant costs and additional social benefits should be taken into account during a drug's value assessment to ensure a more comprehensive evaluation.

4.1.2 Standardize evaluation and pricing calculation processes and methods

Since the implementation of national negotiations for the NDRL, whether the pricing negotiation calculation benchmark is scientific, sound, and accurate has

become the key to a successful negotiation. Take the NRDL update in 2021 as an example, the *2021 Work Plan for the National Reimbursement Drug List Adjustment* pointed out that review experts are responsible for initial assessment and voting, developing lists for inclusions, exclusions, possible exclusions, and payment restrictions. The evaluation experts are divided into two groups, one group to assess the budget impact on BMI funds, and the other that focuses on pharmacoeconomic impacts. Current calculations of the NRDL pricing negotiations are mainly based on cost-effectiveness and impacts on the BMI fund. However, the calculation pathways have not been completely unified and the evaluation process is relatively subjective, affecting the accuracy of companies' pricing calculation, as well as their success in negotiations. This report recommends that relevant authorities gradually unify the calculation process by issuing official guidelines to clarify relevant calculation methodology and formulas, as well as the types of adjustment factors and their influence ratios. Guidelines should also be issued that standardize the source of parameters, and set timeframe limits.[25]

In addition, the NRDL should remove informal caps placed on the maximum annual cost per patient that the BMI fund will reimburse, as this practice sets a ceiling that can undermine the value-based pricing assessment system that is critical to sustained innovation in the pharmaceutical sector. Authorities should also consider elongating the required timeframe for resubmission to be included on the NRDL, which is currently every two years, as the resulting frequent price cuts undermines both the commercial viability of innovative drugs and the value-based evaluation system.

4.1.3 Involve multiple stakeholders in the evaluation process

The use of innovative drugs involves multiple stakeholders. Based on international experience, we see that robust healthcare systems include not only clinical and health economics experts, but also patient representatives as well as medical and industry associations when evaluating whether certain drugs should be included in their medical reimbursement systems. In the United States, payers and service providers often form a Pharmacy and Therapeutics Committee (P&T). The Committee is generally the medical staff committee responsible for managing the formulary system.[26] In China, a team of experts, including experts in pharmaceuticals, pharmacoeconomics, and BMI management, is formed specifically for the NRDL adjustment and pricing negotiation. However, other relevant stakeholders, such as patients, are not yet included. As such, the final decisions for NRDL may not fully reflect the most pressing needs of patients and the value of therapies to patients. Based on this, this report recommends that NRDL adjustments should fully consider the perspectives of government, health

providers, innovative drug companies, and patients. In addition, officials should build an open communication channel that allows different stakeholders to directly communicate and offer their own respective viewpoints. They should also establish a mechanism for appealing decisions and providing feedback to allow relevant stakeholders to offer suggestions on the evaluation results.

4.1.4 Optimize technical evaluation standards to suit national conditions

In 2017, pharmacoeconomic evaluation was listed as an important basis for the NRDL negotiations. Since then, when adjusting the NRDL, the NHSA has also applied the principle of pharmacoeconomics to demonstrate the cost-effectiveness of the innovative drugs.[27] In practice, Cost Effectiveness Analysis (CEA) is usually adopted to evaluate the economic value of an intervention using the Incremental Cost-Effectiveness Ratio (ICER), which is a summary measure representing the economic value of an intervention (a drug or treatment), compared with an alternative (comparator). If the ICER is less than or equal to the cost-effectiveness threshold, the intervention group is more economical than the comparator group, or vice versa.[28] Currently, though there is no official ICER threshold in China, the industry refers to the ICER threshold range recommended by the World Health Organization (2000) at 1-3 times the national per capita GDP. The thresholds used by developed countries, such as the United States and the United Kingdom, tend to differ due to varying social and economic conditions, and their respective purchasing power parity.[29] Studies in China indicate that the average value of China's ICER threshold range is 0.63 times, at 1.5 times per capita GDP. [30,31] However, more research is required to measure the ICER thresholds that would most accurately reflect China's development progress.

The ICER threshold range directly impacts the economic evaluation result of innovative drugs. In addition, the ICER value for drugs for certain specialty therapeutic areas, such as rare diseases, is usually very high due to the lack of a comparator. Therefore, in many countries, the thresholds for rare diseases and terminal illness drugs are appropriately evaluated to better reflect their true values.[32,33] For more objective and appropriate valuations of innovative drugs in China, this report recommends adjusting the ICER threshold to appropriately consider disease profiles when evaluating innovative drugs for specialty therapeutic areas, such as rare diseases and regional genetic diseases.

4.2 Strengthening commercial health insurance (CHI) and other supplementary security systems to support payment for innovative drugs through pilots

4.2.1 Encourage CHI to participate in innovative drug payment

Internationally, innovative drugs are often covered by multiple medical insurance plans, with each plan covering a set proportion of the treatment, or through funds supported by governments and charitable foundations.[34] The goal of the multi-layered medical security system in China is to develop multiple options that will expand patient access to necessary medical treatments. Innovative drugs are an important means to achieve better medical treatments. Based on paying a premium for innovative medicines according to BMI payment standards, the report recommends utilizing CHI and charitable donations to help cover payment for innovative drugs, and specifically leverage the supplementary function of CHI.

