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SPECIAL REPORT

Bridge the Gap: Unlocking Innovative Medical Device Access in India via Evidence-based Reimbursement Models

Contents

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Executive summary

Over the past few years, L.E.K. Consulting's continuous collaboration with relevant stakeholders has revealed crucial insights, identified significant gaps and proposed practical solutions to enhance India's medical device reimbursement landscape for a more equitable and efficient healthcare system. In 2021, our inaugural report highlighted the challenges of the unstructured medical device reimbursement pathway in India and proposed a customized process for national- and state-level reimbursement agencies. The 2022 and 2023 reports focused on suggesting incremental enhancements to the new reimbursement framework introduced by Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY), which integrated health technology assessment (HTA) into reimbursement decision-making. The current report, "Bridge the Gap," delves into the critical issues of affordability, knowledge and data that hinder the widespread accessibility of innovative medical technologies and offers proposed changes.

While PM-JAY has improved access to basic healthcare for India's eligible underprivileged population, budget constraints limit access to innovative medical devices. Nearly 40% of India's total healthcare expenses are still paid by patients themselves. To address this, we propose selective copay models inspired by South Korea, where patients' copayments vary based on disease condition and health risks, promoting cost-awareness, better care quality and efficient resource use. Implementing such copay models requires a concerted effort from government bodies, public and private payers, and healthcare providers, with tailored approaches for different therapy areas and disease severities.

Additionally, the HTA process should be robust enough to determine which medical devices should be reimbursed and at what cost. India's HTA process is still maturing, and clinician engagement, which is vital for health economic evaluations, remains insufficient partly because of limited awareness and motivation. To improve clinician involvement, we recommend a three-pronged approach: enhancing access via a national database, raising awareness through clinical societies, and incentivizing participation with authorship and peer recognition.

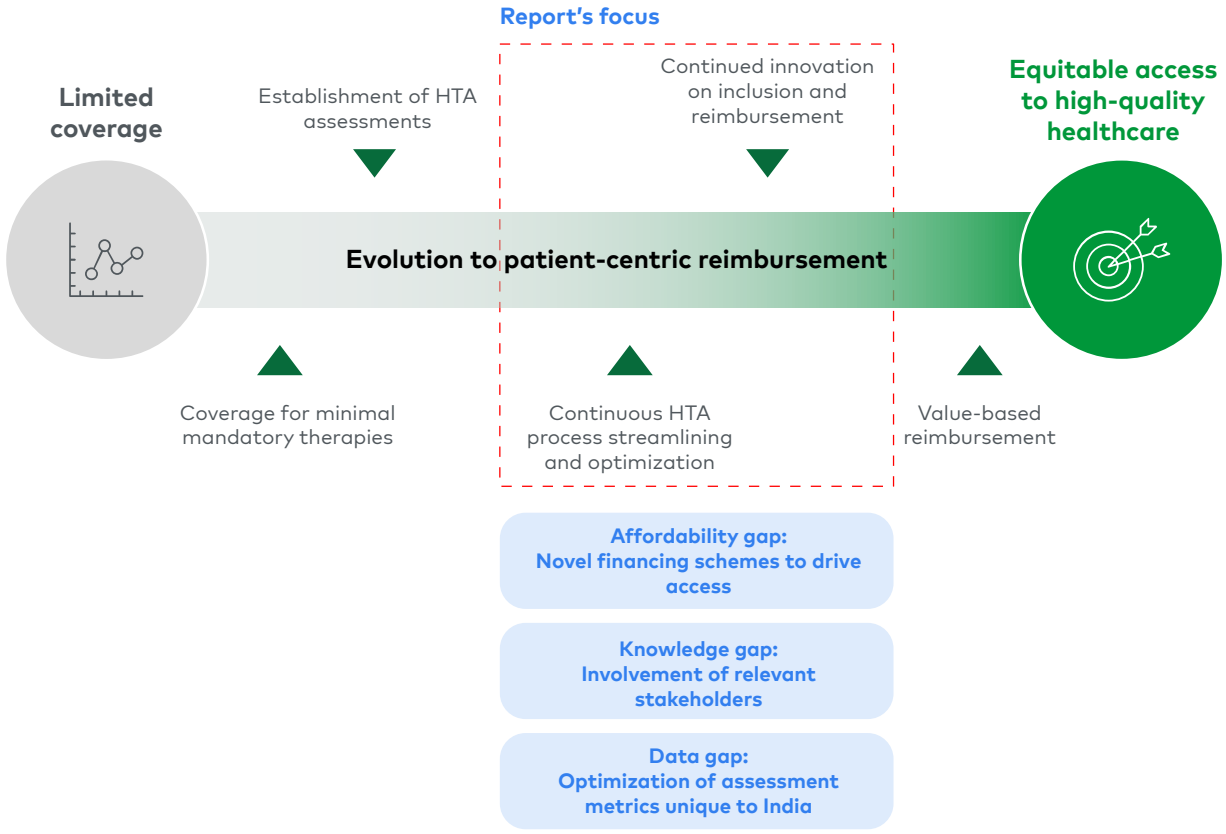
Leveraging real-world evidence (RWE) in the form of health claims and electronic health records from public and private sectors can support regulatory and reimbursement decisions, monitor patient outcomes, and improve market access. To adequately utilize exponentially growing health data, India must address challenges in data collection, standardization, protection and integration by establishing centralized repositories and efficient systems and by adopting global best practices for secure, anonymized data access by researchers.

