ARPA-H
Investor
Catalyst Hub
PART OF THE ARPANET-H
HEALTH INNOVATION NETWORK

Medtech Reimbursement
Network Survey Brief

Authors: The Advanced Research Projects Agency for Health (ARPA-H) Investor Catalyst Hub aggregated and synthesized the results.

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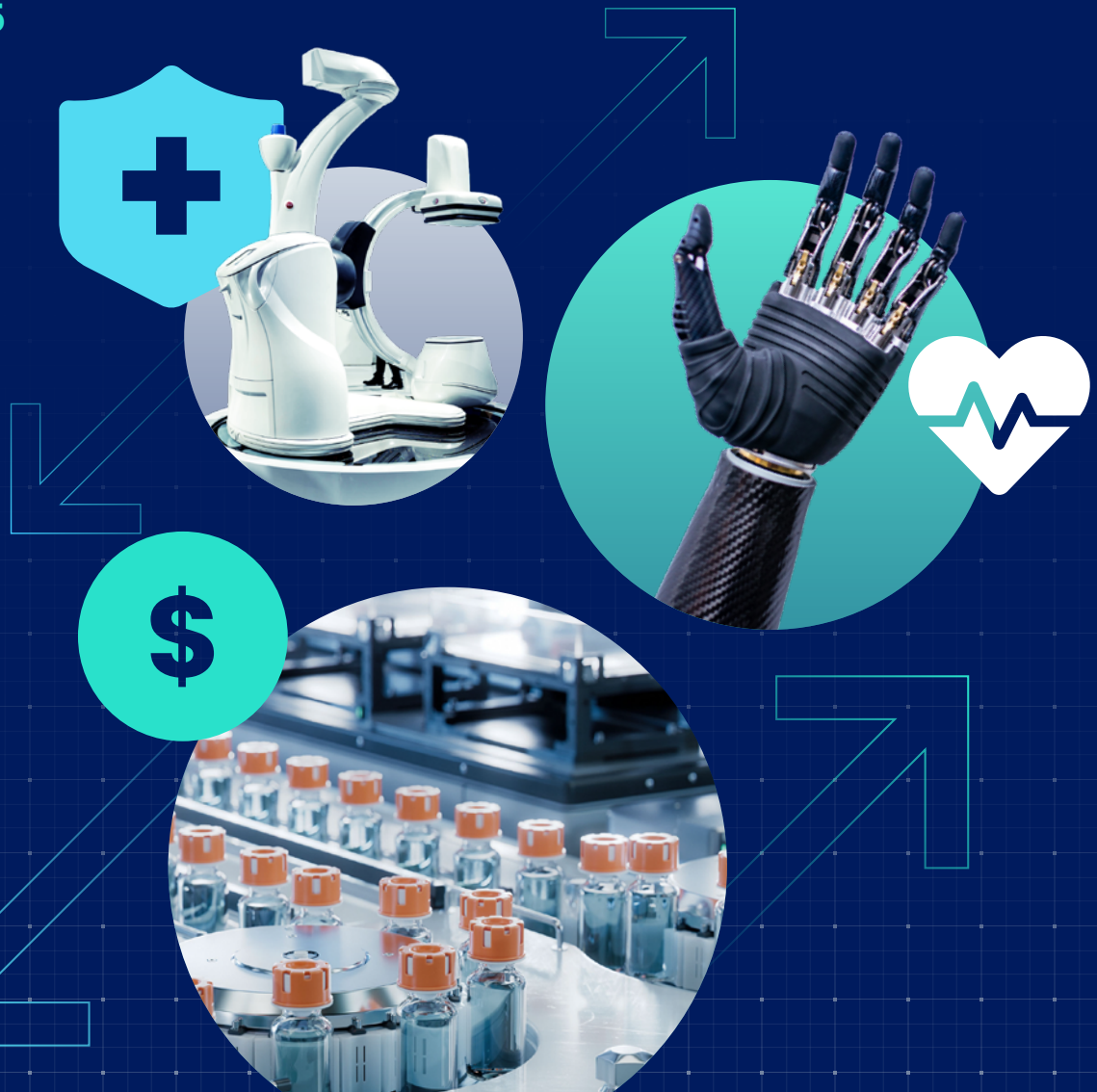


