



October 13, 2026

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: ITEM Coalition Comments in Response to the Regulatory Alignment for Predictable and Immediate Device Coverage Pathway Notice (CMS-3487-NC)

Dear Administrator Oz:

On behalf of the undersigned members of the Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition, we appreciate the opportunity to submit comments in response to the Centers for Medicare and Medicaid Services’ (“CMS”) recently announced Regulatory Alignment for Predictable and Immediate Device (“RAPID”) Coverage Pathway.¹ The ITEM Coalition strongly supports CMS’ effort to establish a more timely and predictable pathway to Medicare coverage for innovative medical devices and appreciates the Agency’s recognition that the current gap between Food and Drug Administration (“FDA”) approval (i.e., authorization) and Medicare coverage can unnecessarily delay beneficiary access to important assistive technologies and medical devices.

The ITEM Coalition is a consumer- and clinician-led coalition comprised of 103 national, non-profit organizations advocating for access to and coverage of assistive devices, technologies, and related services for people 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 limb loss and limb impairment, multiple sclerosis, spinal cord injury, brain injury, stroke, paralysis, cerebral palsy, spina bifida, hearing, speech, and visual impairments, and other life-altering conditions.

The ITEM Coalition supports RAPID’s fundamental objective and believes the pathway has the potential to substantially improve Medicare beneficiary access to innovative assistive devices and technologies. At the same time, several aspects of the proposal should be strengthened to ensure that accelerated coverage decisions remain grounded in Medicare’s reasonable-and-necessary standard and appropriately account for the needs of the diverse Medicare population, including beneficiaries with disabilities and chronic conditions.

¹ Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway, 91 Fed. Reg. 51,718 (August 11, 2026) <https://www.federalregister.gov/documents/2026/08/11/2026-16368/medicare-program-regulatory-alignment-for-predictable-and-immediate-device-rapid-coverage-pathway>

I. Background on Medicare Coverage and RAPID

For an item or service to be covered under Medicare, it must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”² CMS currently makes coverage determinations through several mechanisms, including national coverage determinations (“NCDs”), local coverage determinations (“LCDs”), claim-by-claim adjudication, and coverage with evidence development (“CED”). These existing coverage processes are lengthy and often delay access to innovative technologies to which Medicare beneficiaries are entitled. The proposed RAPID pathway would establish an additional, accelerated process for certain innovative medical devices and technologies.

The RAPID coverage pathway would establish a coordinated CMS-FDA process beginning during the premarket development of eligible FDA Breakthrough Devices. For an eligible Class II or Class III device, CMS would engage with the manufacturer and FDA during the investigational device exemption (“IDE”) pre-submission phase to identify Medicare-relevant clinical health outcomes and ensure that the pivotal IDE study is designed to generate evidence addressing those outcomes in the Medicare population. CMS would also conduct a preliminary assessment of the device’s Medicare benefit category and provide feedback on the evidence needed for a subsequent NCD, while coordinating with FDA to avoid duplicative evidence-development requirements.

If the device demonstrates the agreed-upon clinical outcomes and receives FDA market authorization, the manufacturer would submit an NCD request and CMS would release a proposed NCD on the same day as FDA authorization and publication of the relevant FDA decision document, followed by a 30-day public comment period. CMS would then target a final NCD approximately 60 days after authorization for Class II devices and 90 days for Class III devices. Where the evidence is insufficient to support coverage under Medicare’s reasonable and necessary standard, CED may be used.

This proposed process is a major advance over current coverage pathways. The ITEM Coalition’s comments below focus on ensuring that this accelerated process produces not merely a faster coverage decision, but a sound, predictable, and implementable Medicare coverage pathway.

II. RAPID Represents a Significant Improvement and Should Be Implemented

The ITEM Coalition strongly supports CMS’s proposal to establish the RAPID coverage pathway. RAPID responds directly to the longstanding need for a more timely, predictable, and coordinated process for moving innovative technologies from FDA authorization to Medicare coverage. Medicare beneficiaries, particularly individuals with disabilities and chronic conditions, can face years-long delays in obtaining innovative technologies that may improve their health, function, independence, and quality of life.