Introduction

India's healthcare landscape is highly diverse, with unique problems and varied socioeconomic structures. Given that context, prevalent conditions such as noncommunicable diseases, especially cardiovascular diseases (CVD) and diabetes, necessitate the use of innovative medical technologies for effective and efficient management and treatment. However, the widespread accessibility of these essential technologies is often hindered by several challenges, including evolving adequate medical insurance coverage. PM-JAY has significantly expanded access to basic healthcare services via medical insurance for 40% of India's underprivileged population. As India faces rapid demographic and economic changes, the government's recent announcement to include access for senior citizens aged 70+ years is a crucial step toward universal health coverage (UHC) by 2030.

While PM-JAY has laid a solid foundation and other health insurance models have been compelled to move toward the goal of value-based care with outcome-based payments, improving treatment quality via novel technologies and ensuring equitable access in the future will become essential. The recent introduction of HTA in the Indian healthcare setting is one of the essential steps taken by PM-JAY. HTA involves a multidisciplinary, systematic, evidence-based analysis of health outcomes, factoring in socioeconomic and ethical implications for a specific medical device or treatment at a population level. This approach is designed to be inclusive, transparent and robust, providing policymakers with the necessary information to make informed decisions about including or excluding health interventions within the healthcare system. To conduct an HTA, a large amount of standardized, detailed and credible health data is essential. In this report, we delve into the three critical gaps and potential solutions in India's healthcare system that impact the reimbursement for and access to medical devices — affordability, knowledge and data (see Figure 1).

Figure 1
To drive patient-centric outcomes and reimbursement for high-quality, established medical devices, the current report focuses on bridging the affordability, knowledge and data gaps



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

Key challenges

Reimagining financing mechanism for proven, high-quality medical devices

In India, private insurance is availed by only 12% of the population, primarily the higher-income class or those who are employed, while the bottom 40% relies on government schemes like PM-JAY, per recently published 2021-22 government data.[1] The "missing middle," approximately 40% of the population, encompasses diverse socioeconomic groups across the country that continue to struggle with limited insurance coverage and high healthcare costs.[2] Although India's out-of-pocket expenses (OOPE) have been declining, they remain substantial, accounting for 39% of the total health expenditure in 2021-22.[1]

For insured patients, existing insurance schemes often come with inflexible health benefit packages that overlook patient needs. Despite the availability of medical advancements in India, including both incrementally innovative and disruptive technologies, the current health benefit packages in social health insurance schemes such as PM-JAY remain restrictive, focusing primarily on basic, essential healthcare services.

