China

Market Access & Reimbursement in China

Avania

December 2025

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ADVANCING YOUR MEDICAL TECHNOLOGY

PRIVATE HOSPITAL GROWTH IN CHINA

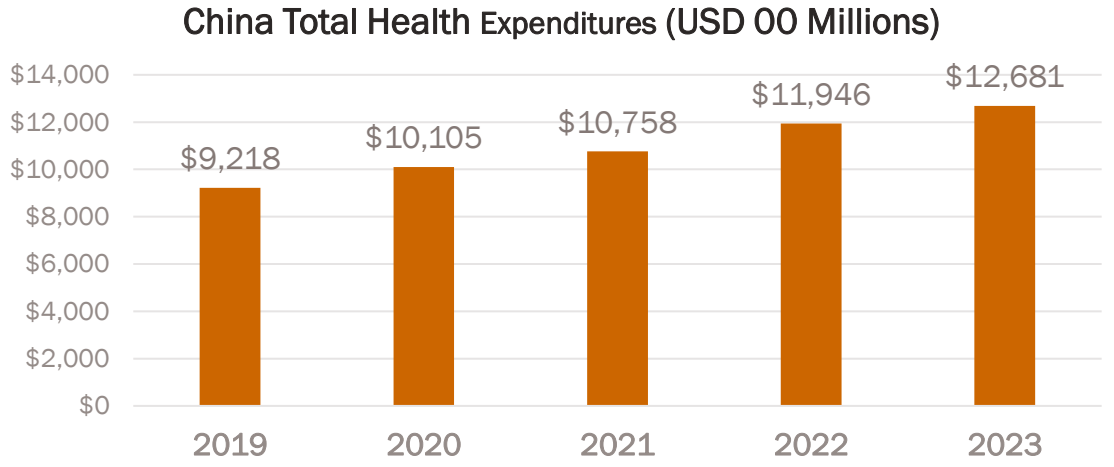
China has a highly regionalized healthcare system. As such, reimbursement relies on provincial level coding and associated procedure / consumable fees.

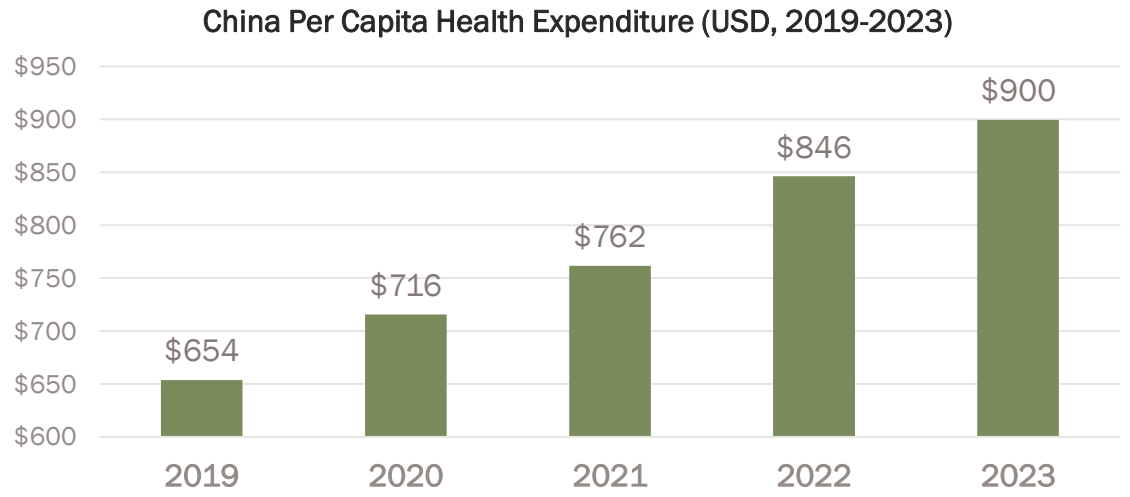
- China has 33 provincial-level divisions:
  - 22 provinces, 5 autonomous regions, 4 directly controlled municipalities (Beijing, Tianjin, Shanghai, and Chongqing) and 2 territories (Hong Kong and Macau).
- In 2023, the average healthcare expenditure per capita was $900 USD.
- China has significant healthcare variations between regions.
  - Relatively low uptake of high-tech medical products in the poorer western regions and in rural areas.
  - Relatively high uptake of high-tech medical products in coastal, urban areas in better financial positions.

Exchange rate (November 2025): 1 USD = 7.11 RMB

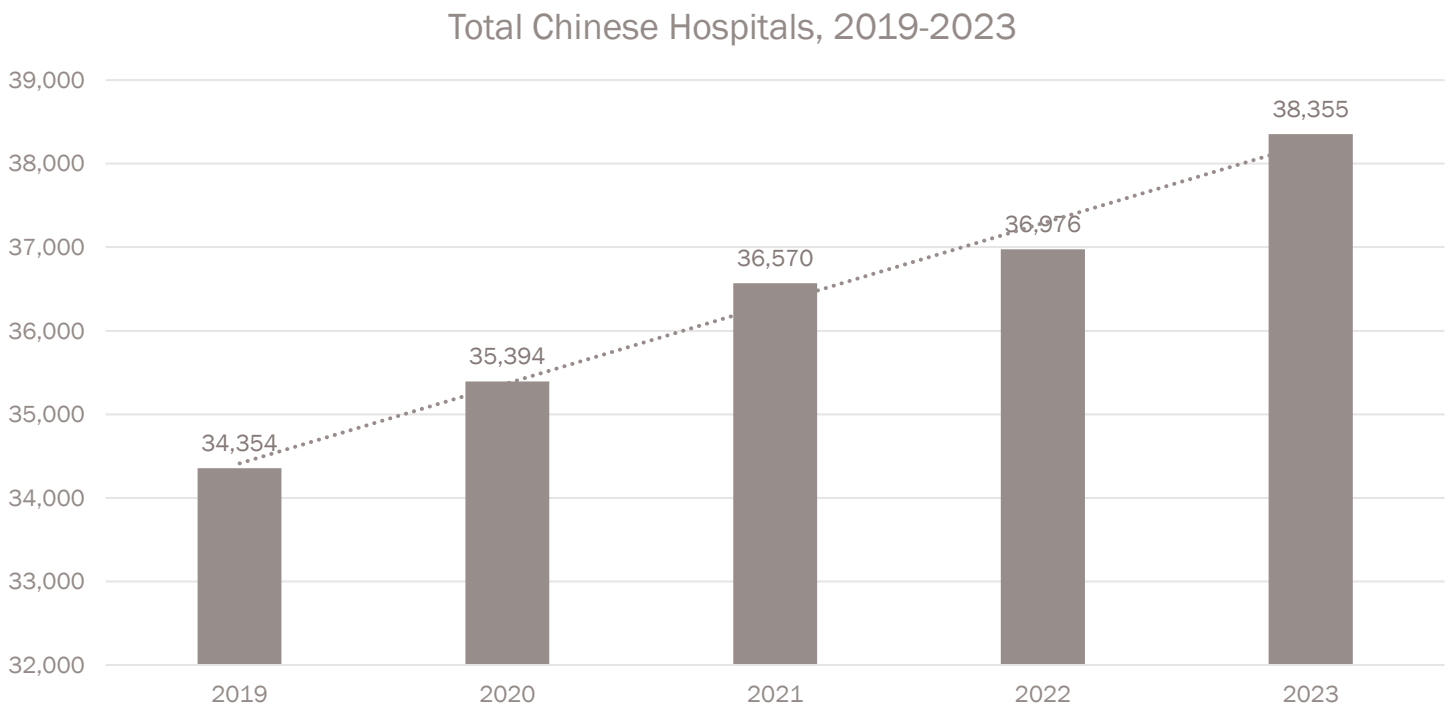
Chinese healthcare spending continues to expand, but is still far below Western markets on a per capita basis.

- Though the investment in infrastructure, research and patient services has expanded at roughly 9% annually, per capital HC spending is still far lower than Western markets.
- A significant part of Chinese investment is allocated to development of infrastructure.
- As it transitions to a comprehensive HC system, China also is seeking ways to curb excess costs, with particular attention to costs of pharmaceuticals and medical devices.