The ITEM Coalition has advocated for reforms to address these barriers for many years. In fact, in our 2023 comments in response to the Transitional Coverage for Emerging Technologies

² Social Security Act, 42 U.S.C. 1395y(1)(A)

(“TCET”) pathway,³ the ITEM Coalition recognized the need for CMS to develop a more streamlined approach to coverage of emerging technologies while expressing concern that the existing NCD and CED processes could not, without significant improvements and resources, provide sufficiently timely or predictable access. We also highlighted the particular challenges facing innovative durable medical equipment, prosthetics, orthotics, and supplies (“DMEPOS”), including the absence of an integrated and expedited benefit category determination (“BCD”) process. In 2025, the ITEM Coalition again urged CMS to establish a more robust and streamlined pathway for timely access to FDA-designated breakthrough technologies.

The ITEM Coalition’s own pending NCD reconsideration request for standing systems in power wheelchairs illustrates why these reforms are urgently needed. The ITEM Coalition submitted a NCD reconsideration request seeking Medicare coverage of standing systems in Group 3 power wheelchairs in September 2020. Although CMS accepted the request and deemed it “complete” in November of that same year, it remains pending over six years later, without CMS opening the NCD for public comment or establishing a clear timeline for action. Standing systems can provide important functional and health benefits for individuals who use power wheelchairs as their primary method of movement, including opportunities to stand, bear weight, and perform Mobility Related Activities of Daily Living (“MRADL’s”) in the home, the standard for Medicare coverage of durable medical equipment. These activities support health, function, and independence. The prolonged uncertainty surrounding this coverage request is Exhibit A in demonstrating the failure of the current coverage process and demonstrates the limitations of the current system.

The ITEM Coalition particularly supports the proposed concept of integrating Medicare coverage considerations into the device-development process rather than waiting until after FDA authorization to begin evaluating whether a technology is appropriate for Medicare coverage. Early CMS engagement can help identify evidence gaps before pivotal studies are completed, improve the relevance of the evidence generated for the Medicare population, and provide manufacturers with greater certainty regarding the information CMS will consider in making a coverage determination.

The ITEM Coalition emphasizes, however, that RAPID must accelerate the Medicare coverage process without conflating FDA’s standard for market authorization with Medicare’s statutory coverage standard. FDA determines whether a device is safe and effective for its intended use; CMS must separately determine whether an item or services is “reasonable and necessary” for Medicare coverage. FDA authorization therefore should not be treated as synonymous with, or automatically determinative of, Medicare coverage. RAPID should instead use the work undertaken during the FDA and CMS premarket processes to enable CMS to make its independent coverage determination more efficiently and predictably.

Recommendation: The ITEM Coalition urges CMS to finalize RAPID and preserve its proposed accelerated timelines while strengthening the pathway to ensure meaningful Medicare access. CMS should ensure that RAPID appropriately accounts for the needs of Medicare beneficiaries with disabilities and chronic conditions and recognizes functional outcomes as meaningful measures of health improvement. CMS should also ensure that RAPID provides an

³ Medicare Program; Transitional Coverage for Emerging Technologies, 88 Fed. Reg. 41,633 (June 27, 2023)

integrated process for benefit category, coding, and payment determinations, and maintains the distinction between FDA authorization and Medicare’s reasonable and necessary standard.

III. CMS Should Define “Health Outcomes” Broadly

The ITEM Coalition strongly supports CMS’s proposal to identify clinical health outcomes during the premarket phase of RAPID and incorporate those outcomes into the design of pivotal IDE studies. However, CMS should make clear that health outcomes encompass the full range of outcomes that are clinically meaningful to Medicare beneficiaries, including functional outcomes that are particularly important for individuals with disabilities and chronic conditions. This is essential to help ensure that RAPID does not inadvertently favor technologies that produce readily measurable traditional clinical endpoints over technologies whose principal benefits are to improve functional abilities of patients.

CMS’s proposed framework appropriately recognizes that health outcomes include how a patient “feels, functions, or survives.” For many rehabilitation and assistive technologies, the most meaningful evidence of clinical benefit may be demonstrated through improvements in function, independence, mobility, communication, self-management, or the ability to perform activities of daily living. These outcomes are not merely secondary measures of quality of life; for many Medicare beneficiaries, they are the direct and clinically meaningful consequences of treatment. A technology that enables an individual to transfer independently, ambulate more safely, perform personal care, communicate effectively, manage a chronic condition, or remain safely in the community can fundamentally alter that individual’s health status and need for other health care services, even if the technology does not directly affect mortality or a conventional disease-specific clinical endpoint.