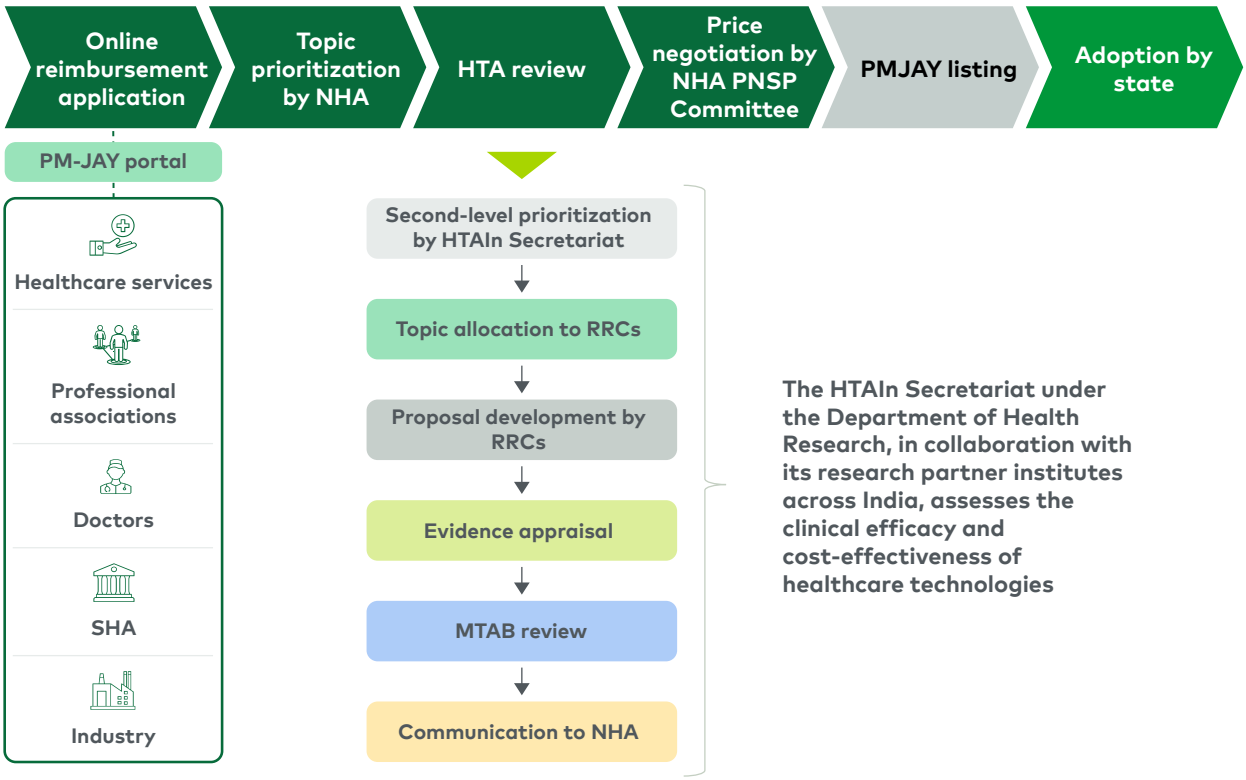
Amid budget constraints and changing demographics within the PM-JAY population, exploring alternative financing mechanisms, such as copay, could be a viable option for catering to patients' needs optimally. This approach could help beneficiaries access high-quality, proven and innovative technologies. However, considering the highly unregulated healthcare provider and fragmented payer system in the country, meticulous effort through collaboration with clinical societies, healthcare providers, payers and patient advocacy groups will be required.

Integrating the expertise of health economists and clinicians for holistic assessments

Another key challenge is integrating the expertise of health economists and clinicians for performing comprehensive HTAs. In developed HTA systems, there are structured processes to incorporate inputs from diverse stakeholder groups, particularly relevant clinical experts to provide necessary insights into framing research questions, defining disease models and interpreting outcomes.

