Reimbursement framework for medical devices in India

Position Paper

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Foreword

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India is an emerging medical device market with huge potential due to its vast population, increasing income, rising healthcare demand, along with increased health insurance coverage. Government-backed schemes such as Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY) have significantly extended the reach of healthcare services (including medical devices) to wider population. Also, the newly instituted Health Financing and Technology Assessment (HeFTA) unit within the National Health Authority (NHA) will have a greater positive impact on the reimbursement framework in the coming years. The growth and sustainability of any market, and making innovative technologies accessible to patients depends on a solid reimbursement framework and open price considerations. Considering India's remarkable growth potential in the medical devices sector, certain aspects of the current reimbursement and pricing framework must be re-evaluated to enable continuing market expansion and access to trailblazing healthcare innovations for patients.

Background

The healthcare sector in India has grown significantly in the last decade. The industry is expected to reach 638 billion USD by 2025 [1], with the medical devices sector growing considerably during this period. In India, medical devices revenue is estimated to reach $5.99 billion by 2023. Cardiology devices will be the largest market segment in 2023, with a predicted market volume of $0.85 billion. The revenue is anticipated to increase by 8.35% each year from 2023 to 2027, resulting in a market volume of $8.26 billion by 2027 [2]. The Indian medical devices industry grew in all segments: consumables and implants, diagnostic imaging, instruments & appliances, patient aids, and other devices. Due to its vast market and consumer base, India is emerging as a favored destination for doing business in the medical device sector for MNCs (multi-national companies). Despite India's remarkable growth potential for the medical device sector, certain aspects of the current reimbursement and pricing framework (for example, the evolving evaluation criteria, discord between the public and private sectors, under-representation of private hospital physicians in the nomination and review of novel therapies, medical device pricing on reimbursement lists, fragmented payer landscape, and difficult nationwide implementation etc.) must be re-evaluated to ensure sustained market growth and patient access to cutting-edge healthcare innovations. Therefore, APACMed and Parexel have collaborated to publish a position paper to discuss India's current medical device reimbursement framework, issues, learnings from other markets, and to offer recommendations.

A robust reimbursement framework and transparent pricing considerations remain key to making innovative technologies accessible to patients.

Market size & pricing regulation of medical devices in India

The Indian medical device industry is expected to grow at 28% per annum to reach 50 billion USD by 2030 [3]. India is the fourth largest Asian medical device market after Japan, China, and South Korea, and is amongst the top 20 medical device markets globally. The Drug Price Control Order 2013 (DPCO) regulates the prices of all medical devices that are marketed in India. This act authorizes the government to fix the prices of essential bulk drugs and their formulations. In 1997, the Indian government established the National Pharmaceutical Pricing Authority (NPPA) to regulate drug prices. In 2013, the NPPA was authorized to regulate the prices and availability of all drugs mentioned in the National List of Essential Medicines (NLEM). NLEM is updated from time to time, and in 2016, coronary stents were added to the NLEM under para (19)-extraordinary circumstances, and their prices were revised in February 2017. In 2017, the NPPA further capped the price of knee implants, reducing them by around 50%. For other medical devices (i.e., the non-scheduled medical devices) the industry must abide by a restriction whereby their maximum retail price cannot increase by more than 10%in any given 12-month period. In July 2021, the NPPA announced that it would regulate the prices of five medical devices using the trade margin rationalization approach (TMR approach) to tackle COVID-19. Trade margin is the difference between the price to patients (i.e., the maximum retail price) and the price at which the manufacturers sell the drugs/devices to distributors. This was required for pandemic purposes but creates uncertainty about India's drug pricing policies.

Current Payer Landscape in India

Overall, India has a fragmented and complex payer landscape involving both government and private payers. Out-of-pocket expense contributes more than 60% healthcare expenditure in India. Under existing government and/or private health insurance schemes, about 70% of the country's population is eligible for coverage. However, the actual health coverage is lower [4]. The payer landscape in India comprises of three types of health insurance schemes which are described in Figure 1.

