October 15. 2021

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

The Honorable Chiquita Brooks-LaSure
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" [CMS-3372-P2; RIN: 0938-AT88]

Dear Administrator Brooks-LaSure:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule repealing the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" final rule. 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, limb loss, and other life-altering conditions.

I. Overview

The ITEM Coalition has a keen interest in coverage of new technologies that benefit people with disabilities and previously offered comments on the proposed MCIT rule in November 2020 (available here), as well as during the subsequent comment period in April 2021 (available here). Under the final rule published in January 2021, CMS was set 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). Additionally, the final rule would have codified in regulation a definition of the term "reasonable and necessary" (R&N) to clarify Medicare coverage standards, revising the definition currently cited in the Medicare Program Integrity Manual.

After multiple delays in the effective date of this final rule, CMS now proposes to repeal the MCIT final rule *in its entirety*, stating that the finalized rule is "not in the best interest of Medicare beneficiaries." The R&N portion of the rule would also be fully repealed, though CMS seeks comment from stakeholders on this aspect of the proposal.

On behalf of the individuals with disabilities and health care providers that we represent, the ITEM Coalition strongly supported the proposal to create the MCIT pathway and allow immediate Medicare coverage of FDA-designated and market-approved breakthrough devices. Thus, we are disappointed in the agency's decision to back away from this proposal and recommend that CMS reconsider whether this is the most appropriate stance to protect Medicare beneficiaries and press forward with an alternative that accomplishes a similar purpose the final rule was intended to achieve.

The ITEM Coalition also realizes that implementing the MCIT final rule by the current effective date of December 15, 2021 would require numerous operational determinations and issuance of significant sub-regulatory guidance, none of which have been released to date. We therefore expect that CMS is likely to move forward with the repeal of this final rule. ***However, we urge CMS to follow through on its stated commitment to explore "other policy options and statutory authorities for coverage that better suit the needs of Medicare beneficiaries." We offer recommendations for such options below.***

II. Delays in Coverage Lead to Beneficiary Access Concerns

The ITEM Coalition's work is focused on the mission of increasing access to assistive devices and technologies, particularly for people with disabilities, illnesses, injuries, and chronic conditions. These populations often face significant barriers to accessing items and services under the Medicare program and beyond, whether due to overly restrictive payment systems and regulations, inaccessible facilities and devices, and/or narrowly defined and tailored coverage policies that seem to prioritize short-term cost savings over access to innovative technologies. Too often, the existing Medicare coverage pathways, as well as the coding and payment systems, do not allow for timely beneficiary access to new technology and pose unnecessary roadblocks to providing patients with devices and related services that can provide improved health outcomes.

As CMS has recognized in previous iterations of the MCIT proposal, the National Coverage Determination (NCD) and Local Coverage Determination (LCD) processes currently utilized by the agency limit the availability of innovative devices to Medicare beneficiaries. While some other payers, especially private insurers, are not so limited by the Medicare coverage regulations, CMS typically sets the precedent for other insurers, 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. Often, a lack of timely Medicare coverage for a new device or technology can lead to a bottleneck that broadly impacts individuals covered by all payers nationwide.

Of course, even when the existing processes operate as intended, the NCD/LCD system is not equipped to move rapidly and respond to the pace of innovation. We are well aware that NCD and LCD applications are often significantly slower than even the coverage regulations state. As outlined in the original MCIT proposed rule, NCDs and LCDs take, on average, 9 to 12 months to finalize. The ITEM Coalition has submitted an NCD Reconsideration Request to expand beneficiary access to critical wheelchair technology, which, after being deemed a "complete NCD request," has languished at CMS for more than a year without even being formally "opened," at which point the clock for at least another year of coverage analysis would begin.

We are aware of numerous other NCD requests that are similarly on hold within the agency. In many cases, these delays can operate as a "black box," keeping stakeholders unaware of the expected timeline for action towards coverage of a given item or service.

When Medicare does not provide a national coverage policy for innovative devices, beneficiaries are unable to access these items. While the agency does allow for case-by-case coverage under the determinations of Medicare Administrative Contractors (MACs), these processes are often complex and difficult to navigate, especially for individuals with disabilities or chronic conditions. MAC determinations may also be inconsistently applied, leaving a patchwork system of coverage which leads to significant beneficiary confusion at best, and a severe lack of access at worst. Administrative Law Judges and the Medicare Appeals Council often overturn good faith coverage decisions by lower levels of administrative review because the technology at issue does not technically qualify as a Medicare benefit, despite the technology being clearly reasonable and necessary. In addition, for many beneficiaries, especially those from underserved populations, out-of-pocket costs are an insurmountable barrier to obtaining these devices and therefore certain beneficiaries are unable to reap their benefits.

