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SPECIAL REPORT

Collaborating for a Robust Medical Device Reimbursement Pathway in India

Contents

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Executive summary

Health technology assessments (HTAs) and evidence-driven decision-making are becoming key hallmarks of India's social health insurance scheme, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), in its ambitious quest to expand healthcare coverage for India's underserved populations. However, longer assessment timelines, delayed adoption by states and lack of formalized reimbursement application tracking mechanisms have emerged as key challenges within the reimbursement process. In this document, we propose key recommendations to streamline the current reimbursement process, with the goal of improving patient access.

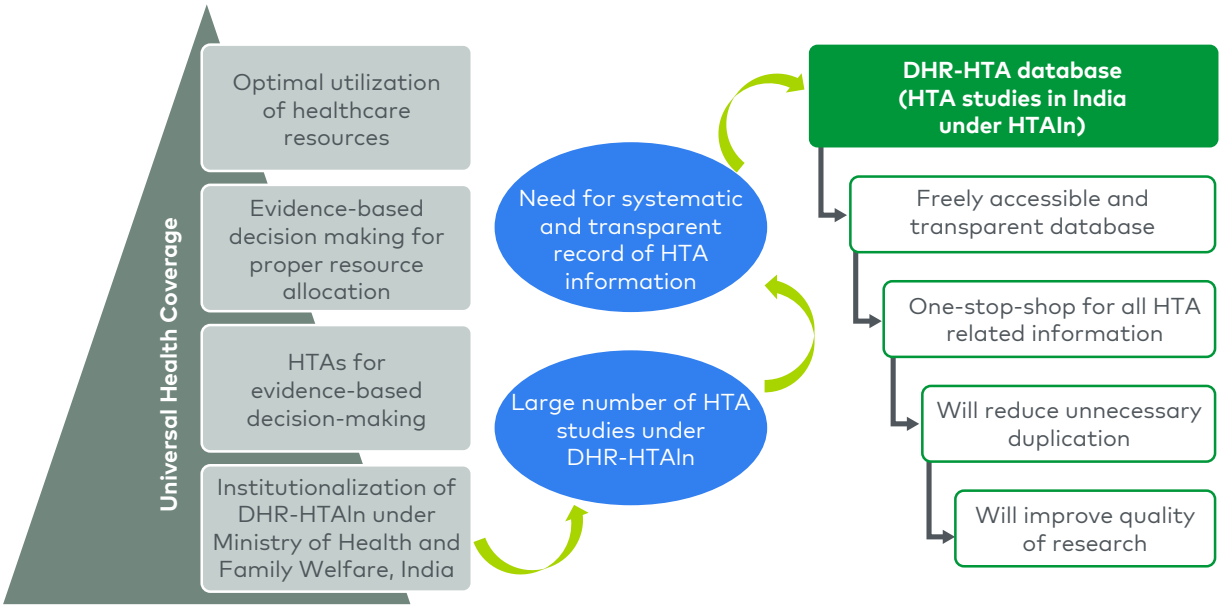
To this end, we propose an enhanced digital-native pathway for the submission of applications, collaborative dialogue, exchange of information and appeal processes. Focusing on digital infrastructure, we highlight potential ways for payors to engage with physicians, manufacturers and neutral third parties through transparent communication channels, allowing them to leverage expertise within these entities and potentially reduce process delays.

Finally, we propose a stronger focus on streamlining the pathway through discretionary use of HTAs, allowing payors to focus limited HTA resources on areas of greatest need and uncertainty.

Introduction

Establishment of a strong health technology assessment (HTA) architecture is increasingly seen as a key indicator of the maturity of the reimbursement process in any health system. The systemic capability to conduct HTAs demonstrates a strong intent to drive equitable access to effective, high-quality health technologies and services, driven by a holistic, patient-centric view beyond mere cost savings. Additionally, HTA capabilities demonstrate that payors have the sophistication necessary to engage in constructive dialogue with the industry, creating an environment conducive to the introduction of new technologies and services within a health system (see Figure 1).