- **Government subsidized health insurance schemes:** These schemes predominantly benefit the poor and the informal sector (enterprises which are own account enterprises and operated by own account workers or unorganized enterprises employing hired workers; essentially proprietary and partnership enterprises; informal workers have no written contract, paid leave, health benefits, or social security). The informal/unorganized sector accounts for more than 50% of the Gross Value added (GVA) in India [5]. PM-JAY launched in September 2018 is the single largest health insurance scheme. PM-JAY provides a fully subsidized healthcare package with an annual coverage of 0.5 million INR per family on a floater basis (under a floater plan, the sum insured can be availed by any member of the family for a particular year).

  The scheme is operational in 33 States and Union Territories (UTs). PM-JAY has a National portability feature that allows beneficiaries to avail of benefits anywhere in India. In addition to the centrally-sponsored PM-JAY scheme, states have their health insurance schemes – also known as extension schemes.

- **Social Health Insurance (SHI) schemes:** Both employees and employers (the government or private enterprises) pay premiums towards government mandated health insurance coverage. The Employee State Insurance Scheme (ESIS) run by Employee State Insurance Corporation (ESIC) is the largest such scheme. Another social health insurance scheme is the Central Government Health Scheme (CGHS) run by the Union Government for its employees.
- **Private Voluntary Health Insurance (PVHI) schemes:** PVHI are contributory and voluntary schemes. PVHI are broadly of two types — individual/family or group business (excluding government).

