IRDAI Master Circular on Health Insurance Business, 2024 – Summary of opportunities for medtech companies

Dr Leena Laloo, Principal & Sr. Healthcare Management Consultant

Milliman

India's health segment is witnessing rapid growth. Per the Insurance Regulatory and Development Authority of India (IRDAI) report from 2023–2024, among various segments under non-life insurance business, the health insurance business is the largest segment, with a contribution of 40.3% (increased from 38.0% in 2022–2023) of the total premium.[1] Health Insurance Segment reported growth of 19.5% (21.3% growth in 2022–2023).[1] India is currently ranked as the 10th largest insurance market in the world, with a premium volume of US$135 billion (with a 2.4% share in global insurance premiums).[1] This rapid growth in the health insurance market is driven by rising health awareness, increasing prevalence of lifestyle-related chronic diseases, and significant investments in medical infrastructure and digital health.[2] A pivotal force behind this momentum is the IRDAI's ambitious initiative, "Insurance for All" by 2047, which envisions universal health insurance coverage for every Indian.[3] This initiative aims to foster greater inclusion by encouraging the development of affordable, accessible, and customized health insurance products for diverse population segments. By promoting simplified products, digital enablement, and collaborations across stakeholders, including insurers, healthcare providers, and medtech companies, the initiative is laying the groundwork for a more resilient and inclusive healthcare system. As this ecosystem evolves, it presents tremendous opportunities for innovation and growth across the health and insurance sectors.

In this paper, we provide a summary of the implications of the IRDAI initiatives on medtech companies. Medtech companies are organizations that develop and manufacture products, services, or solutions used to diagnose, monitor, treat, or prevent diseases and medical conditions through technological innovation. Medtech companies and healthcare solution vendors are important players in the health insurance value chain. Their innovations not only improve patient care but also offer significant opportunities for cost savings, making them integral to the future of sustainable healthcare. However, to fully leverage these benefits, a structured collaboration among all stakeholders is necessary. This approach will ensure that patients have access to the latest medical advancements while maintaining the financial integrity of healthcare systems. Table 1 outlines key regulatory themes introduced by IRDAI and their implications for medtech companies.

Overview of the key regulatory themes & medtech opportunities

FIGURE 1: KEY IRDAI REGULATIONS & OPPORTUNITIES FOR MEDTECH COMPANIES

IRDAI REGULATION THEME	OPPORTUNITIES FOR MEDTECH COMPANIES
Coverage for all ages, diseases, systems, and care types	Entry into new markets (e.g., elderly care, AYUSH-compliant devices)
Health Plus Life Combi products	Partner with life insurers entering the health sector
Mandatory coverage of modern treatments	Push for payer engagement and evidence-based reimbursement discussions
Enhanced coverage of other advanced procedures	Targeted market access strategy for emerging technologies
Cashless claims & faster discharge authorizations	Collaborate to define criteria and billing for modern interventions
Customer Info Sheet (CIS)	Support insurers with coding guides, clinical summaries, etc.
Claims Review Committees (CRC)	Provide medical policy templates and claim adjudication guidelines

The recent master regulation issued by the IRDAI has significant implications for medtech companies. The IRDAI master circular[4] reaffirms the focus on improving accessibility, affordability, and efficiency in healthcare, creating new opportunities for medtech companies to incorporate into their market access strategy.

PRODUCT AVAILABILITY AND CUSTOMIZATION:

- Insurers are required to offer products/add-ons/riders catering to:
  - All ages.
  - All types of medical conditions, including pre-existing and chronic conditions.
  - All systems of medicine, including allopathy, AYUSH, and others.
  - All treatment situations, including domiciliary hospitalization, outpatient treatment (OPD), day care, and home care.
  - All regions, occupational categories, and for persons with disabilities.
  - All types of hospitals and healthcare providers to suit affordability of the policyholder/prospects. Policyholders shall not be denied coverage in case of emergency situations.
- Insurers should also allow customization of products to meet specific customer needs.
- The introduction of "Health plus Life Combi Products" allows life insurance companies to offer health insurance, bringing new players into the market.

