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

Network Survey for Accelerating Medical Device and Diagnostic Reimbursement

Questions for Developers

1. Has your organization pursued reimbursement for one or more novel technologies that did not have existing coding, coverage, or adequate payment?
    a. Yes – one or more solutions that obtained a Breakthrough Designation
    b. Yes – only for solutions that did NOT obtain Breakthrough Designation
    c. No – all solutions had existing coding, coverage, and adequate payment or did not require them [jump to question 14]
    d. Other
        i. [If other, please specify]
2. Broadly, what type of medical technology is your entity developing? (check all that apply)
    a. Surgical tools
    b. Implants
    c. Diagnostic devices
    d. Diagnostic assays
    e. Software regulated as a Medical Device
    f. Other
        i. Please describe
3. What value does your medical technology bring to which user and/or disease areas, and what technologies are you competing with or attempting to displace? (e.g., accurate diagnosis of disease X for patients for the first time at home, competing with laboratory-based diagnostic assays at a hospital) (*free response*)
4. Has your company engaged with any of the following entities as part of your reimbursement strategy (*select all that apply*)?
    a. N/A
    b. The Food and Drug Administration
    c. The Centers for Medicare and Medicaid Services (CMS)
    d. A medical or health care professional society that might be users of your technology
    e. A patient advocacy organization in your disease area
    f. Payor/provider system that may help generate evidence or pay for your medical technology
5. From which types of payors are you seeking coverage for your technology? (Choose all that apply)
    a. Medicare national coverage (via Coverage with Evidence Development or National Coverage Determination)
    b. Medicare local coverage (via Local Coverage Determination)
    c. Veterans Affairs and/or Department of Defense coverage
    d. State Medicaid Payors
    e. Commercial Insurance Plans
    f. Employer-sponsored Health Plans
    g. State Workers' Compensation Plans
    h. Business-to-business (B2B)
    i. Direct-to-consumer sales

   j. Not applicable / have not pursued payor coverage for technology
   k. Other
      i. [If other, please specify]

Branch 1: Medical Technology Developers

6. What steps did you take to establish coding, coverage, and payment for your technology (select all that were done):
   a. Conducted a review of existing coverage policy and codes used by payors with internal staff
   b. Pursued FDA Breakthrough Device Designation
   c. Participated in the FDA early payor access program or other structured way to get feedback from payors
   d. Hired a Certified Coder or other external expert to review existing codes for alignment with your technology
   e. Hired a firm or consultant to develop and/or implement a reimbursement strategy
   f. Used data scientists, actuaries, or other experts to model potential financial and health impact to make a business case for use
   g. Conducted studies within or alongside a provider system to show benefit to the plan members
   h. Other.
      i. Please specify other key steps in your journey
7. If you paid for external expertise to **develop or execute on your reimbursement strategy,** including steps in the prior question, roughly how much did you spend?
   a. N/A - none
   b. <$5,000
   c. $5,000-24,999
   d. $25,000-99,999
   e. $100,000-200,000
   f. >$200,000
8. What types of reimbursement have you pursued for your offerings (select all that are applicable)?
   a. Procedure-based reimbursement
   b. Device-specific / Durable Medical Equipment reimbursement
   c. Fee-for-service arrangements
   d. New Technology Add-on Payment (NTAP)
   e. Transitional Pass-Through Payments: Device
   f. Value-based-care arrangements (capitated payments, bundled services, etc.)
   g. N/A
   h. Other
      i. [If other, please specify]
9. What experience do you have at your **current or past organizations** with taking technology from FDA market authorization to initial reimbursement (coverage, coding with non-temporary codes, and adequate payment):
   a. I have not taken a technology from FDA market authorization through initial reimbursement
   b. I have successfully transitioned one device or diagnostic from FDA market authorization to reimbursement
   c. I have successfully transitioned two or more devices or diagnostics from FDA market authorization to reimbursement

10. On average across your successes, how long did it take from FDA authorization until nominal coverage (defined as national coverage determination by CMS, local coverage determination by a Medicare Administrative Contractor, or implicit coverage aligned to a new billing code)?
    a. 1-11 months
    b. 1-3 years
    c. 4-6 years
    d. 7-9 years
    e. 10 or more years
    f. Other
        i. [If other, please specify]
11. What were the critical factors in your approach that you believe enabled your success? (free response)
12. Has your organization advocated in any way for changes to decisions made about coding, coverage, or payment amount for its technology?
    a. Yes
    b. No
    c. Other
        i. [If other, please specify]
13. [If yes] Briefly describe what actions you took and the outcome [*free response*]
14. Have you abandoned a new project because there was no clear path to reimbursement?
    a. Yes
    b. No
    c. Other
        i. [If other, please specify]
15. Have you abandoned a new device development project because the expected payment was insufficient to cover the cost of the technology?
    a. Yes
    b. No
    c. Other
        i. [If other, please specify]
16. ARPA-H funds innovators through milestone-based contracts. The agency believes that additional support for innovators, which it would source from the private sector, would increase the odds that its R&D investments will impact health outcomes. On a scale of one to five, rate which elements should be included in support resources to prepare medical technology developers to seek reimbursement: (1-5, 1 = low value; 5 = essential)

    a. How-to guides for companies on securing reimbursement for their technologies across multiple buyers/payors, technology types, and provider types
    b. Online interactive tools to determine areas for further reimbursement work by the company such as relevant party identification, value proposition development, provider strategy, advocate engagement, etc.
    c. A database of high-quality reimbursement consultants and experts by stage of development and technology type
    d. Purchasing mechanisms designed to provide modest discounts for reimbursement consulting services
    e. A forum to convene and leverage multiple payors and provider systems to define key questions, run and analyze studies, or aggregate data that cover multiple populations

   f. A boot camp to gain knowledge needed to develop and implement a successful reimbursement strategy.

