



January 4, 2021

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

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

RE: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues Proposed Rule (CMS-1738-P; RIN: 0938-AU17); ITEM Coalition Comments on Medicare Coverage of Low Vision Aids

Dear Administrator Verma:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) payment and policies for calendar year 2021 (the Proposed Rule).

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices and technologies 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 low vision and visual impairments, hearing and speech impairments, multiple sclerosis, paralysis, spinal cord injury, cerebral palsy, brain injury, stroke, spina bifida, myositis, limb loss, and other life-altering conditions.

The following comments are submitted on behalf of the ITEM Coalition's Low Vision Group and the undersigned members of the Coalition; they focus on the Medicare program's regulatory interpretation of the statutory "eyeglass" exception which serves to exclude coverage for low vision aids under the DMEPOS benefit. The ITEM Coalition has also submitted comments regarding general provisions in the Proposed Rule under separate cover.

Medicare Coverage of Low Vision Aids

Individuals with low vision and other vision-related impairments face significant obstacles in carrying out activities of daily living (ADLs). Literature also suggests significant association between visual impairment and a variety of physical and mental comorbidities, including

depression, social isolation, incidence of falls, and dementia.^{1, 2} Various forms of assistive devices exist to treat visual impairment, such as hand-held magnifiers, video monitors, and other technologies that utilize lenses to enhance vision. These tools are often essential for individuals with visual impairments and can allow these individuals to perform essential tasks such as reading prescription labels, mail, financial documents, and other important materials.

Despite the availability of such low vision devices and the numerous benefits to health and function they afford beneficiaries with visual impairments, CMS unnecessarily and preemptively denied coverage of any technology that uses “one or more lenses for the primary purpose of aiding vision” in its CY 2006 proposed and 2008 final DMEPOS rules. This restrictive policy goes far beyond congressional intent in defining the Medicare benefit and denies critical and medically necessary assistive devices for an entire diagnostic category of beneficiaries with specific medical and functional needs. As such, the ITEM Coalition urges CMS to rescind the “low vision device exclusion” and consider coverage of low vision aids under the standard coverage determination process.

Low Vision Device Exclusion

In 2006, CMS proposed to clarify in regulation that the scope of the eyeglass coverage exclusion in the Medicare statute encompasses “all devices irrespective of their size, form, or technological features that use one or more lenses to aid vision or provide magnification of images for impaired vision.”³ This regulatory change was proposed even though the agency recognized the fact that several court decisions found that the Medicare law does not prohibit payment for video magnifiers, a type of low vision device.

This regulation was finalized in 2008⁴, despite overwhelming stakeholder opposition to the proposal, including that of the ITEM Coalition. Public commenters raised a variety of concerns with the proposal, including the vast medical and functional benefits provided by low vision devices, the clear distinction between low vision devices and eyeglasses or contact lenses, the disincentive for innovation and manufacturing of new technology provided by categorical non-coverage, and more. CMS finalized the proposed low vision device exclusion without modification, noting disagreement with stakeholder concerns.

The ITEM Coalition continues to believe that the low vision device exclusion represents an overly restrictive interpretation of statutory language that should be rescinded to ensure that

¹ See., e.g., Court H., McLean G., et al. (2014). Visual Impairment is associated with Physical and Mental Comorbidities in Older Adults: A Cross-Sectional Study. *BMC Med.* 12:181. Doi: 10.1186/s12916-014-0181-7.

² Wood. J., Lacherez, P. et al. (2011) Risk of Falls, Injurious Falls, and Other Injuries Resulting from Visual Impairment among Older Adults with Age-Related Macular Degeneration. *Investigative Ophthalmology & Visual Science* 52 (5088-5092). Doi: 10.1167/iovs.10-6644.

³ Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule, 71 Fed. Reg 83, p. 25659-25660 (May 1, 2006).

⁴ Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Final Rule, 73 Fed. Reg. 224, p. 699009-69910 (Nov. 19, 2008).

beneficiaries are able to access the care to which they are entitled under the Medicare program. Additionally, this interpretation is inconsistent with the treatment of other devices related to statutorily excluded benefits. 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, correctly noting that though these devices improve hearing, they are separate and distinct from the benefits Congress clearly intended to exclude. Equivalently, CMS does provide payment for the Implantable Miniature Telescope (IMT), an intraocular lens intended to treat vision loss stemming from macular degeneration, and (when it was available) for the Argus Retinal Prosthesis for severe vision loss from Retinitis Pigmentosa. As a result, the determination that all other low vision devices, equivalent in their therapeutic intent, are prohibited by the statutory language we believe is simply an overreach.