Figure 1
The role of HTA in universal health coverage and the need for an HTA database in India



Note: HTA=Health Technology Assessment; DHR-HTAIn=Department of Health Research-Health Technology Assessment India; DHR-HTA=Department of Health Research-Health Technology Assessment
Source: DHR-HTA database

In India, as the flagship federal scheme Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) undertakes the ambitious transition from volume-based to value-based care, payors are increasingly relying on HTAs to ensure evidence-driven decision-making for the inclusion of novel therapies and devices.

Key challenges

Despite the presence of sophisticated architecture for evidence reviews and synthesis as well as decision-making, there is a need to streamline the existing process in order to expedite patient access. Furthermore, there is strong consensus that the process requires a greater degree of sensitivity to timelines and the level of available evidence to best serve patient populations.

In this context, we highlight key challenges within the current reimbursement process in India (see Figure 2). Additionally, we highlight global best practices that can be emulated in the Indian healthcare system.

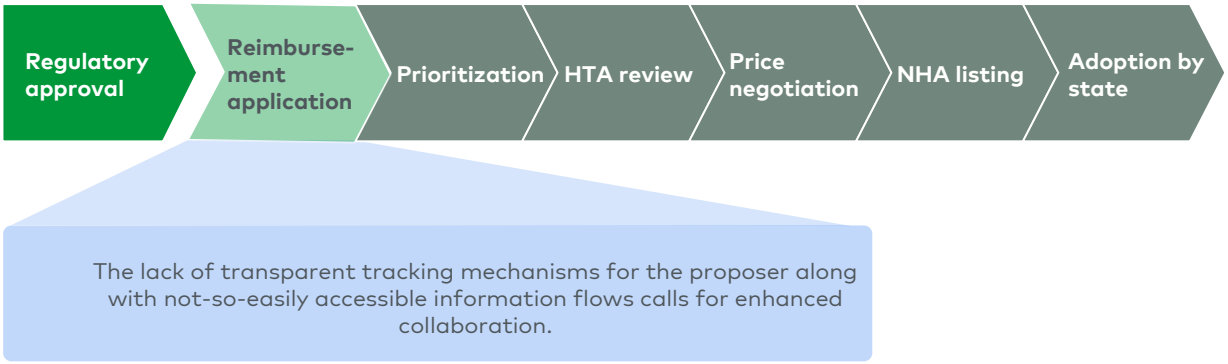
Limited HTA capacity for rapidly advancing medical technologies leads to process bottlenecks, long timelines and delayed decision-making

- Like in other emerging economies, the implementation of HTAs in India has been marked by an increased burden on assessors. This has been attributed to a lack of adequate HTA capacity within the Department of Health Research (DHR) and the National Health Authority (NHA), as well as within partnering academic institutions. The lack of capacity is not surprising given the complex, multidisciplinary nature of HTA evaluation requiring different types of expertise that are often constrained in emerging economies.
- The constraint in HTA capacity availability is further compounded by the absence of a fit-for-purpose evaluation pathway focused on inclusion of high-quality devices. In this context, there is a critical need to use HTAs with discretion, ensuring effective timelines and rapid decision-making.

Limited partnerships with private stakeholders prevent payors from leveraging information and capabilities for robust process development and prioritization

- Lack of strong engagement with private healthcare providers and clinical societies results in a limited understanding of relevant technologies, implementation requirements and costs. This engagement is critical given the role of private healthcare providers as early adopters of novel technologies. A study conducted by D. Parmar et al. (2023) further suggests that AB-PMJAY-covered patients have an increased probability of visiting a private facility, given expedited access to better technology within these facilities.[1]
- Additionally, payors have not been able to effectively tap into resources and capabilities available within the private sector/industry for HTA, health economics and outcomes research, and market perspectives.

