# Research on the Impact of Volume-based Procurement of Coronary Stent in China

Xiang Zhao, Yun Lu\*

China Pharmaceutical University, Nanjing, China

#### Abstract

In 2021, China began to implement the results of the Volume-based procurement(VBP) of coronary stents. It affects the price of stents, and also has a significant impact on the decision on clinical technology, the medical service delivery, and medical technology innovation. Based on investigations with multi-stakeholders, we clarified the impact of the stents VBP on the pharmaceutical industry, and provided suggestions for the comprehensive management of High-value medical consumables.

## Keywords

Volume-based Procurement; High-value Medical Consumables.

## 1. Introduction

Coronary stents are High-value medical consumables for cardiovascular intervention with large clinical usage and high unit price. Coronary stent implantation is a key treatment technique to save the lives of patients with coronary atherosclerotic heart disease (coronary heart disease) and improve their quality of life.

The National Healthcaee Security Administration takes coronary stents as a pilot product for Volume-based Procurement (VBP), and selects the new generation of drug-eluting stents with the largest market share (materials are cobalt-chromium alloy or platinum-chromium alloy, and the drug type is Rapa The category of coronary stents of mycin and its derivatives), based on the negotiation basis of 80% of the total procurement requirements of the alliance area (1.075 million), with a two-year procurement cycle, and the principle of winning the bid at the lowest price, completing 10 product registration certificates The purchase price was determined to be 469-798 yuan, and the average product price reduction rate was 93%.[3]

Coronary stent VBP not only has a direct impact on the selection and price of coronary stents, but also has a significant impact on the choice of clinical diagnosis and treatment technology, medical service delivery models, and medical technology innovation and development. In order to understand the clinical application of coronary stents, conduct field research in medical institutions, conduct special interviews with hospital managers, medical staff representatives, and business representatives, and propose policy recommendations based on the research results to provide decision-making basis for the comprehensive management reform of High-value medical consumables.

## 2. Potential Impact of VBP

The VBP of coronary stents is of great significance to control the inflated prices of medical consumables and reduce the burden of medical insurance. In this round of VBP, the hospital independently declared the intended volume, and 10 types of winning products were all categories with a large amount of clinical use. At present, the average bid-winning price is about 1/4 of the price of similar products in India, and the use of the bid-winning will save 11.7 billion yuan medical insurance fund. The followings are the potential impact of stents VBP.[1][2]

#### 2.1. Research and Development

The most direct impact of price cuts is to hit the development of the medical device industry. China's medical device market has developed rapidly in recent years. The market size of medical consumables is 320 billion yuan, of which High-value medical consumables is 150 billion yuan, with an average growth rate of 19.86%. It is a high-tech field with intensive domestic innovation. Coronary stents are the product with the highest domestic substitution rate and the largest market value of High-value medical consumables. The total market value before the national VBP is about 15 billion. According to the current bid price, VBP reduces the market value to 1 billion. The market value has shrunk rapidly, discouraging the enthusiasm for product research and development and innovation of enterprises.[4]

## 2.2. Guarantee of the Supply of High-quality Products

There are in of different types of High-value medical consumables, and we are still lack of hierarchical standards for the quality. So the quality of bid-winning products needs to be continuously tracked. Winning the bid at the lowest price may lead to low-profit or no-profit operation of pharmaceutical companies, and companies may change their distribution models in order to save money, which can affect the timeliness of distribution and supply. So there are doubts about the long-term timeliness supply and the quality after price cuts.

#### 2.3. Clinical Options

Clinical options are limited. In clinical operations, doctors generally choose appropriate stent products according to the patient's condition. The winning bidder category may not be able to meet the needs of certain subgroups of patients for specific stent categories. And many patients with average family economic conditions still want to use more advanced stents. But the implementation of the VBP restricted the categorys purchased by hospitals and patients.

#### 2.4. Clinical Use

VBP may promote institutional demand. From the perspective of patients, the affordability of coronary stents will increase after the price is reduced, and patients may choose to carry out the operation as soon as possible after the price reduction, resulting in an increase in product usage. From the perspective of public hospital procurement, although 20% of the usage is still reserved for non-winning products according to the VBP document, the current results of the purchase of generic drugs shows that hospitals will generally choose the winning products for the rest, resulting in a increas of the use of bid-winning product. From a doctor's view, due to the limitations of public hospitals' assessment indicators and the future basic medical insurance DIP and DRGs payment system reforms, the use of bid-winning stents will continue to increase.

