

M E M O R A N D U M

To: ITEM Coalition Members
From: Peter Thomas and Joe Nahra; ITEM Coalition Coordinators
Date: January 28, 2021
Re: ITEM Coalition Year in Review 2020

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 2020. As we enter 2021, we want to provide a summary of 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 private health plans for people with disabilities, seniors, and all consumers is evident through its active and productive portfolio of advocacy efforts. Despite the upheaval associated with the COVID-19 pandemic, 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 coalition priorities in 2020 that were developed and affirmed in a vote by the ITEM Coalition membership early last year. Further information on the ITEM Coalition's activities, as well as our advocacy archives, can be found on the [ITEM Coalition website](#). We encourage ITEM Coalition members and funders to review this memo and consider any suggestions for continued or new policy priorities for the Coalition's 2021 efforts to discuss at the upcoming all-member meeting, scheduled for [Friday, January 29 at 12:30pm ET](#). For more information or to RSVP for the annual meeting, please contact Emily Goodwin at Emily.Goodwin@PowersLaw.com.

2020 Advocacy Highlights

In 2020, the ITEM Coalition engaged with Congress, the Trump Administration, and external stakeholders on a variety of key priority issues for the Coalition. Significant additional advocacy efforts surrounded each of these initiatives including in-person meetings with Congressional offices and CMS/HHS officials, as well as grassroots advocacy and direct outreach to Members of Congress, working in coalition with other organizations in many instances. These addressed the ITEM Coalition's stated priorities, which can be found [here](#), as well as additional opportunities to

advance the goals 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 2020, the ITEM Coalition has significantly expanded its efforts to advocate for Medicare coverage of seat elevation and standing systems in power wheelchairs. In February, the Coalition convened a large team of consumer, provider, and clinical experts to volunteer their time to design a coverage strategy for these systems, after conversations with high-level staff at the Centers for Medicare and Medicaid Services (CMS) indicated an opportunity for advancement of coverage. We developed four separate subgroups, focusing on clinical criteria and scientific evidence, reimbursement and technology considerations, legal support, and consumer advocacy and congressional engagement, that met frequently, sometimes weekly, since March. These efforts culminated in the drafting and submission on September 15, 2020 of a formal [request for reconsideration](#) of the National Coverage Determination (NCD) for Mobility Assistive Equipment (MAE).

This request seeks two determinations from CMS in service of the goal to secure coverage of seat elevation and standing systems in Group 3 power wheelchairs:

- 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) Explicit 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.

This request was submitted to CMS along with a [letter of support](#) signed by 60 national disability and rehabilitation organizations as well as multiple addenda. It was well-supported, comprehensively footnoted, and included over 120 clinical, peer-reviewed articles. In conjunction with this effort, the ITEM Coalition engaged with bipartisan staff on the House Energy & Commerce, Ways & Means, and Education & Labor committees and the Senate Finance Committee, other key congressional offices, and other key agencies, including the Administration for Community Living and the National Council on Disability, to garner additional formal and informal support for the request.

Representatives from the ITEM Coalition have also held multiple virtual meetings and calls with CMS staff at both the Technology Coding and Pricing Group (TCPG) and the Coverage and Analysis Group (CAG) as CMS proceeds with the formal review of the request, which was deemed “complete” in November. The ITEM Coalition also contracted with Dobson | DaVanzo, an independent third-party health economist firm, to craft a report on the fiscal impact of coverage for these systems. The overall cost to the Medicare program over ten years was estimated to be \$111.9 million for seat elevation and \$198.5 million for standing systems, for a total of \$310 million.

As CMS continues the process of reviewing this request and proceeding with the requested determinations, the ITEM Coalition will continue to engage with the agency to ensure that all questions are answered and that coverage for these systems can be advanced. The Coalition has also engaged the incoming Administration to ensure new political staff is informed of the ongoing proceedings. This coming year will be very active on this issue. Once CMS “opens” an NCD review on these systems, there will be a public comment period, followed by an opportunity to work with CMS to answer questions they may have. A second comment period will follow once CMS announces its preliminary BCD and coverage recommendation. The ITEM Coalition will need to be active this year to help ensure a positive result to our request of CMS.

