LEK™

SPECIAL REPORT

Unlocking the Potential of Medical Device Reimbursement for Better Health Outcomes

Contents

About L.E.K. Consulting

We're L.E.K. Consulting, a global strategy consultancy working with business leaders to seize competitive advantage and amplify growth. Our insights are catalysts that reshape the trajectory of our clients' businesses, uncovering opportunities and empowering them to master their moments of truth. Since 1983, our worldwide practice — spanning the Americas, Asia Pacific and Europe — has guided leaders across all industries from global corporations to emerging entrepreneurial businesses and private equity investors. Looking for more? Visit **www.lek.com**.

Executive summary

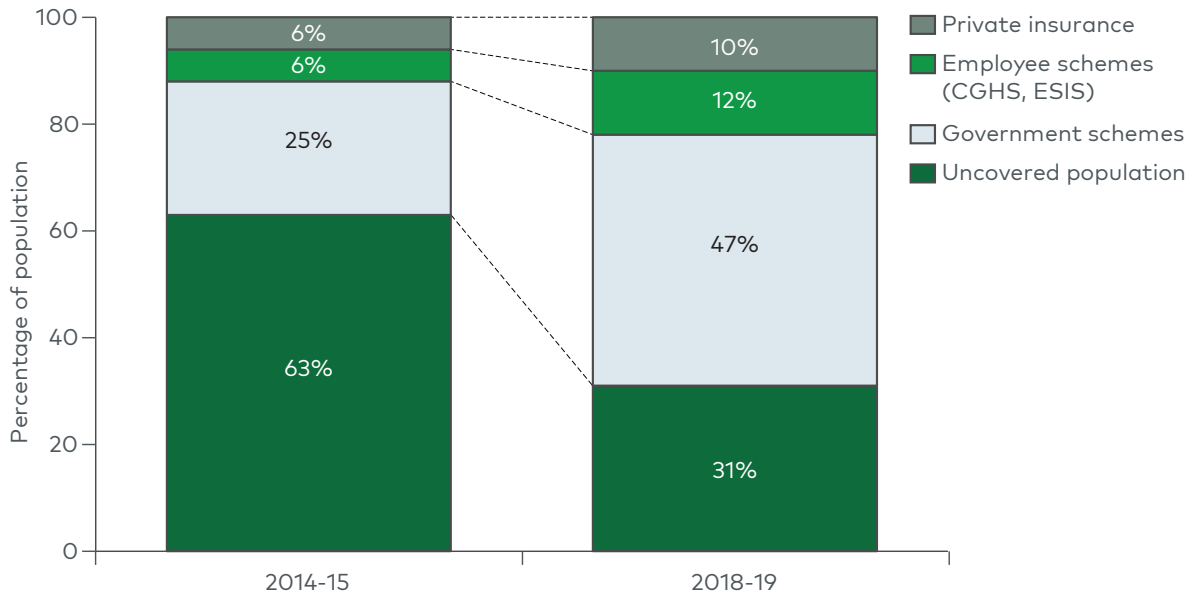
The introduction of India's largest social health insurance scheme, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) has expanded healthcare access for millions of the country's vulnerable population. The project has been marked by a key drive to increase healthcare access in different parts of the country across multiple specialties. Considering these promising changes, we recommend an enhanced patient-centric stance toward improving healthcare outcomes as the way forward. Initiatives for inclusion of high-quality, innovative medical technologies within the reimbursement system is an established approach to improving short- and long-term patient outcomes.

To this end, we propose the creation of a more inclusive reimbursement process that engages physicians and patient stakeholders at every step starting with prioritization, technical appraisal, and final decision. Complementing this approach, the introduction of quality-based incentives for implantable medical devices, in addition to existing service-based incentives within the reimbursement regime, will be the key to achieving a positive impact on patient outcomes. A move toward transparent, value-based pricing is expected to benefit public insurance beneficiaries as well as set positive benchmarks for private insurers to follow suit.

India's transition from volume-based care to value-based care

India's commitment to equality and equity is repeatedly echoed in the initiatives taken within education and social development and more recently in its ambition of providing Universal Health Coverage (UHC) through the launch of Ayushman Bharat Mission in 2018. AB-PMJAY is the world's largest tax-funded social health insurance scheme and provides cashless hospitalization of upto INR 500,000 per year to each family, currently covering over 500 million Indians who are in the country's bottom 40% in terms of socio-economic status (See Figure 1). While focusing on increased coverage is a powerful starting point for India, improving the quality of patient outcomes should also be a key component of UHC.