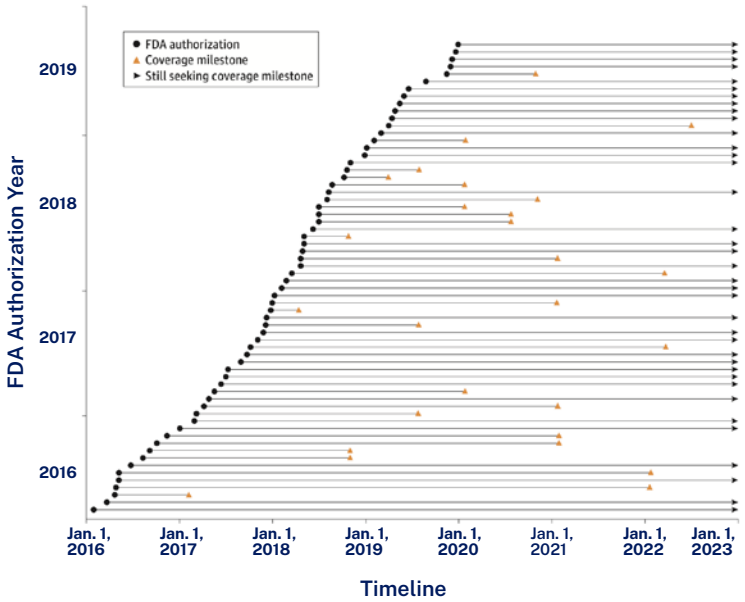
Introduction

Novel medical technologies like diagnostic devices, implants, assistive technologies, and surgical tools are likely to emerge from several of the Advanced Research Projects Agency for Health (ARPA-H)'s programs and small business awards. To transition to market, these technologies must first receive authorization from the United States Food and Drug Administration (FDA) and then navigate a complex journey to secure reimbursement — a process that often takes years. Medical devices approved by the FDA that are not already covered by payors take a median additional 5.7 years to reach a meaningful payment milestone, as highlighted in the figure to the right.

ARPA-H funds performers to support their development of groundbreaking solutions to address some of the most significant challenges in healthcare, achieve critical commercialization milestones, and fast-track those solutions to market. As a funder of technology innovation, ARPA-H aims to better understand the reasons for medtech reimbursement delays, the specific challenges facing novel medical devices and diagnostics, and how best to support performers navigating the reimbursement process.

To support this effort, the ARPA-H Investor Catalyst Hub conducted a network survey to solicit feedback from a diverse group of stakeholders to learn more about the factors that contribute to medtech reimbursement timelines.

Time Spent Seeking a Coverage Milestone



Source: Jama Health Forum, Time From Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies

Demographics & Methodology

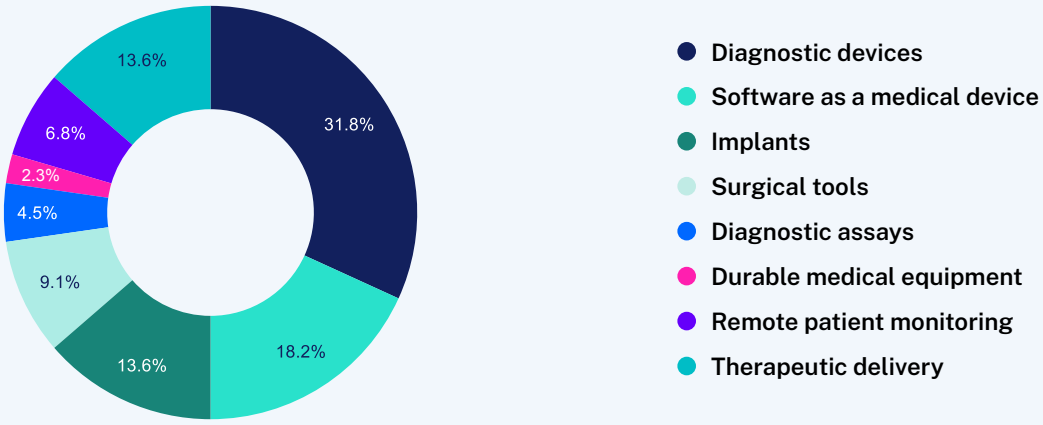
The Investor Catalyst Hub reached out to its network of more than 600 organizations to collect input from members uniquely positioned to provide valuable insight into the medtech reimbursement process, including medical technology developers and manufacturers, government and commercial payors and plan administrators, medical service providers, and associations and key stakeholder consultancies. Fifty-two people responded to the survey and roughly a dozen interviews were conducted. Survey respondents were asked to answer multiple-choice and open-ended questions to enable both quantitative and qualitative analysis. Their responses were corroborated through a series of one-on-one interviews with medical technology buyers; the collected feedback will help develop future ARPA-H services to support performers pursuing reimbursement for medical technologies.

