

MEMORANDUM

To: ITEM Coalition Members

From: Peter Thomas, ITEM Coalition Coordinator
Michael Barnett, ITEM Coalition Coordinator
Leela Baggett, ITEM Coalition Low Vision Subgroup Coordinator

Date: January 23, 2024

Re: **ITEM Coalition 2023 Year in Review**

EXECUTIVE SUMMARY

We write to provide you with an update on the activities of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition in 2023. As we continue our work in 2024, we want to summarize the efforts made on behalf of the ITEM Coalition and its member organizations over the past twelve months.

The ITEM Coalition's strength as a representative coalition of organizations concerned with access to and coverage of assistive devices, technologies, and related services by Medicare, Medicaid, and other public and private payers for people with disabilities, chronic conditions, injuries, illnesses, and all other consumers is evident through its active and productive portfolio of advocacy efforts. This past year was no exception, as the ITEM Coalition engaged with policymakers and federal agencies to advance its targeted agenda of policy priorities.

This memorandum summarizes the ITEM Coalition's work across a number of key priorities in 2023 that were developed and affirmed in a vote by the ITEM Coalition membership early this year. Further information on the ITEM Coalition's activities, as well as our advocacy archives, can be found on the ITEM Coalition's website at www.itemcoalition.org. We encourage ITEM Coalition members and funders to review this memo and consider any suggestions for continued or new policy priorities in 2024. We will discuss our work this year and our plans for next year at the upcoming all-member meeting, scheduled for **Wednesday, January 24, from 12-2pm ET. The Annual Meeting will be held in-person at the Powers Law offices (1501 M Street NW, Washington, DC 20005) with a hybrid virtual option available via Zoom.** The meeting is open to all ITEM Coalition members, and all ITEM Coalition funders have been invited as guests. If you have any questions about the Annual Meeting, please contact Sarah Melone at Sarah.Melone@PowersLaw.com.

2023 ADVOCACY HIGHLIGHTS

In 2023, the ITEM Coalition engaged with Congress, the Biden Administration, and external stakeholders on a variety of key priorities for the Coalition. Significant additional advocacy efforts surrounded each of these initiatives, including outreach to Congressional offices and agency officials, grassroots advocacy, and partnerships with other community stakeholders. These efforts advanced the ITEM Coalition’s stated [2023 policy priorities](#), as well as additional goal of increased access to assistive devices, technologies, and related services. Our advocacy efforts are summarized below.

1. Seat Elevation and Standing Systems in Power Wheelchairs

In 2023, the ITEM Coalition secured a major victory when the Centers for Medicare and Medicaid Services (CMS) published a landmark final national coverage determination (NCD) concluding that seat elevation systems in power wheelchairs fall within the benefit category of durable medical equipment (DME) and is, therefore, covered under the Medicare program. As you recall, in 2020, the ITEM Coalition convened a large team of consumer, provider, and clinical experts to develop and submit a complete and formal [Request for Reconsideration of the NCD for Mobility Assistive Equipment \(MAE\)](#) requesting the following:

- 1) A Benefit Category Determination (BCD) that both power seat elevation and power standing systems are “primarily medical in nature” and thus covered within the DME benefit category under the Medicare program; and
- 2) Affirmative coverage of these systems for beneficiaries with a medical or functional need for these systems in order to perform or obtain assistance to participate in mobility-related activities of daily living (MRADLs), the standard for coverage of DME in the home.

The request was deemed “complete” by CMS in November 2020, but the agency delayed in opening the request for public comment. On August 15, 2022, CMS opened a National Coverage Analysis (NCA) for Power Seat Elevation Systems but did not open the related review of the medical evidence supporting coverage of power standing systems. Although the ITEM Coalition was seriously disappointed both with the decision to split the review of the two systems and the lack of a timeline for opening the standing systems NCA, the ITEM Coalition began a comprehensive campaign to demonstrate public support for coverage of both standing systems and power seat elevation.

On May 16, 2023, CMS published a favorable NCD governing power seat elevation. Under the final NCD, Medicare covers seat elevation in Groups 2, 3 and 5 Complex Rehabilitative Technology (CRT) power wheelchairs when a patient needs seat elevation to transfer from one surface to another—with or without caregiver assistance, assistive devices, or lift equipment—or to improve one’s reach in order to perform MRADLs. In addition, under the final NCD, Medicare covers seat elevation systems in non-CRT power wheelchairs when determined by Medicare contractors to be reasonable and necessary.

