

CURES 2.0 ISSUE BRIEF

**Modernizing Access for Breakthrough Devices:
Cures 2.0 Act Provisions on Medicare Coverage**

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Background

The 21st Century Cures Act (“Cures 2.0 Act”) draft, released June 22, 2021, strives to modernize the Centers for Medicare and Medicaid Services’ (CMS) coverage processes to provide faster and more effective access to new technologies for Medicare beneficiaries.¹ As part of these efforts, provisions in Cures 2.0 seek to facilitate earlier access to breakthrough devices by establishing a transitional coverage and reimbursement pathway. The Duke-Margolis Center for Health Policy (“Duke-Margolis”) has explored issues impacting similar proposals on coverage and evidence needs for breakthrough devices. This issue brief, [one of several Cures 2.0 Act-focused issue briefs developed by Duke-Margolis](#), offers recommendations to ensure the proposed transitional coverage pathway succeeds in providing Medicare patients faster and more effective access to innovative medical devices. Comments are informed by the Center’s independent analyses of the draft legislation and recent convenings with a broad set of stakeholders.

Coverage for Breakthrough Devices

The Cures 2.0 Act includes many provisions that are intended to increase patient access to devices approved through the US Food and Drug Administration’s (FDA’s) Breakthrough Devices Program. That program is an expedited pathway for approving medical devices that are novel, breakthrough, and provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.² The intent of this pathway is to provide timely access to novel devices by speeding up their development, assessment, and regulatory review.

Downstream patient access to breakthrough devices is then a function of FDA approval, payer coverage decisions, and physician adoption. For Medicare populations, CMS makes coverage decisions based on a determination of whether an item or a service is “reasonable and necessary” for Medicare beneficiaries.³ CMS makes reasonable and necessary determinations based on FDA approval and clinical data demonstrating improvement in Medicare beneficiaries’ health outcomes, among other criteria. Breakthrough devices, in part as a result of being in an expedited regulatory pathway, may have limited evidence on important health outcomes for Medicare beneficiaries at the time of approval.⁴ Consequently, CMS may not have sufficient evidence to determine whether the device is reasonable and necessary for some or all segments of the Medicare population. Timely access for breakthrough devices may also be further limited by CMS processes for coverage determinations, which can take up to a year.⁵

The Cures 2.0 Act attempts to address these barriers to access by establishing a “transitional coverage” pathway for breakthrough devices. The transitional coverage proposal provides breakthrough devices with protected coverage during which they have an opportunity to develop real-world evidence (RWE) on health outcomes for the Medicare population. The intent of this coverage pathway is to ensure timely access of breakthrough devices for Medicare beneficiaries who could get substantial health benefits from their use. This pathway offers an opportunity for a predictable and reliable framework through which device manufacturers can get earlier and sustained collaboration with CMS to support coverage needs. This will be particularly beneficial for smaller manufacturers with limited resources who may have uncertainties on how to address evidence needs efficiently. The success of this pathway depends on both providing rapid coverage and supporting post-market evidence generation on key questions relevant to the Medicare population unaddressed at the time of FDA approval.

The proposed coverage pathway in Cures 2.0 is very similar to the Medicare Coverage for Innovative Technology (MCIT) pathway that CMS recently proposed to repeal,⁶ citing concerns that MCIT is not in the best interest of Medicare beneficiaries. Other stakeholders have raised similar concerns. The limitations of the MCIT pathway that led CMS to propose a repeal are therefore also reflected in the design of the Cures 2.0 Act coverage pathway which:

- Limits the authority for CMS to prevent harm to Medicare beneficiaries, as they can only remove coverage for a breakthrough device for limited reasons.
- Provides coverage and resources for breakthrough devices in absence of any data demonstrating Medicare benefits.
- Offers little motivation or support for manufacturers or providers for additional data collection.
- Creates an unfair market advantage to a single breakthrough device and a single manufacturer and restrict competition and product improvements during the automatic coverage period.
- Relies on FDA’s determination for “safety and effectiveness”, which is not sufficient to establish “reasonable and necessary” determination for Medicare coverage.

However, the broad concepts of a transitional coverage pathway for breakthrough technologies, if designed carefully, are still worthy of further consideration as part of improving both patient access to and evidence development on promising medical products. Here, we offer recommendations on how to address these and related concerns in the Cures 2.0 Act to create a coverage pathway that achieves its intended aim of providing Medicare patients faster and more effective access to innovative medical devices.