The current system simply does not work as intended to ensure that Medicare beneficiaries are able to access devices and technologies that can provide significant improvements in medical and functional benefits over and above existing devices and technologies. We appreciate CMS' statements that the agency intends to continue developing future proposals to expand timely access to items and services supported by adequate evidence for beneficiaries and encourage the agency to expeditiously fulfill this commitment.

III. Considerations for Future Expedited Coverage Pathways

While the Coalition continues to support the MCIT pathway and the overall goal of timely access to innovative technology, we recognize that CMS has identified several areas where the original proposal could be improved, many of which we raised in our previous comments. As CMS continues to prepare future rulemaking around this issue, we encourage the agency to emphasize these considerations to maximize the impact for Medicare beneficiaries.

Limitations of the Breakthrough Designation

The original MCIT final rule only applied to 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 Executive Order 13890, *Protecting and Improving Medicare for Our Nation's Seniors*.[1] CMS states in this proposed rule that "there are many drawbacks to limiting coverage through the MCIT pathway only to those devices that are part of the Breakthrough Devices Program," a contention that the ITEM Coalition agreed with in previous comments. The breakthrough designation has specific and limited criteria to determine eligibility, including the requirement that no approved or cleared alternatives exist and that the device provide for more effective treatment or diagnosis of "life-threatening or irreversibly debilitating" conditions.

[1] Exec. Order No. 13890, 84 Fed. Reg. 53573 (2019).

We believe that the issues of variability in coverage and Medicare beneficiary barriers to access to innovative technology expand beyond the comparatively small subset of devices that would be eligible for coverage under the previously finalized MCIT pathway. Many devices currently under development may have the potential to provide a significant benefit to Medicare beneficiaries but may not qualify for the breakthrough designation. For example, rehabilitation devices and related technologies, critical for improving beneficiary function and advancing quality of life, may not be considered as treating life-threatening or irreversibly debilitating conditions.

Further, as CMS notes in this proposed rule, providing expedited coverage only for breakthrough devices may discourage the development and coverage of second-to-market and subsequent devices that nonetheless may be appropriate and provide a significant benefit to individuals in the Medicare program. We urge the agency to develop streamlined coverage pathways for innovative technologies beyond breakthrough devices, especially for those that are critical to improving the health and function of Medicare beneficiaries with disabilities, injuries, illnesses, and chronic conditions.

Appropriateness for Medicare Patients

As part of the justification for repealing the final rule, CMS notes that the breakthrough device designation under the FDA's authorities would not necessarily include evidence that the device in question improves outcomes specifically for Medicare beneficiaries. We recognize that the FDA's market authorization standard is different than the coverage standards used at CMS. However, we also caution that CMS must consider the totality of the Medicare population when identifying innovative devices for potential coverage. In our view, the agency and its contractors often consider the Medicare population to consist of seniors over the age of 65 only. 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.[2] 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 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***

[2] 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)

beneficiaries when reviewing potential avenues to expand timely coverage of innovative devices, including those that may not be frequently or traditionally considered Medicare items, such as pediatric care.

Evidence Development

We note that CMS did not mandate that manufacturers receiving MCIT coverage take steps to develop clinical evidence around the use of their devices during the temporary coverage process. As CMS states in this proposed rule, many commenters suggested that temporary coverage should be contingent on evidence development that includes Medicare beneficiaries. We support actions that would expand the clinical evidence base supporting the use of innovative technology, but do not believe that these requirements should pose undue hurdles to beneficiaries accessing the devices themselves. If requirements around enrollment in clinical trials are instituted, we encourage CMS to prioritize inclusion of individuals with disabilities in such trials, both to maximize the relevance of evidence to this population and to encourage broader inclusion and accessibility for the disability population.

Additionally, we note that while there are some requirements in the FDA for such evidence, there is not currently a mandate for CMS to consider patient experience data in making evaluations of items and services under the Medicare program, nor is there a requirement for applicants to submit such data as part of their requests for coverage. While we encourage CMS to review opportunities to incorporate the patient voice throughout the Medicare program, we believe that streamlined coverage of innovative technology provides an important opportunity to utilize such data. Data collection, especially in the Medicare program, should support the user, and too often, the patient voice in health care is de-emphasized, dismissed, or omitted entirely. Requiring or incentivizing patient experience data and related information as part of the coverage process under an MCIT successor proposal would enhance the consideration of the patient perspective across CMS coverage determinations and ensure a more fully patient-centered health care system.