Figure 2
Post-application submission, there is a need to develop a formalized communication channel between the proposer and the payor

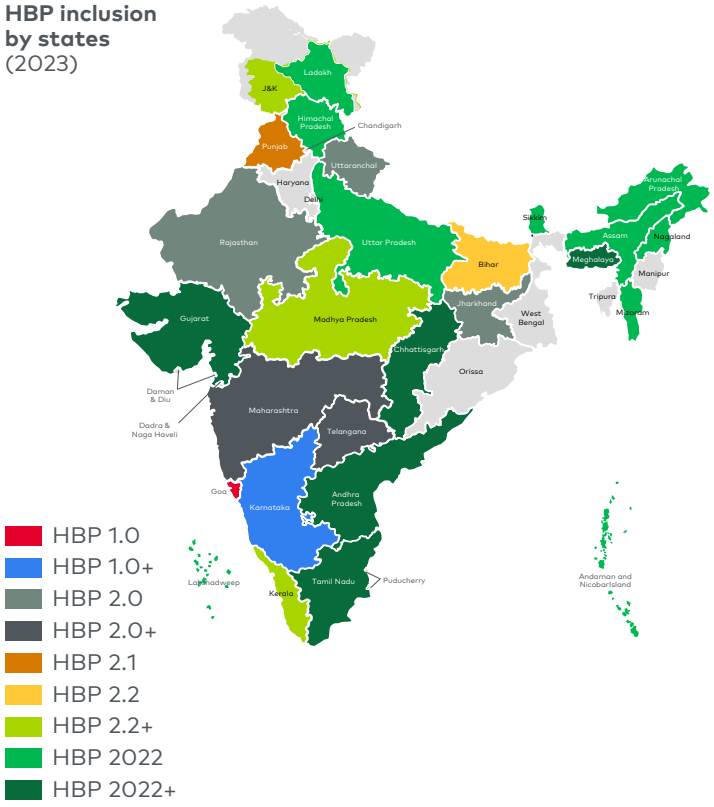


Note: HTA=Health Technology Assessment; NHA=National Health Authority
Source: AB-PMJAY; NHA; L.E.K. interviews, research and analysis

Need for a transparent and predictable pathway and platform for multistakeholder engagement, communication and comprehensive inclusion across federal- and state-level schemes

- A key challenge highlighted in the current system is the lack of transparency within processes. This is further exacerbated by the lack of formalized communication channels specifically aimed at proposers to inform potential stakeholders and provide status updates. Proposers will potentially spend 24-48 months within the reimbursement process, with HTAs potentially emerging as a bottleneck.
- Notably, even after adoption, proposers need to engage continually with state-level authorities to ensure inclusion of nationally approved technologies and avoid further exacerbating the issue of inequitable patient access across Indian states. There is a critical need for harmonization across national and state payors. Ensuring greater transparency and inclusiveness in reimbursement processes and timely implementation between national and state payors would allow for patient-centric outcomes (see Figure 3).

Figure 3
Different states are implementing diversified versions of health benefit packages due to various constraints and considerations, creating an uneven distribution of access to therapy



HBP revision	Key changes
HBP 1.0 to 2.0	• Rate revision for 450 packages • Introduction of 671 new packages • Stratification of 43 existing packages • Discontinuation of 554 existing packages
2.0 to 2.1	Introduction of 63 packages and 94 procedures
2.1 to 2.2	Introduction of one package; rate revisions for 409 procedures
2.2 to 2022	Introduction of 365 new procedures; rate increases for 832 procedures; rate reductions for 122 procedures

Currently, the HBPs adopted by different states have varied widely across India, creating an uneven distribution of access to therapy.

Note: HBP=health benefit package
Source: AB-PMJAY; NHA; L.E.K. interviews, research and analysis

Points of deliberation

Proposed change 1: Enhance robustness and predictability of the current reimbursement process to ensure fit-for-purpose evaluation