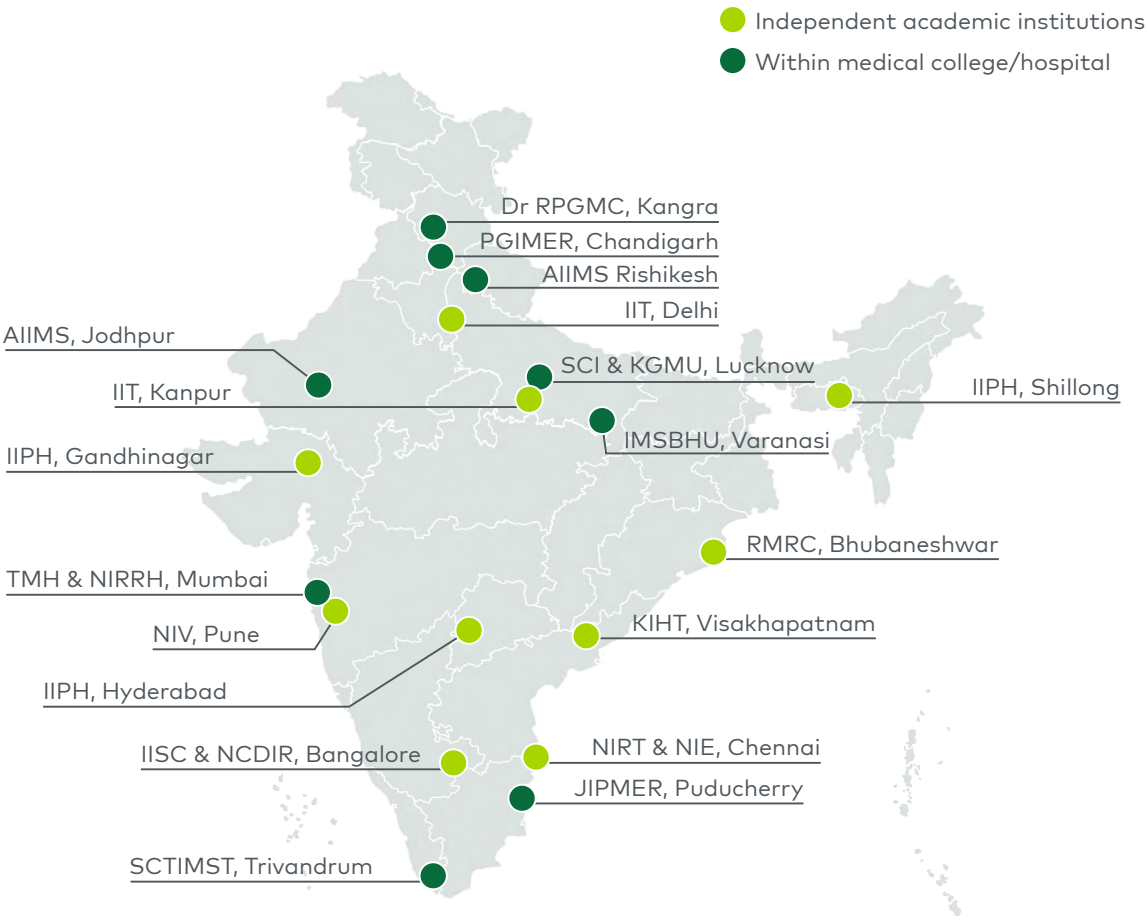
In India, HTA is still evolving, and efforts have been made by the HTA governing body, HTAIn Secretariat, to increase the capacities through partnership with more than 22 reputed research institutes, including medical colleges and independent academic entities (see Figure 2).

Figure 2
General HTA review process, with medium-to-high-degree collaboration warranted from topic allocation to final decision-making through MTAB review phase



Note: RRC=Regional Resource Center; NHA=National Health Authority; MTAB=Medical Technology Assessment Board; PNSP=Price Negotiation and Strategic Purchasing; HTA=health technology assessment; PM-JAY=Ayushman Bharat Pradhan Mantri Jan Arogya Yojana
Source: DHR, MOHFW, https://htain.dhr.gov.in/images/pdf/Process-Manual-2022.pdf

Figure 3
List of 22+ reputed institutes involved in building HTA capacity in India



