



November 2, 2020

**SUBMITTED ELECTRONICALLY VIA [www.regulations.gov](http://www.regulations.gov)**

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: Medicare Coverage of Innovative Technology (MCIT) and Definition of  
“Reasonable and Necessary” Proposed Rule (CMS-3372-P; RIN: 0938-AT88)**

Dear Administrator Verma:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services’ (CMS) proposed rule on the Medicare Coverage of Innovative Technology (MCIT) pathway and the definition of “reasonable and necessary” for items and services furnished under the Medicare program (the Proposed Rule).<sup>1</sup> The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices and technologies for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as multiple sclerosis, paralysis, hearing and speech impairments, cerebral palsy, visual impairments, spinal cord injury, brain injury, stroke, spina bifida, myositis, limb loss, and other life-altering conditions.

**Overview**

The Proposed Rule includes two major proposals. First, CMS proposes to establish a new coverage pathway to allow nationwide, temporary Medicare coverage for innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). Coverage under the MCIT pathway would begin on the date of FDA market authorization (i.e., the date the device receives Premarket Approval, 510(k) clearance, or the granting of a De Novo classification request) and would continue for up to four years. Manufacturers would have the ability to “opt in” to this Medicare coverage, assuming the device falls under an existing Medicare benefit category and is not otherwise excluded from coverage by statute.

Additionally, the Proposed Rule would codify in regulation a definition of the term “reasonable and necessary” to clarify coverage standards, revising the definition currently cited in the

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<sup>1</sup> Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”; 84 Fed. Reg. 54,327 (Sept. 1, 2020).

Medicare Program Integrity Manual (PIM).<sup>2</sup> The proposed definition largely tracks the existing definition in the PIM, but modifies it in at least one material respect.

The ITEM Coalition offers comments on both proposals below.

### **Medicare Coverage of Innovative Technology (MCIT)**

The ITEM Coalition is dedicated to expanding beneficiary access to critical technology and devices that improve health outcomes and function for people with disabilities, injuries, and chronic conditions. *As such, we strongly support the proposal to create the MCIT pathway and allow immediate Medicare coverage of FDA-designated and approved breakthrough devices.*

As stated in the Proposed Rule, the existing coverage pathways for devices do not always allow for timely beneficiary access to new technology. Additionally, these existing pathways often require robust health outcomes data and other clinical evidence that may not be available for new and innovative technologies. We appreciate CMS' efforts to increase access to breakthrough technologies and encourage CMS to move forward with implementing this proposal. We believe that immediate MCIT coverage of breakthrough devices will provide enhanced access for beneficiaries and allow manufacturers sufficient time and utilization experience to develop the data necessary to support long-term coverage.

However, the ITEM Coalition also believes that the current proposal can be revised and expanded to provide more benefit to patients covered under the Medicare program. In order to align with the intention of the President's Executive Order<sup>3</sup> to streamline the approval, coverage, and coding process for innovative technologies, we suggest the following additions to the proposed MCIT pathway.

#### *Length of Coverage Under MCIT Pathway*

Under the Proposed Rule, CMS suggests that coverage under the MCIT pathway would last up to four years, stating that this would provide sufficient time for manufacturers to develop clinical evidence and data regarding the real-world use of their device and its impact on health outcomes. We agree that this four-year time frame would generally be sufficient, and that there is a benefit to limiting the MCIT coverage period to provide CMS with the opportunity to review evidence generated during this time and make a permanent coverage decision. However, *we encourage the agency to consider implementing a process for a short-term extension of the temporary MCIT coverage, if circumstances merit such extension.*

For example, if the manufacturer of a device that has received coverage under the MCIT pathway is undergoing, but has not yet completed, a clinical trial or other significant study which would contribute relevant evidence or outcome data associated with the use of the device towards the end of the fourth year of coverage, we do not believe that Medicare coverage should automatically lapse. We believe that it is in the best interest of beneficiaries and the Medicare

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<sup>2</sup> Centers for Medicare and Medicaid Services, *Medicare Program Integrity Manual* (Rev. 863, 02-12-19), Ch. 13.5.4. “Reasonable and Necessary Provisions in LCDs.” <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf>

<sup>3</sup> E.O. 13980, “Protecting and Improving Medicare for Our Nation’s Seniors,” 84 Fed. Reg. 53573 (Oct. 3, 2019).

program for CMS to allow a manufacturer to apply for an extension (e.g., for up to one year) of the temporary MCIT coverage. This would ensure that ongoing clinical investigations could be completed including the Medicare population in the study and would protect continuity of coverage for Medicare beneficiaries.