Seventy percent of survey responses were from medical technology developers and manufacturers, and 30% were from reimbursement ecosystem partners (health system providers, insurance payors, and industry consultants and leaders). Of medical technology developer respondents, approximately 80% were from small organizations (<1,000 full-time employees (FTE)) and 20% were from large organizations (>1,000 FTE).

While payor and provider insights were represented in the survey, additional conversations with more of these groups could help provide a fuller picture of their important role in the medtech reimbursement ecosystem.

Survey respondents represented four countries. Of the respondents from the United States, 17 states were represented, with notable concentrations in innovation hubs such as Massachusetts (25% of respondents) and California (15%).

Technology Distribution Across Developer Respondents



Aligning Medtech Innovations with an Evolving Reimbursement Ecosystem

Navigating a Complex Landscape

The current medtech reimbursement landscape is experiencing structural and cultural shifts and it's important that medical technology developers stay abreast of changes that could impact their path to achieving coverage milestones. Industry partners are moving away from point solutions, instead looking to consolidate their technology partnerships for more unified platforms to better meet their population's needs.

While survey respondents indicated knowledge of regulatory approval processes, they still struggle to identify different pathways that may improve their chances of securing reimbursement more quickly. They are working to determine when during development they should have a defined reimbursement roadmap, what specific evidence must be generated to drive buyer adoption, and how to gain access to payors and providers to understand investment priorities.

Respondents shared insights based on their experiences developing, covering, or piloting new technologies that could better prepare them for pursuing reimbursement in the future. The most common learning was that "regulatory approval does not equate to reimbursement."

To ensure accurate billing, tracking, and regulatory reporting, all medical technology must be assigned a code that appropriately classifies devices based on similarities to existing technologies and services. However, confusion across a fragmented ecosystem is limiting innovations, pushing developers to focus on existing coding structures that may not be fully representative of their technology's maximum potential and discouraging the creation of novel devices that can't be classified with current codes.

As one industry expert noted, "It is important to start with a reimbursement evaluation and strategy development earlier in the development process. Companies get too far down the pathway and spend too much development money before knowing the reimbursement options."