In the intervening years since the finalization of the rule, the needs of Medicare beneficiaries have persisted. The body of evidence supporting the use of low vision devices, and conversely, the consequences and complications of unaddressed low vision, has grown significantly. Low vision technology has continued to proliferate with new and improved assistive devices, while access to care has continued to be impeded. Medicare's preemptive coverage policy has had a ripple effect on coverage by other payers, leading to access problems for Medicare and other beneficiaries and enrollees in need of enhanced vision. We are committed to working with CMS to improve coverage of these devices for Medicare beneficiaries with low vision.

Low Vision Among Medicare Beneficiaries

Low vision and blindness significantly impact Medicare beneficiaries and the general population. In fact, low vision has been noted as one of the most prevalent causes of disability across the country. Low vision is typically defined (using the World Health Organization's International Classification of Functioning, Disability, and Health) as a best-corrected visual acuity (BCVA) of less than 20/60.⁵ Legal blindness is defined as a BCVA of 20/200 or less.⁶

Recent analyses of data from the National Health and Nutrition Examination Survey (NHANES) demonstrate the breadth of the impact of low vision in the United States. Among older adults, there were 1.48 million individuals with low vision or worse in 2017. When examining populations of all ages, there were nearly 1.85 million individuals with low vision in 2017.⁷ It is critical that the Centers for Medicare and Medicaid Services take into account the full population of individuals with low vision in the United States when reviewing the agency's coverage decisions. Too often, CMS and its contractors consider the Medicare population to consist of seniors over the age of 65 only. This frame of reference excludes the significant portion of the Medicare population that is under 65 (approximately 15% of all Medicare beneficiaries),

⁵ World Health Organization. International classification of impairments, disabilities, and handicaps: a manual of classification relating to the consequences of disease. Geneva, Switzerland: World Health Organization; 1980.

⁶ US Social Security Administration. Disability evaluation under Social Security. 2.02 *Loss of central visual acuity*.

⁷ Chan T; Friedman S; Bradley C; Massof R. Estimates of Visual Impairment, Low Vision, and Blindness in the United States. *JAMA Ophthalmol*. doi:10.1001/jamaophthalmol.2017.4655. Published online Nov 2, 2017.

including those with long-term disability and beneficiaries dually eligible for Medicare and Medicaid coverage.⁸

Of course, the visually impaired population is not static; the prevalence of low vision and blindness is growing quickly, with approximately 480,000 new cases of mild low vision or worse, 180,000 cases of moderate low vision or worse, and 134,000 newly legally blind individuals each year.⁹ By 2030, there are expected to be 2.45 million cases of low vision or worse; this number will continue to grow to nearly 3.3 million by 2050. As Drs. Chan and Massof note in their analysis of the prevalence of low vision, the exponential growth in these conditions implies a greater need for services to treat low vision in the future, especially as the Medicare population continues to age.

Impact of Low Vision

Reduced visual function impacts individuals' lives in myriad ways, reducing participation in activities of daily living, employment, and the community; decreasing individual safety and function; and reducing ability to manage other health conditions.^{10, 11, 12} Appropriate vision rehabilitation, *with effective devices and device training*, can mitigate much of this negative impact.^{13, 14, 15} One recently-published (December 2020) study noted the "significant" functional difficulty associated with age-related macular degeneration, a condition often addressed with low vision aids, resulting in physical impairment even when controlling for comorbidities.¹⁶

The safety risks of low vision include an inability to manage medications; patients with low vision are more than twice as likely to require assistance to manage medications.^{17, 18} Difficulty with reading labels can also lead to misuse of products and difficulty with meal preparation. Low vision also impacts independence, as difficulty with reading can decrease the ability to manage

⁸ Medicare Payment Advisory Commission (MedPAC): Health Care Spending and the Medicare Program: A Data Book, p. 22 (July 2020). http://www.medpac.gov/docs/default-source/databook/july2020_databook_entirereport_sec.pdf?sfvrsn=0

⁹ Chan, et al. Estimates of Visual Impairment, Low Vision, and Blindness in the United States.

¹⁰ Hong T, Mitchell P, Burlutsky G, et al. Visual impairment and subsequent use of support services among older people: longitudinal findings from the Blue Mountains Eye Study. *Am J Ophthalmol* 2013;156:393-9.43.

¹¹ West SK, Munoz B, Rubin GS, et al. Function and visual impairment in a population-based study of older adults. The SEE project. *Salisbury Eye Evaluation. Invest Ophthalmol Vis Sci* 1997;38:72-82.44.

¹² Weih LM, Hassell JB, Keeffe J. Assessment of the impact of vision impairment. *Invest Ophthalmol Vis Sci* 2002;43:927-35.28.

¹³ Van Nispen RMA, Virgili G, Hoeben M, Langelan M, Klevering J, Keuen JEE, van Rens G. Low vision rehabilitation for better quality of life in visually impaired adults. *Cochrane Database of Systematic Reviews*. 2020.