2. Low Vision Aids and Devices

After discussions with a number of internal and external stakeholders at the end of 2019, the ITEM Coalition formed a dedicated effort in 2020 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. To organize efforts opposing this restrictive interpretation, the ITEM Coalition convened several current member organizations, new members, and external advisors to join the Low Vision Group, which convened biweekly for much of 2020.

The Low Vision Group issued a [position statement](#) in June, asserting that the “low vision aid exclusion” amounts to a preemptive denial of *any* technology that uses a lens to aid vision and represents an indiscriminate denial of benefits for an entire subpopulation of people with medical needs and disabilities. The statement urged CMS to rescind the existing low vision aid exclusion and instead evaluate the medical/functional purpose of each individual assistive device and technology at issue.

In June, the Low Vision Group sent a [letter](#) to CMS and the Office of Management and Budget (OMB) requesting that the 2021 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) proposed rule include a Request for Information (RFI) on the coverage of low vision aids. While this was not included in the rule, the Low Vision Group submitted specific comments on the DMEPOS proposed rule, outlining concerns with the low vision aid exclusion, the prevalence of low vision among Medicare beneficiaries, the impact of low vision, and the medical and functional benefits of appropriate low vision and vision rehabilitation.

In 2021, the ITEM Coalition expects to continue efforts to advocate for expanded coverage of low vision aids, including by engaging with the incoming Administration and Congress to advance coverage. The subgroup committed to this issue met in early January and pledged additional funding to support this dedicated effort, but some general ITEM Coalition resources are expected to be utilized this year to support this initiative.

3. Medicare Competitive Bidding Program

In March, the ITEM Coalition Steering Committee sent a joint letter with the Coalition to Preserve Rehabilitation (CPR) Steering Committee to [Congress](#) and [CMS](#) requesting that non-invasive ventilators (NIVs) be exempted from the January 2021 round of the Medicare Competitive Bidding Program (CBP). Given the impact of the COVID-19 pandemic specifically regarding respiratory distress, the coalitions believed it was critical to postpone application of competitive bidding to NIVs. The ITEM Coalition has expressed long-standing concerns that the CBP has the potential to limit access, choice, and quality of care for impacted items. In April, CMS [announced](#) that it was removing the NIV product category from Round 2021 entirely, marking a significant victory for our efforts on this issue.

In July, a Congressional effort (led by Reps. Cathy McMorris Rodgers and Dave Loebsack) arose to delay the 2021 round of the CBP entirely in response to the ongoing impact of the COVID-19 pandemic. Along with other stakeholders, the ITEM Coalition participated in an advocacy campaign among Congressional offices to garner signatures on the Rodgers-Loebsack letter, which urged CMS to delay the CBP for one year or throughout the public health emergency, whichever is longer. The [final letter](#) had more than 100 signers in the House of Representatives.

While CMS did not entirely delay the 2021 round of the CBP, CMS did [announce](#) in October that the agency would not award competitive bidding contracts for 13 of the 15 product categories that were previously competed “because the payment amounts did not achieve expected savings.” CMS also noted that it took into account feedback from stakeholders requesting a delay of the program when finalizing this decision. For 2021, only off-the-shelf (OTS) back and knee braces were awarded competitive bidding contracts, representing 23 Healthcare Common Procedure Coding System (HCPCS) codes. The ITEM Coalition will continue to monitor this program to ensure that access to these benefits is not compromised.

4. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Proposed Rule

The ITEM Coalition prepared comments for the 2021 DMEPOS proposed rule, submitted on January 4, 2021. This year’s rule included several important policy proposals. The full Coalition comments, in addition to separate comments submitted by the ITEM Coalition’s Low Vision Group, addressed a number of issues in the proposed rule:

- *DMEPOS Fee Schedule Adjustments* – CMS proposed an extension of existing “transitional” adjustment methodologies to fee schedule payments for DMEPOS items and services furnished in non-competitive bidding areas beyond the expiration of the COVID-19 public health emergency. The ITEM Coalition supported the transitional methodologies, which protect access, quality, and choice of DMEPOS for Medicare beneficiaries, and encouraged the agency to extend the same transitional methodologies for items furnished in non-rural, non-contiguous non-competitive bidding areas.

- *HCPCS Level II Code Application Process* – CMS proposed to codify a series of processes for new devices and technologies to apply for codes under the Healthcare Common Procedure Coding System (HCPCS). The ITEM Coalition supported some provisions of the proposed process, including the biannual meetings, but recommended several broader reforms for the HCPCS coding process to improve transparency and involvement of stakeholder expertise.
- *Benefit Category and Payment Determinations for DMEPOS* – CMS also proposed to codify the process for BCDs and payment determinations for new DMEPOS items by reviewing these determinations as part of the HCPCS application process. The ITEM Coalition recommended additional modifications to the BCD regulations, including an appeals process for existing BCDs and payment determinations and increased expert input in the reviews.
- *“In the Home” Requirement* – CMS proposed to slightly modify the requirement that DME be “appropriate for use in the home” to allow coverage specifically for certain drugs or biologicals that are infused in the beneficiary’s home via an external infusion pump. ITEM did not oppose the modification, but urged CMS to reconsider the entire “in the home” requirement, which broadly limits coverage for DMEPOS that increase a beneficiary’s ability to perform activities of daily living outside of the four walls of their residence.
- *Exclusion of Complex Rehabilitative Manual Wheelchairs from the CBP* – CMS proposed to implement statutory language permanently excluding manual complex rehabilitative technology (CRT) wheelchairs from the Medicare CBP. The ITEM Coalition strongly supported this proposal and urged CMS to extend key payment protections to ensure beneficiary access to accessories and components used with these wheelchairs. Currently, these components will be paid at reduced rates beginning with the expiration of a temporary delay on June 30, 2021. The ITEM Coalition also sent a [letter](#) to the House Energy & Commerce Committee urging Congressional engagement on this issue in December.

5. Medicare Coverage of Innovative Technology

In November, the ITEM Coalition submitted [comments](#) in response to CMS’ proposed rule on Medicare Coverage of Innovative Technology (MCIT) and the definition of “reasonable and necessary” for items and services furnished under the Medicare program. This rule would 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). The rule would also codify in regulation a definition of the term “reasonable and necessary” to clarify coverage standards, with some modifications to the currently cited definition in the Medicare Program Integrity Manual.

The ITEM Coalition strongly supported the proposed MCIT pathway in order to expand access to breakthrough technologies. The Coalition also provided several recommendations to improve the MCIT pathway, including the implementation of a short-term extension process for the temporary coverage (proposed to be capped at four years), expansion of the “lookback” period for devices

approved by FDA prior to the effective date of the final rule, and expansion of the proposed pathway to encompass additional innovative technologies beyond the breakthrough category.

Regarding the proposed definition of “reasonable and necessary,” the ITEM Coalition recommended that CMS withdraw this portion of the proposed rule, given the far-reaching implications of the provision on coverage of Medicare benefits, and allow for more in-depth discussions with stakeholders to ensure a well-developed proposal is put forth. If CMS decided not to postpone this provision, the ITEM Coalition provided additional recommendations, including ensuring that the definition consider all populations of Medicare beneficiaries, not just those over age 65, when determining “appropriateness” for Medicare patients; adding language to include consideration of maintenance or prevention of deterioration of function as well as functional improvement; and considering commercial insurance policies exclusively as additive to Medicare offerings, not to deny or restrict Medicare coverage based on a lack of coverage for an item or service by private payers.

The ITEM Coalition will keep members updated on any developments regarding a final rule on the MCIT pathway. Due to the transition in Administrations, this rule is currently on hold pending review by the Biden CMS team.