Figure 1
India health insurance population coverage
(2014-2019)



Source: L.E.K. research and analysis

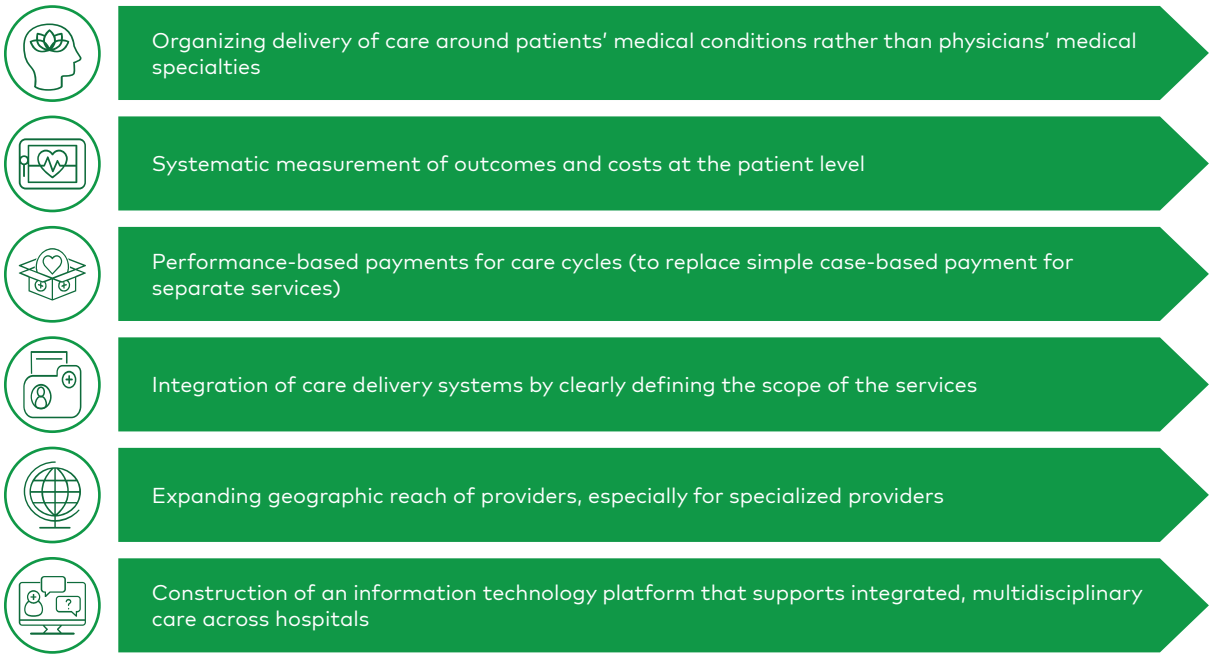
It is notable that across low and middle-income countries, deaths from conditions amenable to health care are often caused by low-quality care, with others resulting from non-utilization of the healthcare system. Unsurprisingly, in these countries, access to quality care is a bigger barrier to reducing mortality than insufficient access. The importance of high-quality care will continue to grow, driven by aging

populations and a higher incidence of non-communicable diseases. Poor-quality care also increases distrust in healthcare systems resulting from adverse events due to poor quality medical devices, persistent symptoms, or loss of function. Promising policy changes in the Indian landscape have bought a value-based healthcare model to the forefront, with policy makers increasingly focused on incentivizing empaneled healthcare providers (EHCPs) to provide high-quality care and improve patient outcomes—a shift from the traditional focus on volume-based care.

A recent policy brief published by the National Health Authority (NHA) elegantly showcases the key goals—reduction in mortality and improvement in patient Health Related Quality of Life (HRQoL)—and a proposed implementation framework for a value-based healthcare delivery model in India (See Figure 2).

