# A Broad Examination of Health Policy Barriers to Access and Affordability of Hearing Treatment for Medicare Beneficiaries

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**ABSTRACT**

In 2016, the National Academies on Science, Engineering, and Medicine (NASEM) released a report titled, "Hearing Health Care for Adults," which detailed the challenges and provided recommendations for improving the access to affordable hearing care for adults in the United States. Arguably the most significant outcome from this report was the subsequent passage of the Over-the-Counter Hearing Aid Act in 2017, which requires the Food and Drug Administration to develop regulations for a class of hearing aids that address mild to moderate hearing loss to be available for sale over the counter (OTC). While this presents an important step toward improving access and affordability of hearing treatment, it does not represent a complete solution. In fact, optimizing the new landscape of hearing care for individuals with hearing loss also may require new policy solutions. This article reflects on the progress achieved since the NASEM report and the policy issues that remain to improve accessibility and affordability of hearing care among older adults.

**KEYWORDS:** Medicare, health policy, access to care, costs of care, hearing care

Age-related hearing loss (ARHL) is the third most common chronic condition among older adults.[1] It is estimated that two in every three Medicare beneficiaries aged over 70 years

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have a clinically relevant hearing loss and only 15 to 20% of these individuals report hearing aid use.[2] The National Academies of Science, Engineering, and Medicine (NASEM) report, "Hearing Health Care for Adults," highlighted the "numerous, complex, and often interconnected" reasons so few older adults seek or receive hearing care.[3] Untreated ARHL is associated with numerous adverse outcomes, including declines in cognitive[4–6] and physical function,[7,8] and social isolation.[9–11] These poor outcomes extend to the experience with the healthcare system reflected in increased risk of 30-day hospital readmission, higher healthcare costs, and longer length of hospital stays.[12] Medicare, the health insurance program for older adults in the United States, is the primary payer of medical costs for older adults and has been on a campaign to manage spending by addressing potentially avoidable costs such as 30-day readmissions. Ensuring treatment for ARHL is both accessible and affordable and is an important goal for the individual with ARHL and the broader healthcare system.

The scope of hearing treatment includes both devices and services; however, the model of hearing care has been built around the sale of a hearing aid. Currently, in most practices, the sale of hearing aids and hearing care services is bundled together. This allows both devices and rehabilitation to be received by way of one payment, that is, a full-service delivery. The payment, however, can be extremely costly. The average cost for a pair of hearing aids with services is $4,700.[3] A study by Jilla and colleagues modeled the affordability of purchasing one hearing aid for the cost of $2,500 among those with functional hearing loss. This study suggests that this purchase would represent a catastrophic healthcare cost for 77% of Americans with functional hearing loss, placing 4% of the population into poverty for the year.[13] The high cost of care was one of the drivers behind the recommendation by the President's Council of Advisors on Science and Technology (PCAST) in 2015 and the subsequent NASEM report in 2016 to have the FDA establish regulations for a class of OTC hearing aids.

## THE OVER-THE-COUNTER HEARING AID ACT OF 2017

In recognition of the challenges to accessing affordable hearing interventions, the NASEM and PCAST reports recommended the development of an additional class of FDA-regulated hearing aids, classifying them as "medical devices" and making them available OTC for those with mild-to-moderate hearing loss. In contrast, existing FDA regulations established in 1977 require the individual with hearing loss to undertake a medical evaluation (or sign a waiver for medical evaluation) prior to purchasing a hearing aid which must be done through a licensed provider.[14] The new recommendations were translated into the Over-the-Counter Hearing Aid Act of 2017 which was passed as part of the FDA Reauthorization Act of 2017. This bill gave the FDA 3 years to develop the regulations which were expected in August 2020. There were delays in the release of these regulations due to the prioritization of COVID-19-related activities, but, at the time of this publication, the FDA has published proposed rules and is receiving public comment.[15]

This new environment of regulated OTC hearing aids for those with mild to moderate hearing loss is expected to reduce costs of hearing aids through improved competition by new market entrants. An increase in accessibility also is expected by enhancing options available directly to the consumer. However, there remain important access and affordability challenges that the OTC Hearing Aid Act does not address, for example, how to increase the awareness and screening for hearing loss among older adults; and it raises new questions, including how access to hearing services that support devices will now be delivered and paid for.

## CHALLENGES TO ACCESSING HEARING CARE

### Screening for Hearing Loss

In 2021, the United States Preventative Services Task Force (USPSTF) updated their recommendation for nationwide hearing

screenings among adults, stating there is insufficient evidence of the benefits and harms of hearing screening of asymptomatic adults aged 50 years and older.[16] Much of the basis for this designation is a lack of methodologically rigorous research into the effectiveness of hearing aids on mitigating negative health outcomes such as cognitive and physical decline. However, this may have unintended consequences. As is the case for other preventive activities, many older adults look to their physicians to raise the issue of hearing loss and treatment.[17] While there needs to be more evidence to understanding the benefits and harms of screening, this messaging from the USPSTF may result in fewer physician-led screenings for hearing loss among older adults through existing support channels. Such channels include the Medicare Annual Wellness Visits where hearing loss is listed as an item to screen for, but it is unknown how often this is completed and if appropriate screening tools/questions are utilized.