6. Assistive Technology Research

In October, the ITEM Coalition sent letters to the [House](#) and [Senate](#) endorsing *H.R. 8581/S. 4343, the Access to Assistive Technology and Devices for Americans Study Act* (the “Triple A” Study Act). This legislation, introduced by Reps. G.K Butterfield and Brett Guthrie in the House and Sens. Marsha Blackburn and Tammy Duckworth in the Senate, would direct the Government Accountability Office (GAO) to craft a report evaluating appropriate coverage and provision of health care services to people with limb loss or limb difference, including information on the following areas:

- Timely access to care, including education for patients regarding their assistive technology options;
- Assessment and guidelines for assistive device determinations;
- Policies for matching specific assistive devices to individual needs;
- Affordability of assistive technology;
- Provision of rehabilitative services to support adoption of assistive technology; and
- Timelines for assessment of assistive technology and any related surgeries.

This report would also compare data on practices and outcomes across payers including Medicare, the Veterans Health Administration, and the commercial insurance market. This legislation would provide important data to inform future policies to increase access to appropriate, safe, medically necessary, and patient-centered care for people who utilize assistive devices and technology. The bill is expected to be reintroduced early in the 117th Congress, and we will keep members informed of future developments and opportunities to support the legislation.

7. Disposable Negative Pressure Wound Therapy

In May, the ITEM Coalition Steering Committee sent a [letter](#) to HHS Secretary Alex Azar and CMS Administrator Seema Verma urging CMS to review and revise burdensome billing requirements for disposable negative pressure wound therapy (dNPWT). Standard NPWT is an important treatment for individuals suffering from skin breakdowns and decubitus ulcers as a result of mobility impairments. In 2017, Medicare began to provide coverage and reimbursement (at the direction of Congress) of the disposable version of this therapy as a cost-effective, convenient, and patient-centered alternative to traditional NPWT. The ITEM Coalition strongly supported and assisted other organizations in passing this important legislation.

Unfortunately, dNPWT has remained underutilized by Medicare beneficiaries in the home setting due to burdensome billing requirements imposed by CMS under the home health payment system. Specifically, CMS requires home health agencies to bill for dNPWT using non-standard forms with which the agencies are unfamiliar and will not allow a home health visit to be reimbursed if the visit is solely for the purpose of administering dNPWT. CMS did not address our concerns about the billing requirements for dNPWT in the CY 2021 home health final rule. The May 2020 letter focused specifically on the potential for increased utilization of dNPWT to protect vulnerable beneficiaries during the COVID-19 pandemic by cutting down on excess contact between patients and providers and decreasing risk of exposure to the virus. The ITEM Coalition will continue to monitor any new developments regarding NPWT, and engage as necessary with CMS and other stakeholders to address the billing concerns and access to dNPWT.

8. New Coalition Members

The ITEM Coalition also added a number of new members in 2020, many of whom joined in concert with our efforts to improve coverage of low vision aids. The new member organizations include:

- American Academy of Ophthalmology
- American Council of the Blind
- American Macular Degeneration Foundation
- Child Neurology Foundation
- National Association of Rehabilitation Providers and Agencies
- Prevent Blindness
- Support Sight Foundation
- Viscardi Center
- Vision Council
- VisionServe Alliance

This brings the total number of ITEM Coalition members to 90 organizations. We look forward to continuing to expand in 2021 and furthering our goal of increasing access to assistive technologies and devices for people with disabilities, illnesses, and chronic conditions. We invite all ITEM

Coalition members to join us (virtually) for our 2021 Annual Meeting, where we will discuss our 2020 accomplishments and our policy priorities for the coming year.

The 2021 ITEM Coalition Annual Meeting will be held on Friday, January 29, from 12:30-2pm ET via Zoom. All current members should have received a calendar invite with the dial-in information; if you have any questions regarding the annual meeting, please contact Emily Goodwin at Emily.Goodwin@PowersLaw.com.