Figure 2

Key components of value-based care in AB-PMJAY

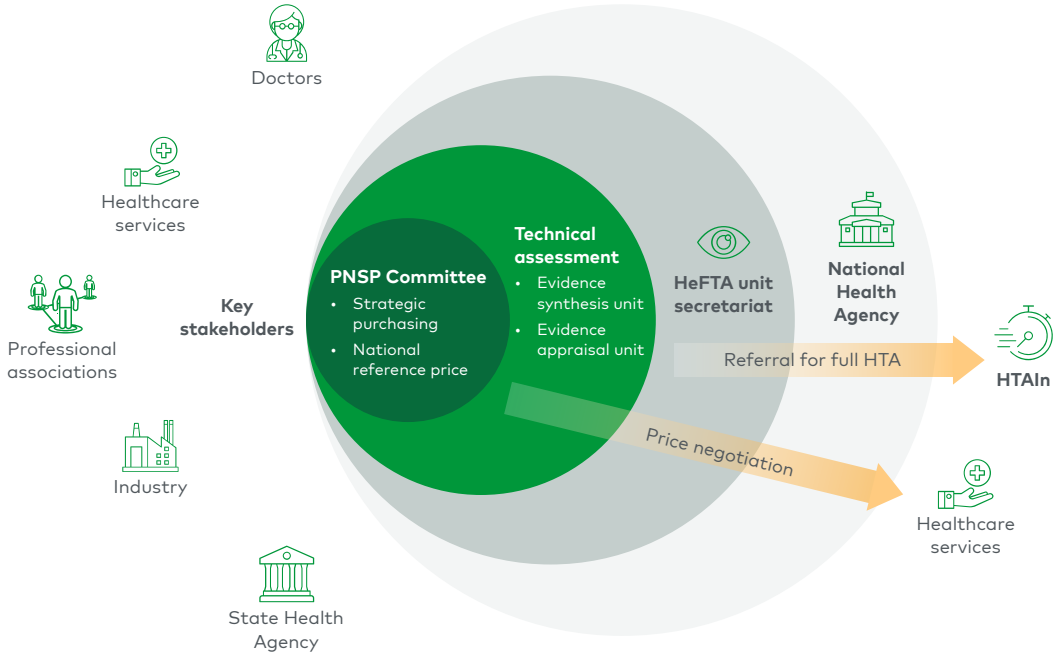


Source: L.E.K. research and analysis

As India transitions toward value-based care, the NHA has increasingly focused on the use of Health Technology Assessment (HTA) for decisions on inclusion of new and innovative health technologies as well as value-based pricing. The NHA recently created the Health Financing and Technology Assessment (HeFTA) unit with a defined institutional and operating structure for new technology inclusion. The HeFTA unit will inform decisions regarding the inclusion and pricing of new technologies/therapies in Health Benefit Packages (HBPs) (See Figure 3). A Price Negotiation and Strategic Purchasing Committee will be established to negotiate the ceiling price of health technologies with providers (hospitals, pharmaceutical companies and medical device manufacturers).

Figure 3

Institutional structure and functioning of the HeFTA unit for new technology inclusion



Note: SHA= State Health Agency; PNSP=Price Negotiation and Strategic Purchasing; HeFTA=Health Financing and Technology Assessment; HTA=Health Technology Assessment; HTAIn=Health Technology Assessment in India
Source: NHA Consultation Paper on Payments and Price Setting under Ayushman Bharat PM-JAY Scheme in India

The NHA has also proposed the introduction of service-based incentives for empaneled hospitals based on both certifications and systematic measurement of outcomes. In the newer policy of providing value-based incentives, a maximum financial benefit of 15% will be provided based on two categories—certification-based incentives and outcome-based incentives—with equal weightage accorded to both criteria.

The NHA has also introduced a Diagnosis Related Group (DRG) pilot in five states under AB-PMJAY, making it the first scheme in India to provide payment through use of DRGs.

Key challenges

In addition to the above promising changes in the policy landscape and an increase in healthcare spends, NHA's initiative to invite stakeholder comments on recent policy papers "Provider Payments and Price Setting under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana" and "Volume-Based to Value Based Care: Ensuring Better Health Outcomes and Quality Healthcare under AB PM-JAY" is a welcome step. However, a strong shift toward a more inclusive reimbursement decision making is yet to be implemented. In this regard, we highlight three key challenges to bringing patient-centric and inclusive reimbursement decision making to the forefront:

1. **Limited involvement of critical stakeholders in reimbursement decisions often leading to partial assessments precluding patient access to innovative technologies**

   - An infrequent involvement of diverse stakeholders often leads to physicians, the actual therapy users having an incomplete view of the topic selection and prioritization process used for reimbursement decisions within the HTAs.

   - A second challenge in this context is the general representation of broader clinical experts (e.g., cardiologists) instead of specialized therapy users (e.g., pediatric cardiologists, electrophysiologists) who can effectively identify patients' interests.

   - Underrepresentation of patient and physician voices disproportionately affects patients with life-threatening diseases, who are most often poorly served by healthcare systems.