Additionally, if CMS is still conducting the process of a permanent coverage decision for a device temporarily covered under the MCIT pathway, whether a National Coverage Determination, National Coverage Analysis, Local Coverage Determination, or other process, the agency should consider extending the MCIT coverage to “bridge the gap” between the expiration of the initial four-year period and the issuance of a permanent CMS coverage decision. As the COVID pandemic has emphasized, real-world circumstances are constantly changing and may not always align with the expected time frames for ongoing activities; Medicare beneficiaries should not suffer a lapse in coverage of breakthrough technology simply because the regulations include a definitive, four-year limit for MCIT coverage.

#### *“Lookback” Period for Previously Approved Devices*

CMS proposes the MCIT pathway as largely available for devices yet to be designated as breakthrough technologies and yet to be covered by the Medicare program. Additionally, the agency proposes a “lookback” period for previously designated devices to receive temporary coverage. Specifically, the Proposed Rule states that devices that received their FDA market authorization “no more than 2 calendar years prior to the effective date” of the final rule and thereafter will be eligible for Medicare coverage in claims submitted on or after the effective date of the rule. CMS also states that breakthrough devices would only be eligible for four years of MCIT coverage from the date of market authorization.

The ITEM Coalition agrees with CMS’ proposal that claims for utilization of breakthrough technologies with dates of service prior to the finalization of the rule would not be eligible for retroactive payment. However, we question whether the limitation of the lookback period to two years only is in the best interest of beneficiaries. As CMS has identified a four-year period as appropriate for coverage of breakthrough technologies, we believe that the lookback period should also be extended to cover the four years prior to the effective date of the final rule.

***For devices receiving market authorization more than two years prior to the effective date of the final rule, we suggest that CMS allow two full years of temporary MCIT coverage,*** ensuring that these devices would receive at least some time with Medicare coverage in order to bolster efforts to collect utilization and outcomes data to support permanent coverage. Making these changes to the Proposed Rule would allow beneficiaries to receive maximum benefit of access to and coverage of breakthrough devices and align with the spirit and goals of the President’s Executive Order and the proposed MCIT pathway.

#### *Limitation of MCIT to FDA-Designated Breakthrough Devices*

We recognize that CMS has proposed to limit the MCIT pathway, at least initially, to only devices designated as breakthrough by the FDA. This decision seems to have been made, in part, due to the fact that breakthrough devices are specifically cited in the President’s Executive Order

on Protecting and Improving Medicare for Our Nation’s Seniors. Additionally, we recognize that the definition of a “breakthrough device” as utilized by the FDA is defined in legislation.<sup>4</sup>

However, we also note that according to the Proposed Rule, only 16 devices have received both a breakthrough designation and FDA market authorization to date. We believe that the issues of variability in coverage and Medicare beneficiary barriers to access for innovative technology expand beyond the comparatively small subset of devices that would be eligible for MCIT coverage under the Proposed Rule.

Therefore, *we urge the agency to finalize this proposal for breakthrough devices, but also to expand the MCIT pathway and find other opportunities to streamline and advance timely coverage of innovative technologies under the Medicare program, especially those devices which are critical for improving the health and function of Medicare beneficiaries with disabilities, injuries, illnesses, and chronic conditions.* There are a great many innovative devices and technologies under development with the potential to provide a significant benefit to Medicare beneficiaries in need of assistive devices and technologies, but the current breakthrough definition is overly narrow, and many devices might not qualify for the designation.

Additionally, *we encourage CMS to work with the FDA and Congress to consider opportunities to expand the statutory definition of breakthrough devices to ensure that innovative technologies are appropriately considered for the designation.* For example, the statute requires that such devices “provide for more effective treatment or diagnosis of *life-threatening or irreversibly debilitating human disease or conditions*” (emphasis added). We believe it is critical that this definition be interpreted to include devices that will improve beneficiary function and advance quality of life, including rehabilitation devices and related technologies.

