

China Healthcare

New supportive policy for innovative chemical drug pricing

Industry Overview

This week, NHSA released the draft version of Notice on Establishing Pricing Mechanism for Newly Launched Innovative Chemical Drugs and Encouraging High-quality Innovations and call for suggestions. The notice mainly introduces the new policy of categorized pricing mechanism for newly launched chemical drugs, which aims to support high-quality innovative drugs in China. Together with the notice, NHSA also released the Self-Evaluation Form for Categorizing of Newly Launched Chemical Drugs Pricing and trial version of Guidelines for Newly Launched Innovative Chemical Drugs Pricing providing more details.

Categorized pricing for newly-launched chemical drugs

The notice states the basic principle of the market-based pricing mechanism for newlylaunched chemical drugs (except anesthetic and Class I Psychotropic drugs). The notice proposed a new policy of categorized pricing for newly launched chemical drugs. According to the guidance, the newly-launched chemical drugs should firstly be scored by the company according to the self-evaluation form established by NHSA. The score would be adopted as the basis for the drugs' initial price assessment by the healthcare security administration, and would be disclosed to receive social supervision and peer review. The self-evaluation form contains three major parts, namely pharmaceuticals (maximum 60 points), clinical value (maximum 60 points) and clinical evidence (maximum 30 points), and consists of 34 criteria in total. During the initial price declaration, the self-evaluation scores ranging [90, 150] were regarded as high scores, [50, 90] as middle scores and [0,50] as low scores. Overall, drugs with the highest scores will enjoy more policy support in terms of review process, price stable period and etc. While drugs with a lower relative score will be subject to ordinary pricing management and enjoy less policy

More support for the high-quality innovation

On the implementation of the categorized pricing, the notice suggests: 1) for drugs with high scores, related companies could determine the price on their own and there is no strict guidance on the pricing; 2) for drugs with middle scores, the treatment cost should be kept within a specific range compared with the control drugs; 3) for drugs with low scores, pricing should fulfill the economic requirement such as no higher than the average price of similar products etc. Additionally, for drugs with high or middle scores, the 1-5 years' price stable period will be granted according to the approval conditions, and during the price stable period, the drug would not be involved in the VBP and no price restrictions would be carried out. Furthermore, regarding the initial launch price reviewing process, centralized assessment could be adopted, and the price assessment result from the assessment will be recognized nationwide. For drugs with high scores, they will automatically be registered on the purchase platform in other provinces with the initial pricing once the review is completed, thus related companies do not need to apply for each province.

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NHSA: National Healthcare Security Administration

VBP: volume-based procurement



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 ≤ 30%

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