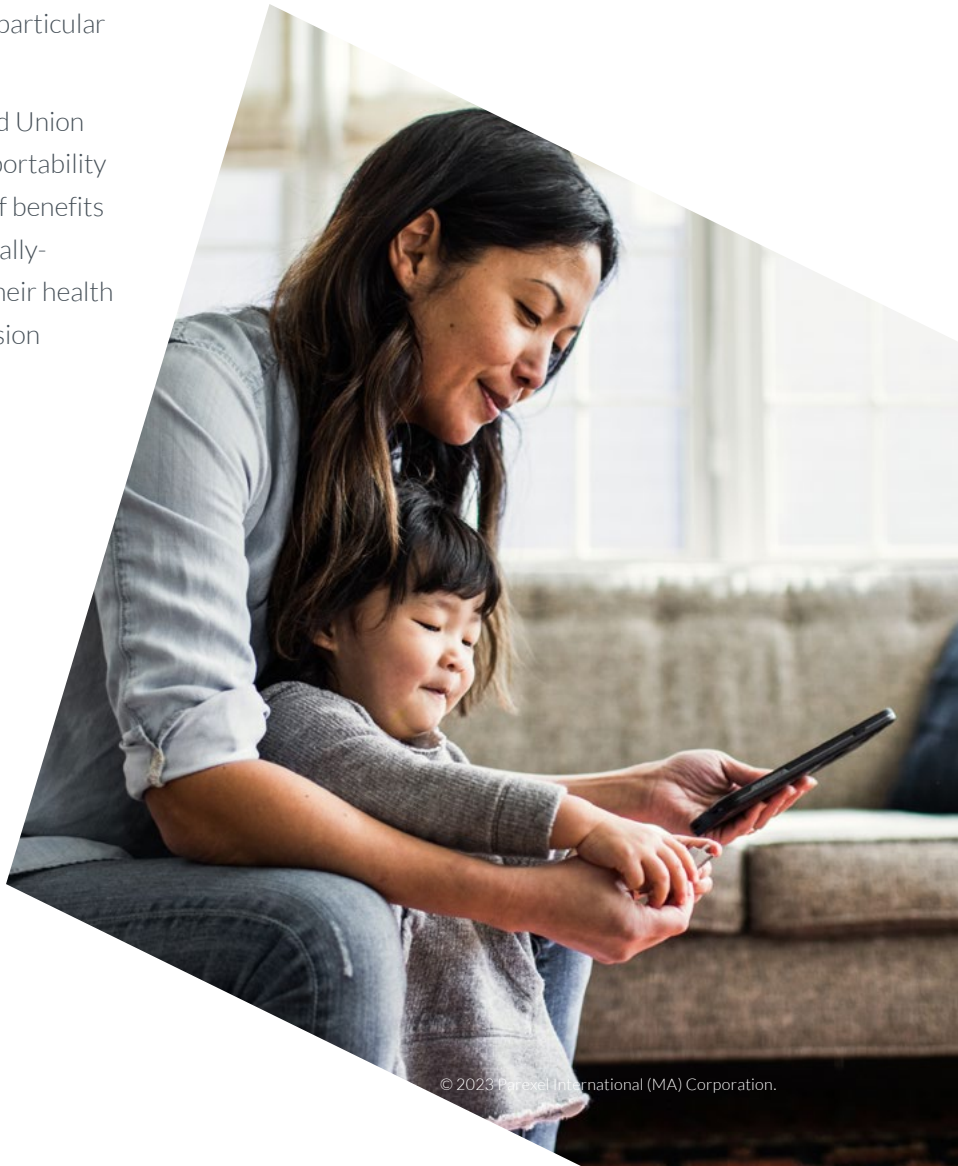


Figure 1. The Indian Health Insurance Schemes

Government subsidized HIS	Social HIS	Private voluntary HIS
› These schemes predominantly benefit the poor and the informal sector (covers 50% of population) › Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY) launched in September 2018 is the single largest health insurance scheme under this category	› Both employees and the employer pay premiums towards government mandated health insurance coverage › Employee State Insurance Scheme (ESIS) is such a scheme under this category › Social and Private voluntary (HIS covers 20% of the population)	› These are contributory and voluntary schemes › Broadly of two categories (individual or family/group).

Current reimbursement model under PM-JAY (India's largest health insurance scheme) & key updates

Currently, PM-JAY uses a case-based bundled payment reimbursement system for making payments to providers. Under this scheme, providers (public and private empaneled hospitals) PM-JAY benefits must be delivered by pre-selected, well-equipped hospitals. Maintaining and growing a network of hospitals that meet quality standards is essential to meet PM-JAY needs and provide quality care to beneficiaries. This necessitates pre-emptive hospital empanelment to ensure beneficiaries' rights are upheld in a convenient, cashless, and high-quality manner [6] and that they are paid a fixed rate for a bundled set of services provided against a defined Health Benefit Packages (HBP). In other words, payment is linked to the cases

treated irrespective of the number of visits and range of services provided. The original HBP rates under PM-JAY were set after reviewing existing health insurance schemes and through inputs received from experts. However, as the scheme evolved and more data on cost matured, refinement of the rates from HBP 1.0 to HBP 2.0 were made. This revision led to an increase in price for 61% of HBPs and a reduction in price for 18% of HBPs. To incentivize the quality of care, there is a provision of incentives to empaneled providers, which is 10% for hospitals with an entry-level of National Accreditation Board for Hospitals (NABH) and 15% for fully accredited NABH hospitals which are over and above the base prices. In addition, hospitals that have PM-JAY Bronze category certification are entitled to a 5% increase in base prices. The existing model of reimbursement is traditional, with a greater focus on quantity and less on patient-centricity. However, there are some welcome steps in this direction by the NHA which has recently released a policy document [4] to infuse the concept of value- based care for reimbursement. Value-based care is a form of reimbursement in which payments to the providers are made based on outcomes as well as the quality of care provided. This policy document intends to seek stakeholders' comments on the proposed methods/ways to make provider incentivization under PM-JAY more efficient, patient-centric, and outcome-oriented. As the reimbursement model under PM- JAY evolves, there are several areas where all the stakeholders (government, industry, and experts) need to work closely to help create an inclusive, effective, and structured reimbursement system. The NHA has also taken positive steps in streamlining the reimbursement process by introducing a new technology inclusion process. The newly instituted Health Financing and Technology Assessment (HeFTA) unit within NHA will utilize Health Technology Assessment (HTA) evidence to inform decisions regarding the inclusion and non-inclusion of therapies under HBP. Since we will be discussing the current reimbursement scenario for medical devices in India as well as challenges and potential solutions in this paper, it is important to discuss and understand reimbursement models in other APAC countries with comparable populations and resources to consider models that may be suitable for the Indian population and learning.

The reimbursement model under PM-JAY is evolving and all stakeholders (government, industry, and experts) need to work closely and share their input.

