Notice of the National Medical Insurance Administration and the National Health Commission on Issuing "Several Measures to Support the High-Quality Development of Innovative Drugs"[1]

Authority: **National Healthcare Security Administration, National Health Commission**

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To the Medical Insurance Bureaus and Health Commissions of all provinces, autonomous regions, municipalities directly under the central government, and the Xinjiang Production and Construction Corps:

In order to implement the decisions and deployments of the Central Committee of the Communist Party of China and the State Council, and to fully support the development of innovative drugs throughout the entire chain, we have formulated the "Several Measures to Support the High-Quality Development of Innovative Drugs." With the approval of the State Council, this is now issued to you for careful implementation in accordance with local conditions.

National Healthcare Security Administration

National Health Commission

June 30, 2025

(Proactively Publicly Released)

Several Measures to Support the High-Quality Development of Innovative Drugs

In order to further improve the full-chain measures supporting innovative drug development, promote high-quality development of innovative drugs, and better meet the diversified medical and pharmaceutical needs of the public, the following measures are proposed:

I. Strengthening Support for Innovative Drug R&D

1. Support the use of medical insurance data for innovative drug R&D. Enhance information interoperability and collaboration among medical care, medical insurance, and pharmaceuticals, manage medical insurance data resources effectively, and promote the use of public data resources in the field of medical insurance. On the basis of ensuring data security, legality, and compliance, explore the provision of necessary medical insurance data services for innovative drug R&D. Utilize the national unified medical insurance information platform to collect and analyze data on disease spectra and clinical medication demand, develop data products tailored

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

to innovative drug R&D needs, and support pharmaceutical companies, research institutes, and medical institutions in rationally determining R&D directions and planning R&D pipelines, thereby improving innovation efficiency.

2. Encourage commercial health insurance to expand investment in innovative drugs. Encourage commercial health insurance companies to provide stable, long-term investment for innovative drug R&D through various means such as innovative drug investment funds, cultivating patient capital supporting innovative drugs.

3. Strengthen guidance on drug formulary access policies. Optimize enterprise reception mechanisms within medical insurance authorities, maintain smooth communication channels between medical insurance departments and innovative drug enterprises, and provide targeted policy guidance on formulary access for innovative drugs. Enterprises whose innovative drug market authorization applications have been accepted by the national drug regulatory authority may simultaneously apply for point-to-point policy guidance from the medical insurance authorities. Medical insurance authorities and enterprises may exchange information regarding main specifications, reference drugs, payment scope, and other aspects of drug formulary access.

4. Coordinate and promote innovative drug R&D. Organize and implement major national scientific and technological projects for innovative drug development, focusing on major infectious diseases, prevalent major chronic diseases, pediatric drugs, rare diseases, and other key areas. Promote implementation of drug R&D-related tasks and improve multi-departmental support mechanisms. Leverage national medical centers and national clinical medical research centers, and support pharmaceutical companies, research institutes, and medical institutions in R&D-oriented scientific research.

II. Supporting Innovative Drugs in Basic Medical Insurance and Commercial Health Insurance Formularies

5. Improve the dynamic adjustment mechanism for the basic medical insurance drug formulary. Based on the affordability of the medical insurance fund, basic medical needs of the public, and clinical technological progress, regularly adjust and optimize the basic medical insurance drug formulary (hereinafter referred to as the “insurance formulary”). While ensuring basic coverage, include qualified innovative drugs in the formulary according to procedures. In special circumstances such as major public health emergencies, temporary inclusion in the medical insurance payment scope may be considered.

6. Reasonably determine medical insurance payment standards for innovative drugs. Fully utilize pharmaco-economics, health technology assessment, and other technical methods. Consider medical insurance fund capacity, clinical demand, patient benefit, market competition, R&D investment, and other factors. Negotiations between medical insurance authorities and innovative drug enterprises should establish payment standards that match China’s national conditions, market positioning, and the clinical value of the drugs. Enhance professional capabilities in insurance negotiation assessment, improve calculation methods, and better reflect the clinical value of drugs. Optimize renewal rules: allow reasonable adjustment of payment standards for innovative drugs in the formulary when sales exceed expectations or indications are expanded, without exceeding the maximum reduction under simple renewal rules, to stabilize enterprise expectations. Supply of drugs to non-insurance designated medical institutions is not subject to insurance payment standards.