An Operational Framework for Coverage

CMS grants Medicare coverage based on a determination of whether or not an item or service is reasonable and necessary for Medicare beneficiaries. Medicare determines that an item or a service is reasonable and necessary if it is--(1) safe and effective; (2) not experimental or investigational; and (3) appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service. FDA approval is only one of several criteria that determines whether an item or a service is reasonable and necessary. CMS has historically emphasized the different evidentiary considerations between FDA’s statutory focus on safety and efficacy for approval and Medicare’s reasonable and necessary considerations for coverage.^{7,8,9}

CMS makes Medicare coverage decisions through both National and Local Coverage Determinations (NCDs and LCDs, respectively) defined by statutes with prescribed timelines in which CMS or local contractors must carry out coverage-related activities. These activities may include conducting an evidence review and health technology assessment, convening the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) if needed, formally soliciting public comment on the proposed decision, and publishing a final decision. CMS then develops Medicare claims system edits for implementation of the final determination. This process is transparent and predictable, with defined expectations for roles and engagement across stakeholders.

Duke-Margolis recommends a complementary, statutorily-defined pathway or operational framework for special expedited coverage of breakthrough devices when this standard coverage process is not adequate for timely and appropriate access. We note that this special coverage process will not be needed for all breakthrough devices. Many breakthrough devices are not relevant for the Medicare population or already have a clear path to coverage. A key tenet of this pathway is early and sustained engagement with CMS to ensure timely coverage, and our recommended operational framework will facilitate implementation of provisions that bolster such engagement currently in Cures 2.0 Act, including:

- Increasing collaboration between FDA and CMS by defining the scope and level of engagement between the agencies;
- Allowing CMS to guide and track premarket evidence development where needed to inform downstream coverage determinations;
- Ensuring that any post-market RWE generation to support coverage is synergistic with FDA post-market requirements through systematic engagement between FDA, CMS, and manufacturers.
- Enabling CMS to use its authorities for coverage with evidence development (CED) and collaborate with manufacturers, providers, and other stakeholders to make RWE development as efficient, time-limited, and nonburdensome as possible in cases where CED can lead to faster and more confident access to a breakthrough device.

The operational framework also addresses CMS' recently stated concerns about MCIT proposals as it:

- Ensures the safety of (and minimizes harm to) Medicare beneficiaries by promoting well-informed and predictable coverage decisions;
- Provides timelier and efficient access to novel technologies;
- Supports evidence development relevant to Medicare beneficiaries.

The operational framework for the expedited coverage process includes the following elements:

Voluntary opt-in prior to FDA approval for expedited coverage: Manufacturers interested in expedited coverage will submit an application to Medicare before expected FDA approval. In this application, manufacturers will include an evidence packet with information on how the technology represents a breakthrough for the Medicare population. To provide clarity about the expected content of a successful evidence submission, CMS should provide an opportunity for consultation and guidance much earlier in the development process. CMS can expand existing interactions with manufacturers that request Medicare coverage for pivotal investigational device exemption (IDE) studies. Advance notice will allow CMS to determine that the device falls within the statutory scope of the Medicare program and to conduct preliminary analyses to inform its coverage decision before FDA approval.

Defined process and timeline following application: After manufacturers notify CMS of their request for coverage, CMS will have a defined timeline for activities to reach a coverage determination. These include: an assessment of whether expedited coverage is needed and appropriate (including guidance to the manufacturer about coverage if CMS determines a special process is not needed), a Medicare benefit category determination, a preliminary assessment of the evidence for the device and—for devices that CMS agrees to cover under this expedited program—guidance on navigating coding and payment processes through the new Technology Coding and Pricing Group. This initial evidence analysis will enable CMS to operationalize and implement coverage quickly following FDA approval. It will also allow CMS to determine whether additional evidence development will be necessary, and if so the most efficient way to develop such evidence. CMS could require Coverage with Evidence Development (CED) if addressing clinically significant evidence gaps could improve access and outcomes in the beneficiary population.¹⁰ CMS would engage with the manufacturer, the FDA, and potentially other entities including National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ) to inform the evidence assessment.

Public comment period: In cases where premarket processes indicate that coverage of a breakthrough device will not be straightforward, CMS will release a proposed coverage determination immediately following FDA approval and open a brief 30-day public comment period. The proposed coverage determination will include a review of the relevant evidence underlying the coverage decision and guidance on how to incorporate iterative and follow-on devices into the coverage policy. In cases that require CED, CMS will issue guidance on how to develop it and the conditions to end any evidence generation requirement. Following the public comment period, CMS will have a maximum of 60 days to finalize the coverage determination and issue implementation instructions.