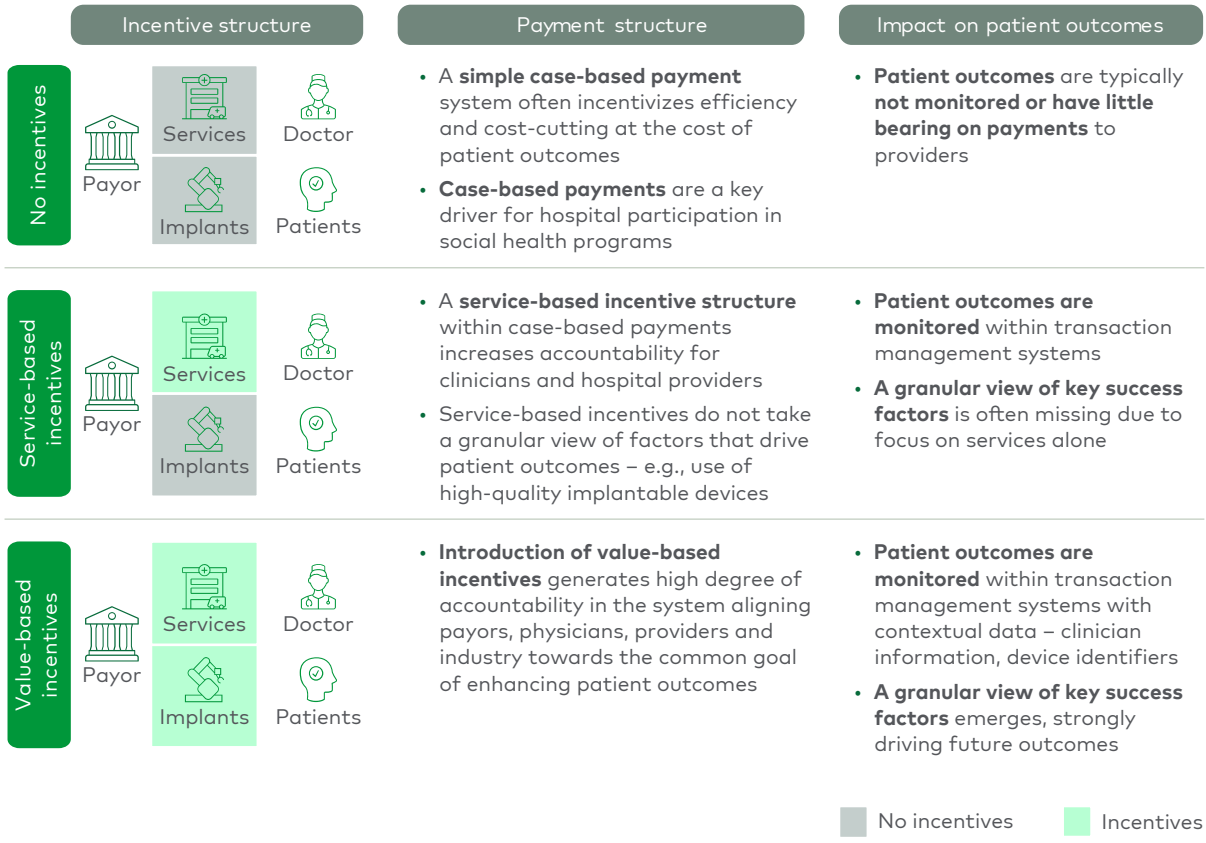
   - A lack of structured physician and patient societies in India and their limited awareness of HTA processes is also an impediment to increased representation of diverse stakeholders within topic selection and technical appraisal committees.

2. An incentive disbursement structure with an uneven focus on healthcare services

- Service-based incentives do not comprehensively capture or reward the key success factors that drive positive outcomes. High quality implantable medical technologies play an equally important part in improving health outcomes. It is thus essential to focus beyond the existing metrics and capture other relevant success factors contributing to quality healthcare (See Figure 4).

Figure 4

Value-based incentives for implantable devices aligns all stakeholders to drive positive patient outcomes



Source: L.E.K. research & analysis

3. Lack of defined measures to reward high quality implantable medical technology

- The current approach for ascertaining the eligibility of a device for inclusion is based on some minimum safety and efficacy data requirements (regulatory approvals). However, long term data to suggest a positive impact of these devices on quality of care or improvement of patient outcomes is largely missing. These devices have varied level of clinical evidence that are often not comparative in nature. Consequently, it is often difficult to ascertain whether these devices will have a comparable impact on long-term patient outcomes.

- The healthcare system currently has no mechanism to promote the use of high-quality medical devices by service providers. The lack of minimum standards and specifications for products and for manufacturers for reimbursement eligibility is a key challenge in this context. Additionally, the absence of real-world evidence to support claims of medical device manufacturers is a common challenge for both private and public payors. This highlights an opportunity for creation of well-defined, evidence-driven measures for rewarding high-quality implantable medical technology.