7. Establish a commercial health insurance innovative drug formulary. To meet the needs of a multi-tiered medical security system, create a commercial health insurance innovative drug formulary (hereinafter "commercial insurance innovative drug formulary"), focusing on highly innovative drugs with high clinical value and significant patient benefit beyond basic medical insurance coverage. Encourage commercial health insurance and medical mutual aid programs to use it as a reference. Reasonably determine settlement prices for drugs in this formulary through negotiation and explore stricter price confidentiality mechanisms. Drugs in this formulary are not counted toward basic medical insurance out-of-pocket ratios or monitored alternative drugs in centralized procurement. Coordinate the linkage between commercial and basic insurance formularies.

8. Strengthen real-world research on innovative drugs. Explore scientific real-world research methods, encourage innovative drugs to undergo real-world research, and link results to formulary access, renewal, and adjustment of insurance payment scope. Develop clinical comprehensive evaluation technical guidelines for innovative drugs, promote broader application of evaluation results, and continuously improve medical institutions' capacity for innovative drug deployment and use.

III. Supporting Clinical Use of Innovative Drugs

9. Optimize drug online listing procedures. Enterprises may select provinces for initial online listing of innovative drugs, conduct quality evaluations, set reasonable prices, and the receiving province shall handle procedures and assume management responsibility. Innovative drugs included in the medical insurance and commercial insurance formularies may be directly listed online according to regulations, with joint review and simplified procedures, pre-submission communication, reduced documentation, shortened processes, and inter-provincial rapid coordination. Provincial centralized procurement institutions should ensure efficient end-to-end services during online listing, including application acceptance, platform entry, and online procurement qualification.

10. Accelerate innovative drugs into designated medical institutions. Encourage designated medical institutions to hold pharmacy committees within three months after formulary updates, adjust drug inventories, or set up temporary procurement channels to ensure clinical treatment needs and patient access. Innovative drugs in insurance formularies are not restricted by hospital drug catalogues or drug ratio requirements. Negotiated drugs in the insurance formulary and commercial insurance innovative drugs are exempt from the "one drug, two rules" restriction.

11. Improve clinical capability for innovative drugs. Guide medical institutions in enhancing clinical use capabilities. Encourage professional societies and medical institutions to summarize usage experience, conduct training, and guide rational use. Consider outputs of pharmaceutical services and develop pricing project guidelines for pharmaceutical medical services.

12. Improve insurance payment management for innovative drugs. For appropriate cases of innovative drug use not suited to disease-based payment standards, allow medical institutions to apply for special case negotiations. Simplify procedures, optimize processes, organize expert reviews quarterly or monthly, and implement project-based payments or adjusted payment standards based on evaluation results.

13. Ensure supply-demand-side insurance services. Improve the “dual-channel” management mechanism, strengthen supply assurance for innovative drugs. Develop the “Medical Insurance Drug Cloud Platform” to provide rapid response and easy access to information for medical institutions and patients. Drugs not supplied as required may be removed from the insurance formulary. Implement prepayment and real-time settlement policies to enhance fund settlement efficiency. Medical institutions shall settle payments with enterprises in accordance with contractual agreements.

IV. Enhancing Multi-Source Payment Capacity for Innovative Drugs

14. Utilize multi-tiered medical security systems. Encourage commercial health insurance, medical mutual aid, and other mechanisms to cover innovative drugs. Facilitate patient access through charitable donations or similar means. Provide cooperation support in data sharing and settlement for qualified commercial health insurance, and cases within the scope of commercial insurance coverage may be paid outside disease-based payment systems after review.

15. Promote global market development of innovative drugs. Leverage China’s large production capacity, market size, and experience to actively promote innovative drug achievements internationally. Encourage exploration of global trading platforms targeting Southeast Asia, Central Asia, and other Belt and Road countries, and support international promotion. Utilize advantages in Hong Kong and Macau to facilitate Chinese innovative drugs reaching the world. Encourage more innovative drugs to enter the Chinese market to better meet public medical needs.

V. Strengthening Guarantee Measures

16. Strengthen organizational leadership. Enhance coordination between medical insurance and health departments, clarify industry management responsibilities, and form a demand-driven innovation development force. Evaluate policy implementation effects, timely adjust policies, and align with relevant reform pilots. Conduct policy publicity to create a supportive environment for innovative drugs. Strengthen medical insurance fund supervision, fully implement drug traceability code applications, supervise prescription circulation processes, and include innovative drug payments in key supervision areas.