Implications: The broad objective of ensuring insurance protection for all creates significant opportunities for medtech companies, particularly with the expansion of coverage to include elderly patients and those with specific diseases or complex chronic conditions. As insurers are now required to cover a wider range of conditions, there is an increased need for the inclusion of new treatments and technologies, especially for complex clinical situations.

Historically, many private and public sector insurers covered chronic conditions and cancers in their portfolios; however, entry age requirements, strict underwriting, and high premiums discouraged wider coverage of this segment in the retail segment. Current products and utilization management (UW) processes discourage older people/people with chronic conditions from getting insurance coverage, which leads to the exclusion of people from the portfolio and fewer claims for conditions that are more prevalent in those age groups, e.g., cancers and chronic conditions tend to be more prevalent in age 65 and over. However, this is set to change as insurers will now be required to offer a broader range of programs and remove age limits for new policies. This shift is likely to lead to the development of disease-specific insurance programs, with a particular focus on covering cancers. To develop these new products, insurers will need to gain a deeper understanding of emerging treatment approaches and formalize billing arrangements with healthcare providers.

COVERAGE OF TECHNOLOGICAL ADVANCEMENTS AND TREATMENTS:

- Insurers are encouraged to include coverage for advanced treatments and technologies, such as uterine artery embolization, high-intensity focused ultrasound (HIFU), deep brain stimulation, robotic surgeries, and more.[4]
- Subject to product design sub-limits may be imposed for any of the above treatments.[5]
- Insurers may endeavor to cover any other modern treatment methods.[5]

Implications: This regulatory update[4] mandated that 12 modern treatments (Table 2) previously excluded from coverage must be included in insurance plans when medically indicated.

FIGURE 2: MODERN TREATMENT METHODS AND ADVANCEMENTS IN TECHNOLOGIES

MODERN TREATMENT METHODS AND ADVANCEMENTS IN TECHNOLOGIES:	
A. Uterine artery embolization and HIFU	G. Robotic surgeries
B. Balloon sinuplasty	H. Stereotactic radio surgeries
C. Deep brain stimulation	I. Bronchical thermoplasty
D. Oral chemotherapy	J. Vaporisation of the prostate (green laser treatment or holmium laser treatment)
E. Immunotherapy – monoclonal antibody to be given as injection	K. Intra operative neuro monitoring (IONM)
F. Intra-vitreal injections	L. Stem cell therapy – hematopoietic stem cells for bone marrow transplant for haematological conditions to be covered

However, the extent of financial coverage for these treatments remains at the discretion of individual insurance companies. While some insurers provide detailed information about what is covered, many do not, leading to potential disputes and challenges during claims processing. As these advanced treatments become more widely adopted and accessible across regions, insurers will need to assess their potential demand, costs, and clinical benefits to determine how best to incorporate them into product coverage. This regulation reinforces the need for medtech companies to engage with payers actively, ensuring that modern treatments are recognized as clinically effective rather than being dismissed as experimental.

In India, limited disease registries, outcome-related research, and formal health technology assessment processes are further compounded by the limited local experience with new technologies, which only a few select centers often adopt. Payers, too, have limited capacity to conduct formal evaluations of these innovations. Health technology appraisal (HTA) is a body established in multiple countries that works with both the government/insurer and the medtech companies to study the benefit and the cost-effectiveness of new health technologies; some examples are listed in Table 3. Medtech companies can play a crucial role in bridging this gap by sharing insights and experiences from other markets, facilitating collaboration between payers and healthcare providers to build a robust local knowledge base.