This distinction is particularly important in the DMEPOS and rehabilitation context. Medicare beneficiaries who rely on wheelchairs, prostheses, orthoses, communication technologies, and other assistive devices frequently use these technologies *not* to treat a disease in the traditional sense, but to ***restore, maintain, or improve function and enable independent living***. Medicare’s reasonable and necessary standard expressly encompasses items and services used to improve the functioning of a malformed body member. CMS should therefore ensure that the RAPID pathway reflects this statutory recognition of function rather than relying primarily on clinical outcomes developed for pharmaceutical interventions or acute medical treatments.

CMS should also avoid defining functional outcomes too narrowly. Depending on the technology and the condition being treated, relevant and meaningful outcomes may include improvements in mobility, transfers, self-care, communication, upper- or lower-extremity function, ability to perform activities of daily living, independence, participation, self-management, prevention of secondary complications, reduced need for caregiver assistance, avoidance of institutional or higher-acuity care, and other measures of health and functional status. The appropriate outcomes will necessarily vary by technology, which is precisely why CMS’s early engagement with manufacturers and FDA under RAPID is valuable. CMS should work with stakeholders to identify outcomes that are clinically meaningful for the population for whom the technology is intended rather than imposing a one-size-fits-all hierarchy of outcomes.

Recommendation: CMS should finalize RAPID with explicit recognition that functional outcomes are legitimate and, where appropriate, primary clinical health outcomes for purposes of the pathway. CMS should ensure that the outcomes selected for RAPID studies reflect the intended population and use of the technology and encompass clinically meaningful improvements in function, independence, activities of daily living, mobility, communication, self-management, and other outcomes that directly affect the health and well-being of Medicare beneficiaries. This approach will help ensure that RAPID fulfills its purpose of accelerating access to innovative technologies without inadvertently disadvantaging the very rehabilitation and assistive technologies that can make the greatest difference in the daily lives of people with disabilities.

IV. RAPID Must Recognize the Diversity of the Medicare Population

The ITEM Coalition supports CMS’s proposal to require RAPID studies to enroll Medicare beneficiaries. However, CMS must ensure that the Medicare population is appropriately and meaningfully represented in the evidence used to support RAPID coverage decisions. Medicare is not exclusively a program for older adults; millions of individuals qualify for Medicare based on disability status, and the clinical characteristics, functional needs, and treatment goals of these beneficiaries can differ from those of beneficiaries who qualify based on age. In other instances, results from studies that include primarily younger adults can easily be applied to a population more advanced in age.

As the ITEM Coalition has previously emphasized, approximately 8 million Medicare beneficiaries under the age 65 qualify for Medicare based on disability. These beneficiaries are not a marginal component of the Medicare population. They include individuals with spinal cord injury, limb loss, brain injury, cerebral palsy, muscular dystrophy, and numerous other conditions that may result in significant functional limitations at significantly younger ages. For these beneficiaries, innovative rehabilitation and assistive technologies may be central to maintaining or restoring function, preventing secondary complications, avoiding institutional care, and supporting independent living. In addition, many disabilities and chronic conditions change with age, creating additional challenges for individuals as they approach the traditional Medicare cohort.

Accordingly, CMS should not determine whether a RAPID study is representative of the Medicare population simply by asking whether it includes an adequate number of beneficiaries age 65 and older. The relevant question is whether the evidence adequately represents the Medicare beneficiaries for whom the technology is intended, taking into account age, disability status, underlying condition, functional impairment, and other characteristics that may affect the technology’s use or outcomes. This is particularly important where a device is designed primarily to address a functional limitation rather than an age-related disease.

A lack of evidence in a particular Medicare subgroup should not automatically be interpreted as evidence that the technology is ineffective or not reasonable and necessary for that population. Where subgroup evidence is limited, CMS should consider the totality of the available evidence, including evidence from younger individuals with comparable conditions and functional impairments, real-world evidence, patient-reported outcomes, and other relevant sources.

Recommendation: CMS should finalize RAPID in a manner that recognizes the full diversity of the Medicare population, including beneficiaries under age 65 who qualify based on disability status. CMS should also require RAPID study designs to evaluate the relevance of evidence based on clinical and functional characteristics rather than chronological age alone.