¹⁴ Lamoureux EL, Pallant JF, Pesudovs K, Rees G, Hassell JB, Keeffe JE. The effectiveness of low-vision rehabilitation on participation in daily living and quality of life. *Invest Ophthalmol Vis Sci*. 2007;48(4):1476-82.

¹⁵ Binns AM, Bunce C, Dickinson C, Harper R, Tudor-Edwards R, Woodhouse M, et al. How effective is low vision service provision? A systematic review. *Surv Ophthalmol*. 2012;57(1):34-65.

¹⁶ Mitchell W, Resnick H, Zebardast N. Age-related Macular Degeneration and Visual and Physical Disability in a Nationally Representative Sample from the United States. *Trans. Vis. Sci. Tech*. 2020;9(13):42.

¹⁷ Feinberg JL, Rogers PA, Sokol-McKay D. Age-related eye disease and medication safety. *Ann Longterm Care* 2009;17:17-22.

¹⁸ McCann RM, Jackson AJ, Stevenson M, et al. Help needed in medication self-management for people with visual impairment: case-control study. *BR J Gen Pract* 2012;62:3530-750.

one's finances, for example, or conduct other crucial activities.¹⁹ Appropriate vision rehabilitation can assist individuals with low vision to utilize devices to allow them to remain in or re-enter the workforce or participate in volunteer activities to support their communities.

These negative impacts of low vision also have wide-ranging ripple effects on individuals with low vision. Multiple studies have shown a strong relationship between visual impairment and falls, a notable risk for older Medicare beneficiaries, often contributing to nursing home and other institutional placements.²⁰ Difficulty participating in society, maintaining independence, accessing information, and ambulating safely and without falls can contribute to poor quality of life and/or diminished mental health.^{21, 22, 23} It is known that individuals with vision loss have greater social isolation and increased depressive and anxiety disorders.^{24, 25}

Background on Low Vision Aids

CMS' current interpretation of the statutory eyeglass exemption treats traditional eyeglasses and contact lenses as indistinguishable from all other devices that utilize a lens in any way to address visual impairments. This conflation of separate and distinct categories of device does a disservice to Medicare beneficiaries who stand to benefit significantly from improved access to low vision aids. Eyeglasses, the category of device intended for exclusion from Medicare coverage in statute, are used to correct or improve the vision of people with nearsightedness, farsightedness, presbyopia, and astigmatism. The lenses used in eyeglasses and/or contact lenses work to focus the light more precisely on the retina to clear the field of vision as much as possible. These lenses are typically worn consistently throughout users' active time and typically assist in a variety of daily activities. Finally, the other ocular tissues of those who exclusively use conventional eyeglasses can be completely healthy.

In contrast, low vision devices are used specifically by individuals with visual impairments (visual disability) that *cannot* be corrected by conventional eyeglasses. These may include, but are not limited to, such devices as hand-held monitors, video monitors, magnifiers, minifiers, prisms, head-borne devices, and other items, as well as emerging technologies, that may alter the image size, contrast, brightness, color, or directionality of an object to enhance its visibility to the user. These tools are typically task-specific and often essential for individuals with low vision to live independently, productively, and safely. Users of low vision devices generally

¹⁹ Hassell JB, Lamoureux EL, Keeffe JE. Impact of age-related macular degeneration on quality of life. *Br J Ophthalmol* 2006;90:593-6.27.

²⁰ Wang JJ, Mitchell P, Cumming RG, Smith W. Visual impairment and nursing home placement in older Australians: the Blue Mountains Eye Study. *Ophthalmic Epidemiol.* 2003;10(1):3-13.

²¹ White UE, Black AA, Wood JM, Delbaere K. Fear of falling in vision impairment. *Optom Vis Sci* 2015;92:730-5.38.

²² Wang MY, Rousseau J, Boisjoly H, et al. Activity limitation due to a fear of falling in older adults with eye disease. *Invest Ophthalmol Vis Sci* 2012;53:7967-72.39.

²³ Ramulu PY, van Landingham SW, Massof RW, et al. Fear of falling and visual field loss from glaucoma. *Ophthalmology* 2012;119:1352-8.40.

²⁴ Chan EW, Chiang PP, Liao J, et al. Glaucoma and associated visual acuity and field loss significantly affect glaucoma-specific psychosocial functioning. *Ophthalmology* 2015;122:494-501.

²⁵ Wang JJ, Mitchell P, Smith W, et al. Incidence of nursing home placement in a defined community. *Med J Aust* 2001;174L271-5.42.

utilize the device only when participating in the activity that the device assists. The other ocular tissues of individuals with low vision are most often not healthy, that is, there is typically an eye disease creating the impairment or disability.