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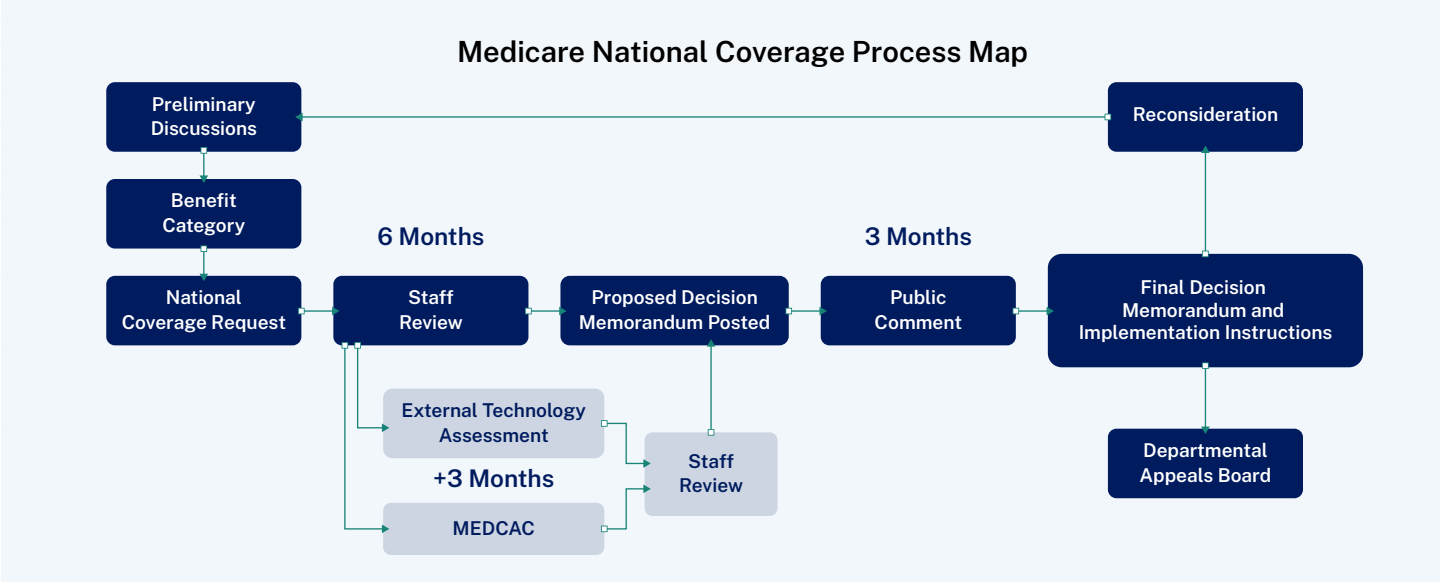


This process map illustrates one possible route toward reimbursement for medical technology developers seeking coverage for a Medicare National Coverage Determination, as **outlined by the Centers for Medicare & Medicaid Services (CMS).** Following thorough review and evaluation, the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) makes evidence-based recommendations to CMS on whether medical devices may be eligible for coverage under Medicare. The process for seeking coverage will look different for companies pursuing other reimbursement pathways, and coverage choices will vary by technology. Additionally, innovators must be aware of unique state requirements that may impact their strategy development.

Respondents represented a range of medical technologies which require different strategies for pursuing coverage and often encounter varied timelines. Survey data demonstrates that in recent years, diagnostics developers have achieved coverage within one to three years while other parts of the sector, like implant developers, average coverage within four to six years.

Larger companies pursuing reimbursement for surgical tools took between one and three years while smaller companies seeking reimbursement for surgical tools waited between four and six years.

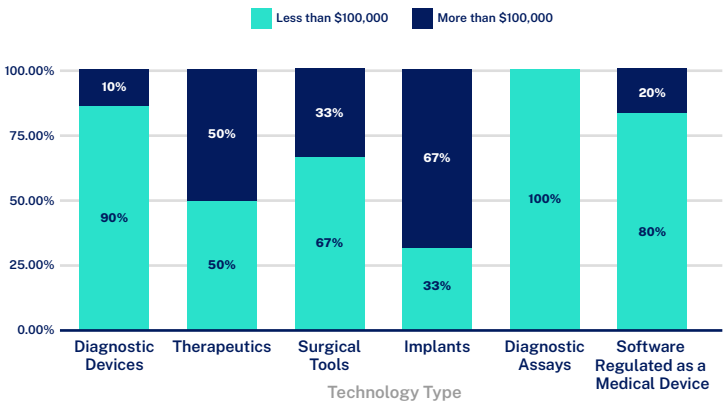
Performance support and market transition are key components of ARPA-H's program journey model. Many ARPA-H performers developing novel medical devices and diagnostics could benefit from tailored support identifying the most appropriate pathways to improve their chances of securing reimbursement more quickly, as well as specific guidance for technologies that do not fit within existing coding structures.

Investing Early in Strategy Development

National reimbursement outcomes for novel medical technology show that success is hardest for the smallest companies, with **less than 20% of small device developers securing reimbursement within five years.** This includes devices that undergo either FDA's premarket approval applications (PMAs), premarket notification [510(k)], or De Novo requests for Breakthrough Device designation. Responses

indicated that small companies (<1,000 FTE) are less able to invest in reimbursement strategy and execution early in the development process compared to larger companies (>1,000 FTE), delaying progress toward market adoption.