V. The Benefit-Category Determination Should Be an Integral Component of RAPID

The ITEM Coalition’s most significant concern with prior versions of TCET was that absence of an integrated, transparent, and expedited benefit category determination (“BCD”) process. ITEM explained in our previous comments in response to the TCET pathway that this problem is particularly acute for DMEPOS because innovative technologies may straddle traditional definitions of durable medical equipment (“DME”), prosthetics, orthotics, and other Medicare benefit categories, making timely and predictable coverage especially difficult. Many benefit category definitions are antiquated and not well-suited to new generations of advanced technologies and medical devices.

RAPID improves upon TCET by requiring CMS to conduct a preliminary benefit category assessment. However, CMS states that participation in RAPID is *not* a final BCD and that the preliminary determination remains subject to change after FDA authorization. *This approach preserves a significant source of uncertainty that RAPID is intended to eliminate.*

A manufacturer could invest years designing and conducting an IDE study based on outcomes identified in coordination with CMS, complete the study, receive FDA authorization, and reach the proposed NCD, only to learn that CMS does not consider the device to fall within a Medicare benefit category. For DMEPOS and other assistive technologies, such an outcome could effectively render the substantial investment made by both manufacturers and CMS moot and leave beneficiaries facing the same coverage uncertainty RAPID is designed to address.

Recommendation: CMS should complete a formal BCD in a timely manner before accepting a technology into RAPID or, at a minimum, provide a binding preliminary BCD that cannot later be reversed absent material changes in the device, its intended use, or applicable law. A definitive BCD should be an integral component of RAPID, not an unresolved issue at the end of the process.

VI. Transitional RAPID Eligibility Process for Devices Already in Clinical Development

CMS specifically requests comment on whether it should establish a temporary process allowing devices that have moved beyond the IDE presubmission stage to enter RAPID.

The ITEM Coalition strongly supports such a transition. Without a transition mechanism, RAPID would create an arbitrary divide between otherwise eligible technologies based solely on where they happen to be in clinical development when the pathway becomes available. A device that began an IDE study shortly before RAPID was announced could have essentially the same clinical evidence, FDA pathway, and Medicare beneficiary population as a device entering RAPID at the IDE pre-submission stage, yet be categorically excluded. Such a development-

stage cliff would undermine RAPID’s central objective of providing a more timely and predictable pathway to Medicare coverage.

Recommendation: CMS should establish a transition period of *at least 24 months* during which otherwise eligible devices already subject to an IDE may apply for RAPID participation. CMS should determine whether an existing IDE protocol sufficiently evaluates the Medicare health outcomes relevant to RAPID. Where additional information is needed, manufacturers should be permitted to supplement the existing protocol or incorporate additional analyses, as appropriate, without being required to restart clinical development. We believe this approach would preserve the rigor of RAPID while ensuring that beneficiaries do not lose the benefit of the pathway simply because a promising technology entered clinical development before RAPID was established.

VII. Avoid Overreliance on CED and Establish Clear Off-Ramps to Permanent Coverage

The ITEM Coalition has longstanding concerns regarding the use of CED as the default solution for emerging technologies. In our prior TCET comments, we cited evidence that CED determinations between 2005 and 2022 lasted between one and 16 years, with only four technologies resulting in an NCD for continued coverage. The ITEM Coalition therefore urged CMS to devote additional resources to streamline the CED process and ensure that CED does not become a prolonged substitute for a definitive coverage determination.

RAPID improves the framework by requiring evidence development to be tied to identified evidence gaps. Nevertheless, CMS states that higher-risk technologies are more likely to have remaining evidence gaps and are therefore more likely to receive CED consideration. CMS should ensure that CED does not become a routine or indefinite condition of coverage. CED should address specific, material uncertainties, not serve as a default extension of the evidence-development process after FDA authorization and a RAPID NCD.

Recommendation: CMS should identify each specific evidence gap supporting CED, the outcome or evidence needed to resolve it, a defined evidence-development period, objective criteria for successful completion, and a target date for reconsideration. Most importantly, CMS should establish a clear off-ramp from CED and remove CED requirements promptly once the identified evidence-development objectives have been satisfied. This will ensure that CED functions as a targeted mechanism for resolving genuine evidence gaps rather than becoming an open-ended barrier to permanent Medicare coverage.