Source: https://htain.dhr.gov.in/resource-centres.html

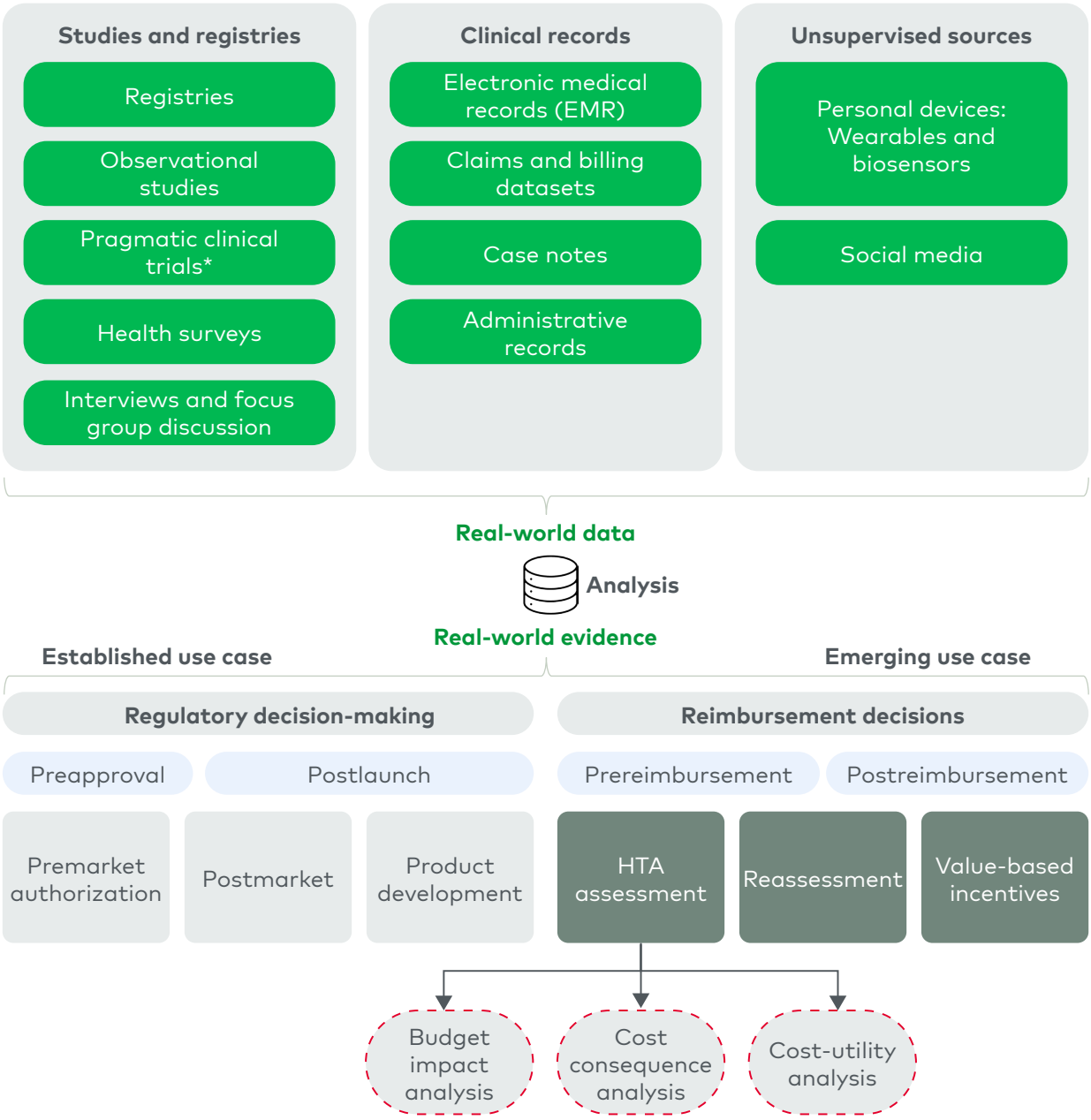
In India, clinician engagement in the HTA process is limited for several reasons, including inadequate exposure to economic evaluation and relevant processes, an unstructured clinical societies system, a high burden on super-specialties physicians and a lower research inclination. Additionally, many new research institutes, especially those not affiliated with medical colleges, struggle to access clinical experts, affecting the quality and timelines of research. This integration will ensure that HTAs are thorough, accurate and reflective of real-world clinical scenarios.

Leveraging the power of insurance data and real-world evidence to support patient-centric decisions

India currently possesses a vast amount of unstructured, nonstandardized health data from both public and private insurers. In 2023, the National Health Authority (NHA) and the Insurance Regulatory and Development Authority of India (IRDAI) collaborated to enhance digital health integration within the insurance sector to streamline data sharing and interoperability via the National Health Claims Exchange. The Insurance Information Bureau, inaugurated in 2010 under the IRDAI, is actively working to standardize and integrate health data across insurers, aiming to provide a robust foundation for evidence-based decision-making in healthcare.