The NCD on power seat elevation systems exceeded our expectations and is being warmly embraced by the disability and rehabilitation communities. This NCD will improve the health, function, and quality of life of your constituents who are Medicare beneficiaries with Parkinson's disease, multiple sclerosis, cerebral palsy, spinal cord injury, paralysis, amyotrophic lateral sclerosis, limb amputation, lupus, rheumatoid arthritis, myositis, and other mobility-related conditions.

As we celebrate this major milestone in seat elevation coverage, we continue to urge CMS to proceed expeditiously with a separate NCA for power standing systems to ensure that Medicare beneficiaries can access these necessary systems. In July, the ITEM Coalition supported a [Dear Colleague Letter](#) organized by the United Spinal Association and led by Representatives Brian Fitzpatrick (R-PA) and Debbie Dingell (D-MI). This letter was supported by 12 Members of Congress, requesting that CMS open the NCA on standing systems in power wheelchairs. For individuals who spend large parts of their day in a seated position, the value of being able to stand, bear weight on the lower limbs, and allow gravity to aid in metabolic functions is well established in the clinical literature. The letter also urged CMS to conduct a full review of its current mobility device coverage coding and payment policies, including the "in the home" interpretation, to determine whether they are suitable in meeting the mobility needs of beneficiaries both within their homes and within their communities.

In September of 2023, CMS [responded](#) to both issues raised in the Congressional Dear Colleague letter. Regarding the standing systems NCD, CMS reiterated that because the evidence base for power seat elevation wheelchair systems is distinct from that of power wheelchair standing systems, CMS is considering these systems separately. CMS also noted that it continues to be engaged in the evaluation of both the research provided by the ITEM Coalition, as well as that found during CMS's own extensive literature searches. Again, no specific timeline was provided regarding the opening of the standing features NCD. Regarding the "in the home requirement," CMS stated that section 1861(n) of the Social Security Act limits the Medicare Part B benefit for DME to equipment used in the patient's home. Accordingly, CMS stated that changes by Congress to the statute are needed to modify the "in the home" requirement in the definition of DME at section 1861(n) of the Act.

In 2024, the ITEM Coalition will continue to advocate strongly for timely action on standing systems and engage with CMS and Congress to ensure that this priority moves forward in 2024. The ITEM Coalition will also work with Representatives Fitzpatrick and Dingell, as well as other Congressional champions, to urge Congress to amend Section 1861(n) of the Social Security Act to ensure that individuals with disabilities can get the support they need to live independently and to participate not just in their homes, but also in their communities.

2. Low Vision Aids and Devices

The ITEM Coalition has also maintained our dedicated efforts within the ITEM Coalition's Low Vision Subgroup to advance Medicare coverage of low vision aids. Current CMS policy holds that all devices that use one or more lens to aid vision or provide magnification of images for impaired vision are excluded from coverage due to language in the Medicare statute prohibiting

coverage of eyeglasses. In 2023, the Low Vision Group focused on both Congressional and Administration advocacy to address the “Low Vision Aid Exclusion.”

In January of 2023, CMS responded to the ITEM Coalition Low Vision Subgroup’s letter requesting that the agency initiate notice-and-comment rulemaking to rescind CMS’s eyeglass exclusion at 42 C.F.R. § 411.15(b). CMS did not commit to amending the regulation.

In March of 2023, the ITEM Coalition Low Vision Subgroup met with CMS to discuss the importance of low vision devices, the significant disparities in access to and use of low vision aids, the impact of lack of access to low vision devices, and the need for Medicare to cover low vision aids.

In December of 2023, the ITEM Coalition submitted a letter applauding Representative Doggett and Senators Cardin, Brown, Blumenthal, Fetterman, Welch, and Merkley for introducing [H.R. 33](#) (the *Medicare Dental, Vision, and Hearing Benefit Act of 2023*) and [S. 842](#) (the *Medicare and Medicaid Dental, Vision, and Hearing Benefit Act of 2023*). These bills include provisions designed to improve low vision benefits for Medicare beneficiaries. The ITEM Coalition Low Vision Subgroup expressed strong support for the provisions of this bill that would:

- Repeal the eyeglass exclusion;
- Define low vision devices as durable medical equipment for purposes of Medicare coverage; and
- Include “necessary services related to eye and vision health” as Medicare-covered services.

The ITEM Coalition Low Vision Subgroup also explored the possibility of supporting a Medicare demonstration of coverage for low vision devices.