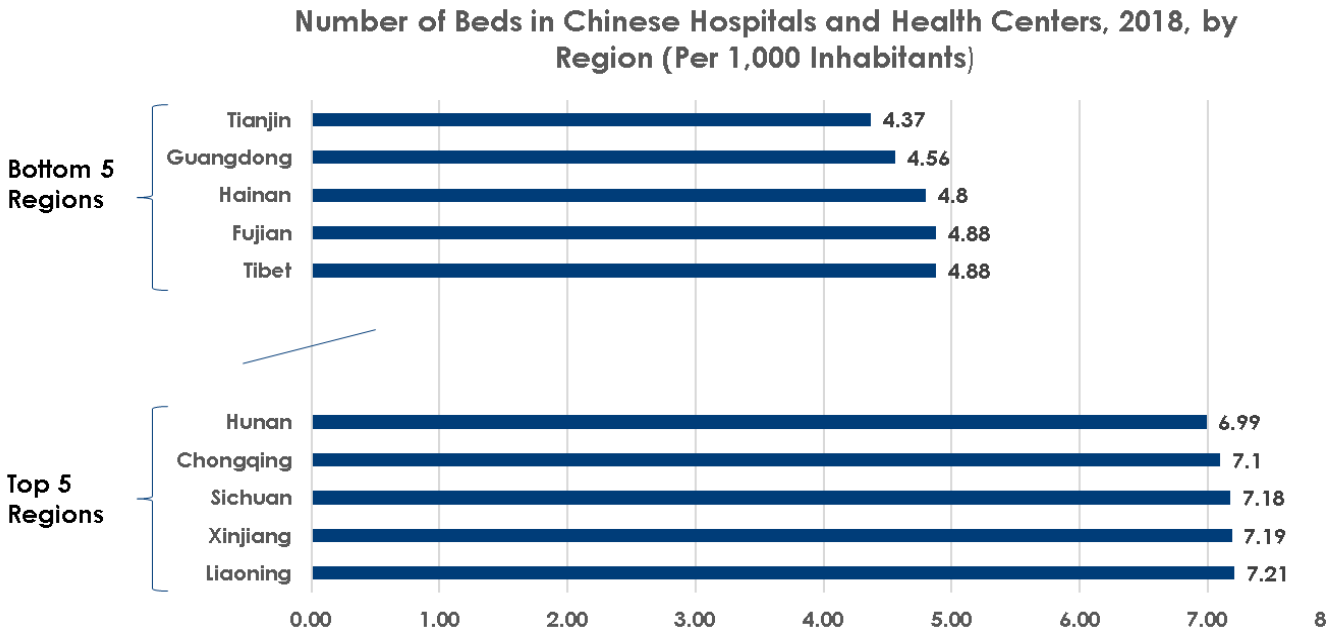




The total number of hospitals continues to grow as China tries to create more equal access in rural areas and private hospitals expand.



China continues to try to address inequities in access and likely will still fund public hospital construction in lagging regions.



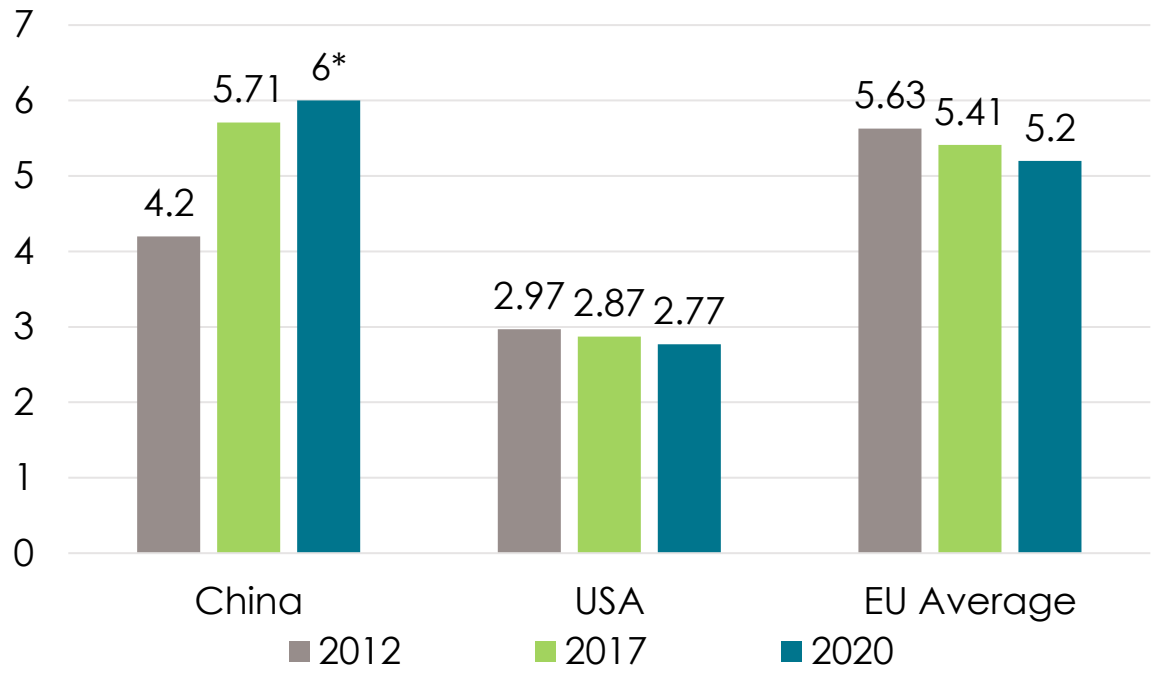
- Disparities between urban areas and regions remains a challenge in China, and consequently the number of beds per 1,000 citizens varies significantly across the country.
- We expect continued public hospital construction in the underserved regulations and more rural areas.
- Private hospital construction will also likely continue, and more frequently as well, especially in wealthier regions.

Source: National Health Commission, *China Health Statistical Yearbook*

Ongoing Chinese investment in hospital infrastructure may lead to oversupply; beds per 1,000 population exceeded the USA and Europe by 2017.