Currently, several payers in India are using proprietary insurance claims data to inform policy-level decisions only to a certain level. However, this data's utilization and role as RWE to complement the published clinical evidence for inclusion decisions on innovative technologies and value-based care is still extremely limited. Given the growing penetration of electronic health records and real-world data (see Figure 4[3]), India has a robust opportunity to leverage insurance data to track patient outcomes, thereby influencing policy decisions at national and state levels.

Figure 4
Nonexhaustive list of real-world data sources and use cases of real-world evidence (non-India-specific)



Note: HTA=health technology assessment
Source: Cavanaugh et al (2023), L.E.K. Research and analysis

However, challenges remain in representative sampling, data depth and access requirements, all of which are essential for practical use. Building standardized data across insurers and various healthcare stakeholders is crucial for meaningful analysis. Moreover, integrating data from diverse sources, including public and private sectors, to build evidence or conduct analyses remains a significant challenge.

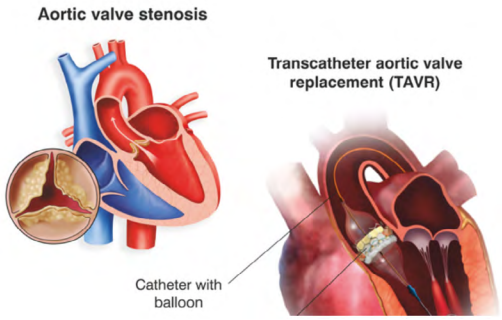
Points of deliberation

Proposed change 1: Develop frameworks to identify critical healthcare needs for medical device copay model, allowing timely amendments for new evidence

Healthcare systems across developed and emerging nations provide key examples of financing mechanisms that enable patients to access high-quality medical technology in concert with government funding.

In Korea, the independent Health Insurance Review and Assessment Service (HIRA) sets copay rates and regulates fee schedules to control costs and ensure quality care. Specifically, HIRA fully covers essential services while providing access to a certain category of medical technology under the "selective benefit items," where differential patient copay rates are implemented (see Figure 5[4]). Singapore's UHC system utilizes a copay alongside a MediSave account, which comprises employees' mandatory contributions for themselves and their dependents' routine healthcare, with private insurance providing access to a wider range of healthcare options. Indonesia's healthcare system combines a social security scheme, BPJS Kesehatan, with private insurance. This allows for broad coverage while potentially using private plans for higher-quality care or care that exceeds government scheme benefit limits.

Figure 5
Detailed case study of South Korea's selective benefit program enabling access to innovative medical technologies



Year	Reimbursement status	Rationale
2013	Noncovered service item	n/a
2015	Patient copay rate - 80% for all risk patients	• Covered under the the first CED program by MoHW • No clear consensus on safety, effectiveness, cost-effectiveness and quality of care in local context
2022	Patient copay rate - 5% for high-risk patients - 50% for intermediate-risk patients - 80% for low-risk patients	• Registry was established under CED to collect clinical and cost data after 2015 HTA • Based on registry outcome, coverage expanded with considerable copay reduction in inoperable/ high-risk patients

Note: CED=coverage with evidence development; MoHW=Ministry of Health and Welfare; HTA=health technology assessment
Source: Health Insurance Review and Assessment Service (HIRA), L.E.K. research and analysis

- **Single-payer public health system:** In South Korea, all citizens are covered under a single-payer public health system requiring mandatory subscription and optional private insurance to supplement any OOPE. The Ministry of Health and Welfare covers 95% of service items, with 4% coming under selective benefit items categories (e.g., cancer, cerebral, heart and rare/intractable disease and 1% noncovered services (e.g., cosmetic surgeries).
- **Copay model:** South Korea's selective benefit program provides a valuable example of managing patient copays of 50%, 80% or 90% or full coverage to balance cost and access to high-quality medical technologies. By assessing eligible treatments based on necessity, cost-effectiveness and ease of use, the program ensures that innovative treatments are more accessible. Selective benefit program eligibility is based on a) high patient burden due to high-cost medical technology but with low clinical necessity, b) innovative health technology with high uncertainty on cost-effectiveness due to lack of robust clinical evidence, and c) ease of use, medical services aimed at improving a patient's or physician's comfort rather than improving treatment outcome.[4]