The FDA’s guidance relating to the breakthrough device program states that FDA considers “a disease or condition associated with morbidity that has *substantial impact on day-to-day functioning* to be irreversibly debilitating” for the purposes of fulfilling the criterion of the breakthrough designation. We agree that enhancing and/or maintaining function is a critical part of the provision of high-quality medical care (as detailed further below), and we encourage CMS in collaboration with FDA to interpret this criterion broadly to ensure that beneficiaries receive the fullest benefit of the breakthrough designation and associated coverage under the MCIT pathway.

### **Definition of “Reasonable and Necessary”**

The Proposed Rule includes a codification of the definition of “reasonable and necessary” for Medicare items and services. The criteria include:

- 1) Whether the item or service is safe and effective;
- 2) Whether the item or service is not experimental or investigational;

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<sup>4</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360e-3(b).

3) Whether the item or service is “appropriate for Medicare patients,” including whether it is:

- a. Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
- b. Furnished in a setting appropriate to the patient’s medical needs and condition;
- c. Ordered and furnished by qualified personnel;
- d. Meets, but does not exceed, the patient’s medical need; and
- e. At least as beneficial as an existing and available medically appropriate alternative.

CMS also proposes to consider coverage in the commercial insurance market as a method to determine whether the item or service is appropriate for Medicare patients.

*Given the importance of this aspect of the proposed rule and the longstanding implications of the medical necessity proposal on coverage of Medicare benefits, we would prefer that CMS withdraw this portion of the rule so that stakeholders and CMS can discuss this issue in greater depth and a separate, well-developed and consensus-based proposal can be considered. However, if CMS is not willing to withdraw the rule, we offer the following comments for CMS’ consideration on provisions of the proposed definition below.*

We offer comments on provisions of the proposed definition below.

#### *Appropriateness for Medicare Patients*

As CMS proposes to codify a definition of “appropriateness” for Medicare patients, we note that, in our view, the agency and its contractors often consider the Medicare population to consist of seniors over the age of 65 only, without sufficient consideration of the entire Medicare population. This frame of reference excludes the significant portion of the Medicare population that is under 65, including those with long-term disability, patients with End-Stage Renal Disease (ESRD), and beneficiaries dually eligible for Medicare and Medicaid coverage.

Approximately 15% of the Medicare population, or nearly 9 million beneficiaries, are under the age of 65.<sup>5</sup> Additionally, these beneficiaries account for a disproportionate share of Medicare spending, according to the Medicare Payment Advisory Commission. While these beneficiaries may not reflect the traditional conception of the Medicare population, they are unequivocally a part of the program and must be considered when developing Medicare policy. Too often, CMS formulates Medicare policy exclusively, or primarily, for seniors, excluding or minimizing the needs of younger Medicare beneficiaries.

This subset of Medicare beneficiaries may have different needs, and different items and services may be considered appropriate for beneficiaries of different ages. For example, what may not be reasonable and necessary for a 75-year old with osteoarthritis may be eminently reasonable and

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<sup>5</sup> Medicare Payment Advisory Commission (MedPAC): *Health Care Spending and the Medicare Program: A Data Book*, p. 22 (July 2020). [http://www.medpac.gov/docs/default-source/data-book/july2020\\_databook\\_entirereport\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/data-book/july2020_databook_entirereport_sec.pdf?sfvrsn=0)

necessary for a 42-year old woman with spinal cord injury. Younger beneficiaries are unequivocally entitled to Medicare benefits that are reasonable and necessary for their conditions. *We therefore encourage the agency to carefully consider the needs of all Medicare beneficiaries when reviewing items and services for reasonable and necessary determinations, including those that may not be frequently or traditionally considered Medicare items, such as pediatric care.*

#### *Functional Improvement*

CMS proposes to consider whether an item or service is used “to improve the function of a malformed body member” when determining whether it is appropriate for Medicare patients. Though this language derives from the Medicare statute itself, we note that functional status is crucial to determining “medical necessity.” The disability community has long advocated that functional improvement is critical to the provision of high-quality medical care and an essential aspect of treating patients. For example, a well-fit prosthetic limb does little to advance the medical status of an individual with limb loss, but it is essential to that person’s ability to function, perform daily life activities, participate in the community, and engage in employment. Proper function is a necessary part of quality of life for Medicare beneficiaries and the items and services covered under the program should reflect this reality.