Proposed changes

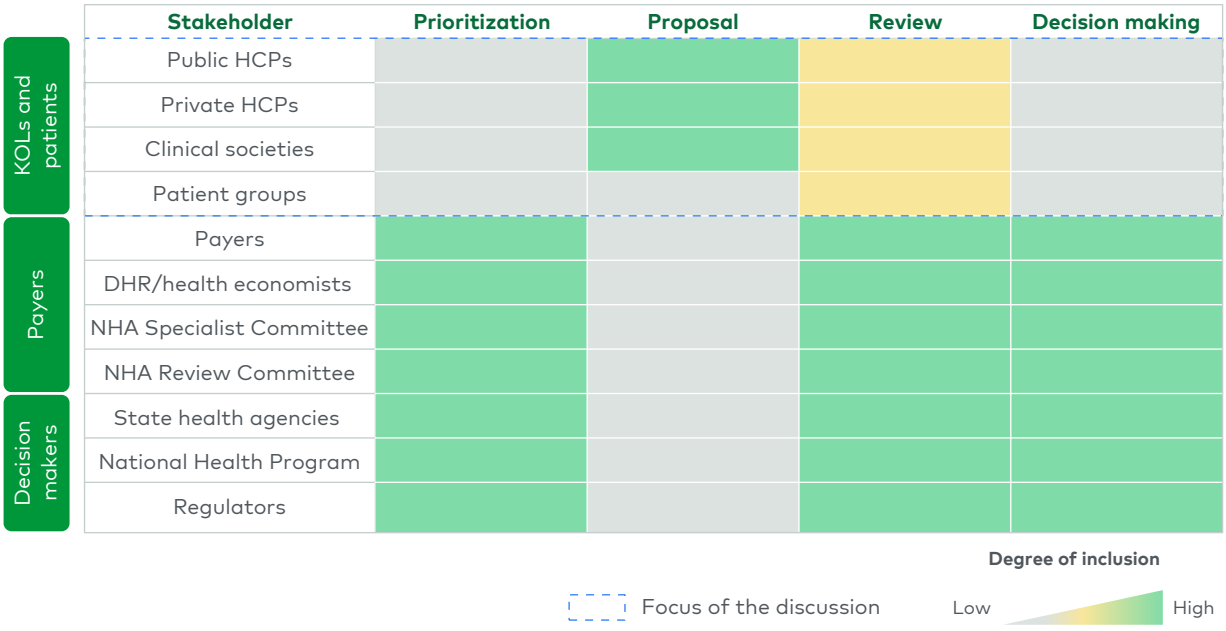
Proposed change 1: Bringing care providers and patients closer to the reimbursement process

- **Proposed change 1A: Deeper involvement of Key Opinion Leaders (KOLs) in topic prioritization**

  One proposed, elemental change is a concerted effort to involve KOLs including therapy users on a rotational basis through a structured nomination and selection process during topic prioritization at NHA level to drive greater focus on patient access in the local healthcare context. Key opinion leaders and patients can be involved in distinct parts of the process (See Figure 5). A study of global approaches on topic selection for health technology assessment (HTA) shows that numerous nations have endeavored to involve stakeholders such as health professional bodies and the general public in this process[1].

Figure 5

Key areas for involvement of key opinion leaders and patients in the reimbursement process



Note: KOL=key opinion leader; HCP= healthcare provider; DHR=Department of Health Research; NHA=National Health Authority
Source: L.E.K. research & analysis

- **Proposed change 1B: Wider representation of clinical experts within the Technical Appraisal Committee (TAC)**

  A second recommended change is to initiate topic specific representation within the TAC of the HTA body through formation of specialist sub-committees composed of public and private physicians as well as industry representatives. For instance, in Korea, the HTA committee comprises 20 permanent members with five additional subcommittees specific to specialties comprising a minimum of 30 members[2].

- **Proposed change 1C: Leveraging clinician and patient societies for generating awareness**

  We recommend driving campaigns through creation of a common platform for knowledge sharing of the latest technologies and HTA processes between the clinical experts and the evaluation body. The technical complexity of these topics merits a continuing dialogue with the public aimed at creating awareness and encouraging stronger involvement from diverse stakeholders.

- **Proposed change 1D: Creation of a mechanism for feedback collection and incorporation**

  We propose creation of a formal, streamlined process for wider feedback collection and dissemination and focused consultation with therapy users, patients, and professional societies on HTA proposals and outcome reports. Use of email campaigns, telephonic contact, and roundtable discussions to collect feedback on key issues is highly recommended.

  Another recommended change is the creation of a mechanism for reappeal, post publication of an HTA outcome report, with an appeal panel also composed of independent reviewers. This will allow diverse stakeholders, including patients, physicians and manufacturers, to have ongoing dialogue with the HTA body on individual decisions. For instance, The National Institute for Health and Care Excellence allows appeals to be lodged against the final draft guidance by any of the appraisal consultees within 15 days on specified grounds (e.g., unfair assessment, unverified recommendations, etc.). The five-member appeal panel also includes four independent reviewers, giving medical technologies a fair chance in patient care.

Proposed change 2: Introduction of a two-step pathway for provision of value-based incentives for implantable medical devices