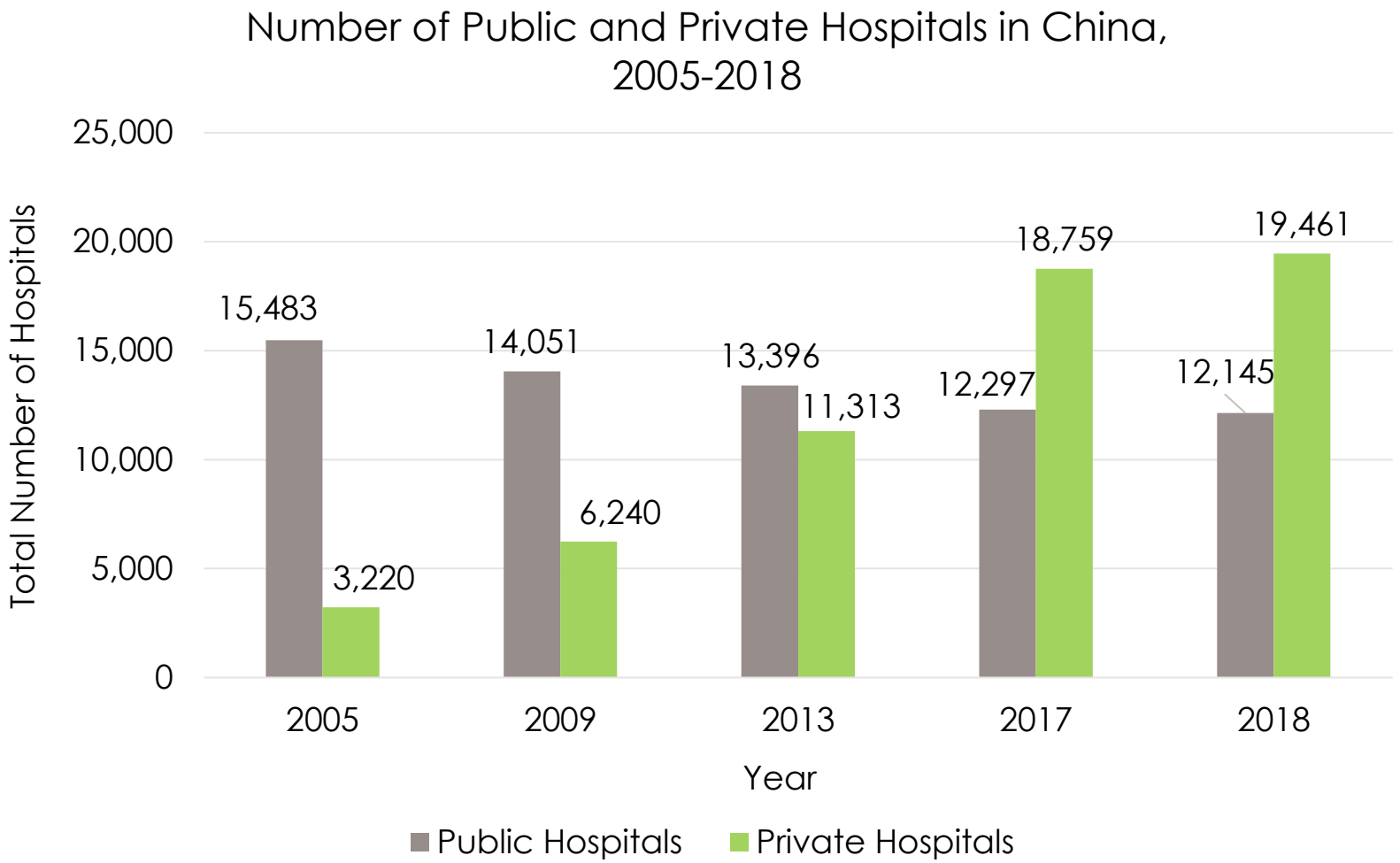
- By 2017, China had exceeded the number of beds per 1,000 citizens found in the USA and EU, on average.
- This trend may continue, as China has further investment in rural and Western regions, and the private sector continues to build new hospitals.
- By 2025, it is anticipated China will have 9.4 beds per 1,000 citizens; while still higher than the USA and Europe, it is less than Japan(13.05) and South Korea (12.27).
- This trend in oversupply of beds is related to the linkage of reimbursement to inpatient admitted care in China.

Hospital Beds per 1,000 Population, China, USA and EU Avg.



Source: National Health Commission, *China Health Statistical Yearbook 2019*. OECD.

Since 2005, the number of private hospitals has increased consistently, while the number of public facilities has slowly decreased.



Source: China Medtech Meeting 2018

The private market will need to overcome many regulatory and quality hurdles before it is regarded at the same level as the public market.

- Hospitals within the private sector are not standardized or held to the same regulatory standards as public hospitals, and as such, violations are more common.
- KOL Expertise: It is difficult for private hospitals to recruit high quality physicians as they are more drawn to the public sector.
- A common theme among respondents was that private hospitals are unable to provide the same quality of care as public institutions.
- Our industry experts outlined a series of barriers that private hospitals will face as the market continues to evolve, including:
  - A lack of quality physicians;
  - A lack of advanced equipment to enable high-level procedures;
  - Increased regulations that may limit growth;
  - Financial risk from medical disputes between patients and the hospitals; and
  - Higher fees that may deter publicly insured patients.

"It is hard for private hospitals to recruit reputable doctors. Good doctors do not want to leave public hospitals (the platform is very important)." -Payer, Guangdong

HEALTH INSURANCE IN CHINA

There are two (2) main social health insurance schemes; China claims to have achieved 95% coverage of its population.

- Urban employee-based basic medical insurance scheme (UEBMI) provides health insurance to state and private company employees while the urban resident-based basic medical insurance scheme (URBMI) is a voluntary health insurance plan for those not covered by employers.
- Coverage under both insurance scheme varies by region, hospital class, and disease / procedure.

Social Health Insurance Schemes in China

Social Health Insurance Scheme	Description	Covered Population in 2020 (millions)	Coverage
Urban employee-based basic medical insurance scheme (UEBMI)	• Mandatory for urban employees of state-owned and private enterprises • Contributions from both employer and employee	344.23	• Insurance reimburses: – 50-95% for inpatient care – 50-90% for outpatient care • Varies by region, employment status, age, hospital class, and disease • As of 2023 covers 78.9% of urban employees
Urban and rural resident-based basic medical insurance scheme (URRBMI)	• Voluntary plan for those not covered by UEMBI	1,016.77	• In Shanghai, insurance reimburses: – 60-90% for inpatient care – 50-70% for outpatient care • Varies by age, hospital class, and disease • Covered 2/3 of China's population as of 2023

Each procedure is classified into one of three categories

Self-Paid Services (i.e., patient cash-pay)

Partially Reimbursable (After Copay)

"Fully" Reimbursable (After Cost sharing)

City-level commercial health insurance (CHI) in China is more recent and supplementary.

City Health Insurance (CHI)	
Description	• A city-based commercial insurance guided by local government and administered by private insurers • CHI is supplemental to national public insurance, primarily covering medical expenses not included in public insurance. • Compared to private insurance, CHI is lower cost and covers pre-existing conditions.
Availability	• 150 cities across 29 regions had implanted their respective CHIs (end of 2022)

While value-based care remains challenging in China, private insurance and City Health Insurance can act as alternative reimbursement pathways.

- In China, the national public insurance system is still primarily focused on basic medical needs for the general population.
- Value-based pricing and reimbursement (i.e., premium price or coverage for high-cost innovative technologies) is difficult to achieve.
- City Health Insurance has become an alternative reimbursement pathway to the national public insurance for innovative procedures not yet reimbursed by national insurance
- CHIs can serve as a supplementary insurance program for innovative procedures that are not yet reimbursed by national insurance.
  - **Example**: Guangzhou's CHI has a specific coverage of consumable reimbursement for Type I diabetes patients aged 18 and below with reimbursement rate of 70% up to $7,700.
    - For instance, a patient can be reimbursed one insulin pump every three years up to $5,880 and specified consumables are reimbursable for up to $1,820 per year.

Conversion factor: 1 RBM = 0.14 USD, rounded to nearest whole dollar

FUNDING AND REIMBURSEMENT FOR HOSPITAL CARE

In China, pricing and reimbursement are distinct processes and market access phases, with procedures and consumables treated separately.

Pricing refers to the total amount / cost for procedures or consumables and is primarily determined at the provincial level.

- Each province has a distinct process and pricing template for requesting price approval for procedures and single-use devices.
- Pricing approval is required for patient out of pocket payments, even for non-reimbursable procedures and consumables.

Reimbursement is the portion of the total procedure or consumable cost subject to reimbursement by health insurance. Reimbursement varies by province, region, insurance scheme, and hospital.

- Patient cash-pay constitutes a significant portion of overall costs, even for fully reimbursable services, as almost no hospital care is fully reimbursed by insurance in China.
- Initially, most innovative, high-cost procedures are self-funded by patients with reimbursement following several years after pricing approval.
- Most procedures have an allowable top line maximum, including the amount chargeable to the patient.

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Pricing is a distinct concept in China, with local pricing approval required for all procedures and consumables, regardless of reimbursement status.

Key Pricing Concepts in China

Private Hospital Pricing	Public Hospital Pricing	VIP Pricing	IMC Pricing
• Pricing approval by the National Healthcare Security Administration (NHSA) is extremely flexible	• Subject to strict procedure price calculations and overall cost, including disposables • Must be affordable for Chinese patients to support sufficient volumes	• Public hospitals can obtain authorization for premium pricing with patient cash-pay for select procedures, with strict limitations on volume • The total number of VIP procedures cannot exceed 10% of the total number of procedures in the hospital	• For international patients; allows premium pricing with volume restrictions

Key organizations in market access and reimbursement in China.