Updates during expedited coverage: For the subset of breakthrough products that require further RWE generation, manufacturers will be required to share regular interim reports with CMS on how evidence development is progressing. These reports will help CMS plan for long-term coverage, including any outstanding evidence generation needs, and work with the manufacturer to address any challenges in evidence development. If these requirements are not met, CMS would have the authority to terminate coverage under the expedited program. CMS and the regional Medicare Administrative Contractors (MACs) would then determine coverage through the existing coverage processes such as NCD, LCD, or claim by claim adjudication.

While there is a growing volume of breakthrough device designations, most breakthrough devices are not expected to have significant evidence issues and thus would not require significant guidance and support for additional evidence development. Further, some breakthrough devices may already have an existing coverage framework base and may not have the need for an expedited coverage pathway for Medicare populations. The operational framework is intended to be flexible based on the specific circumstances of each breakthrough device. For breakthrough devices that will require post-market evidence generation, earlier engagement will allow stakeholders to establish a data collection infrastructure sooner and avoid access gaps after FDA approval. Earlier engagement between CMS and manufacturers can ensure timely, efficient, and evidence-based coverage, just as early engagement between FDA and manufacturers has accelerated development and review processes for breakthrough devices.

In cases where an entirely new class of products has significant uncertainties around coverage and evidence expectations, this pre-approval process would support CMS engagement with external experts, including MEDCAC, NIH, the Patient Centered Outcomes Research Institute (PCORI), and (with manufacturer agreement) relevant health care providers and private organizations that support evidence generation to help ensure that key evidence needs for Medicare beneficiaries can be addressed before or soon after approval. Through these early efforts, CMS could also provide guidance on relevant pre-market evidence development to help assure timely and predictable coverage.

Efficient and Effective Evidence Generation

The transitional coverage pathway for breakthrough devices also supports broader Cures 2.0 Act goals around advancing the use of RWE to increase access to and effective use of new technologies, and to speed permanent coverage decisions. Medicare beneficiaries are often underrepresented in clinical trials, and data on critical longer-term clinical outcomes may not be available at the time of approval.¹¹ Furthermore, RWE on patient selection criteria, provider capabilities and experience, and post-market product refinements can inform appropriate use of a breakthrough device. Consequently, as the Cures 2.0 legislation highlights, RWE can enable coverage that is more evidence-based with greater outcome benefits.

By adopting a breakthrough coverage framework that includes early interaction with CMS to anticipate any significant post-market evidence issues, a revised proposal in the Cures 2.0 Act could lessen the provider burden of data collection and advance more efficient and coordinated RWE development. The framework could include the following expectations for CMS:

Facilitate an efficient infrastructure for addressing critical CED questions: Current CED studies often place a high data collection burden on providers, and may be hampered by a lack of advance planning and engagement of key stakeholders in putting reliable data collection systems in place. Early engagement with CMS should help determine both whether CED is needed for critical questions, and determine whether a manufacturer would benefit from a collaborative effort facilitated by CMS to develop the evidence as quickly and efficiently as possible. For example, early engagement of CMS and providers facilitated broad CED for implantable cardioverter defibrillators and transaortic valve replacement.^{12,13} It is possible that more efficient means of data collection could be implemented in the future with improving electronic data capture technologies, increased interoperability to support longitudinal patient follow-up, and better analytic methods – all of which the Cures 2.0 legislation aims to advance. The expedited coverage framework should enable CMS to support stakeholder efforts to create CED approaches that generate minimal burden and better evidence development.

Facilitate CMS claims data linkages and integration with different sources of RWE: One valuable type of RWE analysis involves linking Medicare claims data with registries or other clinical study data with appropriate data security and confidentiality protections. These data linkages support the evaluation of long-term health outcomes and resource utilization of Medicare patients. The legislative framework could direct CMS to review data linkage restrictions and remove those that unnecessarily limit such analyses.

Increasing CMS Resources to Support Coverage Activities

Ensuring CMS has adequate resources and capacity to engage with manufacturers leading up to and during the transitional coverage period will be crucial to the success of the pathway. The Cures 2.0 Act will broadly create new requirements for CMS' time, capacity, and expertise to fulfill the goals of the expedited pathway. CMS resources in areas related to new technology assessment and access have declined over the past decade, even as breakthrough innovation has expanded and the resources to support it at FDA have grown rapidly.¹⁴ CMS is therefore not adequately resourced to fulfill the expectations presented in this legislation.