In 2024, the ITEM Coalition Low Vision Subgroup will continue to advocate before the Administration and Congress to advance Medicare coverage of devices for individuals with vision impairments. The Powers firm has also been working with the VisionServe Alliance to highlight the lack of coverage of low vision services across all payers. The ITEM Coalition’s Low Vision subgroup is aware of this initiative and recognizes the advantage of promoting enhanced coverage for both low vision devices and services moving forward.

3. Accessible Web Information and Services of State and Local Government Entities.

In October of 2023, the ITEM Coalition [responded](#) to a DOJ proposed rule covering broad ICT accessibility issues, particularly regarding state and local governments’ obligations to provide websites and other ICT that are accessible to and usable by people with disabilities. While not perfect, the proposed rule represented a positive step forward in protecting the rights of individuals with disabilities, and our comment letter applauded the DOJ for issuing this regulation while offering some suggested refinements to better protect the vulnerable population it is intended to protect.

4. Accessible Medical Equipment and Technology

As in past years, the ITEM Coalition worked to expand adoption of accessible medical equipment for all people with disabilities. The U.S. Access Board promulgated technical standards in 2017 for accessible medical diagnostic equipment (MDE), including examination tables and chairs, weight scales, mammography and MRI machines, and more. However, these standards were not adopted into regulation by an enforcement authority like the Department of Justice (DOJ) or the Department of Health and Human Services (HHS) Office for Civil Rights (OCR). Unfortunately, many people with disabilities continue to encounter significant barriers to accessing medical equipment they encounter in a physician's office or other setting.

In November of 2023, the ITEM Coalition [responded](#) to HHS' proposed rule, which would implement requirements under Section 504 of the Rehabilitation Act of 1973 prohibiting recipients of federal financial assistance from discriminating on the basis of disability in their programs and activities. Our comments focused on proposals that would improve health equity by addressing equitable access to a number of benefits and services for people with disabilities, including: the prohibition of discrimination in medical decisions; the prohibition of the discriminatory use of value assessments; clarification regarding accessibility standards for web, mobile application and kiosk accessibility; and the establishment of enforceable standards for accessible medical diagnostic equipment.

The ITEM Coalition will continue to advocate for expanded accessibility of all technology used in a health care setting in 2024.

5. Exoskeletal Technologies and Powered Orthoses

In June of 2023, the ITEM Coalition hosted a special luncheon and briefing on exoskeletal technologies for people with disabilities. All ITEM Coalition members were invited to attend and special guests included ReWalk Robotics and Ekso Bionics, the two primary developers of the exoskeleton technology. The luncheon and briefing featured an in-person demonstration of the exoskeletal device by a ReWalk user.

In July of 2023, CMS published a proposed rule that would codify the current definition of an orthotic brace under the Medicare benefit ("rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body"). The proposed rule also clarified that exoskeletons and powered features designed to assist with traditional bracing functions are considered orthoses. In August, the ITEM Coalition submitted [comments](#) supporting this proposal. CMS finalized its definition of a brace in November of 2023.

This exciting and new technology has major implications on individuals with physical disabilities and the ITEM Coalition will be working with the Biden Administration and Congress to ensure that this technology is accurately and appropriately covered and coded to ensure access for Medicare beneficiaries who need it most in 2024.

6. Additional Medicare Issues

Intermittent Catheter Coding and Coverage Reform

The ITEM Coalition continues to advocate for improvements to the Medicare coding, coverage, and payment processes in order to ensure that people with disabilities have timely access to medically necessary technology. In June of 2023, the ITEM Coalition submitted a [letter](#) to CMS in support of intermittent catheter coding reform to ensure that individuals with disabilities and chronic conditions have access to the catheter that best meets their unique medical and functional needs. Specifically, the letter urged CMS to reform the current Healthcare Common Procedure Coding System (HCPCS) code set for intermittent catheters to better reflect advancement in technology design, promote the agency's goal of increasing health equity, ensure that patients receive medically appropriate intermittent catheters, facilitate the development of research and evidence-based guidance, and provide greater accountability in claims processing. The ITEM Coalition believes that a more precise code set will allow prescribers to better identify catheter features that align with the patients' exact medical and functional needs. We anticipate the HCPCS Workgroup to render a preliminary coding determination on this matter in 2024.

Additionally, CMS has not released a standalone proposed DMEPOS policy rule in 2023 although the agency did update the DMEPOS fee schedule as required in December 2023. Although the most recent update of the Administration's regulatory agenda does not include a DMEPOS rule projected for 2024, there is always a chance of additional rulemaking impacting the DMEPOS benefit in the coming year.

