

Value Assessment of Innovative Medical Technology under DRG Reform

– Current Status, Challenges and Key
Considerations Moving Forward

(In Brief, 2022)

Context

APACMed China launched the DRG-based value assessment project in 2021, with the purpose of identifying key challenges facing innovative medical technologies in China's ongoing DRG reforms. APACMed China set up a DRG Working Group to collaborate with key policymakers, Key Opinion Leaders (KoLs) and Health Care Practitioners (HCPs) in China and developed the first industry research report in 2021. Below is an abridged English version of the original report. APACMed China advocates for increased access to innovative medical technologies to ensure patient benefit.



Commonalities in Adopting Innovation in DRG Reform Across the World

Developed in the 1960s in the United States, the “diagnosis-related group” (DRG) is a patient grouping scheme that classifies cases by comprehensively considering the factors of patients' disease diagnosis, treatment methods, individual characteristics etc., based on principles of similar clinical processes and similar resource consumption. At present, DRG is widely used internationally, and varies between countries in terms of practice, characteristics and effect. The report compares DRG characteristics in advanced markets (see figure 1 in the Appendix), including in the United States, Australia, Germany, France and Japan, and based on which, draws the following conclusions on the common features of adopting innovation in DRG reform across the world:

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| DRG grouping rule | Based on country-specific circumstances in medical insurance systems and medical resource capacity, with equal attention given to risk management. |
| Number of DRG groups | Determined in a scientific and sophisticated way to allow adjustment based on clinical practice and technology development. Two trends stand out: (i) grouping in line with clinical practice and technology upgrading, and (ii) a unified information coding system as the foundation. |
| Items covered | Focus mainly on hospitalization services, with a few countries like Germany also focusing on drug payment. |
| Cost calculation | DRG points and DRG relative weights are two effective ways to allocate medical insurance funds, regardless of differences in operation mode, hospital behavior and medical insurance management. |



Practices of Pilot Cities in China: Taking the Lead in Adopting Innovation

The report introduces pilots that have adopted innovative medical technologies, and four distinctive cases stand out:



Beijing: Developing the Exception Rule for Innovative Technologies

In July 2022, Beijing Healthcare Security Administration issued the *Notice on the Method of New Drugs and Technologies Excluded from DRG Payment under CHS-DRG* (trial) to give equal weight to both technological innovation and clinical outcomes. According to the Notice, payment for innovative drugs and medical devices that are impacted greatly by DRG can be independent from DRG payment.



Zhejiang: Promoting Innovative Technology with DRG Points-Based Payment

In 2019, Zhejiang Healthcare Security Administration released the *Opinions on the Reform of Basic Medical Insurance in County Medical Communities in Zhejiang Province*, together with relevant departments (No. 12, 2019), to set up a “1+4+11” policy system to push for DRG reform. Four types of innovative medical technologies, including the da Vinci surgical robot, Transcatheter Aortic Valve Implantation, VisuMax laser vision correction surgery, and TomoTherapy are encouraged for adoption via the DRG points-based payment mechanism.



Xuzhou: Exploring Targeted and Refined DRG-Based Payment

Since 2020, DRG payment has achieved positive results in Xuzhou based on a seven-indicator approach, including medical record qualification rate, number of DRG groups, case mix index, reimbursement ratio within the policy scope, average hospitalization cost, time consumption index, and cost consumption index. The Xuzhou Municipal Medical Insurance Bureau strives to build an effective and efficient medical insurance payment mechanism that reflects Xuzhou characteristics.



Guangdong: Quick Expansion to Expect Earlier and Full DRG/DIP Coverage

At present, among 21 prefecture-level cities in Guangdong, DIP and DRG coverage has been achieved in six pilot cities.

Policymakers of Guangdong vow to complete DIP/DRG coverage ahead of the national target.



What are the Operating Difficulties in the Current Reform Pilot?

The report analyzes current challenges through multiple avenues, including an Expert Dialogue held in June 2022 to provide a multi-stakeholder perspective, a survey of HCPs and KoLs, and typical industry cases.



DRG Session on the APAC Value-Based Market Access (VBMA) Symposium on June 27th, 2022

Based on these approaches, the report presents the following findings:

Issues Faced by Pilot Cities:

Despite the achievements so far, there are complexities in DRG implementation and operation, especially in grouping management. The complexities in epidemiology and unbalanced medical resource distribution, lack of unity in data standards, coding, terminology and grouping rules result in challenges in grouping management and appropriate policymaking for pilot cities.

