MEMORANDUM

To: ITEM Coalition Members
From: Peter Thomas and Joe Nahra, ITEM Coalition Coordinators
Date: January 26, 2023
Re: ITEM Coalition 2022 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 2022. As we continue our work in 2023, we want to summarize the efforts made on behalf of the 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 2022 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 2023. We will discuss our work this year and our plans for next year at the upcoming all-member meeting, scheduled for Thursday, February 2, from 12-2pm ET. The Annual Meeting will be held in-person at the Powers Law offices (1501 M Street NW, Washington, DC) with a hybrid virtual option available via Zoom. The meeting is open to all ITEM Coalition members.

If you have any questions about the Annual Meeting, please contact Emily Goodwin at Emily.Goodwin@PowersLaw.com.
2022 Advocacy Highlights

In 2022, 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 meetings with Congressional offices and agency officials, grassroots advocacy and direct outreach to Members of Congress, and working in coalition with other organizations. These efforts addressed the ITEM Coalition’s stated policy priorities, as well as additional opportunities to advance our shared 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 2022, the ITEM Coalition advanced our multi-year effort to advocate for Medicare coverage of seat elevation and standing systems in power wheelchairs. 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 National Coverage Determination (NCD) for Mobility Assistive Equipment (MAE). This request sought two determinations from the Centers for Medicare and Medicaid Services (CMS) in service of this goal:

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 durable medical equipment (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 considerably 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. While 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 Coalition began a comprehensive campaign to demonstrate public support for coverage during the initial 30-day comment period.

The ITEM Coalition prepared a grassroots website, www.rise4access.org, to serve as a “one-stop shop” to guide individuals and organizations through the process of submitting comments. The website included draft talking points, background materials, step-by-step instructions, and more resources for comment submission. In addition to the website, we prepared a comprehensive awareness campaign including email blasts, social media posts, and direct outreach to ensure that all interested stakeholders were aware of the comment period and encouraged to submit their feedback. By the end of the 30-day comment period, CMS received more than 3,500 comments, unanimously supportive of coverage for power seat elevation systems. The agency will release a proposed decision by mid-February 2023, which will trigger a second 30-day public comment
period and will release a final decision by May 2023. The ITEM Coalition’s comments can be found here.

The ITEM Coalition advocated tirelessly with Congressional champions to produce two bipartisan letters signed by 22 Senators and more than 80 Representatives, calling on CMS to expedite the NCA for power seat elevation systems, topromptly issue an NCA for power standing systems, and to advance coverage for both systems. The House letter was led by the outgoing chair and incoming leaders of the Bipartisan Disabilities Caucus (Reps. Jim Langevin, Brian Fitzpatrick, and Debbie Dingell) as well as Rep. John Rose. The Senate letter was led by Sens. Tammy Duckworth, Bob Casey, and Marsha Blackburn.

The ITEM Coalition also partnered with the National Council on Disability to host a Roundtable Discussion on coverage for both systems on August 3, 2022, which included speakers representing the U.S. House and Senate, the National Council on Disability, the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), wheelchair users, health care providers, caregivers, and ITEM Coalition members. A summary report on the Roundtable and series of recommendations from the Council is forthcoming in early 2023.

The ITEM Coalition will continue to advocate strongly for timely action on both systems and engage with CMS and Congress to ensure that this priority moves forward in 2023.

2. Low Vision Aids and Devices

The ITEM Coalition has also maintained our dedicated efforts within the Coalition’s Low Vision Group to advance Medicare coverage of low vision aids. Current CMS policy holds that all devices that utilize a lens to aid or enhance vision are excluded from coverage due to language in the Medicare statute prohibiting coverage of eyeglasses. In 2022, the Low Vision Group focused on both Congressional and Administration advocacy to address the “Low Vision Aid Exclusion.”