- **Reevaluation:** The copayment percentage is reevaluated every five years by cross-sector teams based on five selected criteria: clinical usefulness, therapeutic effectiveness, cost-effectiveness, replaceability and social demand. See the Figure 5 inlay that explains the example of the evolution of transcatheter aortic valve implementation coverage — specifically, how it has moved from a noncovered item in 2013 to a 5% patient copay for high-risk patients in 2022.

South Korea's selective benefit program could be customized and applied in India as per the local healthcare setting. Considering the Indian healthcare reimbursement system, we recommend a three-tiered approach — essential, desirable and optional health benefit packages with a differential copay system providing flexibility for accessing innovative medical technology options. While designing such packages, we suggest involving patient advocacy groups, in addition to all other relevant stakeholders, to ensure a collaborative and transparent approach that will build trust, especially between patients, providers and payers.

Proposed change 2: Bolster clinician collaboration in comprehensive HTA evaluations by considering a three-pronged approach: enhancing access, awareness and acceptance

Enhance access: The Department of Health Research (DHR), in collaboration with Regional Resource Centers (RRCs), can take the lead in identifying individual clinicians who can serve as HTA champions. As a starting point, RRCs can refer to the expert committees constituted by the Indian Council of Medical Research (ICMR) for different clinical specialties to render their clinical opinions. Simultaneously, by creating a national database of clinicians by specialty, health economists will have easy access to these experts, ensuring that relevant clinical insights are readily available and fostering more comprehensive and accurate assessments of innovative medical technologies. Additionally, implementing a real-time database update mechanism can help monitor capacity requirements and be mindful of all stakeholders' time.

Enhance awareness: Expanding awareness of HTA among a larger number of clinicians is equally crucial to ignite their interest and promote more active involvement. Clinical societies at both national and regional levels can play a pivotal role in this effort. Through consultative meetings organized by the DHR and RRCs, clinicians can be educated on HTA processes, terminology and the significance of their contributions.

Enhance acceptance: Strengthening acceptance of HTA among clinicians involves adequate training and making evaluation processes more inclusive and participatory through regular stakeholder consultation meetings. Embedding basic HTA concepts in the medical education curriculum will ensure future clinicians possess essential knowledge of these critical processes. To further enhance HTA skills, a structured competency framework can be used similar to the one developed by Dixon et al., which outlines key domains such as HTA principles, economic evaluation, clinical evidence review, information resources and statistics/study design.[5] Implementing this framework through targeted training programs and continuous professional development will foster a culture of acceptance and active involvement, leading to more effective and widely accepted HTAs. Additionally, a structured incentivization program (e.g., authorship, official designation within HTA advisory committee, recognition among physician committee and peers) could be created to encourage clinician involvement in HTA evaluations or processes.

Learning from global examples can also be incorporated to ensure a fair and holistic evaluation of medical device technology (see Figure 6).

Figure 6
Reimbursement/HTA bodies globally take clinical inputs at every step of the process to ensure a fair and holistic evaluation

Health Insurance Review and Assessment Service (Korea)

- The MoHW gathers clinical inputs from the clinical society during technology evaluations, including both HTA and premium price decisions.
- Clinical societies present the usefulness of technology from a clinician's perspective at meetings with the reimbursement authority.

Ministry of Health, Labour and Welfare (Japan)

- When the new reimbursement category is established, the MHLW asks the clinical society to define target patients and clinical indications. The statements of the societies are applied as reimbursement conditions.
- The applicants, mainly the device manufacturers, nominate physicians as their clinical advisors during meetings with the MHLW.

National Health Insurance Administration (Taiwan)

- The NHIA commissions HTAs for new and innovative medical technologies.
- Clinical societies and KOL groups are consulted for selected HTA items to determine the actual indications in the population, incorporating international guidelines and foreign reimbursement status.