Observations Expressed by HCPs:

HCPs in Beijing, Shanghai and Wuhan were surveyed, including those from hospitals affiliated to the National Health Commission, renowned public tertiary hospitals affiliated to municipal governments, universities and selected specialty hospitals. HCPs were from

Neurosurgery, Cardiovascular Surgery, Hepatobiliary Surgery, Orthopedics, Breast Surgery, Tumor Radiotherapy, Nephrology, Rheumatology and Immunology and infection-related departments. The following key observations are presented:





Insights from the MedTech Industry:

The APACMed China DRG Working Group has made the following observations:

1) Dynamic Adjustment of DRG Grouping in line with Clinical Situations

There have been active moves by some local policymakers to adjust the DRG codes:

Examples: Transcatheter Aortic Valve Implantation (TAVI) and Percutaneous Left Atrial Appendage Closure (LAAC) moved into the latest DRG grouping. Upon evidence-based suggestions by clinical experts, a specific disease group FL39 was allowed for TAVI in Beijing in the CHS-DRG 2022 version, which has reflected the actual clinical reality, satisfied the needs for innovative medical technologies, and made it easier to implement at the hospital-level. We support these actions and advocate for continued progress, so advanced medical technologies will have quick access to market for patient benefits. LAAC was included in the medical insurance catalogue in October 2021. Based on health economics and clinical evidence, Zhejiang Healthcare Bureau requested to adjust the grouping of LAAC from DRG FM2 to FL1, which was approved by the NHSA.

While we applaud actions by Chinese national and local healthcare securities authorities to dynamically adjust DRG grouping, we would advocate for continuous efforts to better reflect opinions of clinical experts and jointly shape an enabling environment for innovative medical technologies:

| Typical cases | Description |
|---|--|
| <ul style="list-style-type: none"> ✧ The innovative PressureWire X Guidewire | The world's only wireless physiology wire can measure pressure and temperature to calculate Resting Full-Cycle Ratio (RFR), Fractional Flow Reserve (FFR), Index of Microvascular Resistance (IMR), and Coronary Flow Reserve (CFR). Such technology is grouped under diagnosis instead of treatment stream, with a lower payment line. |
| <ul style="list-style-type: none"> ✧ HARMONIC ✧ Targeted Temperature Management (TTM) | HARMONIC devices are considered the undisputed ultrasonic leader proven to minimize impact on tissue. With HARMONIC HD 1000i Shears, experience unmatched precision and strength for improved tissue dissection, faster transection, and more secure sealing. Targeted Temperature Management (TTM) can be an important intervention for some critically ill patients. The Arctic Sun 5000 TTM system, along with the ArcticGel Pads, helps to monitor and control patient temperature non-invasively in patients of all ages. The DRG reform mainly calculates weight based on three-year data, which might pose challenges for technologies with no historical data. |



2) Minimally Invasive Surgery: More Differentiation from Traditional Surgery Needed

Minimally invasive surgery is now grouped with traditional open surgeries with no difference in DRG group and payment criteria. A study placed 4,500 patients diagnosed with an inguinal hernia in three tertiary hospitals in Zhejiang from 2016 to 2019.

Compared with open surgery, laparoscopic surgery reduced hospitalization days from 5.7 to 4 days, reduced rates of infection and complications, and increased healthcare service quality and efficiency with cost-saving and higher life-quality benefits. It suggests considering clinical, economic and patient values in DRG grouping rules and weighted payment criteria at different hospital-levels for high-quality development. ***Moving forward, more differentiation from traditional surgery might be needed.***

3) In-Vitro Diagnostics (IVD): Comprehensive Value Assessment of IVD Products Needed

The value assessment framework of IVD, despite the differences in types and application scenarios, should be a targeted one that reflects the needs and value of precision medicine. Patient centricity should be prioritized in making medical decisions.

Given significant differences in IVD technologies, a targeted value assessment framework needs to be developed to help hospitals and decisionmakers choose the qualified products. Innovation and strict clinical values need to be considered.

Thus, we advocate for more collaboration between hospitals, governments and suppliers to produce a comprehensive and tailor-made value assessment mechanism for IVD technologies.



Key Considerations of Establishing a Value Assessment Framework for Innovative Medical Technologies

Moving forward, there should be synergy between the scientific management of medical insurance and the demonstration of the value of medical technologies.