#### 2.5. Development of PCI Technology

The development of PCI technology may slow down. The innovation and development of coronary stent technology and the development of clinical PCI technology are complementary to each other. As the innovation of coronary stent products slows, the development of clinical PCI technology will also slow down. Relevant clinical research will also be affected by restrictions on the use of innovative products.

The construction of chest pain centers at all levels is advancing rapidly, playing an important role in the implementation of the hierarchical diagnosis and treatment system and the improvement of China's overall cardiovascular disease treatment capabilities. Without relevant supporting measures, it will attack the enthusiasm and desire of young doctors in primary medical institutions and major hospitals to carry out PCI, which will lead to a gap in the talent echelon and limit the development of PCI technology.

#### 2.6. Hospital Operation and Management

Hospital cash flow will be decreased. Medical consumable is an important source of cash for public hospitals. In the case of insufficient compensation for the operating and development costs of public hospitals, the reduction in the price of coronary stents can reduce the hospital's cash flow and affect the operation of public hospitals.

Hidden costs will increase. The cost of consumables for PCI surgery after VBP will indeed decrease, but the original training and accessories costs borne by the company will be transferred to the hospital. In addition, it also increases the cost of doctor-patient communication. On the one hand, doctors need to invest extra time to explain and communicate with patients about the new policy, especially the impact of price cuts, the difference between domestic and imported products, and the selection of products outside the bid. On the other hand, if there is a quality problem with the winning product, this risk is likely to be passed on to hospitals and doctors, leading to an increase in the cost of handling medical disputes and doctor-patient conflicts.

#### 3. Conclusion

#### 3.1. Carry out Follow-up Evaluation of the Implementation of Reform Measures

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Evaluate the clinical use of the first batch of coronary stent products, and clarify the impact of the reform policy on the operation of public hospitals and the PCI service delivery system. Using health technology assessment as a starting point and reform lever, building a systematic evidence chain to effectively meet the evidence needs of key decision-making links in the life cycle governance of High-value medical consumables to meet the requirment of safety, effectiveness, economy, innovation and suitability of the technique.

#### 3.2. Establish an Incentive and Restraint Mechanism

Increase the compensation for public hospitals and support the stable operation of the hospitals. Through the measurement and calculation of the entire process service cost of the PCI standardized diagnosis and treatment path, the basic technical elements, the content of the service items and the payment standards are determined, and the cost standards and compensation mechanism should be formulated reasonably. The severity and complexity of the patient's disease and the operation time should be combined to establish a scientific grouping standard to achieve effective compensation for medical staff's technical contributions and operational risks. Efforts should be made to build a performance appraisal system for personnel and departments that is oriented towards quality and efficiency improvement, so as to realize the effective transmission of incentive policies to medical staff.

#### 3.3. Strengthen Clinical Service Quality Control and Management

Based on the health technology assessment (HTA), determine the indication management standards and clinical quality control standards, establish the clinical classification tools for patients with acute coronary syndromes, and establish the standards of the suitability of PCI operation.

Guide public hospitals to strengthen PCI service performance evaluation. Based on clinical guidelines and suitability standards, combined with HTA evidence to improve PCI diagnosis and treatment guidelines, standardize preoperative preparations, intraoperative operations, and postoperative Follow-up services. Promote public hospitals to establish a sound management mechanism for patients after surgery, strengthen postoperative Follow-up management to provide a basis for technology optimization.

#### 3.4. Strengthen Policy Interpretation and Publicity

Strengthen the interpretation and publicity of VBP, and collect feedback from stakeholders in a timely manner. Preach and interpret reform policies for relevant departments, public hospitals, doctors and patients, and the general public, avoid misinterpretation of policies, help local goverment and hopicals accurately grasp principles of policy. Popularize the knowledge of coronary heart disease and preventive agents of acute myocardial infarction and angina to patients and the public, to help them objectively recognize the role of coronary stents and the value of medical services. So they can cooperate with the implementation of reforms, and build a harmonious doctor-patient relationship [5].

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