Notice of the National Healthcare Security Administration on Piloting a System for the Preliminary Establishment of Medical Service Pricing Items for Advanced New Technologies and Products[1]

Authorities: National Healthcare Security Administration (NHSA)

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To the healthcare security administrations of all provinces, autonomous regions and municipalities directly under the Central Government, and the Xinjiang Production and Construction Corps:

In order to further harness the guiding role of medical service pricing policies, promote the translation and application of scientific and technological innovations, accelerate the introduction of advanced new technologies and products into clinical practice, and enable scientific and technological innovation to better benefit the public, the following notice is hereby issued concerning the exploration and establishment of a system for the preliminary establishment of medical service pricing items (hereinafter referred to as "preliminary pricing item establishment").

I. Exploring the Implementation of Preliminary Establishment of Medical Service Pricing Items

Provincial healthcare security authorities may, upon application, undertake preliminary pricing item establishment from the date on which a new medical technology is authorised to enter clinical research (or an application for the clinical translation of a new biomedical technology is accepted by the health authorities), or a new product is admitted to the drug regulatory authorities' special review procedure for innovative medical devices, until formal approval for clinical application is granted. Through early involvement, they shall provide medical institutions with pricing policy guidance and lay the groundwork for the rapid inclusion of new technologies and products within the scope of chargeable medical services following formal approval. The aim is to achieve substantially seamless coordination between approval for application and the establishment of pricing items, stabilise expectations of financial returns, promote the digital and intelligent development of healthcare for all, and ensure that the public has access to higher-quality and more efficient diagnosis and treatment services.

II. Scope of Preliminary Pricing Item Establishment

Preliminary pricing item establishment shall focus on clinical needs, prioritise patient benefits and support high-quality innovation. It shall apply to advanced new technologies and products for which financial returns must be generated through medical service charges, principally newly proposed pricing items involving the following: first, new technologies offering substantial clinical

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

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value and breakthroughs in diagnosis and treatment; second, new equipment that meets major clinical needs, effectively addresses diagnostic and therapeutic challenges in key areas, and improves the efficiency and precision of diagnosis and treatment; and third, new consumables that address unmet diagnostic and therapeutic needs, primarily benefit patients and change surgical approaches.

To concentrate resources on supporting advanced new technologies and products, the following shall fall outside the scope of preliminary pricing item establishment: products appropriately charged for as drugs or medical consumables that do not require the establishment of an accompanying pricing item; products constituting iterative upgrades to existing medical consumables or equipment; and diagnostic reagents other than new Class III diagnostic reagents meeting the diagnostic and therapeutic needs of major diseases.

III. Procedures for Preliminary Pricing Item Establishment

Provincial healthcare security authorities shall be responsible for preliminary establishment of medical service pricing items. They shall ensure accessible application channels and follow a process consisting of an application by a medical institution, acceptance by the provincial healthcare security authority, guidance from the National Healthcare Security Administration, and a determination by the provincial healthcare security authority.

One tertiary hospital shall take the lead in submitting an application directly to the provincial healthcare security authority, together with the Application Form for Preliminary Establishment of Medical Service Pricing Items (template attached) and supporting evidence. Where the application materials are insufficient, the provincial healthcare security authority shall issue a single consolidated request for supplementation and improvement. Once the first application for a particular technology or product has been submitted, other medical institutions need not submit duplicate applications, and provincial healthcare security authorities shall not accept duplicate applications.

The provincial healthcare security authority shall formulate a preliminary assessment within the prescribed time limit and fulfil its reporting obligations in respect of significant matters. The National Healthcare Security Administration shall, as appropriate, organise relevant parties to undertake studies and assessments and, where necessary, formulate guidance on innovation, equity, economic value and other matters within a specified period.

The provincial healthcare security authority shall make a determination in accordance with the prescribed procedures and undertake the follow-up work. Where the requirements are met, preliminary pricing item establishment shall be granted. Where the requirements are not met, it shall be refused and reasons shall be given. Where evidence of economic value or other relevant matters is insufficient, preliminary pricing item establishment may be granted after the applicant and relevant parties have given an undertaking concerning the anticipated price. Following acceptance of applications by provincial healthcare security authorities, the National Healthcare Security Administration shall regularly compile and circulate updates on processing progress.

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IV. Implementation of the Outcomes of Preliminary Pricing Item Establishment

The provincial healthcare security authority that originally accepted the application shall undertake follow-up work in light of the status of the relevant prior approvals. For new technologies and products formally approved for application, it shall efficiently advance the introduction or optimisation of pricing items. For new technologies and products for which clinical research fails, efficacy is unsatisfactory or approval by the competent authorities is refused, it shall terminate the procedure for introducing a new pricing item.

The outcomes of preliminary pricing item establishment shall be implemented through the following approaches:

1. Introduction of a new pricing item. Where existing pricing items cannot cover the medical services associated with a new technology or product, the provincial healthcare security authority that undertook preliminary establishment shall rapidly introduce a new pricing item through an expedited procedure. Priority shall be given to cases in which a high-quality comprehensive value assessment for medical insurance purposes has been completed. Other provincial healthcare security authorities may promptly follow suit, creating a coordinated approach under which "establishment in one province is followed nationwide".

2. Conditional introduction of a new pricing item. Where the clinical or economic value of a new technology or product remains to be verified, the provincial healthcare security authority that undertook preliminary establishment may introduce a pricing item subject to conditions, allowing a limited number of medical institutions within its jurisdiction to charge for the service in accordance with the applicable rules. The medical institution that applied for preliminary establishment shall conduct a real-world comprehensive value assessment for medical insurance purposes within the period to which it has committed. Subsequent action, including transition to an appropriate pricing item arrangement, price reduction or termination, shall be considered in light of the assessment results.