VIII. Explicitly Prohibit QALYs and Similar Disability-Discriminatory Measures

The ITEM Coalition has historically expressed concern that quality-adjusted life years (“QALYs”) and similar measures, including equal value of life-years gained (“evLYG”), can discriminate against people with disabilities by assigning less value to improvements in their lives and failing to adequately capture outcomes meaningful to these populations. Such measures are particularly problematic in the context of rehabilitation and assistive technologies, where principal benefits may include improvements in function, mobility, independence, participation, and the ability to perform activities of daily living rather than changes in longevity.

Recommendation: CMS should expressly prohibit the use of QALYs, evLYGs, or any substantially similar methodology that assigns differential value to health improvements based on disability status, age, life expectancy, or assumptions about an individual’s quality of life or functional capacity. CMS should also require contractors, evidence reviewers, and other entities supporting RAPID NCDs to disclose whether any cited evidence or analytic methodology incorporates such measures, allowing CMS and the public to identify and evaluate any potential disability bias in the evidence supporting a coverage determination.

IX. Preserve Meaningful Public Participation in the Expedited NCD Process

The ITEM Coalition stresses to CMS that the speed of RAPID must not come at the expense of meaningful public participation. CMS proposes a 30-day public comment period on the proposed NCD and anticipates finalizing the NCD “as early as” 60 or 90 days after FDA authorization. While the ITEM Coalition supports an expedited process, the abbreviated timeline makes transparency and meaningful stakeholder engagement particularly important.

Stakeholders must have timely access to the evidence and analyses underlying CMS’s proposed determination so they can meaningfully evaluate and respond to them within the available comment period. For technologies affecting people with disabilities, patient and clinical organizations can provide critical information about functional outcomes, clinical practice, caregiver needs, real-world use, and implementation considerations that may not be fully captured in clinical studies.

Recommendation: CMS should make publicly available, to the greatest extent permitted by law, the clinical outcomes identified during the premarket process, as well as the evidence and analyses supporting the proposed NCD. CMS should also make available any relevant Medicare beneficiary subgroup analyses, the preliminary and final BCD, the proposed coding and payment pathway, any proposed CED requirements and the evidence gaps supporting them, and a clear explanation of how CMS applied the Medicare reasonable and necessary standard. CMS should provide this information sufficiently in advance of the close of the public comment period to allow stakeholders a meaningful opportunity to review and respond.

CMS should also provide appropriate opportunities for beneficiaries, clinicians, and other relevant stakeholders to engage with the Agency during the premarket process, before key outcomes and evidence requirements are established. Finally, the ITEM Coalition encourages CMS to establish firm maximum timeframes for completing RAPID NCDs rather than characterizing the proposed timelines merely as targets. CMS should track and publicly report its performance against those timeframes and use this performance data to justify requests from Congress for additional resources to improve such performance and timely decision-making.

X. RAPID Must Include Coding and Payment Readiness

The ITEM Coalition stresses to CMS that a Medicare coverage determination is of limited practical value if beneficiaries cannot actually obtain the covered technology because the necessary coding or payment mechanisms have not been established. Coverage, coding, and payment are interdependent components of meaningful Medicare access and should be addressed together rather than sequentially after an NCD is finalized.

This issue is particularly important for DMEPOS and assistive technologies, where innovative products may not fit neatly within existing Healthcare Common Procedure Coding System (“HCPCS”) codes or benefit categories. The ITEM Coalition has repeatedly emphasized that outdated or overly broad HCPCS coding can impede beneficiary access, complicate evidence generation, and create uncertainty for providers and manufacturers. The ITEM Coalition has also previously raised concerns that inadequate or outdated DMEPOS payment methodologies can make new technologies effectively unavailable to beneficiaries even after Medicare coverage has been established. This problem has become more acute in recent years and dozens of examples exist to illustrate this problem that ITEM Coalition representatives would be happy to discuss in depth with CMS.

Recommendation: CMS should make coding and payment readiness an affirmative component of RAPID. Once a device enters RAPID, CMS should not only identify the benefit category but also identify the applicable HCPCS code and payment pathway, determine whether existing coding and payment mechanisms are adequate, and identify any coding or payment changes necessary to implement the anticipated coverage determination. Where existing mechanisms are inadequate, CMS should initiate the appropriate coding payment process early enough for applicants to challenge initial payment recommendations before implementation when the NCD takes effect.