Reimbursement models in other APAC countries

In this section, we provide an overview of reimbursement models implemented in certain key APAC regions with recent advancements in their healthcare policies and we compare it with existing reimbursement models established in India. The other APAC region countries have both procedure and product reimbursement models for medical devices. Unlike India, many of the APAC countries have an established HTA assessment board for reimbursing medical devices.

Taiwan: Fee-for-service and Diagnosis Related Groups (DRG)/ fixed prospective payment scheme methods are widely used in Taiwan to reimburse medical devices. Any medical device falling under these methods is fully reimbursable. In addition, some special medical devices, called special devices, are not fully reimbursed by the National Health Insurance (NHI). NHI covers only part of the price, and the consumer pays the remaining amount. This method of reimbursement is called the balance-billing system. Under this system, either innovative/first-in-class medical devices or medical devices offering an advantage over the other listed devices are reimbursed.

Japan: Primarily Japan has a fee-for-service reimbursement model for medical devices. In Japan, medical devices are broadly classified into two categories for reimbursement. The first category consists of Special Designated Treatment Materials (STMs) which include most of the high-cost, medium- to high-risk single-use devices that are disposable or implantable. Reimbursement prices for these are determined by the Ministry of Health, Labor, and Welfare (MHLW). The second category consists of non-STMs which include low-risk medical devices, reusable, and durable diagnostic devices. These are part of procedure reimbursement and are not eligible for standalone reimbursement. There are different reimbursement categories based on the functional class of medical devices. Medical devices under the C category are those which are not covered under an existing functional category (based on their structure, purpose of use, efficacy, and effectiveness/ performance). Medical devices under the F category are considered to be extremely innovative.

South Korea: Fee-for-service is the main payment method in South Korea for reimbursing medical devices. The DRG payment system was introduced in January 2002, but it has only been applied to a few procedure groups. Any medical device with new technology must undergo HTA by Evidence- based Healthcare Collaborating Agency (NECA) for reimbursement decisions. If the device is in the first-in-class category with no comparable product available, then either the existing treatment cost of similar diseases or the price in other countries is considered for deciding the reimbursement price.

China: Medical device approval and reimbursement in China is complex. Reimbursement prices vary at the provincial level. MNCs must go through a complex, lengthy, and uncertain process. This process includes NMPA (National Medical Products Administration approval, patient price approval (including national and provincial medical device reimbursement), and provincial bidding.

Reimbursement challenges in India

To propose a transparent reimbursement framework with wider acceptability, current challenges with the Indian market need to be discussed (Figure 2).

Figure 2: Current Challenges with the Indian Market

1. Cost as a primary criterion

- In the current reimbursement framework, device cost remains the primary reimbursement criterion without considering other important parameters like clinical effectiveness, procedural efficiencies (i.e., reduced invasiveness, facilitating the procedure, reduced procedure time), functional improvements (i.e., fixation strength, improved biocompatibility, improves the accuracy of procedure), overall cost-effectiveness (longevity due to enhanced durability, reduced other resource utilizations), and quality-of-life benefits.

2. Limited data

- Considering factors other than cost, availability and credibility of data remains key for reimbursement decision-making by government or private payers. The unavailability of data points related to safety, efficacy, and health outcomes remains a challenge. Moreover, lack of clarity around economic considerations and funding threshold with the limited role of HTAs in the region poses additional challenges for private payers for considering a device in their reimbursement list. Electronic medical records (EMRs) have altered the way medical data are recorded in India and have the potential to be a reliable data source for reimbursement decision-making in the future. An example of the progress in this direction is Tata Memorial Hospital, which over time has gone completely electronic with patient medical records and generates a huge volume of data in oncology. However, deduplication of all EMR data, capturing data with uniformity and adapting these for the usage of medical devices across all private and government hospitals will be required to utilize for effective reimbursement decision-making.

3. Limited resources

- Generating India-specific data and subsequent utilization, analysis and interpretation of this data require trained resources, requiring significant investment from the government. Limited training and undergraduate/postgraduate programs covering health economics and HTA in Indian universities make it more challenging to train and provide relevant exposure to the workforce. The availability of trained resources will also help to increase the frequency of review of reimbursement lists, invitation of nominations, appraisals, and revisions for innovative devices.