Benefits of Low Vision Aids

In 2009, researchers conducted a well-regarded review of the existing literature on the effectiveness of assistive technologies for low vision rehabilitation. The authors concluded: “The findings of our review indicated that optical devices (electronic and nonelectronic) are effective and accessible rehabilitation options. Moderately strong evidence indicates that electronic stand-mounted or handheld CCTVs can improve reading performance and are generally preferred by persons with low vision over standard nonelectronic optical devices. Simple nonelectronic magnifiers are still preferred by individuals when portability and cost may be an issue.”²⁶

An array of clinical studies indicate the various benefits of the utilization of low vision devices, when paired with effective, evidence-based low vision rehabilitation services. One trial noted that integrating mental health services with low vision interventions, including the use of relatively inexpensive (< \$350 per person) low vision devices, was able to halve the incidence of depressive disorders in patients with age-related macular degeneration (AMD).²⁷ Another demonstrated that visual rehabilitation, including device prescription and training, improved patients’ health-related quality of life, self-esteem, and mental health.²⁸

It is clear that the provision of low vision aids, along with necessary training and services, can significantly impact the health of Medicare beneficiaries, and reduce the incidence of injuries and other conditions that are major common drivers of both negative health outcomes and high costs to the Medicare program.

Low Vision Services Under Medicare

Currently, the Medicare program does provide coverage for vision rehabilitation services for beneficiaries with visual impairments ranging from low vision to total blindness. Vision rehabilitation under Medicare encompass a number of services covered for other conditions, including therapies to enhance mobility, ability to perform activities of daily living, and other medically necessary rehabilitation goals. Additional criteria define the limits of coverage for these services, similar to coverage conditions for other rehabilitation services, including clear and defined goals, potential for restoration or improvement of lost functions, and provision by qualified physicians or therapists.²⁹

²⁶ Jeffrey W. Jutai, J. Graham Strong, and Elizabeth Russell-Minda. Effectiveness of Assistive Technologies for Low Vision Rehabilitation: A Systematic Review. *Journal of Visual Impairment and Blindness* 2009; Vol103, No4

²⁷ Rovner BW, Casten RJ, et al. Low Vision Depression Prevention Trial in Age-Related Macular Degeneration: A Randomized Clinical Trial. *Ophthalmology* 2014;121:2204-11.

²⁸ Kuyk, T, Liu L, et al. Health-related Quality of Life Following Blind Rehabilitation. *Qual Life Res* 17:497-507 (2008).

²⁹ Centers for Medicare and Medicaid Services. Provider Education Article: Medicare Coverage of Rehabilitation Services for Beneficiaries with Vision Impairment. Transmittal AB-02-078, May 29, 2002. Accessed December 13, 2020.

However, the utilization of assistive technology, including low vision devices, is a critical component of effective vision rehabilitation. The treatment of low vision devices as categorically excluded from Medicare coverage results in beneficiaries who are unable to access these devices and thus achieve the full benefit of their course of rehabilitation prescribed by their provider and covered by Medicare.

As outlined above, low vision is a widely prevalent condition among Medicare beneficiaries, contributing to significant negative impacts for beneficiaries' health and function and leading to numerous secondary conditions. Access to low vision aids and devices is critical for many beneficiaries who 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. Low vision aids are clearly distinct in both form and function from traditional eyeglasses and contact lenses. They are prescribed and customized to meet the specific medical and functional needs of individuals with low vision resulting from a variety of medical eye conditions.

Current Medicare policy represents an overly restrictive regulatory interpretation of the "eyeglass exemption" in the Medicare statute, and unduly prevents Medicare beneficiaries from accessing critical vision care to which they are entitled. This policy represents an indiscriminate denial of benefits based on a particular set of diagnoses for an entire subpopulation of people with medical needs and disabilities.

The ITEM Coalition urges CMS to rescind the existing low vision aid exclusion and instead evaluate the medical and functional purpose of each individual assistive device and technology in the category of "low vision aids." By revisiting this policy, CMS can ensure that beneficiaries are provided with the benefits they need to maximize their health and function and appropriately carry out legislative intent. The ITEM Coalition and our member organizations stand ready to work with CMS to ensure that any policy changes are implemented appropriately, and offer ourselves as a resource to agency staff in whatever way we can be helpful.

Thank you for your consideration of our comments. Should you have further questions regarding this letter, please contact the ITEM Coalition coordinators at Peter.Thomas@PowersLaw.com and Joseph.Nahra@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition Low Vision Group

American Academy of Ophthalmology
American Council of the Blind
American Macular Degeneration Foundation
American Optometric Association
Assistive Technology Industry Association
Blinded Veterans Association
Prevent Blindness

Support Sight Foundation
The Vision Council

Additional Supporting Organizations

Department of Ophthalmology & Visual Sciences, University of Alabama at Birmingham
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