CMS should also provide manufacturers with clear written determinations regarding the applicable coding and payment pathway and identify any unresolved issues that could delay beneficiary access. For technologies requiring new coding, a new payment methodology, or pricing under an existing methodology, CMS should establish a clear process and timeline for resolving those issues in coordination with the NCD process.

RAPID should therefore produce more than a timely coverage decision. By the time a RAPID NCD is finalized, the coding and payment infrastructure necessary to implement that coverage decision should be established or sufficiently advanced to permit beneficiaries to obtain the technology without a new series of delays.

XI. RAPID NCDs Should Be Written Broadly Enough to Apply to the Relevant Technology of Clinical Indication

CMS should ensure that RAPID NCDs are not unnecessarily limited to a single manufacturer or device when the evidence supports coverage of a broader category of technology or clinical indication. Device-specific NCDs could require CMS to repeat essentially the same coverage analysis each time a substantially similar technology reaches the market, unnecessarily delaying beneficiary access and creating the potential for inconsistent coverage of clinically comparable technologies.

Where supported by the evidence, CMS should structure RAPID NCDs around the relevant clinical indication, patient population, functional need, or category of technology rather than the identity of a particular manufacturer or product. This approach would allow RAPID to serve as a scalable coverage pathway and align Medicare coverage more closely with the clinical evidence rather than with individual product launches.

Recommendation: CMS should make clear the RAPID NCDs may be written at the appropriate clinical or technology-category level when supported by the evidence, rather than limiting coverage determinations unnecessarily to individual devices.

XII. RAPID Should Not Displace Coverage Opportunities for Other Innovative Technologies

The ITEM Coalition is concerned by CMS’s proposal to prioritize RAPID NCDs over non-RAPID NCDs on the NCD waitlist if CMS lacks sufficient resources to address both. While the ITEM Coalition strongly supports the goal of accelerating access to breakthrough technologies, CMS should not achieve that objective by diverting resources away from other technologies that may be equally important to Medicare beneficiaries. Otherwise, CMS could simply shift delays from one group of beneficiaries to another.

Many important rehabilitation and assistive technologies and devices may not receive FDA Breakthrough Device designation despite representing substantial clinical advances. Others may not satisfy RAPID’s Class II/TAP or Class III eligibility requirements. These technologies should not be disadvantaged simply because they fall outside the eligibility criteria for this new expedited pathway.

CMS should also establish an expedited transition mechanism for technologies that were previously preparing for or participating in the TCET pathway. Manufacturers should not be disadvantaged because they invested in clinical development and evidence generation in reliance on a CMS coverage pathway that has now been paused. Where a technology otherwise presents an appropriate candidate for expedited Medicare coverage review, CMS should permit the manufacturer to leverage evidence and CMS-FDA engagement developed through TCET rather than requiring the technology to restart the coverage-development process under RAPID.

Recommendation: CMS should dedicate sufficient, separately identifiable resources to RAPID so that implementation does not delay existing or pending NCD requests. CMS should also work with Congress to secure sufficient long-term resources for its broader coverage operations to address the existing NCD backlog and ensure timely consideration of innovative technologies both within and outside RAPID. RAPID should not be funded by diverting personnel or capacity from the broader NCD process.

CMS should use RAPID as an opportunity to strengthen and modernize the broader NCD infrastructure and develop additional mechanisms for timely review of innovative technologies that fall outside RAPID’s eligibility criteria. RAPID should be an additional pathway to coverage, not a substitute for improving Medicare’s underlying coverage infrastructure.

XIII. CMS Should Expand RAPID Beyond Its Initial Eligibility Criteria

The ITEM Coalition recognizes that CMS is appropriately beginning RAPID with a defined population of devices. However, the initial eligibility criteria should be treated as a starting point rather than a permanent limitation on technologies that may benefit from a more coordinated and predictable Medicare coverage process.

As proposed, RAPID would be limited to certain Class II Breakthrough Devices participating in the TAP and planning to submit a De Novo request, as well as Class III Breakthrough Devices planning a Premarket Approval (“PMA”) application. These criteria exclude numerous technologies that may offer substantial clinical benefits to Medicare beneficiaries but do not happen to fall within these particular FDA pathways.

