Notice on Piloting a System for the Preliminary Establishment of Medical Service Pricing Items for Advanced New Technologies and Products

China – NHSA National Healthcare Security Administration

Main information

Scope of Application:

Providing price policy guidance from the time a new technology is approved for clinical research (or a new product enters the NMPA's special review procedure for innovative medical devices) until it is formally approved for clinical application

Effective Date:

September 15th, 2026

Related Provisions:

- Medical Service Price Item Project Establishment Guidelines
- Medical Service Real-World Value Evaluation Guidelines (Trial for implementation)

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Key Topics

Framework

- **A Consistent "Value-Based" Framework:** The pre-project establishment system mirrors the logic of drug price negotiations. Just as innovative drugs are evaluated for clinical value and pharmacoeconomic before entering the medical insurance catalog, new medical technologies are now assessed for their clinical necessity and cost-effectiveness before a price item is established.
- The regulation is a piece of the NHSA's broader strategy to manage the total healthcare budget. By making the payment pathway for new medical services more predictable and value-driven, it complements the existing drug pricing mechanisms, ensuring that the fund's spending—whether on drugs or procedures—is increasingly tied to demonstrated clinical benefit and economic reasonableness

What's new

- **"Technology Not Yet Approved, Price Item First" Approach:** For the first time, the NHSA formally establishes a pathway for price item preparation to begin **before** a technology or product receives final market approval. This is described as a "forward-looking" approach to ensure that once a product is approved, it can quickly enter the charging system without a lengthy administrative lag
- **Expected Price Commitment for Insufficient Economic Evidence:** If economic evidence is insufficient but other criteria are met, the applicant and relevant parties may make an **expected price commitment** in order to obtain pre-project establishment

Sensitive Factors

- The NHSA will **suspend the pre-project establishment acceptance qualification** of provincial departments that relax quality standards or repeatedly issue conclusions inconsistent with macro policy direction
- The Notice requires guiding the **reasonable formation of medical consumable prices** and conducting real-world value evaluations. Even with accelerated price item establishment, the NHSA retains authority over the pricing of the associated consumables

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Drivers

- **Early Engagement Through Hospital Partners**: Since only tertiary hospitals can initiate applications, companies with high-level technologies or products in the clinical research or innovative device review stages should proactively identify and partner with leading tertiary hospitals to prepare the pre-project establishment application. Early application means the price item can be ready when the product is approved, avoiding a post-approval revenue lag
- **Real-World Value Evaluation:** The "conditional price item" pathway requires the applying institution to conduct real-world value evaluation. Companies should design post-market real-world data collection plans in advance, ensuring that clinical and economic data can be generated to support conversion to a full price item or to defend against potential price reductions