According to Title 42 Part 410 of the Social Security Act, Medicare beneficiaries are covered for an annual wellness visit provided by a physician that includes providing personalized prevention services. As part of this annual visit, the medical provider is responsible for reviewing the beneficiary's functional ability and level of safety which must include, at a minimum, the assessment of hearing impairment, ability to perform activities of daily living, risk of falling, and home safety. Despite approximately 20% of traditional Medicare beneficiaries having an annual wellness visit and the high prevalence of hearing loss, only 3.5% of those enrolled in traditional Medicare in 2018 were referred for audiologic evaluation.[18] More research is needed into understanding how often and by what method screening is completed within the annual wellness visit and whether policy initiatives are necessary to increase screening compliance.

## Prior Authorization

For audiologists to be reimbursed by Medicare for their diagnostic services, a Medicare beneficiary must first receive a referral from a physician prior to seeking audiology services. This prior authorization for services puts unnecessary burdens on an individual with hearing loss to access services and is inconsistent with the policies of other government-funded programs such as the Veteran's Health Administration and those with Federal Employee Benefit plans that allow direct access to audiologists. According to the Medicare Benefit Policy Manual, Medicare only covers "audiology tests… for the purpose of obtaining information necessary for the physician's diagnostic medical evaluation." As hearing aids are statutorily excluded from the Medicare program, tests "ordered for the specific purpose of fitting or modifying a hearing aid" are not covered under Medicare.[19] Opposition to the removal of the prior authorization has focused on safety concerns, suggesting that serious conditions may be missed. However, evidence suggests that hearing loss among Medicare beneficiaries is overwhelmingly aged-related[1] and therefore, in most cases, does not need a medical evaluation. Additionally, one study found that audiologists regularly refer for medical evaluation when warranted and did not refer in patients who needed a medical evaluation in less than 1% of cases.[20] The additional time and cost burdens that prior authorization presents to those seeking hearing care may result in reduced access to necessary care. Research on the use of red flag conditions to instigate medical referrals by hearing aid dispensers is needed to ensure quality and safety in the provision of hearing aids.

## Classification of Audiologists

Additional barriers to accessible care exist through the classification of audiologists as "suppliers" within the Medicare system. This classification frames audiologists as a conduit to the hearing device rather than a healthcare professional responsible for the diagnosis and treatment of hearing and balance conditions. The classification of "supplier" is also inconsistent with most other healthcare provider classifications under Medicare and can impact what newly granted provisions are extended to audiologists. A recent example is of the extended access to telehealth services provided by "practitioners" and "physicians" through the CARES Act of 2020, during the early phases of the

COVID-19 pandemic. Since this was a blanket rule for "practitioners" and "physicians," audiologists, as "suppliers," were not supported to offer telehealth alternatives to their clients as they would not be able to receive Medicare reimbursement for services otherwise eligible.

Additionally, audiology services are classified as diagnostic in the Medicare program which limits the services audiologists can be reimbursed for to diagnostic services, despite scope of practice definitions across all 50 states including both diagnostic and treatment services. Some aspects of treatment services, such as aural rehabilitation, are available to other providers, such as speech pathologists, to be reimbursed for under the Medicare program. This inhibits access to care, as Medicare beneficiaries are either required to pay for those treatment services provided by an audiologist out of pocket or not receive those services at all. Furthermore, all services that directly relate to hearing aids are excluded from reimbursement under Medicare due to the statutory exclusion of hearing aids.

## CHALLENGES IMPACTING AFFORDABILITY OF CARE

### Separation of Services and Devices

Through regulated OTC hearing aids, the delivery of hearing care services will be detached from the sale of the devices. This change provides greater transparency for individuals with hearing loss as to what they are paying for, and allows for choice and transferability across providers, but puts greater pressure on hearing care professionals to demonstrate the value of their services. While those with hearing loss can access direct-to-consumer devices without the support of a hearing care professional, many may still require support for that device or could benefit from hearing rehabilitation services provided by a hearing care professional.[21] A study of Medicare beneficiaries with hearing aids found that those who received services of a hearing professional reported better hearing outcomes[22] and lower healthcare spending[23] than those who did not receive services from a hearing professional. The value of these services may therefore extend not just to the individual but also to the healthcare system if there are downstream savings that can be achieved by better hearing outcomes and lower healthcare costs to Medicare. Establishing a separate fee schedule for hearing care services not bundled into the sale of the device will be important for consumer choice and the fiscal viability of the hearing care professionals. Without financial support through Medicare's reimbursement of hearing services, access to these services may be limited, particularly among low-income older adults.