Organization	Abbreviation	Purpose
National Medical Products Administration	NMPA	China's regulatory body responsible for the supervision of drugs, medical devices, and cosmetics.
National Healthcare Security Administration	NHSA	Primarily oversees the state-backed China Healthcare Security including general health insurance plan, maternity insurance, and medical aid programs.
Urban Employee-based Basic Medical Insurance	UEBMI	A mandatory, government-run health insurance program in China launched in 1998 to cover employed urban workers and retirees.
Urban and Rural Resident Basic Medical Insurance	URRBMI	A social security system in China that aims to provide basic health coverage for residents in both urban and rural areas.
China National Health Development Research Center	CNHDRC	A governmental research body responsible for creating and developing HTA policies and procedures.

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Multiple reimbursement categories exist, with each one subject to different reimbursement calculations.

Reimbursement Categories in China

Self-Paid (Patient Cash-Pay)	Partially Reimbursable	Fully Reimbursable
• Costs are not subject to reimbursement calculations • The entire cost is paid by the patient • Cosmetic surgery, dental procedures, PET-CT, DNA tests, etc. fall into the self-paid category	• Only a portion of the cost is subject to reimbursement calculations • A fixed percentage of the procedure fee is paid directly by the patient • Remaining cost is reimbursed according to the patient's insurance plan (50%-95%) and patient co-insurance • **Example Calculation:** Procedure fee of $1,000 USD – The patient would be immediately responsible for 10% or $100 USD – The remaining $900 would be divided between the insurance company and the patient according to their insurance plan • Some accompanying procedures (i.e., MRI) are partially reimbursable	• Entire cost is subject to reimbursement calculations • Patient insurance will pay a portion of the cost, according to the patient's insurance plan (50%-95%) • Remainder of the cost is paid out-of-pocket by the patient (similar to co-insurance in the US) • Majority of procedures fall into the fully reimbursable category

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Under the traditional pathway, coverage and reimbursement of medical procedures and products relies on GreenBook coding.

- The National Healthcare Security Administration (NHSA) publishes charge codes in a national "GreenBook", an extensive index of covered procedures and products.

- National CCHI codes are added or removed from the GreenBook following extensive review and deliberation. Historically, however, many national CCHI codes were not fully implemented at the provincial level.

- Updates to the national GreenBook can be unpredictable but generally occur once every 3-5 years.

- The NHSA encourages provincial governments to accept applications for new local codes and to accelerate their evaluation processes. The addition of new local codes is not restricted by the contents of the national GreenBook.

国家医疗保障局
National Healthcare Security Administration

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Example: Existing provincial level codes describing spinal nerve blocks are fully reimbursable, with payments ranging from $13 to $59 per nerve.

- While these procedures are not associated with a separately charged consumable, drug costs are paid separately.
- There are no indications or use-cases specified for nerve root block injection in the Medical Service Item Tariff Lists in Shanghai or Guangdong; however, Chinese guidelines indicate medical branch blocks (MBBs) are a first-line treatment for back pain.
- Spinal injection procedures can be performed at pain management, orthopedic, or spinal surgery departments, depending on hospital specialty set-up and availability.

Reimbursement for Spinal Injection Procedures

Province	Procedure Code	Code Description	Procedure Fee *	Allowable Separately Charged Consumable	Reimbursement Category
Beijing	HCP48101	Spinal nerve block analgesia [per nerve]	$59	None (bundled procedure)	Fully Reimbursable
Shanghai	310100027	Nerve block therapy [per nerve]	$20	None (bundled procedure)	Fully Reimbursable
Guangdong	310100027	Nerve block therapy [per nerve]	$13	None (bundled procedure)	Fully Reimbursable

Conversion factor: 1 RMB = 0.14 USD, rounded to nearest whole dollar
* Reimbursement rates vary between regional insurance schemes

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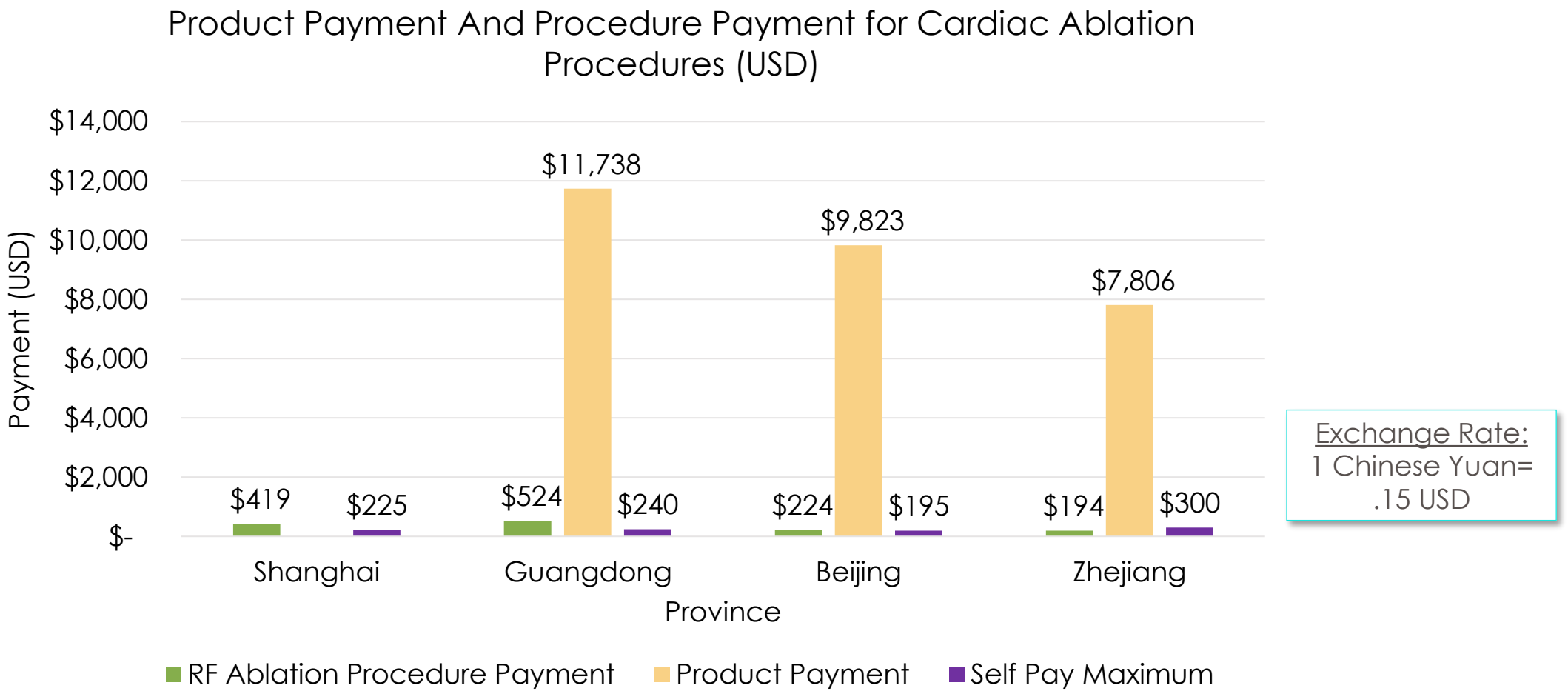
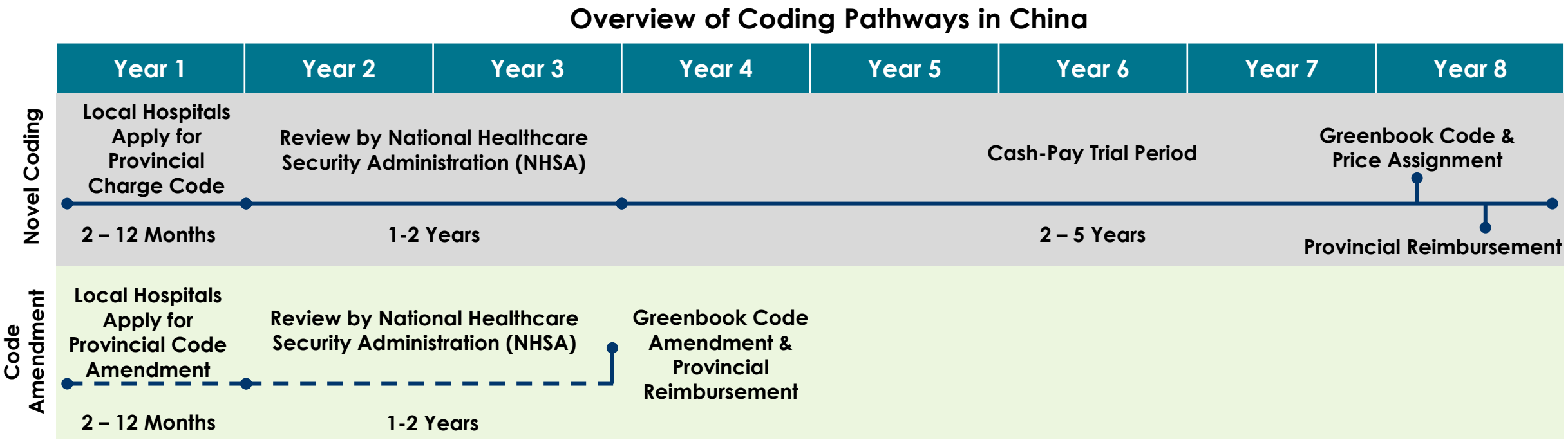
Example: Product payment rates among the provinces examined varied from $7,806 to $11,738, while procedure payment rates varied from $194 to $524.



