

# Improving access to treatment is the key to promoting high-quality development of the cell and gene therapy (CGT) industry

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## Executive Summary

Cell and gene therapies (CGTs) are a cutting-edge biopharmaceutical innovation, of which cure rate, efficacy, and safety show outstanding potential. However, lack of access to and affordability of high-value CGT products pose great challenges for patients and the industry. Improving access to CGTs has profound value and social significance, such as improving health equity, establishing China's global leadership in biopharmaceutical innovation, and elevating China's solutions to help address healthcare affordability.

China has made significant progress in advancing access to innovative medicines. However, there is still room for improvement in some areas.

- China has yet to establish a comprehensive multi-layered CGT payment system.
- Neither basic medical insurance (BMI), special funds, nor commercial health insurance (CHI) are capable of reimbursing CGTs independently and effectively.
- No CGT product has been included in the *National Reimbursement Drug List (NRDL)* so far and is not currently reimbursed by BMI.
- Currently, existing CGT special funds in China only focus on R&D, and do not support payment for CGT products.
- CGT products have been listed in some CHI plans, but issues persist such as CHI's relatively small market size, insufficient reimbursement, and sustainability risks.
- In China, some CGT manufacturers started to offer outcome-based agreements (OBA) for patients to reduce the risks of failed treatment. However, risks are mainly shared by patients and the manufacturers. Payers have yet to participate in risk-sharing agreements.

Global practices demonstrate that public health insurance supplemented by special funds and commercial health insurance can sufficiently pay for high-value innovative products, including CGTs. In addition, innovative payment methods

such as risk-sharing agreements can effectively help manage the uncertainties of CGTs.

Taking both global practices and China's current situation into consideration, this report endeavors to make recommendations for improving China's multi-layered medical security system (MLMSS) to make CGTs more accessible to patients.

### **1. Establish a multi-layered payment system for CGTs**

Strengthen the “top-level design” and implementation of the system and ensure BMI plays a major role in funding. Empower the new *Class C Drug List* to pay for high-value innovative medicines. Establish a government-led special fund for high-value innovative medicine payments. Support CHI to effectively and sustainably pay for CGTs.

**2. Explore innovative payment methods for risk-sharing.** Reduce uncertainties of CGT by adopting finance- and/or outcome-based risk-sharing agreements.

**3. Optimize the health technology assessment (HTA) of CGTs.** Apply evidence- and value-based pricing mechanisms during the HTAs of CGTs for accelerating its inclusion in NRDL and incentivizing real innovation.

**4. Encourage local CGT payment pilot programs.** Pilot programs should be encouraged on local levels before establishing a national multi-layered payment system for CGTs.