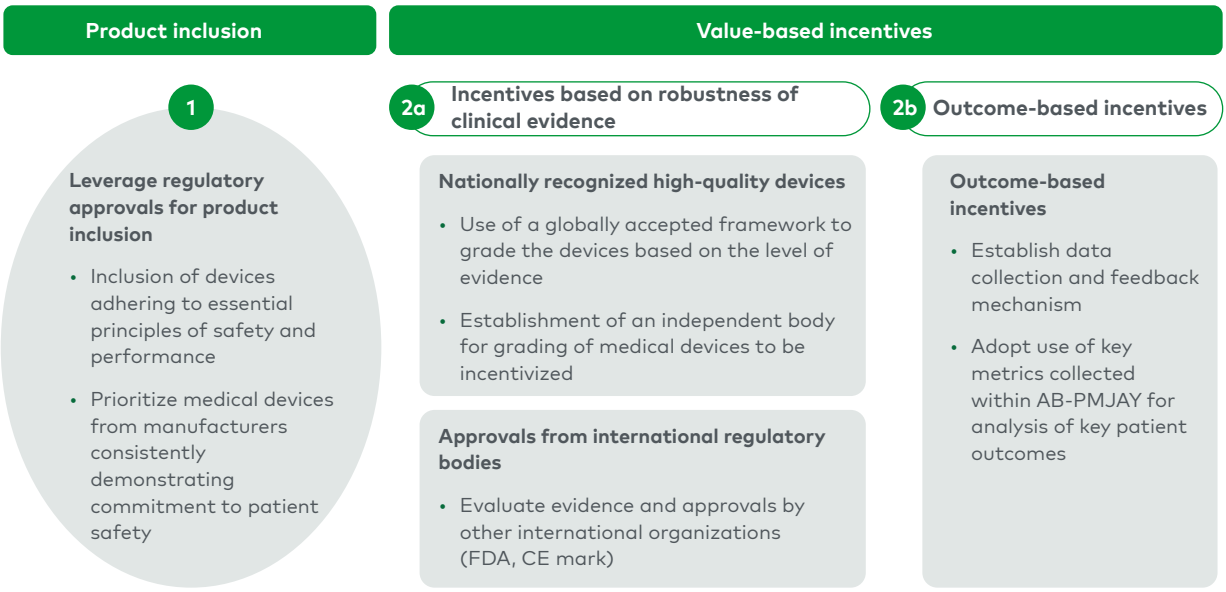
The use of high-quality, newer technologies contributes to reduced mortality, shortened recovery times and significant improvements to HRQoL among patients with life-threatening diseases (e.g., ischemic heart disease). Therefore, addition of value-based incentives for medical devices along with the existing service-based incentives in the current structure will encourage delivering high-quality healthcare and improve patient outcomes. We propose a two-step pathway for reimbursement aimed at provision of high-quality implantable medical devices in India.

All included products should adhere to essential principles of safety and performance for implantable devices established by the regulatory body. Manufacturers that demonstrate a commitment to patient safety (e.g., consistent product event report filing, clinical evidence, strong documentation) should be preferentially considered for reimbursement eligibility. This will further encourage manufacturers to strengthen their product quality processes and systems where lacking.

As a second step, manufacturers will be invited to submit additional information supporting their application for value-based incentives. Here, we recommend adopting the existing framework of value-based incentives ideated by AB-PMJAY for medical devices. We recommend providing incentives based on two key categories—incentives based on robustness of clinical evidence and outcome-based incentives—with equal weightage given to both criteria (See Figure 6).

Figure 6

Proposed pathway for value-based reimbursement of high-quality implantable medical devices in India



Note: FDA=U.S. Food and Drug Administration
Source: L.E.K. research & analysis

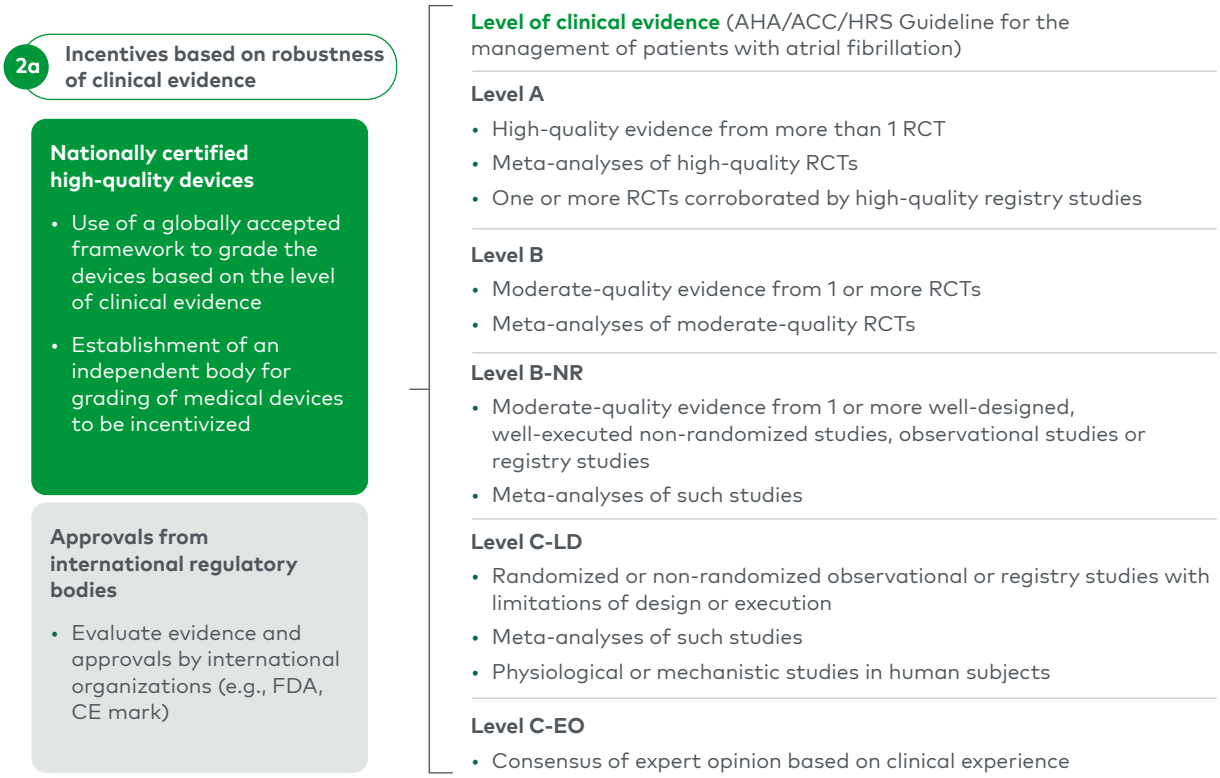
- **Incentives based on robustness of clinical evidence**