TABLE 3: HEALTH TECHNOLOGY APPRAISAL (HTA)[6,7,8]

	USA	UK	INDIA
Agency	The Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Institute for Clinical and Economic Review (ICER)6	The National Institute for Health and Care Excellence (NICE)8 is the formal authority. Centre for Health Technology Evaluation oversees the process.	HTA In Department of Health Research, Ministry of Health and Family Welfare7
Focus	Medicare/ Medicaid programs Private health insurance	NHS in England and Wales	National Health Insurance program, PMJaAY essential benefit plan, and coverage
Process	Systematic evaluation of a technology's clinical effectiveness, cost-effectiveness, and other relevant factors to inform decisions about its use and coverage	NICE's Technology Appraisal Programme issues mandatory recommendations. Once NICE approves a treatment, the NHS is legally required to fund it.	Facilitates transparent and evidence-informed decision making in the field of health in India. Research and consensus. Driven approach in collaboration with academic institutions.
Setup	Set up in 1972	Set up in 1993	Set up in 2017

Many medtech companies operating in global markets offer information summaries for practitioners that include updated information about guidelines, billing, and coding rules for health insurance reimbursement.

A helpful reference is the collaborative work of the IRDAI Health Insurance Standardization Working Group,[5,9] which, through stakeholder consultations and market benchmarking, recommended coverage for the 12 modern treatments (Table 2). In the absence of formal HTA processes for private medical insurance priorities, insurers must regularly update and align their coverage policies as new treatments and technologies emerge.[5,9]

Moreover, medtech companies can proactively gather and share best practices from other markets, such as clinical practice guidelines, health outcomes data, cost-benefit analyses, and coverage determination policies and frameworks. This shared knowledge would facilitate a formal review process, enabling insurers to adapt and localize these practices effectively for the local context.

Leveraging their relationships with thought leaders and key figures in the healthcare provider community, medtech companies can also act as facilitators, bringing together health experts and insurers to collaborate. This collaboration can help insurers better understand clinical needs and develop consensus-driven policies that reflect the realities of modern treatment options.

Additionally, by comparing how different insurers handle coverage for modern treatments, medtech companies can help healthcare providers navigate these practices more effectively. This proactive approach not only promotes greater consistency in coverage but also ultimately benefits policyholders by ensuring fair and equitable access to innovative therapies.[10,11]

CUSTOMER INFORMATION SHEET (CIS):

- A CIS must be provided with every policy, detailing key features, exclusions, sub-limits, deductibles, waiting periods, and claims procedures.

Implications: The introduction of CIS, which mandates the inclusion of detailed coverage information, will require insurers to clearly declare their coverage for new technologies. This transparency will foster consistency and accountability across the market.

For medtech companies, this creates a significant opportunity to assist insurers in standardizing coverage statements for modern treatments, fostering a more consistent approach to handling insurance claims. Medtech firms can play a crucial role by helping insurers define clinical indications, set utilization guidelines, and establish cost reference benchmarks for new treatments.

APPROVAL FOR CASHLESS FACILITY:

- Insurers must aim for 100% cashless claim settlement and provide pre-authorization within one hour. Delays in final authorization for discharge from the hospital must not exceed three hours.

Implications: This regulation emphasizes the importance of clear agreements between payers and healthcare providers on the clinical needs and costs of services to ensure claims are processed within the required timelines.

Many smaller healthcare providers may lack the resources or expertise to develop detailed guidelines independently. Medtech companies can bridge this gap by facilitating discussions between payers and providers. They can help establish common criteria for what constitutes medical necessity, define the minimum infrastructure and experience required for providers to offer modern treatments, and set clear cost benchmarks and billing formats.[12]

Creating these standardized medical policies and coverage statements during the contracting phase can significantly reduce disputes and delays at the time of pre-authorization and claims processing. For example, if a small clinic wants to offer a new, advanced treatment, medtech companies can help ensure that both the clinic and the insurer agree up front on the billing format and clinical summary, necessary qualifications, and infrastructure, which would streamline the claims process later.