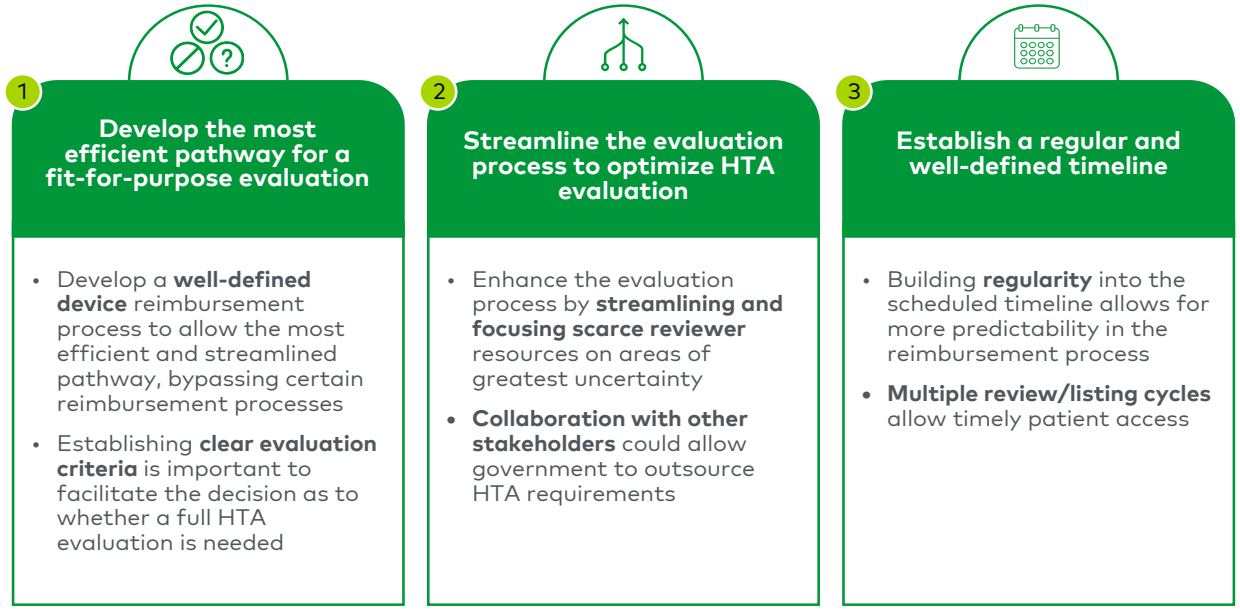
Proposed change 1A: Develop mechanisms to ensure the discretionary use of a comprehensive HTA and an adaptive HTA based on device innovation

One proposed elemental change is the development of mechanisms to ascertain context and requirements for a comprehensive HTA (see Figure 4).

The discretionary use of a comprehensive HTA is critical given constraints within the system that limit the performance of comprehensive HTAs at high throughput. For instance, medical technologies reimbursed in other comparable countries with established clinical evidence should be assessed based on a streamlined pathway, leveraging clinical and economic evidence pertaining to comparator products within the market.

In addition to current NHA efforts to develop in-house HTA capacity, we also recommend developing in-house and systemic capabilities for adaptive HTA evaluation. Leveraging available published evidence, economic evaluation and supporting literature for reimbursement decisions will be key to overcoming capacity constraints, ensuring reviews focus on areas of greatest uncertainty. Finally, allowing the private sector/industry to submit independent HTA evaluations validated by recognized institutions, as is the case in other health systems (such as in Korea and Australia), can ensure appropriate evaluation as well as remove critical delays within the overall process.

Figure 4
Proposed structure of a defined reimbursement process to allow fit-for-purpose evaluations