Coverage provisions in the Cures 2.0 Act will have significant and sustainable impact if accompanied by steps to ensure adequate capacity at CMS for implementing and operationalizing these provisions. Our framework aims to provide more clarity around the process—and thus the resources—that will be needed to support predictable, timely, and productive interactions between CMS, manufacturers, and other stakeholders to meet program expectations. We believe these resource requirements will be modest relative to their impact on innovation and coverage. To ensure appropriate use of these resources, there could be a requirement for an assessment of the impact on key goals, such as the timely occurrence of meetings and development of clear guidance to manufacturers on coverage-related issues, and time to coverage. The program could be assessed after five years of operation, and funded by initial appropriations to determine its viability and whether modifications are needed. As a parallel example, the FDA received \$500 million in appropriations over the course of 9 years to implement the changes required by 21st Century Cures Act passed in 2016.¹⁵ Increased transparency from FDA regarding breakthrough devices could help inform the resource and support needs for an expedited coverage pathway.

In the absence of additional resources, CMS could potentially coordinate more with FDA and manufacturers, or leverage existing collaboration with the FDA for subspecialty expertise to inform evidence development. However, it is important to recognize that limited CMS staff and bandwidth available for these activities is incredibly limited. As the pipeline of breakthrough therapies grows, CMS will need medical officers with subject matter expertise and additional personnel to assure that operational implementation is timely, reliable, and efficient.

Conclusion

The 21st Century Cures Act 2.0 can provide a structured, efficient, and adequately-resourced coverage process for breakthrough devices. This process complements the Cures 2.0 Act's other steps to accelerate breakthrough device development and regulatory approval, and supports the development of RWE that advances their effective use. These recommendations also reflect the diversity of innovative medical devices, with varying implications for achieving timely and effective coverage.

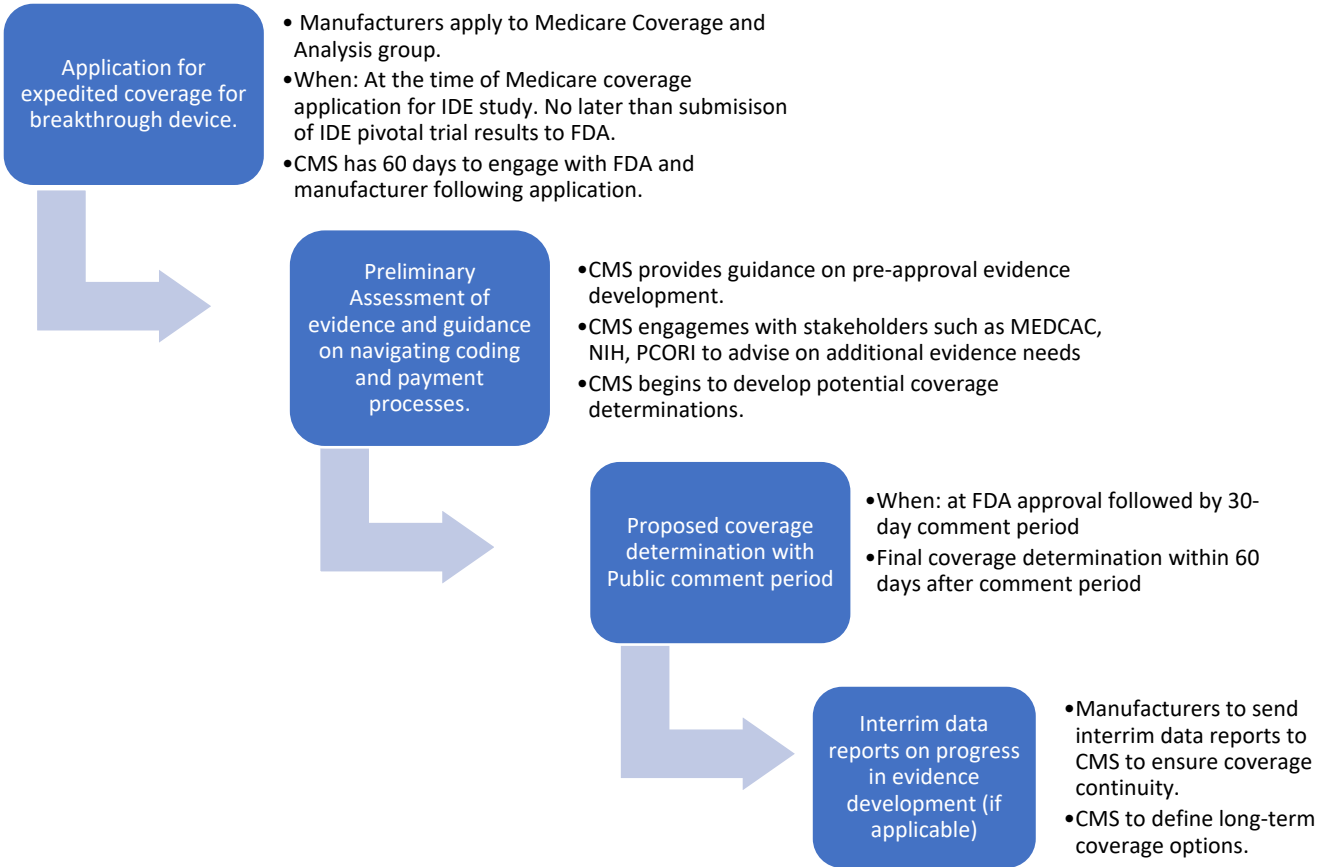
The Duke-Margolis Center for Health Policy will continue to conduct analyses and engage stakeholders on key issues surrounding coverage and evidence needs for breakthrough devices. The Center looks forward to future opportunities to provide input on this vital work.

