EXECUTIVE INSIGHTS

Proposed Changes to Medical Device Reimbursement Evaluation Pathway: Addendum to "Structuring the Unstructured Medical Device Reimbursement in India"

India faces rising healthcare expenditure and a limited government healthcare budget, resulting in a predominantly out-of-pocket (OOP) payer landscape. In a predominantly low-to-middle-income country like India, unaffordable OOP costs constrain access. To reduce OOP payments, several state-level and nationwide government health plans have been implemented.

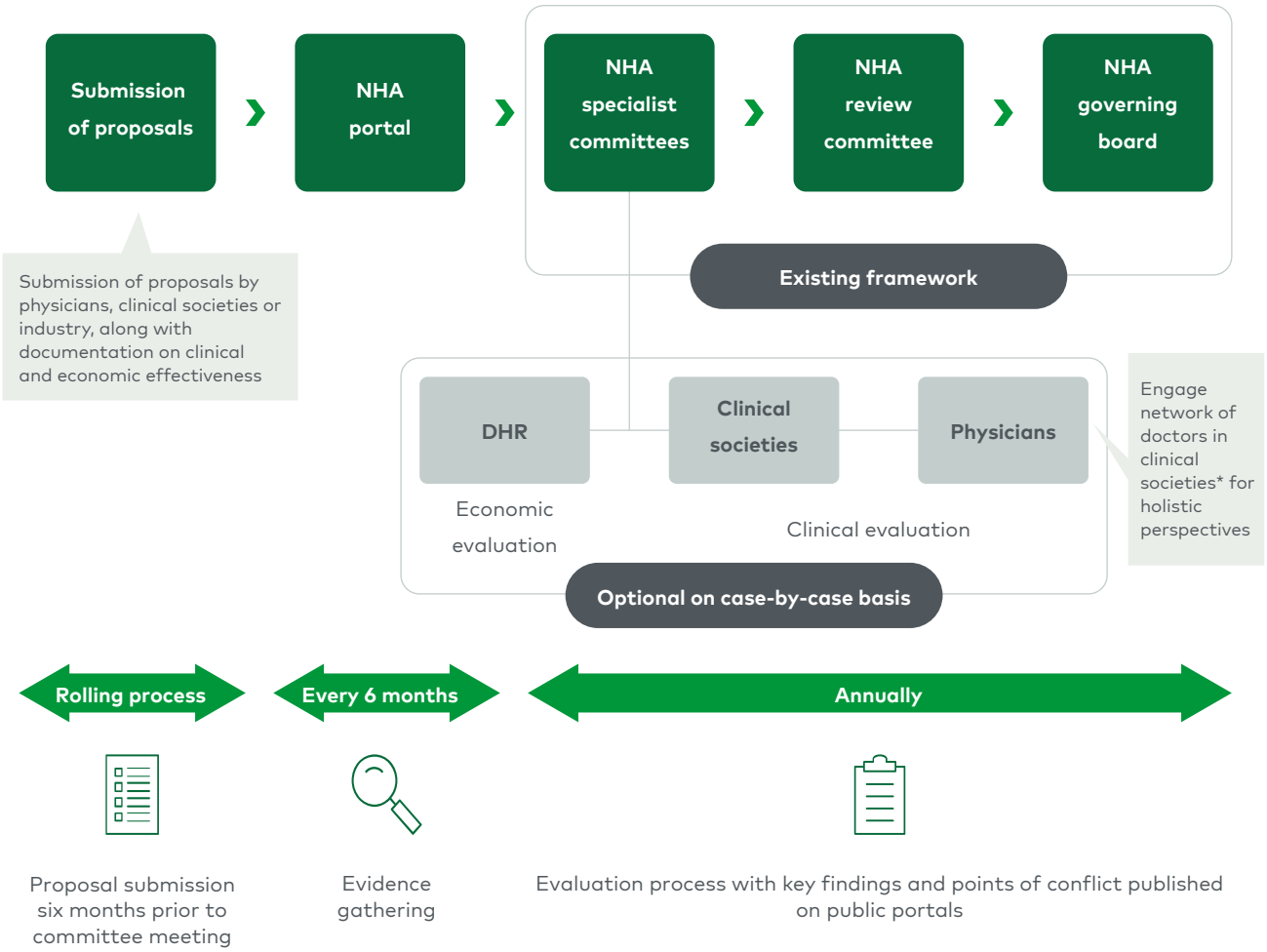
Unfortunately, the reimbursement evaluation criteria of most government health plans put too much weight on cost and too little on long-term outcomes, stemming from limited resources with evolving technical skills to perform health technology assessments (HTAs) and a system that underrepresents the private sector in the decision-making and evaluation process. This partial evaluation further results in low reimbursement prices and deters widespread rollout of government health plans into the private sector.

