

Pay-for-Performance Risk-Sharing Agreements for Medical Technology in China: Application and Prospect

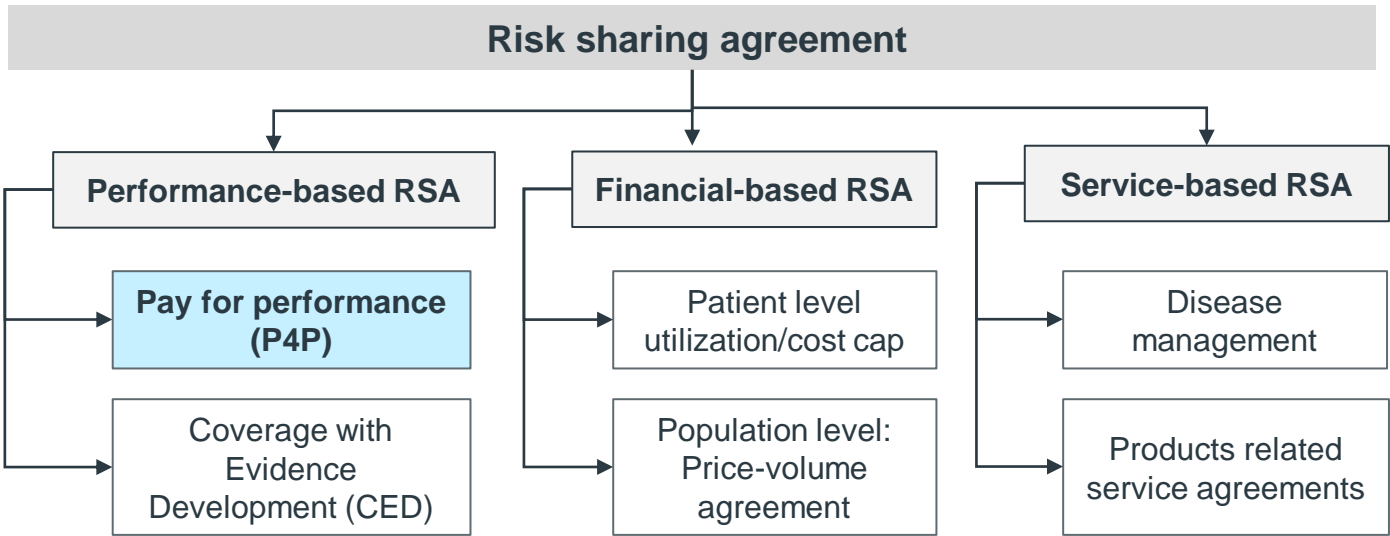
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Background

- Tremendous innovative medical technologies (MedTech) have emerged to improve clinical benefits in recent years. However, lack of solid data on the long-term clinical effectiveness of innovative MedTech leads to clinical and budget uncertainty.
- Risk sharing agreement(RSA) can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize effective their use or limit their budget impact¹. There are six main types of RSA which are commonly used (*Figure 1*). Pay-for-Performance RSA (P4PRSA) can reflect the clinical value by collecting short-term efficacy and address uncertainty concerns, and it is most widely used in the field of MedTech at home and abroad. Therefore, this study will focus on P4PRSA for MedTech .

Figure 1: Six main types of RSA



Objectives

- This study aims to analyze the application and prospect of P4PRSAs for medical devices and provide a reference for the payers and healthcare providers on the value access of innovative MedTech in China.

Methods

- A literature review was conducted to identify relevant publications of P4PRSA practice for MedTech in China.
- Key elements of P4PRSA for MedTech and key considerations for initiating P4PRSA were analyzed based on literature review and expert interviews.
- In addition, expert interviews were conducted to validate key agreement elements and further application.

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Results

- The findings of literature review and expert interviews implicated that the practices related to P4PRSAs for MedTech were still at its preliminary stage in China. We found that P4PRSAs were mainly carried out in economically developed provinces or cities in China such as Shanghai, Zhejiang, and Xiamen²⁻⁵ (*Table 1*).

Table 1: Local RSA practices in medical procedures and medical devices

Procedure/Device	Partners	Indicators	Year/ Area	Risk sharing
<div><div>• Seven microRNA detection</div><div>• Da Vinci Surgical Robot</div><div>• Tumor cryoablation technique</div></div>	Public payer and hospitals in Shanghai	<div><div>• Detection rate</div><div>• Surgical complication rate</div><div>• Tumor reduction or complication rate</div></div>	2021/ Shanghai	If the hospitals did not meet the target, a deduction of 5% of the medical insurance expense was mandated.
<div><div>• Liver transplantation</div></div>	Public payer and hospitals in Zhejiang	<div><div>• Survival time</div></div>	2017/ Zhejiang	When a patient who is 18 years or older is discharged from the hospital, the public payer will cover 90% of the medical insurance expenses. If the patient survives for one year after discharge, the public payer will cover 5% of the medical insurance expenses. If the patient survives for three years after discharge, the public payer will again cover 5% of the medical insurance expenses.
<div><div>• Blood glucose monitor device</div></div>	Manufacture (MNF) and private payer	<div><div>• Blood glucose level</div></div>	2019/ Xiamen	Patients who fail to achieve their target blood glucose control will be provided with a full refund for their out-of-pocket expenses on the blood glucose monitor device by the private payer.

Table 2: Key elements in the design of RSA for MedTech

Key elements	Description
Product selection	<div><div>• Suitable product that can be clearly associated with specific treatment outcomes.</div><div>• Convenient to operate when patients need to operate the product by themselves.</div></div>
Indicator selection	<div><div>• Select indicators that are easy to assess according to product characteristics.</div><div>• Clear and measurable clinical efficacy monitoring indicators.</div></div>
Risk sharing	<div><div>• Depends on whether the product's efficacy meets the predetermined goals.</div><div>• Conduct careful assessment and cost-effectiveness analysis..</div></div>
Partner participation	<div><div>• Public payer tends to initiate RSA with healthcare providers in China.</div><div>• Need to balance the demands of various stakeholders.</div></div>

Table 3: Key considerations for initiating RSA in MedTech

Key considerations	Description	
Policy context	<div><div>• Keeping a close eye on relevant healthcare policy, such as DRG/DIP payment reform, national medical consumable reimbursement list, etc.</div></div>	<div><div>• To assure the successful design and implementation of P4PRSAs of MedTech in China, the key considerations will include keeping a close eye on relevant healthcare policy, satisfying key stakeholders' needs, selecting proper products and establishing appropriate RSA scheme ^{6,7}(<i>Table 3</i>).</div></div>
Stakeholders needs	<div><div>• Satisfying key stakeholders' needs on cost control, clinical outcome improvement, access gain, etc.</div></div>	
Market situation	<div><div>• Selecting proper products considering comprehensive market situation, including competitive context, disease type, product lifecycle stage, etc.</div></div>	
Design & Implementation	<div><div>• Establishing appropriate RSA scheme concerning with large population, data collection, legal consideration and payment, etc.</div></div>	

Conclusion

- P4PRSAs for MedTech were mainly carried out in economically developed provinces or cities and still in their preliminary stages in China.
- This study suggests that P4PRSAs can effectively support the value access for MedTech and promote the use of innovative MedTech in the context of medical insurance payment reform in China.
- In order to develop and implement P4PRSA initiatives effectively, it is essential to consider the broader healthcare reform policies, including DRG/DIP. Additionally, there is a need to explore new payment models, such as RSA, to facilitate the adoption of innovative medical technology.

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