17. If ARPA-H is successful, it will help meaningfully reduce the time between authorization and nominal coverage, which will help improve health outcomes faster. From your perspective, what specific steps are most ripe for acceleration by ARPA-H and what non-policy actions should the agency take to improve them? Nominal coverage is defined as national coverage determination by CMS, local coverage determination by a Medicare Administrative Contractor, or implicit coverage aligned to a new billing code. [*free response*]
18. How much time could these changes ultimately decrease the current median gap of 5.7 years from FDA market authorization to reimbursement? [*Drop-down in number of months from 0-60*]
19. The agency seeks additional meaningful metrics and milestones to understand if its efforts are successful or not. The agency is particularly interested in more immediate measures, in addition to reducing the gap. Examples may include time to develop a reimbursement strategy, spend on external consulting and support, and likelihood of raising financial capital to go to market. What other metrics should the agency share to demonstrate progress? [*free response*]
20. Based on your successes and failures, what have you learned (e.g., insights, evidence requirements, exceptional partners, misunderstandings) that you wish you would have known at the start of your technology development path? [*free response*]
21. What resources and stakeholders were difficult to access or unavailable, beyond those covered elsewhere in this survey, that you believe would be helpful to medical diagnostic and device developers? [*free response*]
22. May we contact you to set up a 30-minute follow-up call?

Branch 2: Medical Technology Developers

23. Has your organization developed evidence for the following dimensions of your technology's economic value (select all that apply)?
    a. Financial value to society and/or patients (e.g., less expensive interventions, productivity)
    b. Revenue to any stakeholders involved in utilizing your technology (physicians, allied health care professionals, hospital or facility, etc.)
    c. The financial opportunity cost to any stakeholder who adopt your technology relative to the revenue they would get from the standard of care
    d. The changes to direct costs for a hospital or facility
    e. The changes to costs that are downstream of successful implementation of your technology (e.g., shorter length of stay, avoided costs, reduced risk factors, reduced readmissions)
    f. Changes to quality-related payments and Star ratings.
    g. Other key types of economic evidence you have developed:
        i. Please Specify
24. If you paid for external expertise to **develop evidence on your technology's economic value**, roughly how much did you spend?
    a. N/A - none
    b. <$5,000
    c. $5,000-24,999
    d. $25,000-99,999
    e. $100,000-200,000
    f. >$200,000

25. ARPA-H funds innovators through milestone-based contracts. The agency believes that additional support for innovators, sourced from leaders in the private sector, increases the odds that its R&D investments will impact health outcomes. On a scale of one to five, rate which elements should be included in support resources to prepare medical technology developers to seek reimbursement: (1-5, 1 = low value; 5 = essential)

    a. How-to guides for companies on securing reimbursement for their technologies across multiple buyers/payors, technology types, and provider types
    b. Online interactive tools to determine areas for further reimbursement work by the company such as relevant party identification, value proposition development, provider strategy, advocate engagement, etc.
    c. A map of high-quality reimbursement consultants and experts by stage of development and technology type
    d. Purchasing mechanisms designed to provide modest discounts for reimbursement consulting services
    e. A forum to convene and leverage multiple payors and provider systems to define key questions, run and analyze studies, or aggregate data that cover multiple populations
    f. A boot camp to gain knowledge needed to develop and implement a successful reimbursement strategy.
26. If ARPA-H is successful, it will help meaningfully reduce the time between authorization and nominal coverage, which will help improve health outcomes faster. From your perspective, what specific steps are most ripe for acceleration by ARPA-H and what non-policy actions should the agency take to improve them for its performers? Nominal coverage is defined as national coverage determination by CMS, local coverage determination by a Medicare Administrative Contractor, or implicit coverage aligned to a new billing code. [*free response*]
27. How much time would these changes ultimately save from the current median of 5.7 years from FDA market authorization to reimbursement? [*Drop-down in number of months from 0-60*]
28. The agency seeks additional meaningful metrics and milestones to understand if its efforts are successful or not. The agency is particularly interested in more immediate measures, in addition to reducing the gap. Examples may include time to develop a reimbursement strategy, spend on external consulting and support, and likelihood of raising financial capital to go to market. What other metrics should the agency share to demonstrate progress? [*free response*]
29. Based on your successes and failures, what have you learned (insights, exceptional partners, misunderstandings) that you wish you would have known at the start of your technology development path? [*free response*]
30. What resources and stakeholders were difficult to access or unavailable, beyond those covered elsewhere in this survey, that you believe would be helpful to medical diagnostic and device developers? [*free response*]

31. May we contact you to set up a 30-minute follow-up call?

Thank you for taking the time to complete this Survey!

1. I agree to receiving communication about reimbursement
    a. [checkbox] Yes, I would like to receive communications about Accelerating Medical Technology Reimbursement