This calls for a more structured reimbursement system to select medical technologies that demonstrate clinical evidence (e.g., improved long-term outcomes) and in turn contribute to overall cost savings, reducing burden on public systems and payers. As such, changes to the current medical device reimbursement evaluation process have been proposed to address limitations (see Figure 1).

Proposed change No. 1: Establishment of an open submission portal

One proposed, elemental change is the establishment of an open portal to facilitate proposal submissions to the NHA by healthcare stakeholders. All stakeholders (industry

Figure 1
Proposed medical device reimbursement evaluation pathway



Note: NHA=National Health Authority, DHR=Department of Health Research
*Ensuring no overlapping interests between evaluators and applicants

players, physicians, clinical societies, etc.) that have the intent and proper documentation for a medical device evaluation should be allowed to submit proposals to the NHA portal. This system helps ensure a more balanced public and private participation in the nomination of novel therapies. Public stakeholders are understandably cautious about the incremental cost of newer medical technologies, so there needs to be reliance on the private sector to contribute valuable insights on their cost-effectiveness given the sector's tendency for earlier adoption.

The portal would have a standardized template for online submission of proposals. Nevertheless, an initial automated checkpoint should be built into the portal to ensure a proposal meets all requirements before submission to avoid review delays downstream. This approach will help streamline the submission process and relieve some internal capacity constraints within the NHA.

Apart from streamlining submissions, the portal has the potential to expedite the evidence-gathering step by serving as an open, centralized platform for stakeholders (e.g., clinical societies, industry, physicians) to share additional health economics and clinical data. It is otherwise estimated that the NHA will require approximately six to eight months (12 to 18 months for highly innovative products) to engage clinical societies and the Department of Health Research (DHR) to gather additional evidence before sending the proposal to the review committee for further discussion and approval. The whole evaluation and subsequent NHA approval should align with the annual health budget allocation process and cycle. Funding of new technologies may need additional budget. The NHA should be able to propose this during their annual budgeting cycle if the evaluation and budget allocation cycles are aligned.

The portal may remain open throughout the review process to allow submitters to upload new or updated data, and to maintain device pertinence during the periodic review of the reimbursement list in subsequent years. Further freed-up capacity from open sourcing allows the NHA to conduct more frequent or even fixed-interval reviews of existing health benefit packages, meanwhile rectifying low rates that impede universal participation of hospitals in the PM-JAY (the Indian public health insurance system).

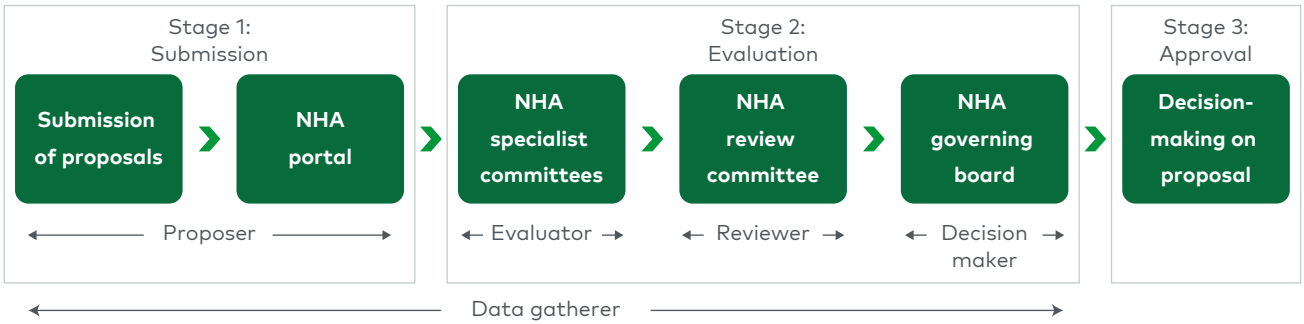
To institutionalize the development of the portal and — subsequently — the portal submission process, directives from the NHA and support from the HTAIn (Health Technology Assessment in India) will be critical. The HTAIn can share learnings of multi-stakeholder submissions from its previous state-level pilot initiatives, while the NHA can pilot the portal submission process along with the ongoing PM-JAY rollout.

