



April 1, 2025

Submitted Electronically (stephanie.carlton@cms.hhs.gov)

The Honorable Stephanie Carlton
Acting Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Recommendation for Deregulation of Rule Barring Medicare Coverage of Low Vision Devices

Dear Acting Administrator Carlton:

On behalf of the Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition’s Low Vision Subgroup, we write to urge the Centers for Medicare and Medicaid Services (“CMS”) to rescind the Medicare “Low Vision Aid Exclusion” as part of the agency’s implementation of two recent Executive Orders.¹ Under the *Executive Order on Unleashing Prosperity Through Deregulation*, the agency must eliminate 10 prior regulations for each new regulation that is promulgated. The *Executive Order on Ensuring Lawful Governance and Implementing the President’s “Department Of Government Efficiency” Deregulatory Initiative* similarly directs each agency to identify unlawful regulations and regulations that undermine the national interest.

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. The ITEM Coalition’s Low Vision Subgroup is comprised of ITEM Coalition members and additional stakeholders representing individuals with blindness and low vision, ophthalmologists, optometrists, therapists, low vision device manufacturers, and others dedicated to addressing the lack of coverage of low vision devices in Medicare.

Access to low vision aids and devices is crucial for many beneficiaries who have a visual impairment to achieve better health outcomes, live more independently, work, care for their loved ones, engage in community activities, and perform everyday tasks. Low vision aids and devices include a broad range of assistive technology other than traditional eyeglasses and contact lenses and are prescribed and customized to meet the specific needs of individuals with visual impairments resulting from a range of conditions involving the eyes. Low vision aids can include, but are not limited to digital magnification devices, optical magnifiers, minifiers, prisms,

¹ <https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/>;
<https://www.whitehouse.gov/presidential-actions/2025/02/ensuring-lawful-governance-and-implementing-the-presidents-department-of-government-efficiency-regulatory-initiative/>.

head-borne optical and digital devices, and other items, including emerging technologies that may alter the image size, contrast, brightness, color, or directionality of an object to enhance its visibility to the user.

Low vision devices are often essential for individuals with low vision, allowing users to live more independently, productively, and safely while performing essential tasks and activities of daily living. The combination of prescribed low vision devices with visual rehabilitation and device training increases users' ability to manage medications, read financial and other personal documents, participate in education or employment, and integrate into the community independently. These benefits have been shown to improve patients' health-related quality of life, self-esteem, and mental health, while reducing the incidence of falls, injuries, and physical impairment, and lessening the risk of cognitive decline and dementia that can be associated with untreated low vision.

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; however, the statutory text does not address other vision-related items and services. In 2008, CMS finalized its regulation at 42 C.F.R. § 411.15(b), commonly referred to as the "Low Vision Aid Exclusion," excluding from Medicare coverage "all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision," subject to certain exceptions.²

CMS issued this regulation with little or no rationale or seeming need to do so. Prior to issuance of the proposed rule, some Administrative Law Judges had, in fact, begun to interpret the statute to allow coverage of certain low vision devices through beneficiary appeals, but there was certainly no risk of flooding the program with low vision device claims. In its comments to the proposed rule, the ITEM Coalition and many of its member organizations objected strenuously to the broad overreach of this proposed rule, which bars coverage for any device that improves low vision for beneficiaries based on the eyeglasses coverage exclusion to the Medicare program. In so doing, CMS broadly interpreted the statute to deny access to medically necessary low vision devices and technologies to an entire diagnostic category of Medicare beneficiaries, despite widespread existence of this medical condition among the Medicare population. This plenary bar in coverage continues to this day with devastating consequences.

Lack of proper supports for individuals with low vision leads to poorer health outcomes and increased strain on the health care system as a whole. Those with low vision experience a greater prevalence of chronic conditions, comorbidities, cognitive decline, preventative falls, and inability to complete activities of daily living than the general population.³ They are also more

² There are three exceptions: (1) post-surgical prosthetic lenses customarily used during convalescence for eye surgery in which the lens of the eye was removed, (2) prosthetic intraocular lenses and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens, and (3) prosthetic lenses used by beneficiaries who are lacking the natural lens of the eye and who were not furnished with an intraocular lens. 42 C.F.R. § 411.15(b)(2).

³ VISIONSERVE ALLIANCE, UNITED STATES' OLD POPULATION AND VISION LOSS: A BRIEFING, 17 (2022), <https://drive.google.com/file/d/1FnyenjMMa4LZNX1gbiaY8klWT-joyZ6D/view> [hereinafter "Vision Loss Briefing"].

likely to self-report their health as poor, and experience higher levels of isolation due to their condition.⁴ This has led to an increased dependency on skilled nursing care provided in nursing facilities in the blind and low vision population, and an annual loss of productivity of over \$8 billion.⁵

The ITEM Coalition believes that the Executive Orders cited in this letter gives CMS a new opportunity to revisit the breadth and lack of evidence for the position that the eyeglasses exclusion preempts Medicare coverage of all devices and technologies that use a lens to improve vision. We believe that CMS misinterpreted the statutory eyeglasses exclusion and engaged in broad regulatory overreach. This resulted in a significant barrier for many beneficiaries with low vision or other visual impairments to access medically necessary and customized devices to meet their medical and functional needs.

Therefore, we believe that the “Low Vision Aid Exclusion” at 42 C.F.R. § 411.15(b) is ripe for elimination under the Executive Orders. The ITEM Coalition formally requests CMS to rescind this regulation and allow Medicare beneficiaries to file claims for low vision devices and technologies, appealing any denials through the administrative appeals process. Our coalition is committed to working with you and the Administration to help ensure that Medicare beneficiaries with low vision finally have access to these important devices and technologies.

Should you have any further questions, please contact Peter Thomas and Leela Baggett, coordinators for the ITEM Coalition Low Vision Subgroup, by e-mailing Peter.Thomas@PowersLaw.com and Leela.Baggett@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition’s Low Vision Subgroup

American Academy of Ophthalmology
American Council of the Blind
American Macular Degeneration Foundation
Assistive Technology Industry Association
International Eye Foundation
Lighthouse Guild
Perkins School for the Blind
Prevent Blindness
Prevention of Blindness Society of Metropolitan Washington
Support Sight Foundation
VisionServe Alliance
The Vision Council

⁴ *Id.*

⁵ *Id.* at 9.

Additional Supporting Organizations

EyeSight Foundation of Alabama
Vispero