  Inferior medical devices often have insufficient high-quality clinical evidence establishing long term patient outcomes. We recommend the use of a globally accepted framework to grade and incentivize devices based on the quality of clinical evidence through establishment of an independent body (See Figure 7).

  Alternatively, the approvals by other stringent regulatory bodies (e.g., U.S. Food and Drug Administration, CE-mark) can act as a proxy for identifying and incentivizing high-quality medical devices.

Figure 7

Suggested clinical framework for grading of implantable medical devices



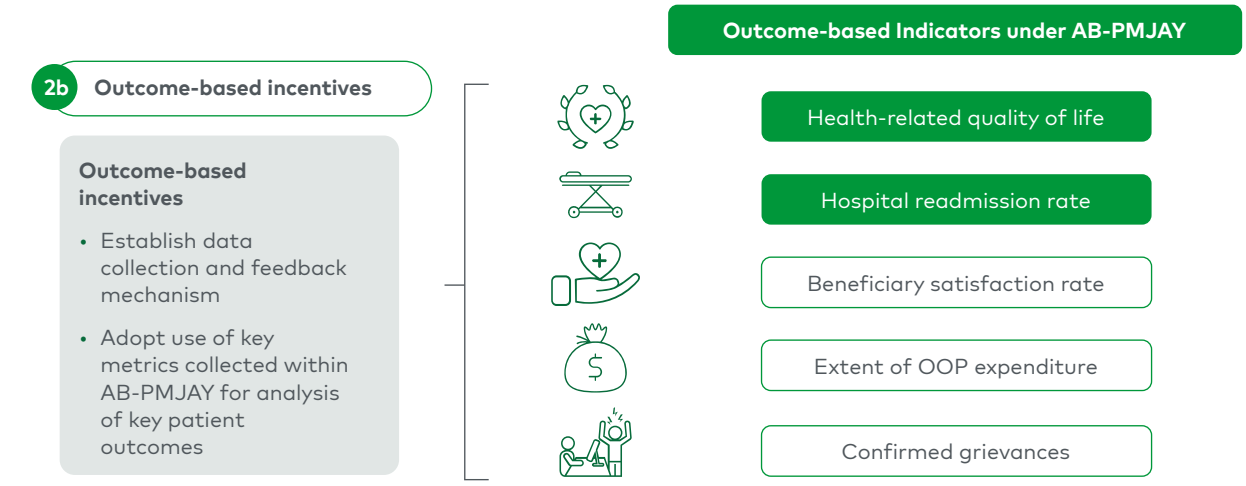
FDA=U.S. Food and Drug Administration; RCT=randomized controlled trial
Source: L.E.K. research & analysis

- **Outcome-based incentives**

  Out of the five existing outcome-based indicators being collected under the AB-PMJAY Transaction Management System (TMS), we suggest adoption of two key metrics for providing outcome-based incentives for medical devices: HRQoL and hospital readmission rate (See Figure 8).

Figure 8

Adapted framework for outcome-based incentives



Note: OOP=out-of-pocket
Source: L.E.K. research & analysis

As an initial step to implement this framework, we recommend collection and linking of minimum device identification data to the TMS to allow long-term monitoring of patient outcomes.

Conclusion

Over 25 key stakeholders (participating experts) across key opinion leaders, government authorities, private insurance experts, health policy experts and industry attended a roundtable meeting to discuss the proposed changes to enhance the medical device reimbursement process in India. This quorum is a key step toward a reimbursement process that facilitates patient-centric decision-making by creating processes for inclusion of diverse stakeholders. Overall, we hope that these key recommendations will enable access to high-quality healthcare through AB-PMJAY with the introduction of quality-based incentives.