In February, the ITEM Low Vision Group met with senior advisors to Dr. Meena Seshamani, Director of the Center for Medicare, to discuss the importance of rescinding the Low Vision Aid Exclusion. Representatives from patient and provider organizations and consumers with low vision detailed the prevalence of low vision among Medicare beneficiaries and the benefits of low vision aids, as well as the health equity considerations regarding disparities in access to these devices. The ITEM Coalition followed up with a letter to CMS urging action in 2023 to advance Medicare coverage of low vision aids.

The ITEM Coalition also addressed the need to rescind the Low Vision Aid Exclusion in our written testimony to the House Ways & Means Committee hearing on Bridging Health Equity Gaps for People with Disabilities and Chronic Conditions in February.

In August, the ITEM Coalition worked with our congressional champions (Reps. Kim Schrier, Tom O’Halleran, Elissa Slotkin, and Suzan DelBene) to prepare and send a congressional letter to CMS urging the agency to remove the Low Vision Aid Exclusion. The letter noted the racial
and ethnic disparities in the use of low vision aids as well as the discrepancy between Medicare’s coverage of low vision rehabilitation services and lack of coverage for low vision devices.

In 2023, the Low Vision Group will continue to advocate before the Administration and Congress to advance Medicare coverage of devices for individuals with low vision.

3. 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 February, the ITEM Coalition participated in a listening session with HHS regarding the forthcoming rule revamping the regulations under Section 504 of the Rehabilitation Act, which mandates that programs receiving federal funding do not discriminate on the basis of disability. During the meeting, the ITEM Coalition urged the Department to incorporate the Access Board’s standards into the Section 504 regulations and make them enforceable for health care providers. We also urged the Department to consider ways to expand the standards or create new standards that would apply to a wider range of equipment, including home-use devices, and apply to a wider range of disabilities (the 2017 standards only cover mobility disabilities and physical accessibility). We also urged the Department to consider the accessibility of information and communication technology (ICT), including websites and other digital technology used in a health care setting, when drafting the Section 504 regulations.

Later in March, representatives of the ITEM Coalition met with senior staff at the Department of Justice to discuss their work in the same area. We raised many of the same issues, as DOJ is expected to work closely with HHS in preparing the Section 504 regulations. DOJ has the ability to make the Access Board MDE standards enforceable across health care providers, whether or not they are covered under Section 504, and is conducting additional efforts around website and ICT accessibility more broadly.

The Coalition reiterated similar recommendations in our comments on HHS’ proposed rule to revise the Affordable Care Act’s (ACA) Section 1557 regulations, which mandate nondiscrimination in health programs and activities governed by the ACA.

In 2023, we expect to see continued rulemaking efforts in this area, including the final Section 1557 rule, along with the proposed rule to revamp the Department’s Section 504 regulations. The Department of Justice is also planning to release a proposed rule directly addressing the Access Board’s MDE standards, as well as a separate 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. The ITEM Coalition will continue to advocate for expanded accessibility of all technology used in a health care setting.

4. Treatment of Wheelchairs during Air Travel

In April, the ITEM Coalition Steering Committee sent a letter to the Department of Transportation regarding the treatment of wheelchairs during air travel. The Department has continued efforts to address numerous concerns with the accessibility of air travel including widespread issues with damaged or broken wheelchairs after flying. Our letter detailed some of the typical experiences of individuals with mobility impairments during air travel and the importance of ensuring safe transport of wheelchairs and other mobility devices. We also clarified that the definition of durable medical equipment, including the “in the home” restriction, is only applicable to CMS coverage standards and should not be used to absolve airlines of the responsibility to protect passengers’ mobility devices during transit.

We will continue to monitor developments regarding the treatment of durable medical equipment during air travel and weigh in as necessary on behalf of the Coalition in 2023.