4. Less involvement of industry and prioritizing only public-funded reimbursement

- Medical device reimbursement is a complex process, in several parts of the world, and few industry stakeholders are involved in the reimbursement process. Very limited involvement of the industry and their stakeholders in the country's current medical device reimbursement framework could be a limitation as the industry possesses data/ evidence available for the device which may not be available in the public domain or peer review publications.
- The Government's main focus remains on the larger population with low-income when including any devices in public-funded government reimbursement schemes, as a result, very costly innovative devices may remain neglected. However, these devices with proven long-term favorable outcomes may be preferred by sizeable middle-income urban populations covered under private or corporate insurance. There is no provision for innovative funding mechanisms like co-pay to help increase the coverage of device-based technologies. Patients currently do not have the option of co-paying for a better, higher-priced device under PM- JAY.

5. Less involvement of patients and specialists

- A lack of participation of Indian patient groups in the reimbursement process, unlike other countries with a mature HTA system in place is another challenge. The cost-effectiveness of a medical device influences reimbursement decisions, but actual treatment decisions are made by physicians in consultation with patients. Conflict arises when reimbursement protocol limits decisions taken by the patient. Sometimes value has different meanings to patients and varies based on their geographies. Therefore, the end user of any device (the patients and their caregivers) needs to be involved in the reimbursement decision-making, rather than just focusing on direct cost and health outcomes achieved per rupee spent.
- Currently, digital therapeutics (e.g., sensors, wearables, telemedicine, etc.) are not considered for most of the reimbursement plans from government and private insurers, and cost remains a major problem in the utilization of digital health technologies, which highlights the need for a financial support system.
- Limited demand for innovative technologies in certain area remains another challenge for innovators to invest in India. Also, lack of involvement of specialists who are the actual users of the technology being reviewed in the reimbursement decision-making process remains challenging for getting appropriate reimbursement for innovative technologies.