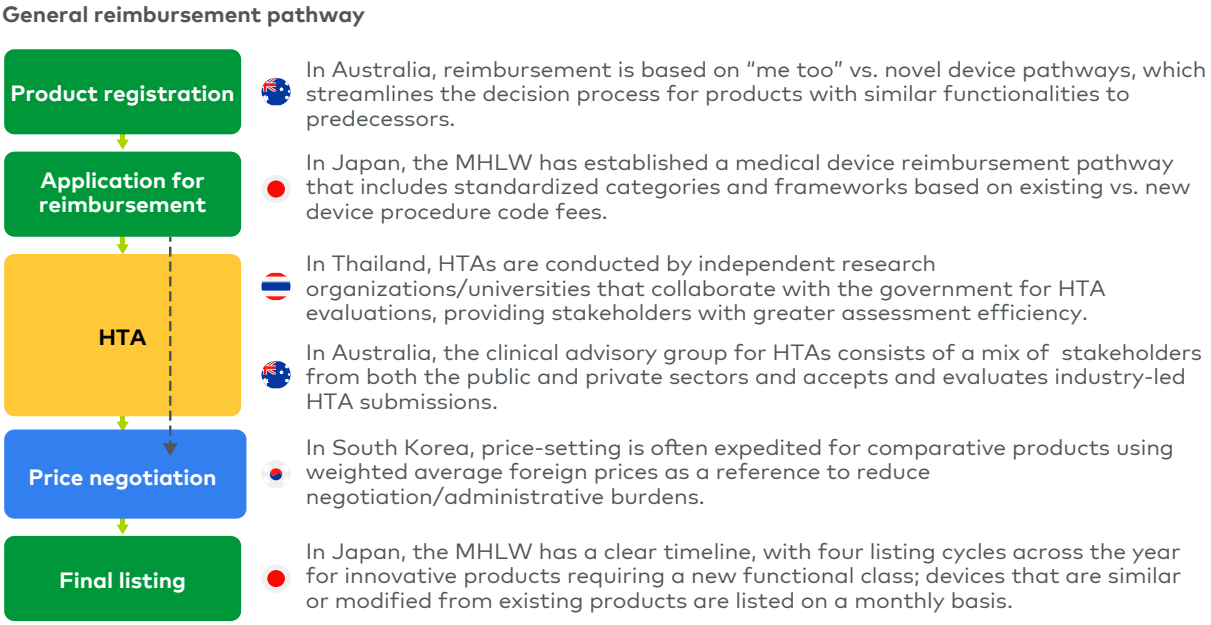


Note: HTA=health technology assessment
Source: L.E.K. research and analysis

Proposed change 1B: Develop formalized communication channels and modes of engagement with a diverse range of stakeholders from the sector, including hospitals, physicians, insurance companies and market participants

A second change is to develop and popularize diverse modes of engagement with private-sector stakeholders. This is key to ensuring physicians in the sector, often pioneers in the use of advanced medical technologies, can voice their opinions on critical patient needs. Additionally, physician opinions can be used to prioritize devices and technologies for HTAs effectively based on local healthcare needs. In this context, we also highlight global benchmarks where HTA mechanisms have been streamlined through continual process improvements (see Figure 5).

Figure 5
Key features implemented in global healthcare systems allowing fit-for-purpose evaluations