5. Additional Medicare Issues

Medicare Coding, Coverage, and Payment 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 February, our testimony to the Ways & Means Committee noted that CMS has typically been slow to determine coverage and other considerations for technology in the DMEPOS benefit, especially in comparison to surgical equipment, medications, and other treatments. We stressed the importance of reforming and improving the Healthcare Common Procedure Coding System (HCPCS) Workgroup as well as the National Coverage Determination (NCD) and Benefit Category Determination (BCD) processes.

CMS has not released a standalone proposed DMEPOS policy rule in 2022 although the agency did update the DMEPOS fee schedule as required in December 2022. Though the most recent update of the Administration’s regulatory agenda does not include a DMEPOS rule projected for 2023, we do expect 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 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 proposed 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).
The ITEM Coalition participated in several stakeholder listening sessions hosted by CMS in February and March 2022 to inform the development of a new rule, now titled Transitional Coverage for Emerging Technologies (TCET). In October, CMS released an article providing some additional details on the framework for the rule, which is expected to be released in April 2023. We expect to respond in detail to the eventual proposed rule and welcome additional input from the membership regarding key provisions and recommendations for an expedited coverage pathway.

*Cochlear Implant NCD*
In March, the ITEM Coalition Steering Committee submitted comments in support of a proposed National Coverage Determination (NCD) reconsideration for Medicare coverage of cochlear implants. CMS proposed to expand the coverage criteria for cochlear implants based on current clinical evidence supporting the benefits of implantation for a wider range of beneficiaries. In September, CMS finalized a revision to the NCD in line with the original request from the field and the ITEM Coalition’s recommendation.

*Medicare O&P Patient-Centered Care Act*
In December, the ITEM Coalition sent a letter to the House and Senate sponsors of H.R. 1990/S. 2556, 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. While the legislation was not included in a year-end package before the end of the 117th Congress, we expect continued activity in the realm of O&P in 2023.

*Better Wound Care at Home Act*
In prior years, the ITEM Coalition has supported the Better Wound Care at Home Act, legislation intended to expand patient access to disposable negative pressure wound therapy (dNPWT) in the Medicare home health benefit. The majority of the legislation was included in the year-end omnibus package (the Consolidated Appropriations Act, 2023), removing key bureaucratic barriers for home health agencies and making it easier for patients to receive this treatment in their home. We expect CMS to issue notice-and-comment rulemaking implementing these provisions in the next Home Health Prospective Payment System proposed rule, which ITEM will be tracking closely.

*Triple A Study Act*
The ITEM Coalition has also supported the Access to Assistive Technology and Devices for Americans Study Act (the “Triple A Study Act”), which would direct the Government Accountability Office (GAO) to study issues related to health insurance and other coverage for assistive technologies, including prosthetic devices and custom orthoses for individuals with limb loss and limb difference. In April, the GAO agreed to initiate the study directly, at the urging of Congressional champions. This represents an important victory towards better understanding the current landscape for access to assistive technology across payers. The ITEM Coalition will continue to monitor the development of this study and support better data on access and utilization of assistive technology for all people with disabilities.
6. New Coalition Members

The ITEM Coalition added three new members in 2022. Our new member organizations include:

- All Wheels Up - [https://www.allwheelsup.org/](https://www.allwheelsup.org/)
- Michigan Disability Rights Coalition - [https://mymdrc.org/](https://mymdrc.org/)
- Muscular Dystrophy Association - [https://www.mda.org/](https://www.mda.org/)

The ITEM Coalition also welcomed Team Gleason to the ITEM Coalition Steering Committee.

These additions bring the total number of active ITEM Coalition members to 94 organizations. We look forward to continuing to expand in 2023 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 2023 Annual Meeting where we will discuss our 2022 accomplishments and our policy priorities for the coming year.

*The 2023 ITEM Coalition Annual Meeting will be held on Thursday, February 2, from 12-2pm ET.* All current ITEM Coalition members should have received a calendar invite with the dial-in information. If you have any questions regarding the meeting or to RSVP, please contact Emily.Goodwin@PowersLaw.com.