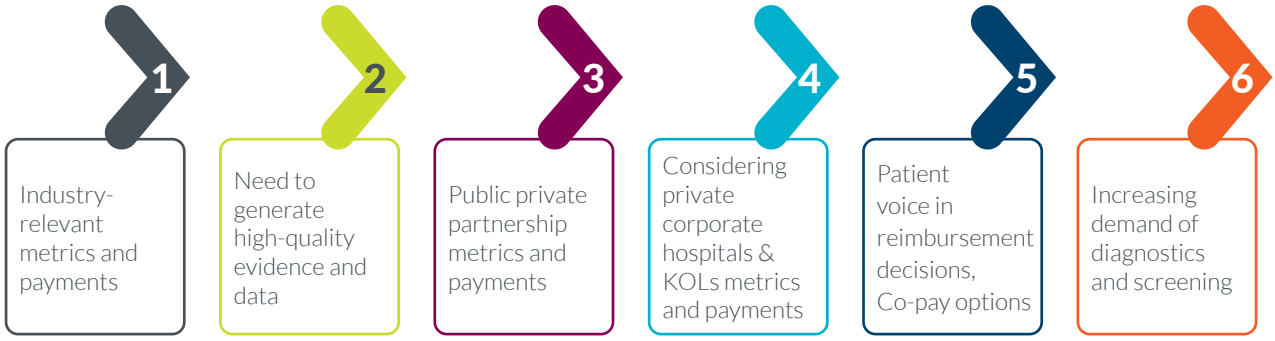
Examples

- According to the U.K. NICE recommendations, Hemodiafiltration (HDF) is considered more cost-effective than high-flux HD [5-7]. HDF is advanced incremental therapy that provides additional benefits to patients i.e., reduced hospitalization, mortality, heparinization, and improved quality-of-life. However, reimbursement in private and public insurance schemes in India does not recognize HDF therapy reimbursement separately and hence for many insurance schemes, patients must pay in full or copay the charge in addition to HD treatment reimbursement in India. Payers should consider long-term favorable outcomes while evaluating such technologies for reimbursement.
- There have been incidences where the usage of improved and costly technologies was not taken under consideration while deciding the price. Same price approval for 2D and 3D cardiac ablation by some insurance companies in India despite the usage of premium specialty catheters and different technology, and different patient indications in 3D Ablation is one example. Alignment between government and private payers remains another challenge in certain cases. PM-JAY is advocating for the single use of catheters and that is reflected in the approved reimbursement amount. However, insurance companies consider the reuse of catheters while deciding the final claim amount.
- Certain procedures like fractional flow reserve and coronary optical coherence tomography are randomly rejected by private payers without considering strong clinical evidence and approval from government insurance schemes.
- There is no provision for additional reimbursement for closed blood collection in many private and government reimbursement schemes. However, the closed blood collection technique helps prevent transmission of infectious disease and multiple samples from a single venipuncture.

Recommendations for reimbursement pathways and framework in India

Several initiatives have been taken by the government and payers, and the results will become visible in the coming years.

Figure 3. Recommendations for reimbursement pathway and framework in India



1. A harmonized way of measuring costs needs to be established along with the consideration for industry-relevant metrics and payments.

Considerations for deciding the cost of a medical device should include value-based purchasing with the consideration of procedural efficiencies and functional improvements, and payments commensurate with innovative technology that improve health outcomes & quality of life. Predictable payment cycles from payers with also help manufacturers with better planning.

2. We always emphasize the need to generate high-quality evidence and data for the reimbursement decision making.

Integrating and utilizing representative local data will define informed decision-making in the future. The Indian government is targeting universal health coverage by 2030 and has recently launched Pradhan Mantri Swasthya Suraksha Yojana and Swasth Digital Health. These initiatives will generate a considerable amount of claims/patient data that could be utilized for reimbursement decision-making in the future.

However, ensuring quality and making these data available to all decision-makers and researchers will decide the utility of data generated from these initiatives in the future. Data from several other initiatives, including the Gates Foundation Initiative, the Integrated Health Information Platform from the Ministry of Health and Family Welfare (MoHFW), National Digital Health, standardized EHRs, and the National Health System Cost Database should be utilized and made available to all decision-makers to achieve more transparent and relevant decision-making.

3. The Indian government has recently established a successful public-private partnership in several healthcare programs and initiatives in the country.

NDHM, Hospital Information System, National Medical College Network, My Hospital Network, Drug and Vaccine Distribution Management System, COVID Dashboard, Health and Wellness Center, Laqshya National Program for the elderly, Mental Health, EMR, and MoHFW budget are examples of recent government partnership with private players which indicated possibilities around the involvement of private MedTech payers and providers in reimbursement decision-making. Collaboration with the device industry can also help capability building in India, which will help wider implementation of HTA and taking data-driven decisions in India. DHR has recently taken an initiative to fill this gap by organizing workshops and starting relevant courses in India. Industry associations should also take initiatives to create awareness and platforms to exchange ideas, bring stakeholders together, and facilitate interactions between industry players and regulators/payers in India. Additionally, NHA has developed a Health Financing and Technology Assessment unit (HeFTA), which will ensure the best value for money in PM-JAY.

4. Private corporate hospitals with a proven track record of improved patient outcomes and their key opinion leaders should also be considered in policy shaping and decision-making.

Making devices available through government schemes in corporate hospitals will help the wider population. Also, including views of corporate hospitals and their experienced key physicians will help government and private decision-makers from payers, to take cautious calls for including innovative technologies in their reimbursement lists.

In case funding is not sufficient to include any innovative technology, the concept of balance billing should be considered to support patients. Corporate hospitals can also be recognized/rewarded with differentiated reimbursement rates at the time of empanelment . This will encourage the quality corporate healthcare provider to participate in the scheme and help to filter quality from non-quality accredited providers.

5. In addition to the cost, patient voice and health-related quality-of-life (HRQoL) should also be considered for reimbursement decision making.

One of the most important parameters to measure quality healthcare systems are long-term patient outcomes. PM-JAY should also consider tracking long-term patient outcomes by collecting HRQoL and inclusion of patient advocacy groups reimbursement decision-making.