3. Coverage under an existing pricing item. Where the service outputs and price components of an existing pricing item can cover the medical services associated with a new technology or product, the provincial healthcare security authority that undertook preliminary establishment shall meet the clinical charging requirements by providing coverage under that item. Other provincial healthcare security authorities may promptly follow that approach.

The National Healthcare Security Administration shall periodically consider incorporating pricing items introduced or extended through any of the above approaches into the national specifications for medical service pricing items.

V. Guiding the Reasonable Formation of Medical Consumable Prices

In undertaking preliminary pricing item establishment, provincial healthcare security authorities shall concurrently pay particular attention to the prices of the associated medical consumables. They shall take the lead in arranging the listing of medical consumables and their prices on

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procurement platforms and guide enterprises to set reasonable medical consumable prices independently and provide written pricing undertakings.

Where medical equipment depreciation or medical consumable costs account for more than 60% of the price components of a new item, or the price of a medical consumable exceeds RMB 5,000, the provincial healthcare security authority accepting the application shall require the medical institutions and enterprises concerned to explain the reasonableness and economic value of the prices and report ex-factory prices and price composition information. It shall guide the alignment of new product prices with clinical value, supply and demand, the competitive landscape and ability to pay, thereby effectively safeguarding the public's lawful rights and interests.

VI. Conducting Real-World Comprehensive Value Assessments for Medical Insurance Purposes

Provincial healthcare security authorities shall establish regular communication mechanisms with medical institutions within their jurisdictions that meet the application requirements, and strengthen the early identification of innovative technologies. Applicants are encouraged to incorporate plans for real-world comprehensive value assessments for medical insurance purposes at the proof-of-concept, laboratory product and clinical research stages, with guidance from provincial healthcare security authorities where necessary.

For pricing items that have already been introduced or extended to cover new services, where economic value or other aspects fall short of expectations, the provincial healthcare security authority that undertook preliminary establishment shall guide the relevant parties in conducting real-world comprehensive value assessments for medical insurance purposes. The assessment results shall inform decisions on the subsequent treatment of medical service pricing items, price adjustments and other matters.

VII. Strengthening Organisation and Implementation

Provincial healthcare security authorities shall reinforce their primary responsibility for medical service price administration, enhance their capacity to discharge their duties independently in accordance with the law, establish expert pools for medical service pricing item establishment, and focus on advanced new technologies and products. They shall carry out preliminary pricing item establishment effectively, develop practical examples of pricing item establishment supporting advanced innovation, and promote the large-scale application of medical scientific and technological innovations.

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Strict control shall be exercised over preliminary pricing item establishment, with careful selection of new technologies and products. Where provincial healthcare security authorities relax quality standards or repeatedly make preliminary establishment determinations inconsistent with macro-policy objectives or the direction of reform and governance, the National Healthcare Security Administration shall, as appropriate, take measures including suspension of their eligibility to accept applications for preliminary pricing item establishment. Where provincial healthcare security authorities identify poor-quality applications by medical institutions or abuse of preliminary establishment application channels, they may, as appropriate, take measures including suspension of the institutions' eligibility to apply.

Annex: Application Form for Preliminary Establishment of Medical Service Pricing Items (Template)

National Healthcare Security Administration

2 September 2026

(For proactive disclosure)

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Annex

Application Form for Preliminary Establishment of Medical Service Pricing Items (Template)

Applicant hospital: _____

☐ National Medical Centre

☐ National Regional Medical Centre

☐ National Clinical Research Centre

☐ Hospital with a National Key Clinical Specialty

Note: Tick the applicable boxes. If the applicant hospital meets more than one criterion, all applicable boxes may be selected.

Applicant department: _____

☐ National Key Clinical Specialty ☐ Other

Note: Tick the applicable boxes. If the applicant department meets more than one criterion, all applicable boxes may be selected.

Person responsible for the application: _____ (name, position and contact details)

Contact person for the application: _____ (name, position and contact details)

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1. Basic Information

☐ New technology (including new biomedical technology)

☐ New equipment

☐ New consumable

2. Compliance Information

☐ Has entered clinical research

(Supporting documentation must be provided.)

☐ An application for the clinical translation of a new biomedical technology has been accepted

(Supporting documentation must be provided.)

☐ Has entered the special review procedure for innovative medical devices

(Supporting documentation must be provided.)

☐ Has entered a programme for the promotion and application of high-end medical equipment

(Supporting documentation must be provided.)

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3. Innovation Information

☐ No other country or region has established this pricing item

☐ Another country or region has established this pricing item

Where the item has been established in another country or region, provide the local price and the prices converted using the exchange rate and purchasing power parity.

3.1 Operating Procedure

Where the national or provincial health authority has issued technical specifications, describe the procedure in accordance with those specifications. Where no technical specifications have been issued but clinical guidelines or an expert consensus have been published, use those guidelines or that consensus. Where neither applies, the applicant hospital shall describe the procedure on the basis of clinical practice.

3.2 Service Outputs

State the item's principal functions, expected effects, scope of application and other relevant matters. The same drafting requirements apply as for the "Operating Procedure" field.

3.3 Comparison with Similar Items

☐ No pricing item with similar functional outputs exists; the proposed item addresses an unmet clinical need

☐ A pricing item with similar functional outputs exists; the proposed item constitutes an innovative technological improvement

Similar items: item name; history and prevalence of use; expert consensus on the substitutability of the existing and proposed pricing items and their order of preference in clinical practice; and the proposed item's clinical advantages supported by published data.

3.4 Estimated Use

State the price level anticipated by the applicant hospital and the estimated volume of use within the hospital and the local area.

4. Matters Requiring Explanation

Background information relevant to preliminary pricing item establishment.

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