Overview of Traditional Coding Pathways in China



- Key elements of reimbursement application:
  - Clinical literature review showing incremental value.
  - Cost effectiveness study issued by Chinese university or center of excellence.
  - Product must show cost effectiveness within a threshold equal to the provincial per capita GDP.
  - i.e., Live saving products can cost up to 3x local per capita GDP; other products only 1x.

A recent requirement for a national review may delay issuance of a provincial charge code by up to two (2) years.

- To obtain distinct provincial coding for a device, local hospitals will need to apply for provincial charge code followed by national review and a period of patient cash pay.
  - Permanent reimbursement for a new provincial charge code can take up to eight (8) years.

- Requesting an amendment to an existing provincial code still requires:
  1. Local hospital and KOL support;
  2. Provincial evaluation of clinical and economic benefit, national review; and
  3. An economic endorsement by a reputable Chinese university (i.e., Fudan University) demonstrating cost-effectiveness in the Chinese context.
  - Amending an existing provincial code does not require hospitals to apply for a provincial charge code or a trial period of patient cash-pay.

ADOPTION OF DRG / DIP PAYMENT SYSTEMS

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DRG payment has been explored in China for many years and is now being phased in across the provinces.

- Today, China has two bundled payment systems running in parallel among different provinces:
  - Diagnosis Related Groups (DRGs)
  - DIP Payment, Diagnosis Intervention Packet, a similar but less complex bundled payment mechanism.
    - Presently 75 Chinese cities use the DIP system. It is a more specific, procedure based payment system with 13,500 DIP payment groups.
    - DIP is simpler to administer than the DRG and is intended to standardize care.

  Following the NHSA Three Year Action Plan for DRG/DIP Payment Reform:

  - 191 "pooled areas" have implemented DRG mechanism and 200 have adopted DIP mechanism.
  - Local authorities can choose from three methods to set rates, including:
    (1) a fixed-rate that remains constant over a period,
    (2) a floating-rate by which an initial rate will be set and be adjusted based on actual annual costs and total weights, or
    (3) a hybrid "elastic" rate that combines both. This flexibility allows for a better fit with a region's specific budget, disease severity, medical consumption and value of medical labor.

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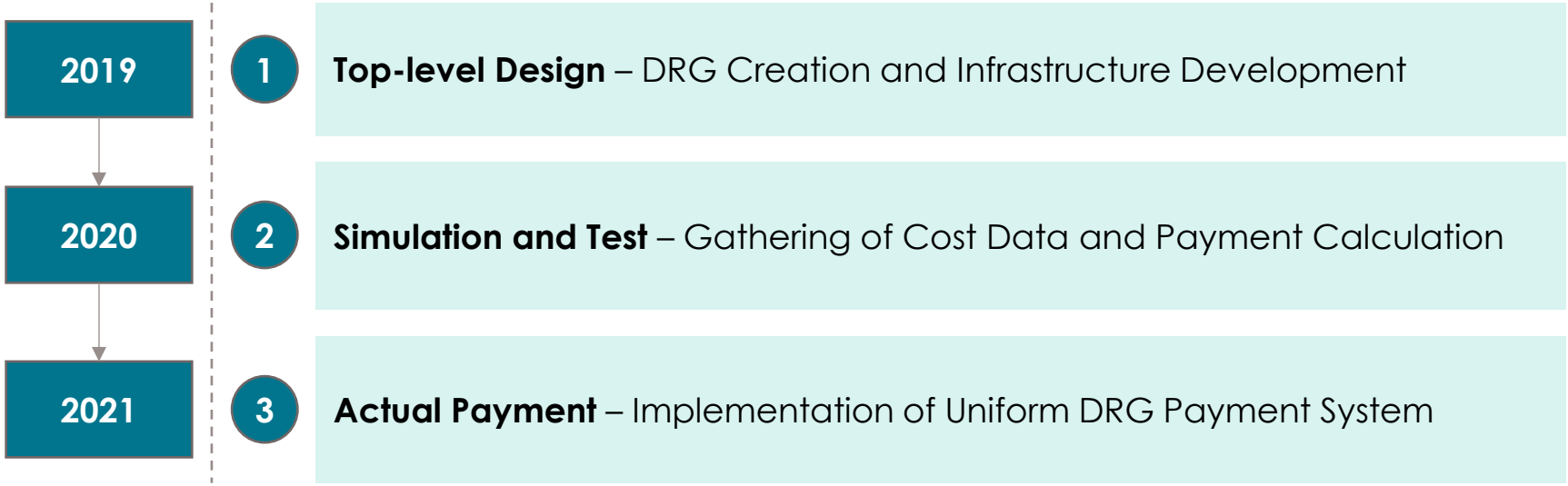
The Chinese Uniform DRG Payment System was fully implemented in 2021 after a three-year integration.