Proposed change No. 2: Multi-stakeholder involvement along the evaluation pathway

There are five distinct roles along each step of the proposed medical device reimbursement evaluation pathway (see Figure 2):

1. **A proposer** is any organization or individual that proposes the introduction of a technology/therapy to the reimbursement list
2. **An evaluator** body is then responsible for selecting the submissions for further consideration and assessing the submitted clinical and economic evidence
3. **A reviewer** entity subsequently further reviews the submission assessment and external comments and provides its guidance on the introduction of the technology
4. **A decision maker** — often a payer body — makes the final decision on the reimbursement inclusion or non-inclusion of the technology
5. **A data gatherer** is any entity that assists in generating or providing scientific evidence in support of the medical technology

Figure 2
Roles along the medical device reimbursement evaluation pathway



Note: NHA=National Health Authority

India's existing medical device reimbursement is decided upon by a review committee that overrepresents the public sector, often resulting in misalignment between broader patients' needs and reimbursed therapies. As such, the second proposed change to the reimbursement evaluation process is the involvement of various other healthcare stakeholders, with each recommended to take up dedicated or various roles along the process (see Figure 3).

Figure 3
Recommended roles of stakeholders

Stakeholder	Proposer	Evaluator	Reviewer	Decision maker	Data gatherer
Industry	High	Moderate	Low	Low	High
Public hospital HCPs	High	High	High	High	High
Private hospital HCPs	High	Moderate	Moderate	High	High
Clinical societies	Moderate	Moderate	Moderate	Low	Moderate
State health agencies	High	High	High	Moderate	Low
NHA specialist committee	Moderate	High	High	Low	Low
NHA review committee	Low	Low	High	Low	Low
Payers	Low	Low	Low	High	Low
DHR/health economists	Low	Low	Low	High	Low
Patients group	Moderate	Low	Low	Low	Moderate
Regulators	Low	Low	Low	High	Low
National Health Program	High	Moderate	Low	Moderate	Low

Level of involvement: High, Moderate, Low

Note: HCP=healthcare providers; NHA=National Health Authority; DHR=Department of Health Research

Industry: Industry participants (medical device companies, startups) may **propose** innovative therapies — along with corresponding **data** to demonstrate their clinical and cost-saving benefits — to the NHA. Industry participants may also be consulted for additional insights (e.g., technical know-how) to assist **evaluation**.

Public hospital healthcare professionals (HCPs): High patient volumes in public hospitals not only provide insights into the biggest unmet needs, but also facilitate pre- and post-market clinical trials and the subsequent aggregation of clinical outcome and cost data. Given this exposure, public hospital HCPs will continue to have a significant influence in **data gathering, proposing, evaluating, reviewing and deciding** to approve new therapies for reimbursement. The NHA should, however, be mindful of including private sector stakeholders in the overall evaluation and decision-making process, given earlier access to innovations.

Private hospital HCPs: Private hospitals tend to be earlier adopters of new medical technologies compared to public hospitals, so private HCPs have more **data** and insights into the long-term impact on patients' health and outcomes to **propose** them. Going forward, private stakeholders should have an increasing role in the **evaluation, review and decision-making committee** to improve the relevance and fiscal feasibility of government health packages in the private sector.

Clinical societies: Physicians in clinical societies keep abreast of new technology developments and may have firsthand experience from conducting clinical and economic validation studies on new therapies commissioned by the DHR. They can be helpful in **proposing** new therapies for reimbursement inclusion, as well as in providing additional evidence required in the **evaluation and review** phases. Moreover, clinical societies can help create Indianized versions of treatment guidelines that incorporate the new technologies, given that this adaption would better accommodate local patients' needs as well as drive technology adoption.

State health agencies: State health agencies are responsible for the implementation of national health plans at the state level. As such, their involvement in every step of the evaluation — from **proposing to reimbursement decision-making** — is important to ensure state-level applicability in terms of the rates and packages decided upon.

NHA specialist and review committee: Specialist physicians are an integral part of the evaluation and review committee given their in-depth clinical understanding of their therapeutic areas and the respective unmet needs. Apart from evaluation, the NHA specialist committee may also **propose** new therapies for submission. The NHA specialist and review committee will further review submissions and ultimately provide guidance on reimbursement inclusion.

Patient groups: A patient group (a support group for people with common experiences concerning a particular disease) is well placed in **proposing** the reimbursement inclusion of unique and customized packages that align with patient needs (e.g., COVID-19 packages). They are also potential contributors of real-world clinical and cost-effectiveness **data** given their access to the patient base.

National Health Program: National Health Program stakeholders have a direct view of which therapeutic areas represent the highest cost burdens and how new therapies may impact budget, so they are well placed to **propose** new therapies and be part of the **evaluation** committee, supporting **decision-making**.