To expand payment coverage for innovative medicines, stakeholders should first support the synergy between CHI and BMI. The government should guide CHI development to focus on covering medical treatments that are not covered under BMI, as well as services that may incur higher expenses. Furthermore, health authorities should clarify the responsibilities of BMI and CHI through the implementation of the BMI treatment list. While gradually improving the NRDL, they should additionally explore the establishment of a commercial reimbursement drug list, focusing on covering innovative drugs that are not included in the NRDL. The commercial reimbursement drug list should be synchronized with the NRDL.

Second, stakeholders should encourage data sharing for CHI to advance insurance product innovation. Data sharing between BMI, healthcare providers, and CHI companies can better support insurance product design and development, such as developing tailored insurance products for rare or genetic diseases and specific population groups. In addition, data sharing will help improve product sustainability for insurance plans, and further enhance risk management within the healthcare system.

Third, the government should broaden the financing channels of CHI to ensure the long-term sustainability of the commercial insurance system. Authorities could explore offering incentives such as preferential personal income tax policies for CHI to encourage consumers to purchase CHI to help scale and expand population coverage. In addition, they should relax restrictions on personal BMI accounts to allow individuals to use their accounts to purchase CHI for themselves and their family members. Local governments or charitable organizations should be

encouraged to purchase CHI for people facing financial difficulties or suffering from serious illness or disease.

4.2.2 Introduce risk sharing mechanisms based on multi-layered medical security system

In addition to strengthening cooperation between different layers of the medical security system, experiences from developed markets offer useful perspectives regarding value assessment for innovative drugs with uncertain clinical efficacy and economic efficiency. To help resolve this uncertainty, China could explore introducing risk sharing agreements, through which drug payers such as insurers and pharmaceutical companies can negotiate an agreement to bear the potential external risks that patients may face when treated with the innovative drugs. The risk sharing could be based on the effectiveness of the treatment (performance-based) or on its impact to the BMI fund (financial-based).[35] For the performance-based agreement, the pharmaceutical companies could guarantee the therapeutic effect by setting certain targets, but would bear the corresponding costs if and when the target results are not achieved. For the financial-based agreement, the BMI fund and the pharmaceutical companies could agree to an upper limit for expenditures on each drug. If the costs exceed the upper limit, the pharmaceutical companies would bear the cost or offer discounts to the costs.

Prior to the clarification of BMI coverage, some regions in China have explored different payment methods for expensive innovative drugs. For instance, based on the negotiated payment standard and the agreed number of users for a particular drug, the individual, BMI fund, and pharmaceutical companies are set to jointly cover the cost for the treatment. However, if the number of users exceeds the agreed number, the pharmaceutical company shall cover the excess expenses.[36] With the positioning of BMI as a healthcare safety net, authorities have been providing further clarity on the upper boundaries for coverage and fund management within BMI. This report recommends establishing a risk sharing model the utilizes supplementary insurance and alternative funding offered within the multi-layered medical security system to provide joint financial support for innovative drugs.[37] In particular, the cost for innovative drugs that exceed the risk-point in the BMI fund could be covered by CHI or shared by CHI and pharmaceutical companies.

4.2.3 Strengthen the exploration of multi-payer models through local pilots

The burden and impact caused by serious diseases with low incidence rates should not be overlooked, considering there are significant regional differences in disease prevalence, economic development, and BMI pool across China. Although local governments need to strictly follow the NRDL, they can adjust the proportion of

the BMI fund payment for innovative drugs within their fund budget, leaving room for other supplementary insurance and alternative funding sources to support. As such, there should be opportunities for local pilots to explore multi-payer models, and to encourage local areas to implement co-payment pilots for common regional diseases and more severe diseases, such as β-thalassemia as mentioned above. This report recommends strengthening the role of CHI and encouraging product development in insurance coverage for specialty diseases, such as rare diseases and diseases with a higher prevalence in specific regions. Alternatively, local authorities can introduce innovative models such as risk-sharing agreements based on the development of their local multi-layered medical security systems, which will create practical insights that can be leveraged for adoptions in other regions in the future.

4.3 Strengthen cross-departmental collaboration and establish a synergy mechanism between different systems

The implementation of a multi-dimensional value assessment system for innovative drugs and multi-payer co-payments requires inputs from a broader group of stakeholders. In particular, multi-payer co-payments under the multi-layered medical security system requires effective synergy and coordination across stakeholders in the healthcare sector. The report recommends strengthening coordination mechanisms and collaboration among all relevant government departments, including between and within central and local governments, as well as between the government and the private sector. In addition, the roles and responsibilities of all government departments involved in assessing the value of drugs and in managing the co-payment system should be clarified, and departments should establish appropriate communication channels to ensure coordination. Lastly, authorities should offer technical support for participants in the multi-layered medical security system through data and information sharing platforms to improve efficiency.

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