Additional Considerations

While we expect that the ITEM Coalition and other stakeholders would provide specific feedback on future proposals for coverage of innovative technology, we note that some of our recommendations to refine the MCIT proposal would apply to other pathways as well. We recognize that an expedited coverage pathway is intended to provide temporary coverage during the early stages of adoption of a new device, and not to permanently supplant the full coverage analysis process under CMS' current regulations. However, we encourage the agency to consider flexibility regarding the timeline for any temporary coverage, specifically to include a process for short-term extensions if circumstances merit. For example, the MCIT proposal was limited to four years only. Such a timeline may generally be sufficient, but we can foresee situations where a clinical trial or other significant study intended to generate evidence for permanent coverage might be ongoing but not completed by the end of a temporary coverage period. In such situations, we do not believe that Medicare coverage should automatically lapse.

Additionally, if an innovative device is being reviewed under a full permanent coverage process (such as an NCD, LCD, or National Coverage Analysis), the agency should consider a process for a "bridge the gap" coverage period between the expiration of a temporary innovative device

coverage and the issuance of a permanent CMS coverage decision, especially given the potential for significant delays in the CMS review process for NCDs and other determinations.

Finally, we note that in order to properly operationalize any new coverage process, whether temporary, expedited, or otherwise expanded, CMS will need to develop accompanying processes for Benefit Category Determinations, coding, and payment around these devices. As we have noted in previous comments, the current processes for these determinations can take months, even years, and are often considered subsequently rather than simultaneously. To achieve the goals of an MCIT-like proposal or other expedited coverage pathway, CMS must develop significantly expedited processes for implementing such coverage and ensure that beneficiaries can actually access these devices once coverage begins. Our comments from April 2021 include additional details around these considerations.

IV. Definition of "Reasonable and Necessary"

This proposed rule would also repeal the previously finalized provisions regarding the definition of "reasonable and necessary" for Medicare items and services. These provisions were not limited to a codification of existing sub-regulatory language; CMS also proposed significant changes to the agency's authorities to consider commercial insurance coverage during the R&N determination process. The ITEM Coalition previously recommended that CMS withdraw this portion of the rule and promulgate any future changes to the R&N definition through separate rulemaking. These proposals would have a significant impact on the Medicare program, beneficiaries, providers, and other stakeholders, and thus should be examined through a separate, well-developed, and consensus-based public engagement.

We are pleased that CMS has decided to pull back this portion of the original final rule and encourage the agency to conduct further discussions with stakeholders regarding future regulations around R&N determinations. We look forward to engaging with the agency during a robust public notice-and-comment rulemaking process. As the agency considers its next steps internally, we resubmit our previous comments on certain provisions of the proposed definition, especially around the makeup of the Medicare population, functional improvement language, and the consideration of commercial insurance coverage.

V. Conclusion

While we are disappointed that CMS does not intend to move forward with the MCIT proposal at this time, we strongly support a continued focus on expanding access to innovative technology under the Medicare program, especially for beneficiaries with disabilities, injuries, illnesses, and chronic conditions. ***We urge the agency not to let this goal fall by the wayside, and to follow through on the stated commitment to both better utilize existing coverage pathways and conduct future rulemaking to expand CMS' authority to cover innovative technology. If the agency does in fact repeal the MCIT pathway, we urge the agency to publicly signal its intention to do so, as well as a timeline for proposing an updated regulation, by December 15, 2021.*** The ITEM Coalition and our members stand ready to assist the agency in developing such rulemaking to ensure that the Medicare program provides robust and timely coverage of and

access to innovative technologies, items, and services that offer medical and functional benefits to the beneficiaries it serves.

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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 and Joseph.Nahra@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready
ACCSES
Advanced Medical Technology Association
ALS Association*
American Association for Homecare
American Association of People with Disabilities
American Association on Health and Disability
American Cochlear Implant Alliance
American Macular Degeneration Foundation
American Music Therapy Association
American Occupational Therapy Association
American Physical Therapy Association
American Therapeutic Recreation Association
Amputee Coalition*
Assistive Technology Industry Association
Association of University Centers on Disabilities
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Medical Device Manufacturers Association
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National Coalition for Assistive and Rehab Technology

National Multiple Sclerosis Society
National Registry of Rehabilitation Technology Suppliers
Paralyzed Veterans of America*
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Rehabilitation Engineering and Assistive Technology Society of North America
The Simon Foundation for Continence
Spina Bifida Association*
The Support Sight Foundation
United Cerebral Palsy
United Spinal Association*
Viscardi Center

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