Most importantly, CMS should remove the TAP participation requirement from RAPID eligibility. Eligibility for a Medicare coverage pathway should not depend on participation in a separate, voluntary FDA program with its own eligibility and capacity constraints. Eligibility should instead turn on whether the technology and its clinical development program can generate the evidence necessary for FDA authorization and CMS’s independent Medicare coverage determination.

Similarly, eligibility should not be driven by the particular FDA submission pathway a manufacturer uses when that pathway does not bear directly on whether CMS can obtain the evidence necessary to make a reasonable-and-necessary determination. CMS should not create incentives for manufacturers to pursue a particular FDA pathway solely to obtain access to Medicare’s expedited coverage process.

CMS itself acknowledges that Parallel Review remains available for a broader universe of technologies and indicates that it intends to consider updates to Parallel Review and other initiatives. CMS should build on these efforts and use experience with RAPID to develop a broader, more flexible framework for timely Medicare coverage of innovative technologies.

Recommendation: CMS should commit to evaluating RAPID after an initial implementation period and expanding eligibility based on experience and demonstrated need. Expansion should include additional Class II devices, Breakthrough Devices that do not participate in TAP, technologies using other FDA regulatory pathways where sufficient evidence can support a Medicare coverage determination, and technologies that do not receive Breakthrough Device designation but nevertheless represent substantial clinical advances. CMS should also consider innovative DMEPOS and assistive technologies that demonstrate meaningful improvements in functional outcomes. RAPID should therefore evolve toward a framework that identifies technologies based on their potential to satisfy Medicare’s coverage standard and address important unmet needs, including improvements in health, function, independence, and the ability to perform activities of daily living.

XIV. CMS Should Include Eligible Diagnostic Technologies in RAPID

The ITEM Coalition has concerns with CMS’s proposal to categorically exclude *in vitro* diagnostic technologies from RAPID. We find that a blanket exclusion is difficult to reconcile with the pathway’s broader objective of providing a timely and predictable process for Medicare coverage of innovative technologies. Diagnostic technologies can have significant implications for diagnosis, treatment decisions, disease management, and patient outcomes and should not be excluded solely because they are diagnostics.

If CMS believes diagnostic technologies require a different evidentiary or operational framework, it should establish a tailored process rather than exclude them altogether. CMS

could initially review eligible diagnostic technologies on a case-by-case-basis or establish a defined diagnostic track that incorporates appropriate expertise while preserving the core RAPID principles of early CMS-FDA coordination, Medicare-relevant evidence development, transparency, and timely coverage decisions. We believe strongly that excluding diagnostics categorically would unnecessarily limit RAPID's potential to address important coverage delays.

Recommendation: CMS should remove the categorical exclusion of *in vitro* diagnostic technologies and establish a mechanism through which eligible diagnostics can receive RAPID consideration, whether through the existing pathway or a tailored diagnostic track. Eligibility should depend on the ability to develop evidence sufficient for CMS to make an independent reasonable and necessary determination, not simply on the fact that the technology is diagnostic in nature.

For these reasons, the ITEM Coalition urges CMS to finalize RAPID with the modifications described above and to use the pathway as a platform for broader modernization of Medicare coverage, coding, and payment policies. Such reforms will help ensure that Medicare beneficiaries, including the millions of individuals who qualify for Medicare based on disability, can benefit from safe and effective innovations that improve health, function, independence, and quality of life.

Thank you for your consideration of these comments. We look forward to working with CMS to ensure that RAPID fulfills its promise of timely, predictable, and equitable access to innovative technologies. Should you have any further questions, please contact the ITEM Coalition Co- Coordinators at Peter.Thomas@PowersLaw.com and Michael.Barnett@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.

ACCSES

Alliance of Wound Care Stakeholders

ALS Association*

American Association of People with Disabilities

American Association on Health and Disability

American Cochlear Implant Alliance

American Congress of Rehabilitation Medicine

American Macular Degeneration Foundation

American Music Therapy Association

American Therapeutic Recreation Association

Association of Rehabilitation Nurses

Autistic Women & Nonbinary Network

Center on Aging and DIS-Ability Policy

Christopher & Dana Reeve Foundation*

Institute for Matching Person and Technology
International Registry of Rehabilitation Technology Suppliers
Lakeshore Foundation
Muscular Dystrophy Association
National Clinician Task Force
Perkins School for the Blind
RESNA
Rifton Equipment
Spina Bifida Association*
Team Gleason*
United Spinal Association*
VisionServe Alliance

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