Clarify the Goal of DRG Reform

The goal of DRG reform is to drive more focused payment system reform, increase the efficiency of medical insurance utilization, and achieve value-based procurement. DRG reform should strike a balance between medical value, clinical needs and medical technology development to achieve sustainable development of China's healthcare system. Moving forward, factors such as health economic effect, social and medical technology value, efficiency and fairness, and price management need to be considered holistically in future reform agenda. In addition, DRG and DIP may need to be implemented together to speed up the adoption of new technologies under the current reform.

Allow Dynamic Changes on the Grouping and True Reflection of Clinical Values

Scientific and dynamic adjustment must be made to allow access to new technologies. For complex diseases, a multi-stakeholder approach needs to be adopted, so that new medical technologies filed by manufacturers and medical institutions will have a holistic assessment mechanism. An assessment team comprised of clinical experts and KoLs will be beneficial in providing an expert perspective on the adoption of new technologies. Such assessment mechanisms will focus on identifying medical institutions suitable for payment, Health Technology Assessment (HTA)-based review, statistical analysis on payment viability etc. to finalize the necessary preparatory work for adoption of new technologies. Equal attention will need to be given to compatibility between DRG and clinical data systems.

Incentivize Medical Institutions on Technology Adoption

Despite the different phases of DRG implementation, medical institutions can play a bigger role to encourage the adoption of innovative medical technologies. A consultation-based principle needs to be adopted to allow DRG grouping updates and a diversified approach to payment; for example, the fee-for-service payment for new technologies (the exception rule or the consultative payment rule). Breakthrough therapies need to have a specific policy arrangement under the current reform.

A Multi-Stakeholder Ecosystem to Ensure Smooth Communication and Optimized Allocation of Resources

Encourage companies, hospitals, HCPs to collaborate with key government bodies to establish a smooth communication mechanism to constantly monitor grouping changes, reduce overlapping, and save resources. As key players of the ecosystem, companies need to have more diversified channels to work with other stakeholders, including sharing clinical

evidence, providing new technology information, drug and medical device use training etc., so that companies can be incentivized to support DRG reform and work towards enhanced quality of care and patient experience.



Appendix:

Figure 1. Comparison of DRG Characteristics in Advanced Markets

| Country | Practice situation | System characteristics | Implementation effect |
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| The United States | The government began to implement the prospective payment system based on DRG in 1984. | All operating costs are paid at a fixed price, highlighting the accuracy of cost information, the disease severity of patients admitted, and the impact of industrial development on costs. | The rapidly rising medical costs are curbed. However, in the early stage of reform, the actual effect of DRG on the control of medical costs in the whole United States was very limited. |
| Australia | In 1988, DRG was introduced from the United States, and a disease diagnosis group AR-DRG, which was more aligned with the local features was developed. | According to the coding information of surgical operation and diagnosis in the case records, the corresponding cases are divided into ADRG group (including internal medicine group, surgery group and non-operating room surgery group). | To some extent, the unreasonable increase in medical costs is controlled, and the hospital operation efficiency is improved, but some negative effects of DRG payment are produced. |
| Germany | Referring to the DRG system of Australia and the United States, the G-DRG system was launched in 2003 and enforced nationwide in 2004. | Based on the principle of high unity from top to bottom, the scheme framework of the "321" overall payment system has been established. | The average hospital stays are significantly reduced, the rising rate of medical costs is obviously controlled, and the quality of medical services is improved to some extent. |
| France | In 2004-2005, the DRG-based payment system was introduced for the payment of emergency medical services in all hospitals. | In terms of the collection of medical cost data and the setting of DRG payment price, the calculation is separately performed in public and private hospitals, and the prices have different contents. | Some long-standing problems in the medical market are solved, and the work efficiency of medical institutions is improved. |

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| Japan | A DPC system with Japanese characteristics was developed in 2001 and finally formed in 2006, having 16 MDCs and 2,347 disease diagnosis groups. | Compound payment and flexible payment. Payment methods include fixed prepayment and non-fixed payment. Due to the voluntary participation model, DRG in Japan has not achieved full coverage in respect of the number of hospitals and payment items. | The average length of stay in designated hospitals implementing the DPC payment system has decreased significantly. However, the medical expenditure of inpatients is higher than that of other hospitals. |
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About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific.

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