Appendix A: Translating Recommendations to the Cures 2.0 Act:

Recommendation	Location in Legislation
General Pathway Specifications	
Limit coverage to devices that fall under Medicare benefit categories.	<p>Clarify language in: “SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM,” “SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES” “(b) COVERAGE” Delete section in “SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM (e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH DEVICES</p>
Expedited coverage will not have a defined period after which the breakthrough device will go through an iterative coverage review. Expedited coverage will end if there is a safety issue associated with the use for the breakthrough device, or manufacturer fails to meet evidence development expectations if part of the breakthrough coverage determination.	<p>Revise language in “SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM,” “SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES” (B)(ii) Under subsection: “(2) PROCESS FOR REGULAR COVERAGE” “If, during the transitional coverage period, CMS finds safety concerns in reported evidence or through FDA communications, the Secretary shall have the ability to limit or halt coverage for the breakthrough device.”</p>
Operational Framework	
Manufacturers must apply for expedited Medicare coverage for their breakthrough device before FDA approval. Manufacturers may seek guidance and meetings from CMS regarding evidentiary expectations at any timepoint following breakthrough designation.	<p>Edit definition of Transitional Coverage Period to reflect this change: “SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM” “SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES” “(B) TRANSITIONAL COVERAGE PERIOD DEFINED.” “Manufacturers shall request to opt-in to the program after receiving breakthrough designation from the FDA, but before FDA approval.”</p>
Following the application for Medicare coverage opt-in notification, CMS shall have 60 days to engage with the manufacturer to discuss coverage pathway milestones and requirements. Within 60 days of first meeting, CMS will conduct a preliminary evidence review and re-engage with the manufacturer and the FDA to discuss evidence needs.	<p>Add operating procedures and timeline to: “SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM” “SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES” Under subsection: “(2) PROCESS FOR REGULAR COVERAGE” “Within 60 days of first meeting, CMS will conduct a preliminary evidence review and re-engage with the manufacturer and the FDA to discuss evidence needs.”</p>
Eliminate the current one-year deadline for CMS to request more evidence to allow for flexibility during the four-year period.	<p>Revise language in “SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM; “SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES” (b) COVERAGE; (2) PROCESS FOR REGULAR COVERAGE; (A) IDENTIFICATION OF ADDITIONAL EVIDENCE” “For breakthrough devices that require post-market evidence, manufacturers will submit annual reports to CMS on such efforts</p>

	and available results to enable CMS to assess whether breakthrough coverage should be modified or ended.”
Modify language that requires CMS to create a permanent pathway to coverage within two years of FDA approval, to require CMS to provide clear guidance on conditions for converting to regular coverage.	Edit language in: “SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM,” “SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES” “(b) COVERAGE” “(2) PROCESS FOR REGULAR COVERAGE” “(B) PROPOSAL FOR COVERAGE AFTER THE TRANSITIONAL COVERAGE PERIOD” “CMS may use a Coverage with Evidence Development (CED) component in the expedited coverage if the preliminary evidence review suggests additional evidence is required to support “reasonable and necessary” determination for coverage. For breakthrough devices that require CED to address outstanding evidence concerns, CMS will provide guidance on specific results needed to conclude CED.”
Medicare coverage shall be extended to any iterative or follow on devices to the original breakthrough device that receive FDA approval. Any permanent coverage determination shall be made for the relevant class of breakthrough devices.	Edit definition of Transitional Coverage Period to reflect this change: “SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM” “SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES” “(a) BREAKTHROUGH DEVICES.”
Increasing CMS Resources	
Provide 5-year appropriations for CMS to assure there are adequate processes, resources, and staff to operationalize the pathway. This will include pre-approval meetings, development of guidance, and performance metrics to ensure pathway is operating as intended.	Include a new section in: “TITLE IV CENTERS FOR MEDICARE AND MEDICAID SERVICES”

