



April 16, 2021

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

The Honorable Elizabeth Richter
Acting 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” Interim Final Rule with Comment Period (CMS-3372-IFC)

Dear Acting Administrator Richter:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition Steering Committee appreciate the opportunity to provide additional comments on the Centers for Medicare and Medicaid Services’ (CMS) interim final 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 Interim Final Rule).¹ 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 ITEM Coalition appreciates the care and consideration that CMS is giving to the previously finalized MCIT rule to ensure that the policy can be operationalized in a way that maximizes benefit to Medicare beneficiaries. The ITEM Coalition previously offered comments on the proposed rule in the [attached letter](#) dated November 2, 2020. We further offer comments on the new questions raised in the Interim Final Rule with Comment Period (IFC) below, including issues surrounding benefit category determinations, coding, and payment for breakthrough technologies; potential overlap with the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) proposed rule; specific value of breakthrough devices to the Medicare population; and the separate proposal to codify the definition of “reasonable and necessary” for purposes of Medicare coverage.

¹ Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”; Delay of Effective Date; Public Comment Period, 86 Fed. Reg. 14,542 (March 17, 2021).

We reiterate our strong support for the creation of the MCIT pathway to provide immediate, nationwide Medicare coverage of medical devices designated as breakthrough and market-authorized by the Food and Drug Administration (FDA). 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. 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. While we offer comments and suggestions for revisions to the IFC and additional considerations below, ***we urge CMS to finalize the MCIT pathway and increase access to breakthrough technologies.*** We do not believe there is any need to withdraw the final rule or significantly delay the effective date of the MCIT pathway.

Considerations for Medicare Coverage of Innovative Technology Pathway

Procedural Issues

As stated above, we urge CMS to move forward with the finalization of the MCIT pathway to allow Medicare beneficiaries to gain access to innovative technologies. We recognize that there are numerous operational issues to be addressed, and that the practical policies surrounding the provision of temporary coverage must be set forth by the agency in order to ensure a smooth rollout of the MCIT pathway. We offer comments on several of these considerations below. We also recognize that operational questions always arise when CMS proposes new coverage mechanisms – these are not entirely novel policy considerations and the agency is well-equipped to develop sound solutions.

In order to fulfill the spirit and goal of the original MCIT proposal and to realize the benefit for Medicare beneficiaries, we urge CMS to promptly move forward with implementing the MCIT coverage pathway for breakthrough technologies. Further, we encourage CMS to work with stakeholders to develop a plan to appropriately operationalize MCIT coverage through further regulation or sub regulatory guidance. In determining these operational considerations, we encourage CMS to maintain the ultimate focus on providing timely access to innovative technologies for beneficiaries. We do not believe a further delay of the MCIT rule or a withdrawal of the final rule is warranted, and we look forward to working with CMS to ensure that interim coverage is provided in a manner that maximizes access for beneficiaries.

Operational Issues

Given the consideration CMS is giving to the policy concerns noted in the IFC, we offer comments below on the most appropriate ways to operationalize the temporary MCIT coverage for breakthrough devices. We encourage CMS to consider these and other public comments and look for additional opportunities to engage stakeholders when developing further regulation or sub regulatory guidance to implement the MCIT pathway. We reiterate that developing responses to the policy issues raised below should not unduly delay the final implementation of the MCIT pathway, and we fully support moving forward with MCIT coverage to increase beneficiary access to innovative technologies.

As noted in the IFC, in order to provide actionable coverage to beneficiaries upon FDA market authorization for MCIT-eligible devices, CMS will need to make several determinations. First, CMS must determine whether the device in question falls into a Medicare benefit category to understand whether MCIT coverage will apply to the device. The final rule explicitly states that MCIT coverage will not be granted to breakthrough items that do not fall within a preexisting benefit category. If an affirmative benefit category determination (BCD) is advanced, the device will have to go through a coding process and CMS will determine reimbursement levels before an individual beneficiary will be able to access the item or service.

