Background
CDRH established the Payor Communication Task Force to facilitate communication between device manufacturers and payors to potentially shorten the time between FDA approval or clearance and coverage decisions. By communicating earlier, manufacturers may design their clinical trials to produce the data required for regulatory approval or clearance and for positive coverage determinations, which may expedite patient access.
Payors include public payors such as Centers for Medicare & Medicaid Services (CMS), private health plans, health technology assessment groups, and others who provide input into coverage, procurement, and reimbursement decisions.

FDA's Center for Devices & Radiological Health (CDRH) evaluates the safety and effectiveness of medical devices for use in the U.S. Usually after FDA approval or clearance, other organizations—for example, public and private organizations that pay for health care (payors) and the professionals who provide health care (providers)—decide whether to cover, pay for, or use a device. Often, the data submitted by medical device manufacturers to demonstrate safety and effectiveness to the FDA may not include data needed by payors to make coverage determinations. As a result, after FDA approval or clearance, there may be a delay in coverage, payment and use decisions that may ultimately delay patient access to medical devices.
For questions, additional information, or to request our presence at an event, please email us at CDRHPayorCommunications@fda.hhs.gov.

Opportunities to Obtain Payor Input
Early Payor Feedback Program – All Payors
CDRH has a voluntary opportunity for medical device sponsors to obtain payor input on clinical trial design or other plans for gathering clinical evidence needed to support positive coverage decisions. All regulatory discussions will continue to follow the processes established within the CDRH Q-Submission Program. Organizations willing to join CDRH meetings are listed below. CDRH has an open request for additional coverage organizations that evaluate clinical evidence and make coverage recommendations or decisions for payors and health plans to join this opportunity.

NOTE: This is a **voluntary opportunity for both the medical device sponsors and coverage organizations.** The decision of a medical device sponsor to participate or not to participate in this Early Payor Feedback opportunity will not alter the regulatory and evidentiary standards FDA uses for decision making. Inclusion on this list does not imply or constitute any endorsement or relationship between these organizations and the FDA. The FDA has not independently verified that these organizations evaluate clinical evidence used to support payor coverage decisions for medical devices or make coverage recommendations to or decisions for payors and health plans regarding medical devices.

List of Current Payor Participants:

Company Name	Company Mailing Address
Aetna, a CVS Health Company	151 Farmington Avenue Hartford, CT 06156
BlueCross Blue Shield Association	225 North Michigan Avenue Chicago, IL 60601
CareFirst BlueCross BlueShield (HealthWorx)	1501 S. Clinton Street, 17th Floor Baltimore, MD 21224
Center for Medicare & Medicaid Services (CMS)	7500 Security Boulevard, Baltimore, MD 21244
Cigna	900 Cottage Grove Road Bloomfield, CT 06002
Clover Health	30 Montgomery Street 15th Floor Jersey City, NJ 07302
Duke Evidence Synthesis Group, Duke Clinical Research Institute, Duke University	2400 Pratt Street Duke Clinical Research Institute Durham, NC 27705
ECRI Institute Headquarters	5200 Butler Pike Plymouth Meeting, PA 19462-1298
Humana	500 West Main Street Louisville, KY 40202
Kaiser Permanente	393 East Walnut Street Pasadena, CA 91188
National Institute for Health and Care Excellence (NICE)	Level 1A City Tower, Piccadilly Plaza, Manchester, M1 4BT, United Kingdom
Premier Inc.	13034 Ballantyne Corporate Pl. Charlotte, NC 28277
United Health Group	9900 Bren Road East Minnetonka, MN 55343

Medicare Coverage For New Technology

Proposal's comments closed on Nov 2, 2020

Medicare pays for or "covers" broad categories of health services (such as hospital and physician services), but the program is prohibited from paying for expenses incurred for "items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Most coverage decisions are issued by Medicare's local contractors, though CMS occasionally issues binding national coverage determinations (NCDs) for certain technologies (primarily devices and diagnostics) deemed controversial or expected to have large budgetary impacts.