Transitional Coverage for Emerging Technology

The ITEM Coalition also continues to advocate for the development of an expedited coverage pathway for innovative technology. The ITEM Coalition had previously supported the Medicare Coverage of Innovative Technology (MCIT) rule finalized in the last days of the Trump Administration, which was then withdrawn by the Biden Administration in late 2021. This rule would have established a new coverage pathway to allow temporary, nationwide coverage for medical devices designated as "breakthrough" by the Food & Drug Administration (FDA).

In June of 2023, CMS published its long-awaited notice with comment period outlining a new Medicare coverage pathway designed to achieve more timely and predictable access to breakthrough technologies for Medicare beneficiaries. The new Transitional Coverage for Emerging Technologies (TCET) pathway uses current national coverage determination (NCD) and coverage with evidence development (CED) processes to expedite Medicare coverage of certain "breakthrough devices," deemed as such by the FDA. The ITEM Coalition [responded](#) in detail to the proposed TCET notice expressing our gratitude to CMS for taking this initial step. However, considering the existing shortcomings of the NCD and CED processes, we noted that it remains unclear whether this pathway will provide the streamlined access to innovative medical devices which it is intended to accomplish. The ITEM Coalition also submitted [written testimony](#) similar to the comments described above for the record to the House Energy and Commerce Health Subcommittee following a hearing that was held on TCET in August.

In December of 2023, the ITEM Coalition sent a [letter](#) of support for H.R. 1691, the [Ensuring Access to Critical Breakthrough Products Act of 2023](#) to House Energy and Commerce Committee leadership. Similar to the since-repealed MCIT pathway, this bipartisan legislation would ensure that FDA-designated breakthrough technologies are temporarily covered under Medicare during a four-year transitional period, while also establishing a pathway to make a permanent coverage determination. While not perfect, the ITEM Coalition believes that this bill would be a positive step in the right direction towards ensuring timely access to breakthrough devices for millions of Medicare beneficiaries.

While H.R. 1691 was ultimately not taken up in the first session of the 118th Congress, we plan to work with Congressional leadership to ensure action on this important legislation in 2024.

Medicare O&P Patient-Centered Care Act

In July, the ITEM Coalition sent a [letter](#) of support to the House sponsors of H.R. 4315, the [Medicare Orthotic and Prosthetic Patient-Centered Care Act](#), legislation focused on ensuring maximum function and independence for Medicare beneficiaries who use orthotic braces and prosthetic limbs while limiting waste, fraud, and abuse in the O&P benefit. This legislation would accomplish the following:

- Exempt certified and/or licensed orthotists and prosthetists from the requirement to have a competitive bidding contract in order to provide off-the-shelf (OTS) orthoses to their patients. This would allow O&P professionals to meet patients' needs efficiently and conveniently in the course of the practitioner's clinical practice, increasing patients' ability to easily access all the O&P care they need in a timely and convenient manner.
- Prohibit the practice of "drop shipping" all prosthetic limbs and custom-fabricated or custom-fitted orthoses. It would also ensure that beneficiaries have appropriate access to a health care practitioner to provide the necessary assessment, fitting, training and follow-up care for the proper use of their orthosis or prosthesis.
- Promote timely access to replacements of custom-fitted and custom-fabricated orthoses in the event that the ordering physician determines that the provision of a replacement is necessary.

While the legislation was not included in a year-end package before the end of the first session of the 118th Congress, we expect continued activity in the realm of O&P in 2024.

7. New Coalition Members

The ITEM Coalition added four new members in 2023. Our new member organizations include:

- **International Eye Foundation** – <https://www.iefusa.org/>
- **Prevention of Blindness Society of Metropolitan Washington** – <https://www.youreyes.org/>
- **Perkins School for the Blind** – <https://www.perkins.org/>

- **VisionServe Alliance** – <https://visionservealliance.org/>

These additions bring the total number of active ITEM Coalition members to 98 organizations. We look forward to continuing to expand in 2024 and to furthering our goal of increasing access to assistive technologies and devices for people with disabilities, injuries, illnesses, and chronic conditions. We invite all ITEM Coalition members to join us, in person or virtually, for our 2024 Annual Meeting where we will discuss our 2023 accomplishments and our policy priorities for the coming year.

The 2024 ITEM Coalition Annual Meeting will be held on Wednesday, January 24th, from 12-2pm ET. All current ITEM Coalition members and funders should have received a calendar invite with the dial-in information. If you have any questions regarding the meeting or to RSVP, please contact Sarah.Melone@PowersLaw.com.