While the BCD, coding, and payment determination processes are largely laid out in statute and regulation, we note that these processes are often lengthy and arduous for manufacturers. Applying these processes without modification to the MCIT devices could seriously undercut the goal of providing timely access to innovative technologies. The ITEM Coalition and other stakeholders have also long aired significant concerns about these processes for standard Medicare coverage, including lack of transparency, lack of opportunities to challenge negative determinations, and more. Finally, the IFC notes that a separate proposed rule is currently being reviewed by CMS, which would set forth changes to the process for establishing BCDs and making payment determinations, and that stakeholders were not able to consider this proposal when commenting on the MCIT proposed rule.

Expedited Processes are Needed to Achieve the Benefit of MCIT Coverage

Both the MCIT final rule issued in January and the interim final rule issued in March note that benefit category and payment determinations must be made for CMS to operationalize coverage under the MCIT pathway. However, neither rule lays out a specific process for doing so. We have long noted concerns with the existing processes for coding, coverage, and payment for Medicare items and services. Our primary concern with the application of these processes to MCIT devices is the time it will take to make determinations for each product. The current process for BCDs, coding, and payment determinations can take months, even years, and often are considered subsequently rather than simultaneously. To achieve the goals of the MCIT pathway, these processes are simply not workable.

The purpose behind the proposed MCIT pathway is to “accelerate the coverage of new, innovative breakthrough devices to Medicare beneficiaries.” If MCIT coverage is granted without an accompanying BCD, appropriate coding, and adequate reimbursement levels, this coverage will not result in real access for Medicare beneficiaries. Whether or not the time to carry out these processes is counted against the four years provided for MCIT coverage, the end result will be that the Medicare population will not be able to achieve the practical coverage to which they will be entitled.

We urge CMS to develop significantly expedited processes for BCDs, coding decisions, and payment determinations for MCIT devices. The MCIT pathway was developed with the intention of filling the gap in coverage for innovative devices while the existing process for coverage unfolds (including evidence development, coverage analyses, coding, payment, and more). If MCIT devices are forced to undergo the standard processes for these determinations, beneficiaries will not be able to access these devices for significant periods of time.

It is critical that CMS exercise its authority to establish expedited processes to operationalize MCIT coverage to fulfill the goals of the program.

We note that there are myriad options for these expedited processes that can provide temporary coding and payment for MCIT devices without undermining the requirements of the existing processes for standard Medicare coverage. For example, CMS could utilize temporary Healthcare Common Procedure Coding System (HCPCS) codes for MCIT devices to sidestep the arduous coding process during the interim coverage period. Similarly, CMS could use the Manufacturer Suggested Retail Price (MSRP) or other easily obtained payment levels in order to ensure adequate reimbursement on an interim basis. Given the underlying goals of the MCIT pathway, it is important that these operational determinations do not provide a roadblock to beneficiary access to these devices.

We believe that whatever process CMS chooses to make these interim determinations, decisions should be made within 90 days of the identification of a newly eligible MCIT device (or within 90 days of the manufacturer's opt-in notice for the pathway). This will ensure that beneficiaries are able to access the devices in a timely fashion. We also believe that the four years of temporary coverage should begin once these determinations are made, that is, beginning on the first day on which a beneficiary could practically access the device in question. Additionally, manufacturers of MCIT-eligible devices should be afforded a clear and timely process to challenge negative determinations, especially benefit category determinations.

Finally, we urge CMS to utilize all available information on patient experience with MCIT devices during the initial determination process as well as during the four years of MCIT coverage to inform eventual permanent coverage decisions. Patient experience with Medicare-covered devices is a critical but often under-utilized category of information on the use of a device, and we believe that full consideration of such metrics aligns with the underlying goals of the MCIT program.

CMS Must Address Existing Problems with the Coding, Coverage, and Payment Processes

While the above recommendations apply particularly to the temporary MCIT coverage, we encourage CMS to consider opportunities to revise and improve the standard coding, coverage, and payment processes for the general Medicare program. We have long held concerns that the existing HCPCS coding process and the BCD process in particular have hampered the ability of manufacturers to effectively understand and participate in these processes, which lack transparency and are in many cases inconsistently applied. We have outlined many of these concerns in our recent [comments](#) on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues proposed rule issued in November 2020. We look forward to future actions by CMS regarding the proposals in this rule and future opportunities to engage with the agency to improve the coding, coverage, and payment processes. Ensuring a robust, actionable, and meaningful process to make these determinations is critical to providing necessary access to appropriate items and services for Medicare beneficiaries.