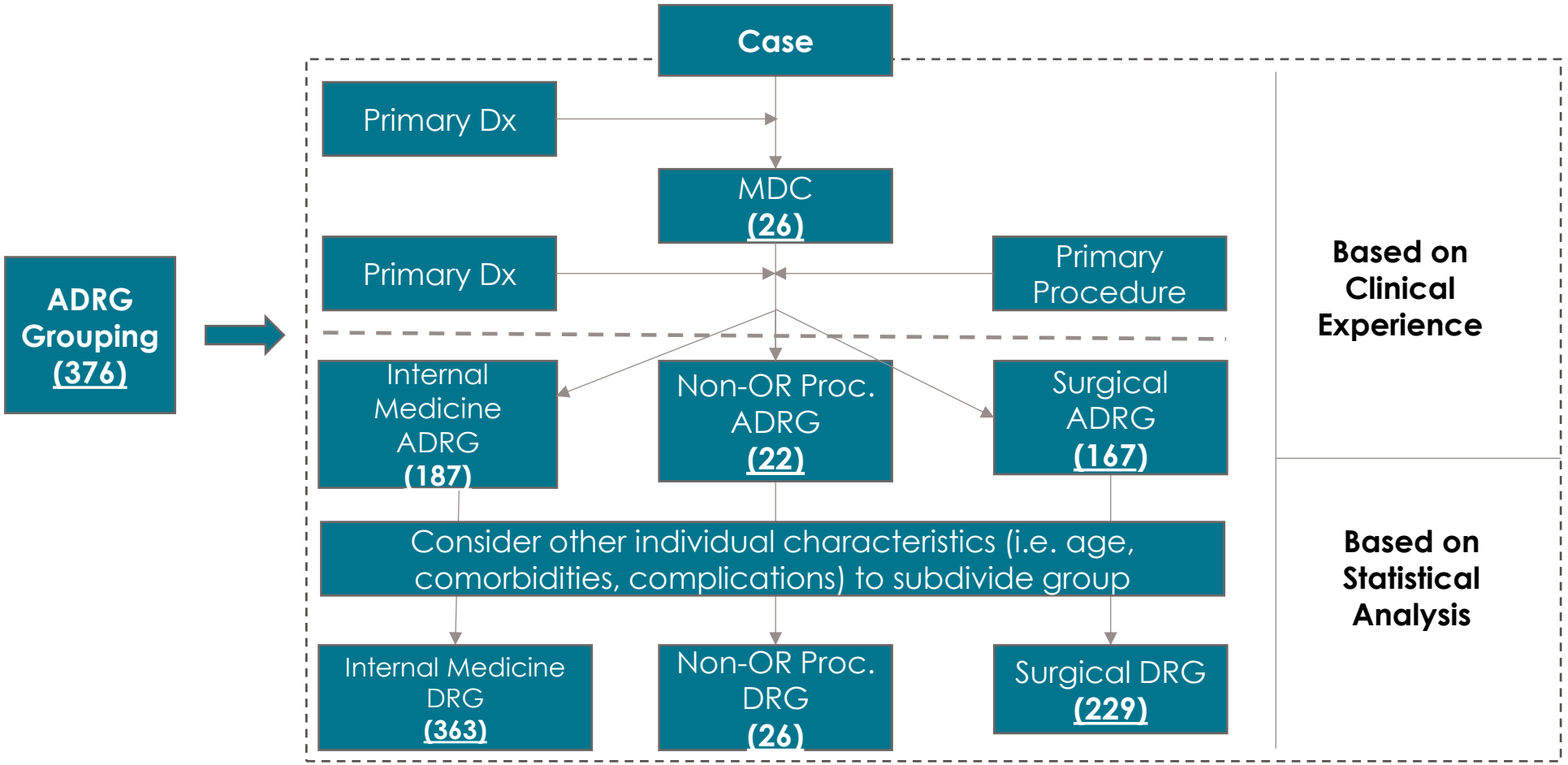
- The pilot program included 30 cities:
  - 4 directly controlled municipalities: Beijing, Shanghai , Tianjin, and Chongqing; and
  - 26 cities from 26 provinces, 1 city per province: Jinhua (Zhejiang province), Foshan (Guangdong province),Wuxi (Jiangsu province), etc.

- The DRG payment system reform was implemented in China through three major steps:



The DRG system relies on a similar grouping methodology used by the US Medicare program.

- Like the US Medicare Severity Related DRG (MS-DRG) payment system, the overall structure of the Chinese DRG payment system is based on similar grouping concepts.
- Overall, the DRG has 634 separate DRGs, and provinces are supposed to be able to expand this, if needed.



DRG payment has been explored in China for many years and is now being phased in across the provinces.

- In 2009, the State Council announced a hospital payment reform by moving from a fee-for-service (FFS) to other forms of prospective payment, notably DRGs.
- Beijing was the first city to attempt to implement a DRG-like payment system and was followed by several other provincial pilots, which ultimately failed due to a lack of consistency with coding, billing and data collection and integrity.

1996 Establish Beijing DRGs Project Team

Start to develop BJ-DRG

1998 Issue technical guidance for improving quality of discharge data

2002 Start to collect standardized discharge data

Complete the development of BJ-DRG and conduct comparison study

2007 Determine base rate and relative weights using discharge data

Implement DRG payment for 300 DRGs in 6 tertiary general

2008 Scale up DRG payment for 300 DRGs in 39 tertiary hospitals

2020 Scaled up to current DRG payment system with 634 DRGs used to pay for services for all public health insurance beneficiaries.

2023 Expansion to DRG Plan 2.0, Development of DRG Add on Payments in Certain Provinces

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Refinement of New Technology Add-on Payment Eligibility

Criteria	Explanation	Zhejiang	Beijing
Newness	Requires the technology, service, or drug to be within the jurisdiction-defined newness period, starting from NMPA approval, BMI listing, or new service price item approval.	4 yrs & NMPA Class 1, 2, 5.1 (drug)	3 yrs
Cost	Requires the average charge per case to exceed jurisdictional thresholds.	> 50% of avg. DRG exp.	significantly impact DRG pmt stds
Clinical Improvement & Innovation	The new service or technology markedly improves clinical outcomes over existing options.	safety , efficacy & innovation scorecard	comparison to SOC
Case Volume	The technology must be used in a min # of basic medical insurance cases annually within the applying medical institution or risk-pooling jurisdiction. Rare disease treatments are exempt.	50 (drugs)/15 (services/consumables) /hospital	50 (drugs/devices)/15 (services) citywide
Insurance Classification & Coding	The technology must first receive medical insurance classification and coding from the NHSA.	Y	Y

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MEDICAL DEVICE PROCUREMENT AND TENDERING

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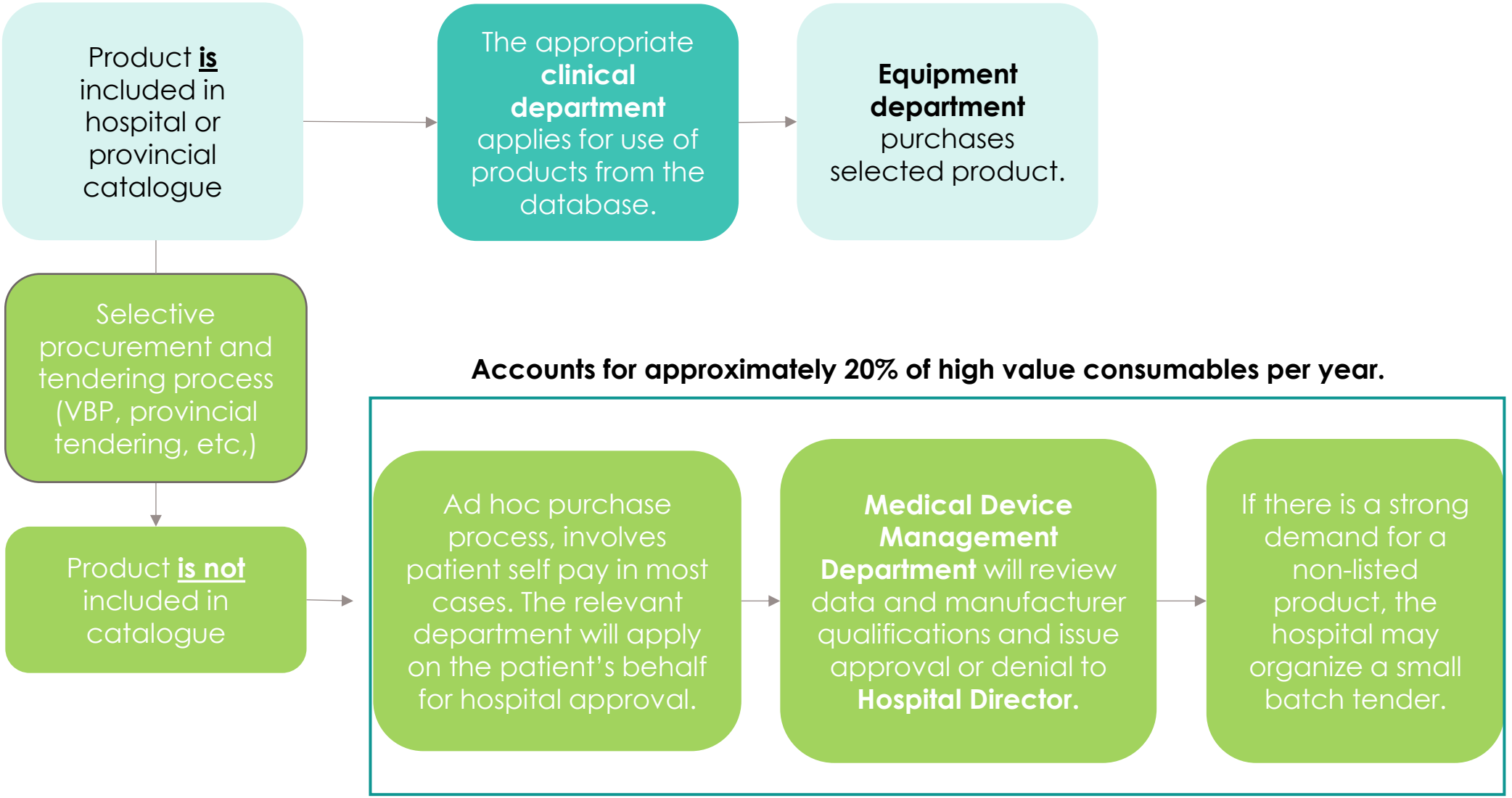
There are two distinct review processes for hospital purchasing of novel technologies; depending on listing in provincial and hospital catalogue or procurement platform.