In the U.S. market, the Centers for Medicare and Medicaid Services (CMS) establishes detailed coverage criteria known as national coverage determinations (NCDs), which serve as a common reference for payer and provider reviews.[13] In addition, commercial evidence-based tools such as MCG Care Guidelines and InterQual Criteria are widely used to assess medical necessity and support claims adjudication.[14]

SETTLEMENT OF CLAIMS:

- No claim can be repudiated without approval from a Claims Review Committee (CRC). Insurers and third-party administrators (TPAs) must collect required documents directly from hospitals rather than from policyholders.

Implications: This reminder is designed to enhance compliance with existing regulations. Insurance companies will need to bolster their capabilities to effectively manage the eligibility and clinical- and cost-related challenges of claims. CRCs must develop internal policies, criteria, and references to support their decision-making processes. The Ministry of Health and Family Welfare, India (MOHFW) commissioned a task force on standard treatment guidelines to collate and review the existing standard treatment guidelines as well as identify the procedures/conditions where fresh development of standard treatment guidelines is required.[15]

This presents a valuable opportunity for medtech companies to assist insurers by providing clinical guidelines, coverage determination summaries, and medical policy templates that can guide CRC decisions. The medical policy should detail the clinical indications, billing protocols, and quality monitoring criteria, which can aid payers and providers in their contracting efforts.

To support insurers in this effort, medtech companies in India can provide valuable information on the clinical indications and outcomes of new technologies, helping insurers make informed decisions about product coverage[16,17]

Furthermore, this framework could be advocated to regulatory bodies. For reference, see the link[1] to a sample of a coverage determination policy utilized by Medicare in the U.S. Implementing such policies could also facilitate smoother negotiations between healthcare providers and payers.

CONCLUSION

New treatments and technology will continue to grow and become mainstream for healthcare, as they always have.[18] Some of these new treatments may be high-cost, which may challenge the available budgets or assumed costs of insurance. Regulatory agencies, government authorities, industry players, and health insurers must work together transparently to align on health priorities. This collaboration is crucial to balancing expenditure with savings, ensuring that the integration of innovative therapies does not disproportionately impact the financial stability of healthcare systems.

In mature markets, there is ongoing discussion and experimentation to strike a balance among access, affordability, and innovation. A range of policy reforms, procurement models, and innovative coverage arrangements are being tested to develop sustainable approaches, such as outcome-based contracts, volume-based agreements, indication-specific pricing, value-based pricing, carve-out programs within employer-sponsored plans, results-linked reimbursements, and reinsurance mechanisms. As active participants in these initiatives, medtech companies play a central role. Indian medtech firms can draw on these global experiences and explore how such models might be adapted or localized for the Indian market.[19]

By fostering a cooperative environment, stakeholders can jointly develop frameworks that prioritize patient access to the latest medical technologies while maintaining fiscal responsibility. Such frameworks would ensure that new treatments are evaluated not only for their clinical efficacy but also for their cost-effectiveness, thus aligning with broader health economic goals.

The IRDAI master circular[4] presents multiple opportunities for medtech companies to engage with insurers and support the implementation of these regulations, thereby enhancing market access strategies and contributing to a more inclusive and efficient healthcare system.

1. A local coverage determination for venous angioplasty utilized by the Centers for Medicare and Medicaid Services is available at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35028.

REFERENCES:

1. The full text of the IRDAI Annual Report 2023-24 is available at https://irdai.gov.in/document-detail?documentId=6436847.
2. Sarwal, R., Prasad, U., Madangopal, K., Kalal, S., Kaur, D., Kumar, A., Regy, P., et al. (2021). *Investment Opportunities in India's Healthcare Sector*. NITI Aayog. Retrieved August 14, 2025, from https://www.niti.gov.in/sites/default/files/2021-03/InvestmentOpportunities_HealthcareSector_0.pdf.
3. More information about the IRDAI's "Insurance for All" initiative is available at https://irdai.gov.in/web/guest/document-detail?documentId=1624671.
4. Insurance Regulatory and Development Authority of India. (2024). Master Circular on Health Insurance Business, Ref: IRDAI/HLT/CIR/PRO/84/5/. Retrieved August 14, 2025, from here.
5. Insurance Regulatory and Development Authority of India. (September 27, 2019). Guidelines on Standardization of Exclusions in Health Insurance Contracts. Retrieved August 14, 2025, from https://irdai.gov.in/hi/document-detail?documentId=392498#:~:text=2.,ensure%20uniformity%20across%20the%20industry.
6. Banta, D. (2003). The development of health technology assessment. *Health Policy*, *63*(2), 121-132. https://doi.org/10.1016/s0168-8510(02)00059-3
7. More information about the NIHR Health Technology Assessment program is available at https://www.ncbi.nlm.nih.gov/books/NBK97562/.
8. National Institute for Health and Care Excellence. (n.d.). About technology appraisal guidance. Retrieved August 14, 2025, from https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance.
9. Insurance Regulatory and Development Authority of India. (October 2018). Report of the Working Group for Standardization of Exclusions in Health Insurance Contracts, Chapter 5. Retrieved August 14, 2025, from https://irdai.gov.in/hi/document-detail?documentId=389872.
10. Pearson, C., Schapiro, L., and Pearson S. D. (2022). The next generation of rare disease drug policy: ensuring both innovation and affordability. *Journal of Comparative Effectiveness Research*, *11*(14). https://doi.org/10.2217/cer-2022-0120
11. Muscular Dystrophy Association. (n.d.). Navigating Insurance: Gene Therapy. Retrieved August 14, 2025, from https://www.mda.org/sites/default/files/2024/09/GTx-Navigating-Insurance-Process-2024.pdf.
12. Biogen. (n.d.). Resources for getting started on Spinraza. Retrieved August 14, 2025, from https://www.spinraza.com/en_us/home/taking-spinraza/getting-started.html.
13. CMS's National Coverage Determinations Manual is available at www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ncd103c1_part1.pdf.
14. More information about MCG Care Guidelines is available at https://www.mcg.com/care-guidelines/care-guidelines/.
15. The MOHFW's Standard Treatment Guidelines are available at https://clinicalestablishments.mohfw.gov.in/en/standard-treatment-guidelines.
16. Medtronic. (n.d.). Reimbursement resources. Retrieved August 14, 2025, from https://www.medtronic.com/en-us/healthcare-professionals/reimbursement.html.
17. MedicalExpo. (n.d.). All Abbott catalogs and technical brochures. Retrieved August 14, 2025, from https://pdf.medicalexpo.com/pdf/abbott-67555.html.
18. Gelijns A. C. (Ed.). (1990*). Modern Methods of Clinical Investigation: Medical Innovation at the Crossroads: Volume I*. National Academies Press. Retrieved August 14, 2025, from https://www.ncbi.nlm.nih.gov/books/NBK235486/.
19. Allen, J., Berry, D., Cook, F., Hume, A., Rouce, R., Srirangam, A., Wellman, J., et al. (2023). Medicaid coverage practices for approved gene and cell therapies: Existing barriers and proposed policy solutions. *Molecular Therapy Methods & Clinical Development*, *29*, 513-521. doi.org/10.1016/j.omtm.2023.05.015

Solutions for a world at risk™

Milliman leverages deep expertise, actuarial rigor, and advanced technology to develop solutions for a world at risk. We help clients in the public and private sectors navigate urgent, complex challenges—from extreme weather and market volatility to financial insecurity and rising health costs—so they can meet their business, financial, and social objectives. Our solutions encompass insurance, financial services, healthcare, life sciences, and employee benefits. Founded in 1947, Milliman is an independent firm with offices in major cities around the globe.

milliman.com

CONTACT

Leena Laloo
Leena.Laloo@milliman.com