Endnotes

[1] Qiu Y, Thokala P, Dixon S, Marchand R, Xiao Y. Topic selection process in health technology assessment agencies around the world: a systematic review. Int J Technol Assess Health Care. 2022 Feb 7;38(1):e19. doi: 10.1017/S0266462321001690. PMID: 35129112.t

[2] Kim, C. (2009). Health technology assessment in South Korea. International Journal of Technology Assessment in Health Care, 25(S1), 219-223. doi:10.1017/S0266462309090667

About the authors

Stephen Sunderland
PARTNER, SINGAPORE
Stephen is a Partner based in L.E.K.'s Singapore office. He has more than 20 years of experience spanning Asia and Europe working with multinational corporations, midsize companies, social enterprises and nonprofits, financial investors, and governments. He leads L.E.K.'s Healthcare and Life Science practice in South East Asia, L.E.K.'s Medtech practice in China and is the Executive Director of L.E.K.'s Asia-Pacific Life Sciences Centre of Excellence.

Ashwin Goel
PARTNER, INDIA
Ashwin Goel, based in the Mumbai office, is a Partner at L.E.K. Consulting. Ashwin co-leads the Healthcare and Life Sciences practice in India and is a member of the Global Education Practice. Within the healthcare sector, Ashwin advises biopharmaceutical and manufacturing services clients over a range of topics such as growth strategy, new market entry, international expansion and buy- and sell-side commercial due diligences.

Shruti Srinivasan
LIFE SCIENCES SPECIALIST, INDIA
Shruti Srinivasan is a Life Sciences Specialist at L.E.K. Consulting's Mumbai office and is a member of the Southeast Asia Healthcare and Life Sciences Practice. Shruti has worked with clients across diagnostics, Medtech, and digital health focused on regulatory and reimbursement pathways.

Participating experts

(In alphabetical order)

- Arif Fahim, Regional Director, Health Economics & Reimbursement, Asia Pacific, Abbott
- Dr. Abhijit K Chattoraj, Dean, Programme Chairperson, PGDM and Professor, Birla Institute of Management Technology
- Dr. Ajay Nair, CEO, Swasth Alliance
- Dr. Anil Saxena, Executive Director- Cardiac Pacing & Electrophysiology, Fortis Escorts Heart Institute
- Dr. Anita Saxena, Vice Chancellor, Pandit Bhagwat Dayal Sharma University of Health Sciences, Rohtak
- Dr. Bhabatosh Mishra, Director Underwriting, Products & Claims, Niva BUPA
- Dr. Deepika Singh Saraf, Member, National Health Research Policy Committee, Ministry of Health & Family Welfare, GoI, Former Deputy Director General, Indian Council of Medical Research, New Delhi
- Dr. K. Madan Gopal, Sr. Consultant (Health), NITI Aayog
- Dr. Kirti Kataria, Associate Manager, Health Economics and Reimbursement, Abbott
- Dr. Monika Pusha, Head, Market Access India & Subcontinent, Health Economics & Reimbursement, Abbott
- Dr. Neeraj Awasthy, Director, Paediatric Cardiology, Fortis Escorts Heart Institute
- Nikhil Apte, Chief Product Officer, Product Factory (Health Insurance), Royal Sundaram General Insurance Co. Limited
- Dr. Priyanka Bhadoria, Consultant, Health Policy and Quality Assurance, NHA
- Dr. Ratna Devi, CEO and Co-founder, Dakshayani and Amaravati Health and Education
- Dr. Sandeep Sharma, General Manager, H,S&E Medical, Indian Oil Corporation
- Dr. Sangeetha M R, Assistant Project Manager, Suvarna Arogya Suraksha Trust, Karnataka
- Dr. Shankar Prinja, Professor of Health Economics, Department of Community Medicine and School of Public Health, PGIMER, Chandigarh
- Dr. Shayhana Ganesh, Head of Health Risk Management, Aditya Birla Health Insurance
- Dr. Sitanshu Sekhar Kar, Professor and Head, Preventive and Social Medicine, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER)
- Dr. Sree Ganesh, Chief Medical Officer, Medi-Assist India
- Dr. Sudha Chandrashekar, Executive Director, Health Policy and Hospital Engagement, NHA
- Dr. Surendra Gulabchandra Jain, Assistant Director, PMJAY - Mukhyamantri Amrutum Yojana, Gujarat
- Dr. Vivek Chaturvedi, Professor & Head of Department, Department of Cardiology, Amrita Hospital, Faridabad
- Dr. Viveka Kumar, Principal Director & Chief of Cath Labs (Pan Max), Cardiac Sciences, Max Healthcare
- Jayakrishna Thadakamalla, Consultant, Health Economics and Reimbursement, Abbott
- Kumar Vikram Singh, Senior Vice President, HDFC ERGO General Insurance Co. Ltd.
- P Sashidharan Nair, Insurance Industry Expert
- Richa Debgupta, Chief of Strategy & Operations, Fortis Healthcare

Disclaimer

The scientific initiative has been made possible with the support of St. Jude Medical India Pvt Ltd. (now Abbott). The opinions expressed in this paper reflect the opinion of the group of participants at the annual healthcare payers' 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.

LEK™