The Proposed MCIT Pathway
The proposed rule would create a new pathway, "Medicare Coverage of Innovative Technology (MCIT)" for medical devices designated by FDA as breakthroughs, allowing national coverage for on-label uses of devices for four years, after which CMS would determine further coverage status. The FDA designates devices as **"breakthrough" products if they meet certain criteria (e.g., providing an important medical advance or having no approved or cleared alternative).** Medicare officials have emphasized that the MCIT pathway, which device manufacturers could pursue on a voluntary basis, would provide Medicare national coverage on the same day as FDA market authorization for breakthrough devices (italics are CMS's). Upon sunset of MCIT coverage, product manufacturers "would have all the current Medicare coverage options available" (e.g., national or local coverage).

This proposed rule would establish a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). **After the final rule is effective, the Medicare Coverage of Innovative Technology (MCIT) pathway would begin national Medicare coverage on the date of FDA market authorization and would continue for 4 years**. We are also proposing regulatory standards to be used in making reasonable and necessary determinations under section Start Printed Page 543281862(a)(1)(A) of the Social Security Act (the Act) for items and services that are furnished under Part A and Part B.

We propose this MCIT pathway because the prescribed statutory timeframes for the National Coverage Determination (NCD) process limit CMS' ability to institute immediate national coverage policies for new, innovative medical devices. NCDs and Local Coverage Determinations (LCD) take, on average, 9 to 12 months to finalize. Because of this length of time, there may be coverage uncertainty between the period of FDA market authorization and CMS finalization of an NCD or a Medicare Administrative Contractor's (MACs) finalization of an LCD. During this time period shortly after market authorization, MACs make coverage determinations on a case-by-case (individual beneficiary) basis, but those decisions do not usually establish agency policies for future claims because a case-by-case decision is for a particular beneficiary and their health circumstances.

Value-based purpose **means:**

(1) Coordinating and managing the care of a target patient population;
(2) Improving the quality of care for a target patient population;
(3) Appropriately reducing the costs to, or growth in expenditures of, payers without reducing the quality of care for a target patient population; or
(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Examples of payment models in medtech[10]

Innovative contracting models *with* risk sharing
Outcome guarantee model Manufacturers give providers large discounts or rebates if certain clinical/economic outcomes are not met
Medtronic-Tyrx antibacterial sleeve Medtronic has 1,000 contracts requiring the company to reimburse hospitals for select costs if its Tyrx antibacterial sleeve fails to prevent infection in patients who receive cardiac implants.
St. Jude Medical (acquired by Abbott)–Quadra heart rhythm device The agreement is with HealthTrust (GPO), wherein St. Jude promises to pay hospitals a 45 percent rebate on the net price for cardiac resynchronization therapies if a lead revision is needed within the first year of implantation as a result of specific factors.
J&J–Thermocool catheter ablation procedure If the provider needs to repeat the same procedure within a year of treatment using J&J's procedure, the company guarantees a discount on the cost of the device during the second procedure.
Gain sharing model Manufacturers provide products at a low price, but providers/payers agree to share with manufacturers a portion of the cost savings/revenue gains from the use of the products
Medtronic-Aetna partnership The arrangement is for people living with Type 1 and Type 2 diabetes who use multiple daily insulin injections. Part of Medtronic's payment is based on improving clinical outcomes for Aetna members who transition from multiple daily injections to a Medtronic insulin pump. The agreement will look at improvement of the patient experience and clinical outcomes and the total cost of care.
Bard Medical (subsidiary of Becton Dickinson) antimicrobial catheter Bard Medical offers to sell the antimicrobial catheter at a lower price than a normal catheter (US$5.85), as long as the hospital will split any savings from the prevention of UTIs with Bard Medical as a result of using its antimicrobial catheter.