Medical Service Advisory Committee (Australia)

- The MSAC/HTA process has several milestones/opportunities to incorporate clinical inputs throughout the process such as PICO assessment, letter of support, public consultation or targeted consultations. These enable multiple touchpoints, ensuring a fair and holistic evaluation.
- Since it is industry-led HTA submission, there is an opportunity to incorporate clinicians' perspectives through endorsement letters and face-to-face meetings with the department.

Note: MoHW=Ministry of Health and Welfare; HTA=health technology assessment; NHIA=National Health Insurance Administration; KOL=key opinion leader; MHLW=Ministry of Health, Labour and Welfare; MSAC=Medical Service Advisory Committee
Source: Ministry of Health government websites; L.E.K. research and analysis

Proposed change 3: Expand and optimize real-world data use for better-informed medical device reimbursement and policy decisions via real-world evidence

Create and optimize centralized real-world data (RWD) repositories that integrate claims and electronic health data from both public and private sectors to support patient-centric decisions and improve medical device reimbursement. These repositories will offer comprehensive RWE, focusing on patient outcomes and convenience. Drawing on global best practices can guide data utilization in the Indian context. For example, the U.S. Food and Drug Administration uses RWE from electronic health records and claims data to evaluate the safety and effectiveness of certain technologies. In the EU, RWE from national registries and postmarket surveillance studies complements randomized controlled trial findings under the Medical Device Regulation. Health Canada uses RWE from the Canadian Joint Replacement Registry to monitor long-term outcomes of hip and knee implants, while Sweden's Medical Products Agency employs data from national diabetes registries to broaden the application of health technologies for patient groups that were either excluded or had limited representation in the clinical trials.[6]

At the onset, expanding the national health claims exchange data platform to serve as a central repository for medical devices at the national level could facilitate its use to build RWE. This could help develop frameworks for ongoing assessment and reassessment of covered medical devices to ensure sustained coverage for those with proven strong patient outcomes (see Figure 7). Implementing these frameworks will enable the use of RWD and RWE for monitoring and potentially excluding devices with suboptimal outcomes based on postmarket surveillance data, while including novel efficient technology.

Furthermore, these standardized pathways, along with aggregated and anonymized data ensuring data safety and integrity, could be made accessible to relevant stakeholders, including industry for its use in building RWE, promoting a patient-centric healthcare system, and encouraging cost-effective innovation.

Figure 7
Summary of key use cases of RWE in India and key recommendations to enhance RWD access and generate robust RWE

Key use cases in India

Real-world evidence

- Establish frameworks to assess RWE for high-quality devices, with a **focus on patient outcomes and convenience**
- Frameworks for ongoing assessment/reassessment of covered devices to ensure **sustained coverage for high-quality devices** with established proof of strong patient outcomes
- Develop a strong mandate to use RWE for **monitoring and eventual exclusion of devices** with evidence of suboptimal outcomes within postmarket surveillance data

Key recommendations

- Establish a strong **framework for harmonization of RWE** in the country, driving sustained **collection of data across different healthcare providers** in a **decentralized manner**
- Leverage the **diversity of data sources** within the country, including private insurance data, transaction management system, hospital records, etc.
- Further **develop and expand the mandate for the National Health Data Exchange** as a **central repository** for device data at the national level
- Develop standardized pathways for **industry access and evidence usage** for development of dossiers

Note: RWE=real-world evidence
Source: L.E.K. research and analysis

Conclusion

Over 25 key participating experts in the roundtable supporting diverse views of the patient, provider, payer and industry came together to discuss challenges and propose key changes for equitable medical device access in India.

Bridging the gaps in affordability, knowledge and data is essential for improving access to high-quality medical devices and achieving patient-centric outcomes. By implementing selective copay models, enhancing clinician engagement in HTA and leveraging robust data analytics, India can create a more equitable and efficient healthcare system.

Importantly, the lessons learned from international practices can provide valuable guidance in practical implementation, ensuring that all stakeholders work together in an iterative process to bridge these critical gaps. Overall, we believe that active, continuous and collaborative efforts between government bodies, private insurers, healthcare providers and clinical societies are crucial in order to drive these initiatives forward.

For more information, please contact us.

Endnotes

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Disclaimer

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