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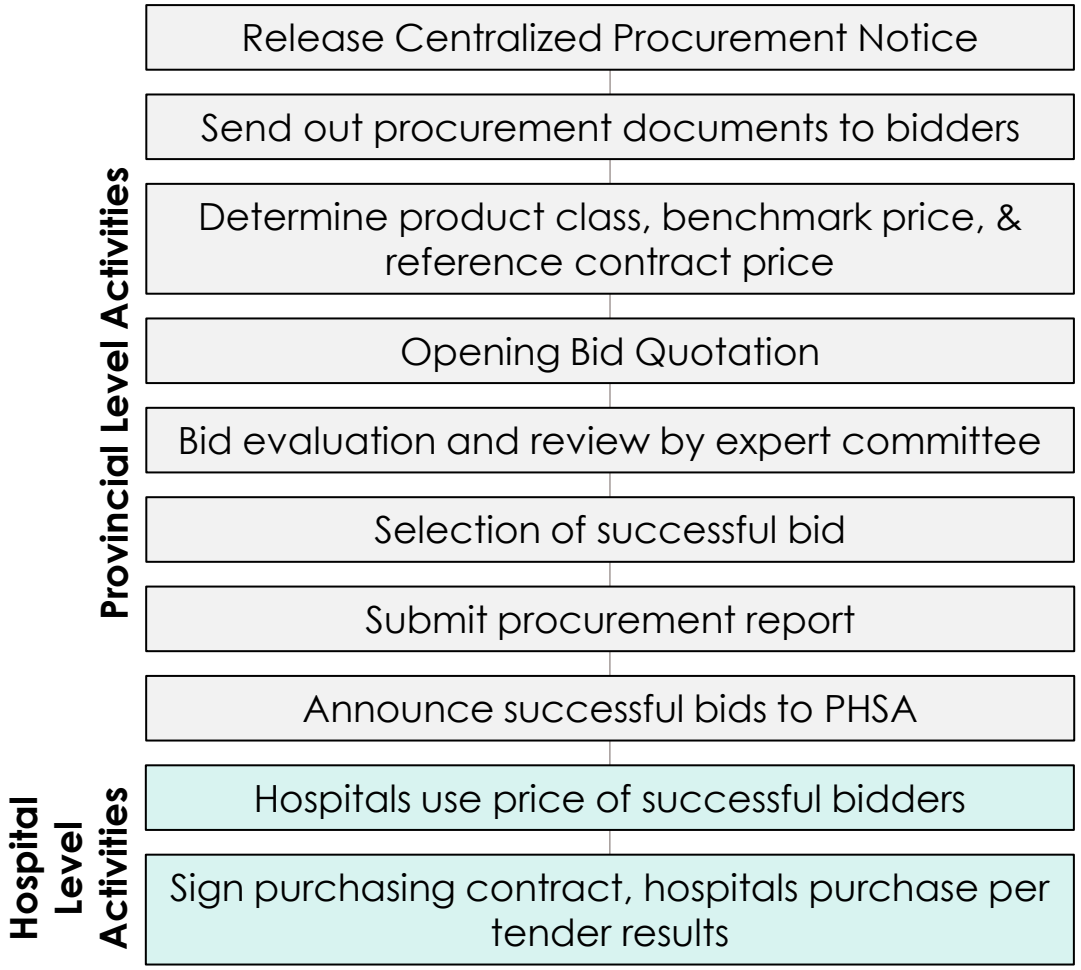
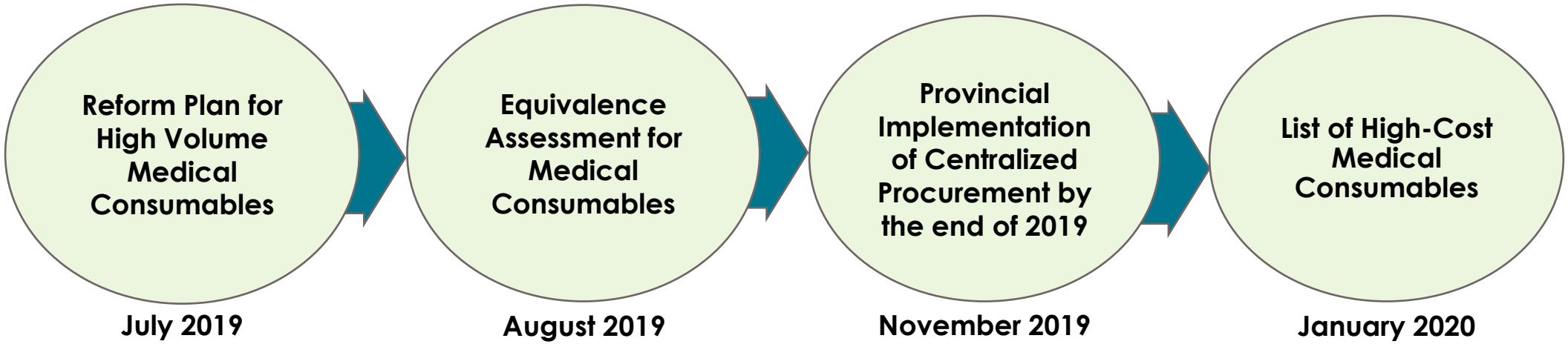
Traditionally, provincial-level tenders used in China were designed to achieve the best pricing scenario and help smaller hospitals obtain better pricing.

- Tenders only mention product technical specifications and never reference brand.
- Provincial tenders will begin with a survey of pricing obtained in other provinces, whereby **price is the most important aspect.**
- Provincial level tenders are designed to achieve best pricing for their constituent hospitals and to help smaller hospitals obtain better pricing.
- For some higher-end implantable products, such as pacemakers, heart valves, etc., hospitals place more emphasis on performance, quality and service.
- A province will choose 2-3 manufacturers or distributors, with one that is preferred, and the others will act as back-up.
- Hospitals then purchase medical supplies based on the pricing and volume agreements negotiated at the provincial level.



Recent policies enacted across China have pushed for more centralized volume-based procurement intended to drive down prices of high-cost medical devices.



- **Latest Development (2020): Plan for Nationally Organized Procurement of Coronary Stents**
  - A plan for high-value consumable procurement at the national level based on price-volume agreements.
  - Coronary stents will be the starting point to explore the new high-cost procurement system.
  - All public hospitals that used over 1,000 coronary stents in 2019 will participate in the pilot plan.

"Now that the national procurement is starting, it will have a further impact on provincial/hospital procurement for products included in volume-based procurement at national level. We will need to follow centralized processes and not have separate procurement anymore." – Industry Expert and Distributor, Shanghai

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The national tendering program has targeted only selected products.

- There will be a high-value medical consumables basic health insurance listing system with the gradual implementation of reimbursement listing through price negotiation. The ultimate goal will be to obtain volume-based pricing.
- In general, this plan calls for more centralized procurement based on:
  - Pricing;
  - Quantity; and
  - Volume agreements.

Product Categories Included in the 2019 Reform Program	
Orthopedic implants	Pacemakers
Ophthalmic	Extracorporeal circulation
Stapler	Blood purification
Electrophysiology	Artificial organ/tissue
Structural heart disease	Hernia patch
Neurosurgery	Dental
Non-vascular interventional devices	

- **A complementary list of high-cost medical consumables was released in January 2020.**
  - The list outlines 18 categories, including stents, balloon dilation catheters, and implantable cardioverter defibrillators.

