



June 24, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

The Honorable Russell T. Vought
Acting Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: FY 2021 DMEPOS Proposed Rule; Request for Information on Low Vision Devices

Dear Administrator Verma and Acting Director Vought:

On behalf of the undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition, we urge the Centers for Medicare and Medicaid Services (CMS) and the Office of Management and Budget (OMB) to include a Request for Information (“RFI”) on Medicare coverage of low vision devices in the Fiscal Year (FY) 2021 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) proposed rule. We understand this proposed rule is currently pending at OMB for clearance and hope it is able to be amended before being published as a proposed rule.

The ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as visual impairment, vision loss, hearing and speech impairments, multiple sclerosis, spinal cord injuries, brain injuries, stroke, paralysis, limb loss, cerebral palsy, spina bifida, and other life-altering conditions. The ITEM Coalition has also convened a Low Vision Working Group, comprised of ITEM Coalition members and additional advisors representing low vision device manufacturers, ophthalmologists, optometrists, and others, to address the issue of coverage for low vision devices in Medicare.

We have attached the ITEM Coalition’s position statement on the coverage of low vision devices as an appendix to this request and it can be found online [here](#).

As CMS and OMB prepare the FY 2021 DMEPOS proposed rule, we hope the agencies will consider including a solicitation for stakeholder feedback on the potential coverage of low vision aids and devices.¹ Access to low vision aids and devices is crucial for many beneficiaries who

¹ Low vision devices are those that alter the image size (magnification or minification), contrast, brightness, color, or directionality of an object through the use or combination of lenses, prisms, or other technology. Such devices include, but are not limited to: magnifiers and minifiers (hand-held, stand, and head-borne versions), telescopes (monocular or binocular and hand-held, head-borne, or spectacle-mounted versions), closed-circuit televisions

have a visual impairment to achieve better health outcomes, live independently, work, care for their loved ones, engage in civic functions, and perform everyday activities. However, existing CMS policy unnecessarily and preemptively denies coverage for any technology that uses “one or more lenses for the primary purpose of aiding vision” under the Low Vision Aid Exclusion promulgated in 2008.²

This policy interpretation serves as a significant barrier for many beneficiaries with low vision or other visual impairments to access prescribed and customized devices to meet their medical and functional needs. The Medicare statute prohibits payment for eyeglasses, eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, and procedures performed during the course of such examination to determine the refractive state of the eyes, but the statutory text does not address other vision-related items and services.³ The ITEM Coalition has long held that the existing regulatory interpretation of this section of the statute goes far beyond congressional intent and serves to deny critical and medically necessary benefits for an entire diagnostic category of beneficiaries with specific medical and functional needs. For example, the Medicare statute also prohibits payments for hearing aids or related examinations, yet CMS has determined that payment for cochlear implants is allowable. Additionally, CMS does provide payment for the IMT, an implantable intraocular lens intended to treat vision loss from macular degeneration, and for the Argus Retinal Prosthesis for severe vision loss from Retinitis Pigmentosa. The determination that all other low vision devices, equivalent in their therapeutic intent, are prohibited by the statutory language is simply an overreach.

Unfortunately, during the comment period for the proposed low vision aid exclusion in 2008, CMS largely dismissed the concerns of the ITEM Coalition and stakeholders across the disability community who commented at the time. In the intervening years, the needs of Medicare beneficiaries with low vision have persisted and the body of evidence supporting the use of low vision devices and, conversely, the consequences and complications of unaddressed low vision has grown. Low vision technology has continued to proliferate with new and improved devices, while access to care has continued to be impeded. On behalf of the ITEM Coalition Low Vision Working Group, we are committed to working with the federal agencies and the U.S. Congress to improve coverage of these devices for Medicare beneficiaries with low vision.

To that end, we request that CMS include in the FY 2021 DMEPOS payment rule that is currently under review at OMB a solicitation of public comment regarding the low vision aid exclusion and coverage of low vision aids and devices in the Medicare program in the form of a non-binding Request for Information.

It has been more than a decade since the low vision aid exclusion was finalized in regulation, and we believe it is crucial for stakeholders representing patients, providers, and the disability

(CCTVs), electronic optical enhancement devices (EOEDs), and optical character recognition (OCR) technology. Low vision devices do not include traditional eyeglasses or contact lenses when their sole purpose is to correct refractive error.

² Medicare Program; Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Final Rule. 73 Fed. Reg. 224 (Nov. 19, 2008).

³ 42 U.S.C. § 1395y(a)(7).

community to have a forum to provide the agency with updated clinical and scientific evidence regarding potential coverage of these devices. We hope that this narrowly tailored comment opportunity will serve to restart discussions with the agency about the path forward for improving coverage and Medicare support for beneficiaries with low vision.

Thank you for your consideration of our request. Should you have any further questions regarding this issue, please contact Joe Nahra, ITEM Coalition coordinator, by email at Joseph.Nahra@PowersLaw.com or call 202-349-4243.

Sincerely,

The Undersigned Members of the ITEM Coalition

American Academy of Ophthalmology
American Macular Degeneration Foundation
Assistive Technology Industry Association
Blinded Veterans Association
Prevent Blindness
The Support Sight Foundation
The Vision Council
VisionServe Alliance

Additional Supporting Organizations

Sage Vision
Vispero

CC:

Demetrios Kouzoukas, Director, Center for Medicare, CMS
Elizabeth Richter, Deputy Director, Center for Medicare, CMS
Jason Bennett, Acting Director, Chronic Care Policy Group, CMS
Jeanette Kranacs, Deputy Director, Chronic Care Policy Group, CMS
Joel Kaiser, Director, Division of DMEPOS Policy, CMS

Michelle Williams, Chief of Staff, OMB
Barbara Menard, Chief, Health, Education, Veterans, and Social Programs Branch, OMB
Lois Altoft, Assistant to the Director, OMB