Public-private partnering, identifying priority therapeutic areas with payer and provider claims and hospitalization data, and tracking improved patient outcomes including the voice of the patient should be the path ahead.

6. Increasing demand for covering diagnostics and screening products

Increasing demand for covering diagnostics and screening products outside the IPD settings under private and government insurance schemes will increase demand for medical devices and encourage investment in better prevention and early detection of disease. The inclusion of wearable and integrated mHealth-based devices in reimbursement plans should also be considered.

Healthcare budgets are limited and with the increasing burden of disease and inflation in the cost of providing healthcare, there is a need for payers to consider innovative funding mechanisms. This will ensure more coverage and better patient outcomes. For example, providing the option of co-pay for technologies that are effective but expensive in terms of the current reimbursement rates can help provide access to advanced medical technology to the insured population. Understanding and learning from the journey of other established HTA agencies like NICE and CADTH could also provide a few short-term solutions to meet the current reimbursement challenges in India.

Conclusion

Though several initiatives for an improved reimbursement framework for medical devices have been taken by the Indian government and payers in recent years, some of these may be inadequate or will have a greater impact in the coming years. Focusing only on cost, limitations of data and resources, prioritizing only public-funded reimbursement, and limited involvement of patients and industry remain major challenges with the current reimbursement pathway in India. Industry-relevant metrics and payments, generating/integrating high-quality region- specific data, and more involvement of private hospitals, patients, and industry in reimbursement decisions making should be the path ahead.

Meet the experts

Rishabh Pandey PhD
Director & Regional Delivery Head, Access Consulting, Parexel

Rishabh holds a doctorate in Pharmacology, trained at the Indian Institute of Public Health in conducting health economic evaluations, and has also been certified on health technology assessments by the University of Sheffield. He has published and presented more than 35 papers in national/ international journals & conferences, and reviewed manuscripts for leading publication houses like Elsevier, SAGE, Bentham science, Springer, and Informa. His experience spans a period of about 15 years including academics, HEOR, RWE, value communications, and medical information with various organizations including Parexel, IQVIA, Syneos Health, and SIRO Clinpharm. He provided consultancy for numerous public health, epidemiology, real-world evidence, health economics and outcomes research projects including various TAs like oncology, neurosciences, cardiovascular, respiratory, vaccines, metabolic disorders, and medical devices. He remained a member of various task forces of organizations like ISPOR and ISMPP. He contributed to various policy-shaping initiatives, roundtables, and white/ position papers.

Jitender Takyar M.Pharm
Associate Director, Access Consulting, Parexel

Jitender is an Associate Director with Parexel with close to 11 years of experience in Health economics and outcomes research, evidence-based medicine, commercialization and clinical excellence, asset evaluation, Pharmacovigilance and Regulatory evidence. He has been providing consultancy and preparing global strategies for charting the most-efficient course through global market access and reimbursement processes covering long-term data collection studies, real-world evidence generation plans, and health economics projects across numerous Tas like oncology, vaccines, metabolic disorders, cardiovascular diseases, autoimmune disorders, and rare disorders. He is a subject matter expert in UK reimbursement pathways, and other international markets like Canada, Germany, Republic of Ireland, France, and Italy. He has authored 21 publications in the HEOR and reimbursement domain. Jitender is a postgraduate in Pharmacology.

Saipriya J MPH
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Saipriya is a highly experienced consultant in the HEOR field, with over 5.5 years of experience in the healthcare industry. She holds a master's degree in Public Health from Drexel University (US), which has provided her with a deep understanding of the scientific principles, methodologies, and analytical tools used in HEOR and Epidemiology. Throughout her career, Saipriya has worked extensively in the oncology and medical devices therapeutic areas and has gained extensive experience in the North American and European markets, allowing her to provide valuable insights and recommendations to clients operating in these regions. She has been working as a Consultant at Parexel for 1.5 years and has expertise in conducting literature reviews including SLRs and TLRs, writing dossiers including GVDs, CVDs, and business cases, landscape assessments, HTA assessments, as well as conducting quantitative and qualitative analysis of data.

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