Appendix B: Process map for Expedited Coverage



References

- ¹ Diana DeGette and Fred Upton, “21st Century Cures Discussion Draft” (2021), https://degette.house.gov/sites/degette.house.gov/files/Cures%202.0_DISCUSSION%20DRAFT.pdf.
- ² Center for Devices and Radiological Health, “Breakthrough Devices Program,” FDA, January 5, 2021, <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>.
- ³ Centers for Medicaid & Medicare Services, “Medicare Program Integrity Manual, Ch 13” (CMS, February 12, 2019), <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf>.
- ⁴ James L. Johnston et al., “Early Experience with the FDA’s Breakthrough Devices Program,” *Nature Biotechnology* 38, no. 8 (August 2020): 933–38, <https://doi.org/10.1038/s41587-020-0636-7>.
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- ⁶ Centers for Medicaid & Medicare Services, “Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary,”” *Federal Register* 86, no. 176 (September 15, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-09-15/pdf/2021-20016.pdf>.
- ⁷ Health Care Financing Administration, “Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services,” *Federal Register* 60, no. 181 (September 19, 1995), <https://www.govinfo.gov/content/pkg/FR-1995-09-19/pdf/95-23132.pdf>.
- ⁸ Centers for Medicaid & Medicare Services, “Medicare Program; Revised Process for Making Medicare National Coverage Determinations,” *Federal Register* 68, no. 187 (September 26, 2003), <https://www.govinfo.gov/content/pkg/FR-2003-09-26/pdf/03-24361.pdf>.
- ⁹ Centers for Medicaid & Medicare Services, “Medicare Program; Revised Process for Making National Coverage Determinations,” *Federal Register* 78, no. 152 (August 7, 2013), <https://www.govinfo.gov/content/pkg/FR-2013-08-07/pdf/2013-19060.pdf>.
- ¹⁰ Coverage with Evidence development (CED): CMS have used its authority under Section 1862(a)(1) (A) and Section 1862(a)(1) (E) of the Social Security Act (the Act) to require data collection as a condition of coverage for certain medical products. The CED policy was developed to provide access to technology that had insufficient evidence to satisfy criteria for Medicare coverage
- ¹¹ US Food and Drug Administration, “Public Workshop: Evaluating Inclusion and Exclusion Criteria in Clinical Trials” (Washington, D.C.: The National Press Club, 2018), 12, <https://www.fda.gov/media/134754/download>.
- ¹² CMS. Implantable Defibrillators. National Coverage Analysis. Decision Memo. CAG-00157R3. 2005. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAid=148>. Accessed 10/1/2021
- ¹³ CMS. Transcatheter Aortic Valve Replacement. National Coverage Analysis. Decision Memo. CAG-00430N. 2012. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=257>. Accessed 10/1/2021
- ¹⁴ “Access For 21st Century Cures: Updating Medicare’s Approach To Coverage And Payment | Health Affairs,” accessed September 1, 2021, <https://www.healthaffairs.org/doi/10.1377/hblog20191217.27121/full/>.
- ¹⁵ Office of the Commissioner, FDA, “21st Century Cures Act,” FDA (FDA, January 31, 2020), <https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act>.

Disclosures

Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomiQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

About the Duke-Margolis Center for Health Policy

The Robert J. Margolis, MD, Center for Health Policy at Duke University is directed by Mark McClellan, MD, PhD, and brings together expertise from the Washington, DC, policy community, Duke University, and Duke Health to address the most pressing issues in health policy. The mission of Duke-Margolis is to improve health, health equity, and the value of health care through practical, innovative, and evidence-based policy solutions. Duke-Margolis catalyzes Duke University's leading capabilities, including interdisciplinary academic research and capacity for education and engagement, to inform policy making and implementation for better health and health care. For more information, visit healthpolicy.duke.edu.