Medicare Patient Benefit/Protection

In the IFC, CMS raised potential concerns from some experts about how well breakthrough technologies will work for Medicare beneficiaries, specifically seniors. We believe that these concerns should not stand in the way of implementing the MCIT coverage. Though the evidence developed during the FDA breakthrough designation and market authorization process may not reflect outcomes specific to the Medicare population, this should not prevent the offering of temporary Medicare coverage. As noted in the final rule, CMS has the authority to remove a breakthrough device from the MCIT pathway if the FDA notes specific safety concerns via a warning letter or revocation of market authorization. We encourage CMS to continue monitoring additional evidence as it develops for MCIT devices throughout the temporary coverage period in case any specific concerns arise.

Additionally, we reiterate that considering the Medicare beneficiary population as synonymous with seniors over the age of 65 only does exclude 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. This group represents approximately 15% of the Medicare population, or nearly 9 million beneficiaries. Additionally, these beneficiaries account for a disproportionate share of Medicare spending, according to the Medicare Payment Advisory Commission. In fact, these beneficiaries may receive even more benefit from temporary MCIT coverage, given their unique needs. 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. Providing appropriate coverage of breakthrough devices via the MCIT pathway will help the Medicare program to better serve the needs of the entire beneficiary population.

Definition of “Reasonable and Necessary”

As stated in the ITEM Coalition’s previous comments, we would prefer that CMS withdraw this portion of the rule so that stakeholders and CMS can discuss this issue in greater depth. The proposed definition of “reasonable and necessary” will have longstanding implications for the coverage of Medicare benefits, and is not limited to the MCIT pathway. Therefore, we believe that it would be more appropriate to separate these two unrelated regulations, as they are entirely distinct. This proposal should instead be promulgated through a separate rulemaking process to allow more robust stakeholder engagement and the creation of a consensus-based proposal. Any action by CMS to revise, withdraw, or further delay the finalization of the “reasonable and necessary” definition should not impact the finalization of the MCIT pathway, which we continue to support.

Additionally, we continue to raise potential concerns with the consideration of commercial insurance coverage when determining whether an item or service is “appropriate for Medicare patients.” In our comments on the proposed rule, we supported this consideration of the commercial market, provided that CMS ensure this avenue is used to expand, rather than restrict or deny coverage. In the final rule issued in January 2021, CMS did not codify the proposed

modification to the Program Integrity Manual allowing commercial insurer policies to be the sole determinant of appropriateness for Medicare coverage. However, CMS did put forth regulatory language allowing the agency to consider “the majority” of commercial insurers in the event that an item or service does not meet the separately codified appropriateness criteria. CMS also stated that the agency would publish for public comment additional draft methodology for considering commercial policies.

As CMS considers how to develop this methodology, we continue to urge CMS to make clear that commercial coverage should be considered as additive to Medicare offerings, and not to use this authority to deny or restrict Medicare coverage. We believe that the regulatory language finalized in January does in fact address these concerns but encourage CMS to further clarify in future regulation and/or guidance. In instances where there is not a clear “majority” position by commercial insurers on coverage of an item or service, CMS should adopt the least restrictive coverage policy to fulfil the goal of ensuring the availability of and access to appropriate items and services for the Medicare population.

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 Steering Committee

ALS Association
Christopher & Dana Reeve Foundation
Paralyzed Veterans of America
Spina Bifida Association
United Spinal Association



November 2, 2020

SUBMITTED ELECTRONICALLY VIA 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).¹ 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

¹ 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).² 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 Order³ 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

² 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>

³ 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.⁴

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;

⁴ 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 65.⁵ 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

⁵ 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

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.

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

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***