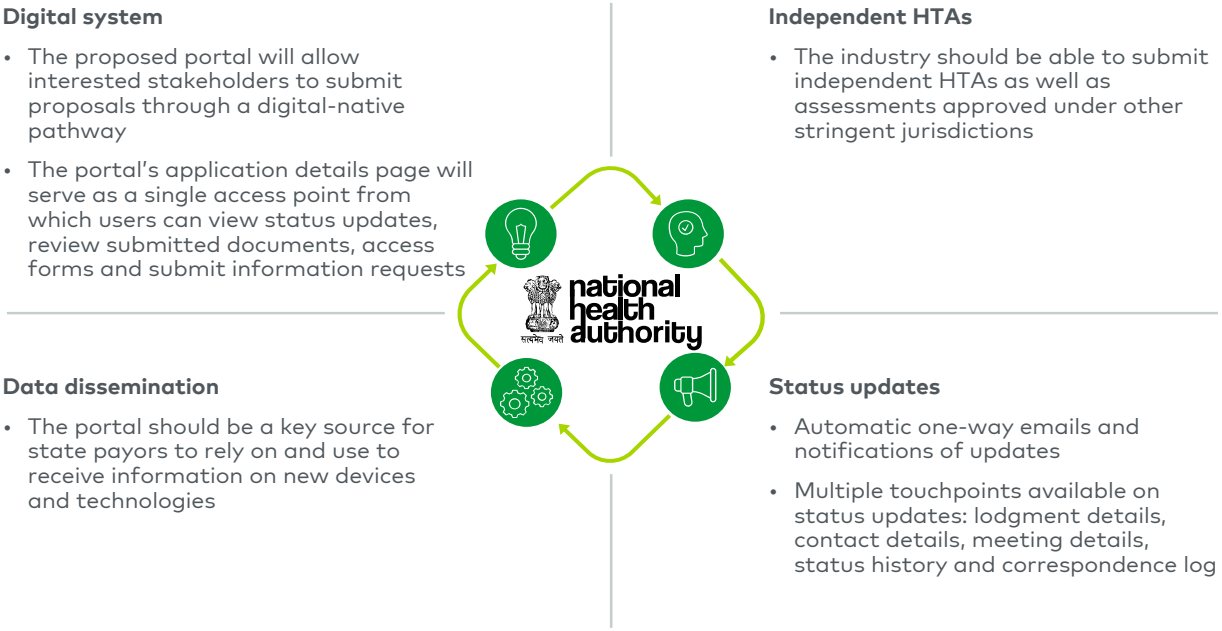


Note: MHLW=Ministry of Health, Labour and Affairs of Japan; HTA=health technology assessment
Source: Government and agency websites; Abbott; L.E.K. analysis

Additionally, the involvement of private healthcare providers, physicians and insurers can provide critical information on costing data, allowing for the effective development of health benefit packages that can support patients and providers. We also propose mechanisms to engage key patients and patient advocates throughout the process to ensure decisions are focused on patient benefit and impact overall.

Proposed change 2: Increase transparency and collaborative dialogue within the reimbursement process (see Figure 6)

Figure 6
Proposed digital-native pathway



Note: HTA=health technology assessment
Source: L.E.K. research and analysis

Proposed change 2A: Developing digital infrastructure for a transparent reimbursement process

We further propose key upgrades to the current digital portal, moving beyond its current use case for submitting applications and viewing outcomes.

- Like the Indian medical device registration system, the reimbursement portal should incorporate online status checking systems, providing industry and other stakeholders a clear view of progress. Such mechanisms have been proven to be successful in many other health systems, such as in Australia, South Korea and Japan.
- These online status checks must further provide a granular view of the overall process, emerging as a key information resource for patients, physicians and the industry.

Proposed change 2B: Develop a platform with diverse modes of engagement with key stakeholders

- The digital portal must aim to drive collaborative dialogue by allowing private-sector participants, third-party stakeholders (e.g., independent HTA bodies)

and clinical societies to submit studies as well as comment on evidence, helping build a strong consensus on the product/device.

- The digital portal should also allow these stakeholders access to evidence review, synthesis and comments from assessors, with mechanisms for reappeal where appropriate.
- We further recommend use of the digital platform for the dissemination of information on new applications to state payors.

There should be a special focus on faster/real-time adoption of approved technologies by state payors to enable timely patient access. This can be achieved potentially by implementing multiple national payor review and listing cycles in a year and enhanced harmonization between the center and the states.

Conclusion

Over 25 key stakeholders (participating experts) including key opinion leaders, government authorities, private insurance experts, health policy experts and industry attended a roundtable meeting to discuss the proposed changes to streamline the medical device reimbursement process in India.

Overall, we suggest a stronger approach to discretionary use of health technology assessments, with greater transparency and harmonization across different systems to ensure benefits to patients in different parts of the country.

We further suggest provisions to use external agencies for HTA assessment, voluntary assessment submissions, as well as the use of costing data from other sources. Finally, we suggest a greater degree of transparency within the process by establishing a digital native pathway.

This quorum is a key step toward a reimbursement process that facilitates patient-centric decision making. Overall, we hope that these key recommendations will enable access to high-quality healthcare by creating processes that ultimately expedite access to under-served patients.

Endnotes

1 Divya Parmar, Christoph Strupat, Swati Srivastava, Stephan Brenner, Diletta Parisi, Susanne Ziegler, Rupak Neogi, Caitlin Walsh and Manuela De Allegri (2023), "Effects of the Indian National Health Insurance Scheme (PM-JAY) on Hospitalizations, Out-of-pocket Expenditures and Catastrophic Expenditures," Health Systems & Reform, 9:1. DOI: 10.1080/23288604.2023.2227430

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Disclaimer

This scientific initiative has been made possible with the support of St. Jude Medical India Pvt. Ltd. (SJM, now Abbott). The opinions expressed in this paper reflect the opinions of the group of participants at the annual healthcare payors roundtable hosted by SJM and are purely academic and personal in nature. Abbott and L.E.K. Consulting do not have any influence on the expressed views in any form.

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