Payers, DHR/health economists and regulators: Other traditional healthcare stakeholders will continue to be involved in decision-making.

Proposed change No. 3: Streamlined reimbursement evaluation criteria

Medical devices can be segmented based on innovation level (see Table 1).

Table 1
Medical device segmentation based on innovation level

Device innovation level	Definition
Me-too	A device that has an identical or essentially **similar comparator** device already available in the market
Incremental innovation	A device that is **improved** in comparison to existing technology, but not novel
Disruptive innovation	A **novel device** that is significantly different in terms of its intended purpose, technology, mode of action or performance

Irrespective of whether a comparator already exists in the market, all new medical devices should go through the full NHA evaluation prior to reimbursement inclusion to ensure safety and efficacy. Given NHA's limited resources to perform HTAs, however, evaluation for "me-too" devices should be streamlined by leveraging clinical and economic evidence gathered from precedent comparators approved in India. The use of a me-too device is often established in clinical guidelines, waiving the need for clinical trial assessment. Existing comparators also effectively serve as a reimbursement price benchmark, eliminating the need to perform further budget impact or cost-effectiveness analyses. The overall evaluation timeline for me-too devices is expected to be six months, accounting for time needed to compile recommendation letters from local key opinion leaders (KOLs) for the minimum assurance of a brand's safety and efficacy.

In contrast, innovative devices have no immediate comparators, so their clinical efficacy must first and foremost be demonstrated through global or multi-country clinical trials

that have sufficient representation of Asian ethnicity, or that have been approved by other renowned regulatory bodies (e.g., U.S. FDA), followed by recommendations from local KOLs. However, without a definitive guideline recommendation, reimbursement for innovative devices will remain difficult to justify.

Similarly, setting reimbursement prices for innovative devices is cumbersome as it inevitably calls for a budget impact analysis and a cost-effectiveness analysis relative to an indirect or nonexistent benchmark. Considering the extent of required clinical and economic evidence, the approximate evaluation timeline for an innovative device can range from 12 to 18 months, or even longer for high-cost, disruptive innovations.

There is, however, room to streamline the HTA of an innovative device by employing an adaptive HTA method. Adaptive HTA differs from traditional HTA in that it leverages or adapts available international data, economic evaluations and models from published literature or from established HTA agencies in other countries to inform local reimbursement decisions. Adaptive HTA makes up for the constraints in low- and middle-income countries (i.e., limited technical and administrative capacity, paucity of data, lack of governance) and serves as a more pragmatic approach to rapidly assess a new medical technology. By minimizing the amount of effort required to review technologies that have been well studied internationally, more resources and capacity can be made available to conduct more intensive HTAs on innovations that are local priorities or that are not well studied in other countries.

Conclusion

Over 25 key stakeholders across regulatory agencies, government authorities, key opinion leaders and industry players have come together to develop a pragmatic and concrete call for change to improve the current practice and protocols (process, evaluation, data gathering and communication) of the medical device reimbursement pathway in India. This dialogue is a first step in establishing a transparent working relationship across stakeholders and driving improvement in health priorities — balancing expenditure and savings and patient access with the ultimate objective of ensuring access to innovative therapies while meeting fiscal constraints. The group hopes that these recommendations can serve as a base to support systemic changes.

Glossary

Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY): A public health insurance system implemented in 2018 with the aim of providing free access to healthcare to India's economically vulnerable sector (poor/lower-middle-income households), which comprises 40% of the population in the country.

Department of Health Research (DHR): A department within Ministry of Health and Family Welfare (MoHFW) established with the aim of bringing modern technologies to the public by encouraging research and development (R&D) and commercialization of products related to diagnostics, treatment methods and vaccines.

Health technology assessment (HTA): A systematic evaluation of the properties and effects of a health technology. It is used to evaluate the social, economic, organizational and ethical issues of a health intervention to guide informed policy decision-making.

Health Technology Assessment in India (HTAIn): An institution under India's Department of Health Research entrusted with the responsibility to collate or generate evidence related to the clinical effectiveness, cost-effectiveness, and safety of medicines, devices and health programs.

Healthcare professional (HCP): Any member of the medical, lab, nursing, allied health professionals (e.g., psychologists, physiotherapists, dietitians, midwives), accident and ambulance staff and paramedics, and other professionals who have direct patient contact (e.g., pharmacists, radiologists).

National Health Authority (NHA): An apex body set up for the implementation of India's flagship public health insurance system, called Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY).

Out-of-pocket (OOP) payments: Direct payments made by individuals to healthcare providers at the time service is provided.

U.S. FDA: United States of America Food and Drug Authority is the regulatory body responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, etc.

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