### Coverage Alternatives

Although Medicare beneficiaries have a high need for hearing care, few coverage options exist. Traditional Medicare (Parts A and B) lacks comprehensive coverage for hearing care.[24] As previously stated, traditional Medicare covers diagnostic services, like hearing tests, as well as cochlear implants for those with profound hearing loss, but does not cover hearing aids or the services for the treatment of hearing loss provided by audiologists. For other services that Medicare does not cover, like dental and vision care, beneficiaries have the option to purchase supplementary insurance in the form of standalone plans. However, these standalone plans are uncommon for hearing care at this time. Given this lack of coverage, there is little support available to cover the costs of hearing aids for Medicare beneficiaries in the traditional Medicare program which represents almost two-thirds of Medicare beneficiaries.[25]

Medicare Advantage (MA) plans can provide more coverage for hearing care than traditional Medicare, but coverage can vary significantly by plan. For the one-third of Medicare beneficiaries enrolled in MA, 52% are in plans with hearing benefits.[24] Although just over half of MA enrollees have some hearing coverage, the utility of this benefit is questionable. A 2016 analysis found that MA recipients with hearing coverage still paid, on average, three-quarters of the cost of the hearing aids out of pocket.[24] With this limited coverage, hearing aid costs may still be a barrier for some MA recipients.

High costs of hearing care are particularly limiting for older adults with lower incomes.

Medicare beneficiaries with low incomes who reported trouble hearing were almost half as likely to have hearing aids compared with those with high incomes.[26] Coverage of hearing aids under the Medicaid program, the health insurance program for low-income individuals, is determined at the state level. In 2016, twenty-eight states covered some hearing care in their Medicaid plans, with substantial variation in the specific services covered.[27] As OTC hearing aids become more widely available, it is not known whether the price of these devices will be sufficiently low enough to be affordable for low-income individuals. It is also unclear whether state Medicaid programs that cover low-income older adults will include coverage of OTC hearing aids when they become available or whether they will only provide reimbursement for traditional hearing aids.

Even among those states that include hearing benefits in the Medicaid program, there still may be challenges to accessing care due to provider availability and participation in the Medicaid program. As is the case with other provider services—if the Medicaid reimbursement is not at a reasonable rate, few providers will opt-in to participate, increasing access barriers for Medicaid enrollees. An analysis of the availability of audiologists across the United States found that there were fewer counties with audiologists in states whose Medicaid program covers audiology services for adult beneficiaries than in states that do not cover audiology services under Medicaid.[28] Instead, audiologists congregated in counties with younger populations and higher median incomes. An analysis across 15 states found that reimbursement rates for infant and children hearing services in the Medicaid program was 67% of Medicare rates, and 38% of commercial rates.[29] Coverage does not guarantee access in these settings, and to ensure access to hearing aids among low-income individuals enrolled in Medicaid, provider availability and reimbursement will need to be considered.

### Thresholds of Hearing Loss

A particular group that would benefit from changes to coverage in the Medicare program would be those with greater than moderate hearing loss, as they are unlikely to benefit from the OTC hearing aids being developed for mild to moderate hearing loss. Consequently, these older adults will continue to have to bear the full cost of traditional hearing aids that are provided by an audiologist or hearing aid dispenser. While some individuals with greater than moderate hearing loss may be eligible for cochlear implants that are covered by the Medicare program, many of these individuals may not be audiological candidates for cochlear implantation or elect not to pursue this treatment option. Similarly, there may be some individuals with mild and moderate hearing loss, particularly those with medical diagnoses or auditory disorders, greater hearing in noise deficits, and comorbidities, who do not benefit from OTC devices and instead would be better served by the traditional hearing aids. Consideration should be given to how the cost barriers that remain for accessing traditional hearing aids can be addressed, particularly for those who do not benefit from OTC hearing aids. There is precedent within the Medicare program for coverage of treatment services by severity of illness, for example, coverage of external insulin pumps for those beneficiaries with diabetes who meet certain criteria. Given the cost exposures to Medicare beneficiaries with greater than moderate hearing loss that will remain after the introduction of OTC hearing aids, developing a policy response that targets this population may be warranted.

## POLICY DIRECTIONS

Both preceding and in the 5 years since the NASEM report, there have been numerous legislative efforts to address the accessibility and affordability of hearing care for Medicare beneficiaries. While there has been success with the passage of the Over-the-Counter Hearing Aid Act in 2017, challenges to accessing affordable hearing care by older adults remain. Across all the ongoing challenges raised here, none of the policy responses have comprehensively addressed all the challenges, but instead focus on addressing coverage gaps[30] or are specific to the classification or delivery of audiology care in the Medicare program.[31] It may be that incremental policy advancement is the

most likely pathway to successfully addressing the needs for hearing testing and treatment among older adults. Importantly, any policy efforts should consider the triple aim of improving health for populations, ensuring quality and safety, and containing costs of care.[32]

The objective of this article was to focus on many of the access and affordability challenges and hearing treatment opportunities for Medicare beneficiaries, including coverage gaps, prior authorization, screening decisions, provider classification, and reshaping the delivery of care with OTC devices. This review does not aim to consider all challenges related to the delivery of hearing care for all populations. However, as these challenges are being discussed and debated among federal law makers, it is critical that these barriers to hearing care and the benefits and harms related to action or inaction are better understood by a broad range of stakeholders.

CONFLICT OF INTEREST
None declared.

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