Additionally, we recommend that the definition be expanded to include maintenance or prevention of deterioration of function as well. For many beneficiaries, especially those with disabilities, injuries, illnesses, and chronic conditions, maintaining existing function is crucial for health outcomes and quality of life. Though improving functional outcomes for Medicare beneficiaries is always ideal, for certain beneficiaries, *increasing* the patient’s level of function is not realistic or achievable. In fact, the *Jimmo v. Sebelius* settlement affirms that Medicare covers care to maintain or prevent deterioration of a patient’s functional status, as opposed to improving functional abilities. *Therefore, we suggest the proposed regulatory language at §405.201(b)(3)(i)(A) be revised to read, in part:*

“Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or **to improve, maintain, or prevent the deterioration** of the function of a malformed body member.” (additions in bold)

This addition will ensure that the newly codified language will include maintenance of function as a necessary pillar of care under the Medicare program.

#### *Consideration of Commercial Insurance Coverage*

Under the Proposed Rule, an item or service would also be considered “appropriate for Medicare patients” if the item or service is covered by commercial insurers, unless there is evidence supporting clinically relevant distinctions between commercially insured individuals and Medicare beneficiaries. We support this consideration of the commercial market, provided that CMS ensure this avenue is used to expand, rather than restrict or deny coverage. CMS should consider coverage of items or services that are made available by commercial insurers but should not determine that a lack of coverage in the commercial market should drive a CMS decision not

to cover a certain device. As the largest health care payer in the United States, CMS sets the precedent for other payers, both commercial and federal – it is common practice for commercial insurers to model their policies on Medicare coverage determinations or even explicitly link their policies to Medicare. We understand that private payers should render their own coverage determination and not defer to the Medicare program, but this often occurs nonetheless, and therefore, Medicare plays a special role in establishing important benchmarks for national coverage of benefits.

***We urge CMS to consider commercial insurance policies as additive to Medicare offerings, and not to use this proposal to deny or restrict Medicare coverage.*** We also believe that in instances where commercial coverage policies vary widely, CMS should adopt the least restrictive coverage policy would align with the goals set out in the President's Executive Order and ensure that innovative items and services are widely available and appropriately reimbursed.

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We appreciate your consideration of our comments. Should you have further questions regarding this letter, please contact the ITEM Coalition coordinators at [Peter.Thomas@PowersLaw.com](mailto:Peter.Thomas@PowersLaw.com) and [Joseph.Nahra@PowersLaw.com](mailto:Joseph.Nahra@PowersLaw.com) or by calling 202-466-6550.

Sincerely,

**The Undersigned Members of the ITEM Coalition**

ACCSES

***ALS Association\****

American Academy of Physical Medicine and Rehabilitation

American Association for Homecare

American Association on Health and Disability

American Cochlear Implant Alliance

American Congress of Rehabilitation Medicine

American Council of the Blind

American Macular Degeneration Foundation

American Music Therapy Association

American Network of Community Options and Resources

American Occupational Therapy Association

American Physical Therapy Association

***Amputee Coalition\****

The Arc of the United States

Brain Injury Association of America

***Christopher & Dana Reeve Foundation\****

Clinician Task Force

Council of State Administrators of Vocational Rehabilitation

Epilepsy Foundation

Hearing Loss Association of America

Institute for Matching Person and Technology

Lakeshore Foundation

National Association for Home Care and Hospice

National Association for the Advancement of Orthotics and Prosthetics

National Association of Councils on Developmental Disabilities

National Association of Rehabilitation Providers and Agencies

National Association of Rehabilitation Research and Training Centers

National Coalition for Assistive and Rehab Technology

National Multiple Sclerosis Society

National Registry of Rehabilitation Technology Suppliers

***Paralyzed Veterans of America\****

Rehabilitation Engineering and Assistive Technology Society of North America

The Simon Foundation for Continence

***Spina Bifida Association\****

Support Sight Foundation

United Cerebral Palsy

***United Spinal Association\****

Viscardi Center

***\* ITEM Coalition Steering Committee Member***