If you paid for external expertise to develop or execute on your reimbursement strategy, roughly how much did you spend?



Survey trends showed diagnostic device and assay developers currently spend less than $100,000 on average on their reimbursement strategy whereas developers of other technology types are spending more, particularly implants and therapeutics developers.

The lack of available capital and competition with larger companies that have existing relationships with hospital buyers and reimbursement partners exacerbates a growing divide. Providers are moving away from establishing partnerships with smaller companies in favor of contracting with partners at incumbent — and often larger — institutions, making it harder for new technologies and companies to break through and secure reimbursement.

Survey data revealed a delay in strategy development, with companies often waiting to initiate critical reimbursement discussions until after their technology had been cleared by the FDA. Though, as many respondents noted, successfully gaining approvals and coding does not equate to future coverage. As one respondent shared, “Unless there is already an existing code with acceptable payment structure, it can take five years before anyone will pay for your product. Planning for the clinical and economic studies before any clinical work begins can shorten that timeframe by two years. Plan to raise enough money to get through that gap before FDA authorization and you are a company valued on revenues.”

Only 17% of respondents pursued reimbursement for novel technologies that lacked established coding or coverage pathways. Many respondents cited that such reimbursement is not pursued because investors tend to focus on products that fit into existing codes. Across all medical technology

100%

of **larger medical technology developers** spent money on external expertise to validate their reimbursement strategies, averaging about **$125,000 on outside expertise**.

63%

of **small medical technology developers** spent less than **$25,000 on outside expertise**.

developer companies — though more acutely noted by smaller developer companies — there is a strong desire for the development of specific reimbursement guidelines to help lower the barrier to entry and support developers in driving buyer adoption beyond available codes.

Soliciting Feedback Earlier to Improve Outcomes

Building outside current coding structures requires more capital to cover longer evidence generation cycles and gain payor buy-in. To improve timelines to coverage and decrease overall spend, developers are actively seeking clinical champions to help articulate the demand for their technologies, offer early feedback, and gain access to clinical trial partners to prove value in improving patient outcomes and optimizing healthcare costs. Survey data suggests that early engagement with professional societies provides an equitable, structured pathway for navigating the complex medtech reimbursement landscape. In particular, small developer companies view this as the critical first step to validate the potential adoption and coverage of their technologies.

73%

of respondents said professional societies are serving as their initial entry point for reimbursement strategy development.

Despite the access offered by professional societies, the hurdle to success most frequently named by developers was a lack of feedback from payors and clinical partners. To address this gap, developers are seeking early access to technology review committees to help inform their decision-making and build partnerships in real-world evidence generation to drive the best outcomes for patients and hospitals.

When asked which entities companies have engaged in the creation of their reimbursement strategy, 83% of large developer companies leveraged providers and payors to help generate evidence compared to only 30% of small developer companies, underscoring how company size and capital availability can inform an institution's ability to access early feedback from stakeholders to align on outcomes — delaying timelines and increasing

the overall budget. As one respondent noted, “Understanding payor and provider requirements for clinical and economic evidence early can prevent costly delays later. Aim to focus trial designs on outcomes that are most likely to drive reimbursement decisions.”

Conclusion

Survey results emphasize the complexity of the reimbursement ecosystem for all medical technologies and how significantly an institution’s resource constraints drive end-user adoption. Support solutions must aim to connect the fragmented pieces of the medtech reimbursement landscape to improve timelines and successfully integrate novel health solutions into the healthcare system to improve patient outcomes.

As ARPA-H works to accelerate the transition of breakthrough technologies to market, opportunities to support innovators in securing reimbursement will remain a priority. The findings of this survey could inform future development of ARPA-H novel services and partnerships to maximize the potential of agency-funded efforts in achieving reimbursement and improving health outcomes.

To learn more about how you can engage with ARPA-H and Investor Catalyst Hub opportunities in the future, please sign up to receive our newsletter or apply to become part of our network today.