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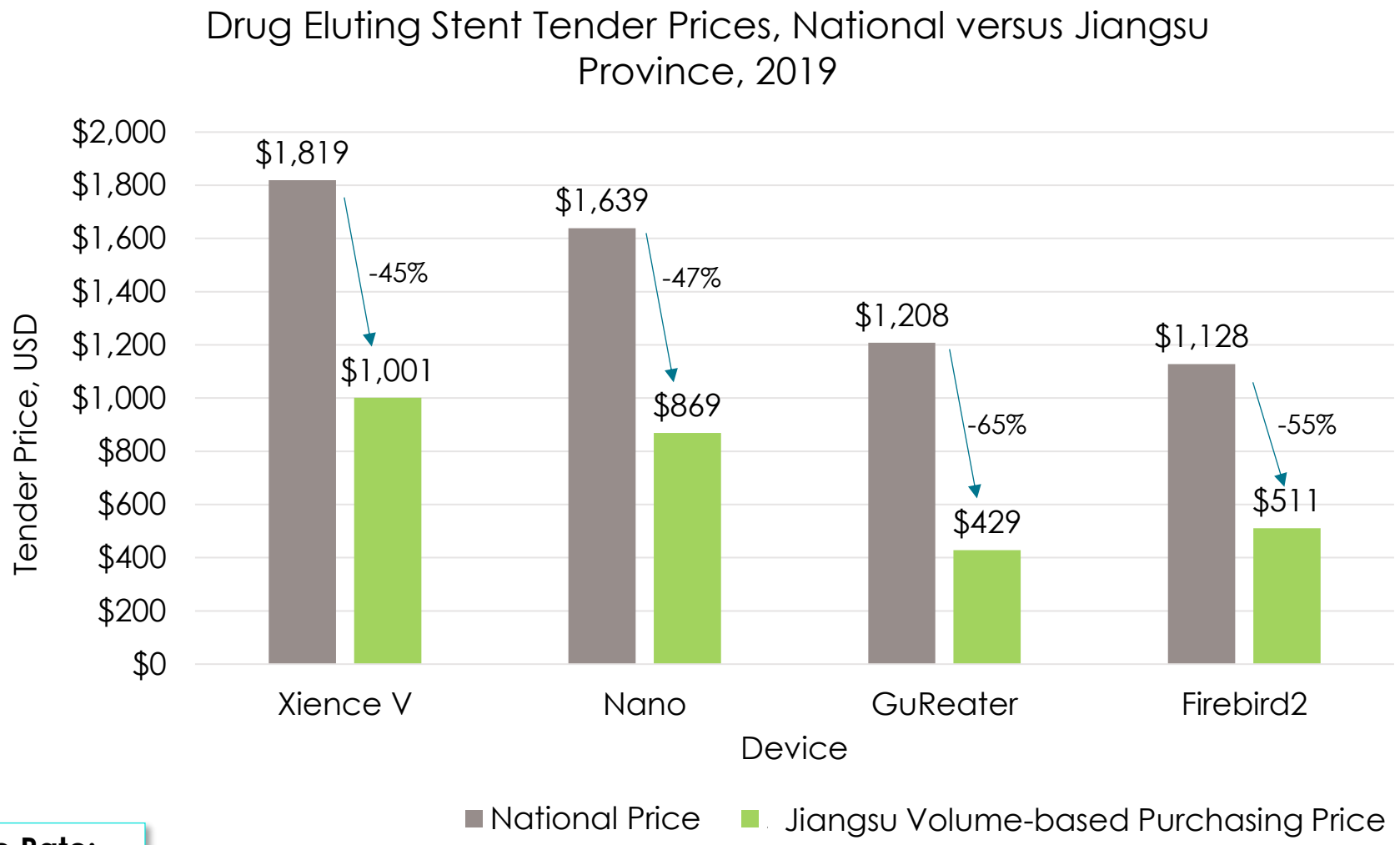
The national volume-based tendering has meant drastic cost cuts for certain medical devices in China.



Exchange Rate:
1 Chinese Yuan= .15 USD

Centralized, provincial volume-based procurement practices will further drive down prices and impact manufacturers' ability to engage in the process.

1. Generally, the province releases a centralized procurement notice that mentions product specifications, but never a specific brand.
2. Once bids are received, the province chooses 2-3 manufacturers or distributors: one preferred supplier and one to two back-ups.
3. Public hospitals must purchase products based upon volume and pricing agreements determined at the provincial level. This consolidates the annual volume from all the public hospitals in the province to only those tender winners.

In response to changes in tendering and procurement policies, Group Purchasing Organizations (GPOs) have formed across China.

- GPOs can be made up of entire provinces, municipalities, or hospitals.
- The purpose of GPOs is to create transparency and promote data sharing across regions and hospitals, driving procurement prices down.
- GPOs often focus on a certain category of device, including cardiac technologies, anesthesia, artificial joints, etc.

GPO	Group Members
The 3+5 Purchasing Alliance	Beijing, Tianjin, Hebei, Liaoning, Inner Mongolia, Jilin, Heilongjiang, Shanxi
Anhui Province Centralized Procurement Pilot	Hospitals within the Anhui province
Jiangsu Provincial GPO	Public Hospitals within the Jiangsu Province
Hebei Cross Provincial GPO	Hebei Province, Tianjin Municipality, and Beijing Municipality
Shandong Provincial HAS Joint Tender (plan released in 2020)	Cities of Zibo, Qingdao, Yantai, Weifang, Weihai, Dongying, and Binzhou

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HEALTH TECHNOLOGY ASSESSMENTS & EVIDENCE REQUIREMENTS

Although HTAs have gained traction in China over the last 10 years, there is currently no national body that conducts HTAs, as they are not systematically used to create policy or determine reimbursement.

- The China National Health Development Research Center (CNHDRC) is a governmental research body responsible for creating and developing HTA policies and procedures.
- Historically, governmental Institutions, academic Institutions (e.g., the National Health Commission's Key Laboratory of HTA at Fudan University), and independent consulting companies have conducted most HTAs in China.
- HTAs have gained traction in China over the years, but rollout and inclusion in reimbursement policies has been slow and fragmented.
- Currently, HTAs are not widely acknowledged or used to create policies; however, it has become more common for them to be used in price negotiations and procurement processes for medical device companies.
- In 2019, the China National Health Development and Research Center (CNHDRC) incorporated the requirement of real-world data into HTA assessments.
- Real-world data is used for clinical evaluation during the full product life cycle, including pre-market and post-market clinical evaluation. This data is used as a complement to existing clinical evidence and is not intended to replace the current path for clinical evaluation.

There is not a standard process across provinces for the inclusion of real-world evidence in adoption decisions for innovative devices.

- Clinical evidence is not required for adoption if the product is approved by the NMPA.
- Hospital level adoption is largely based on clinician preference, product price, and whether other hospitals are using the product.
  - Any information, including health economic data, is seen as a bonus, but is not required.
  - Chinese data is preferred but foreign data is also accepted.
- For new products, a comparative analysis is often performed internally to compare existing products to new products; this assessment is based on product specifications and information sheets.
- Respondents indicated that as long as the manufacturer can prove that the device has been purchased in other hospitals and their own clinical department has endorsed adoption of the device, a systematic assessment will not be performed.
  - Other hospitals' judgement and decision to purchase these devices is used as a proxy for credibility.

"I must admit that the evaluation and decision-making is not very systematic and scientific, but more subjective than objective. In my experience, the physician's preference is the key factor in deciding whether a product is used."-Hospital Purchaser, Shanghai

"Although the hospital will not ask for specific economic and clinical data, the more information a manufacturer or distributor provide, the more convincing the product will be and the more chance they will have of being adopted." -Hospital Purchaser, Zhejiang

Innovative technologies can launch in early access zones.

- Innovative medicines and devices can have early access in several medical zones, including **Hainan Boao Hope City** and **Guangdong–Hong Kong–Macao Greater Bay Area**.

- Early access in these zones can help manufacturers gain physician support and in-country experience, as well as collect real world evidence (RWE) for future regulatory approval and reimbursement evaluation.

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