

# FDA OTC Rule and Medicare Legislation: Hearing Aid Market Development Impact

## Executive Summary from Nancy M. Williams, Auditory Insight Founder and President

The FDA released its [proposed rule for Over-the-Counter \(OTC\) hearing aids](#) in October 2021. A month later, the House passed the Build Back Better Bill, which included a [Medicare hearing benefit](#). These two governmental actions appear to create dual forces that could catalyze hearing aid market development in both the OTC and prescription segments.

However, we believe that **the OTC category would have greater impact on hearing aid market development** than the Medicare hearing benefit (assuming the proposed OTC rule becomes final with minimal changes and the Medicare hearing benefit becomes law). We identify two key reasons why the OTC category is more likely to drive market development:

- Given the FDA's proposed maximum output level, **the OTC category covers the vast majority of the hearing aid market**, even when accounting for the fact that hearing aid usage increases significantly with severity.
- Medicare's 20% coinsurance requirement could potentially **render prescription hearing aids uncompetitive against OTC hearing aids from a price perspective**, important since price is the number one adoption barrier.

Perhaps the most significant item of the Medicare legislation is that it **reclassifies audiologists as practitioners and covers audiologist treatment services**. As a result, audiologists could realize revenue streams independent of hearing aid sales, enabling them to unbundle and remain more competitive as OTC devices come to market.

We look forward to discussing this research note with our valued clients.



## Hearing Loss Severity Categories Are Important Foundation

Both the FDA proposed rule for OTC hearing aids and the House legislation for a Medicare hearing benefit frame their targeted populations in terms of hearing loss severity categories. The chart below crystallizes both the magnitude and the scope of each severity category from a market development perspective. **As severity increases, population sizes decrease. About 90% of people with hearing loss fall into the ‘mild’ and ‘moderate’ categories.**

A hearing test measures a person’s ability to hear tones across multiple frequencies. The average of hearing thresholds, referred to as a pure-tone average, determines each person’s resulting severity category. Within each category, the pattern of peoples’ hearing loss across the frequency range can vary substantially.

**The labels for the severity categories of ‘mild’ and ‘moderate’ are misleading.** A person with a so-called ‘moderate’ hearing loss struggles to hear another person speaking in a soft voice only three feet away, constraining their ability to function in professional and social environments. To term such a loss as ‘moderate’ underestimates its impact.

### Auditory Insight Framework for Interpreting Hearing Loss Severity

| Hearing Loss Severity<br>(in dB HL) | Types of Voices<br>Unable to Hear | Share of People with<br>Hearing Loss |
|-------------------------------------|-----------------------------------|--------------------------------------|
| Mild (26 to 40)                     | Whispering voice                  | ≈Two thirds                          |
| Moderate (41 to 55)                 | Soft voice 3 ft away              | ≈One quarter                         |
| Moderately-Severe (56 to 70)        | Normal voice 3 ft away            | 5% to 10%                            |
| Severe (71 to 90)                   | Raised voice 3 ft away            | <2%                                  |
| Profound (91 plus)                  | Shouted voice in ear              | <1%                                  |



## Overview of FDA Proposed Rule for OTC Hearing Aids

The FDA's proposed rule spells out requirements for labeling, design, and electroacoustic performance for OTC hearing aids, as well as the preemption of state regulations governing the sale of hearing aids. The graphic below summarizes the most salient points for evaluating the impact of the rule on market development.

|  |   |
|--|---|
| <b>Indication</b><br>Adults over 18 with "perceived mild to moderate hearing impairment"   | <b>Power</b><br>Maximum OSPL90 output level of 120 dB SPL w/ input-controlled compression and user-controlled volume                                    |
| <b>Self-Fit Aspect</b><br>Tools, tests, and software that allow users to configure the hearing aid to their needs and control it based on environments | <b>Coverage</b><br>Some health plans, especially Medicare Advantage, could cover with OTC benefit   |
| <b>Channel</b><br>Available over-the-counter, in-person or online, without prescription or supervision of licensed person                              | <b>Preemption of State Regulations</b><br>No state regulation may restrict sale of OTC hearing aids by only licensed professionals                      |
| <b>Prescription Hearing Aids</b><br>Air conduction hearing aids that are not OTC now defined as "Prescription"   | <b>Timing</b><br>Effective by ≈Sept 2022 (90-day comment period, 180 days for FDA to revise rules, 60 days after published in <i>Federal Register</i> ) |

## Significance of the Maximum Output Level

One of the proposed rule's **most significant items is the maximum output level**. Coupled with the FDA's decision not to limit hearing aids' decibel gain, this rule ensures that OTC hearing aids should perform well for not only people with mild hearing loss, but also moderate and moderately-severe.

Professionally fit hearing aids tailor the maximum output to users' hearing loss, frequency by frequency, and by users' preference for loud sounds. OTC hearing aids may sacrifice that personalization in order to increase access for consumers.

The 120 dB limit only applies if the OTC device contains user-controlled volume settings and a technology to make loud sounds softer called compression. Otherwise, the maximum output level drops to 115 dB SPL.

The FDA's stated goal is to balance between allowing devices to communicate desirable peaks in sound--such as cymbals during a symphony—while providing users time to react to uncomfortably loud sounds by turning off or removing their hearing aids. The agency wants OTC hearing aids to be comfortable so that indicated consumers will wear them and treat their hearing loss.

Labeling requirements for inside the package include a statement that “the sound output should not be uncomfortable or painful.” In addition, consumers may report adverse events.



## Overview of Medicare Hearing Benefits Passed by the House

On November 19, 2021, the House adopted H.R. 5376, the Build Back Better Act, which includes a provision for Original Medicare hearing benefits of hearing aids and hearing care. The salient aspects of the benefits are outlined below. The act would cover **not only hearing aids but also rehabilitation services, helping users acclimate to wearing the devices**. However, as this research note went to press, the fate of the Act remained uncertain, with President Biden lacking the necessary votes for passage in the Senate.

|  |  |
|--|--|
| <b>Indication</b><br><br>Medicare beneficiaries with moderately-severe to profound hearing loss  | <b>Coverage</b><br><br>Hearing aids once every 5 years, per ear<br><br>Hearing care (rehabilitation and treatment) by qualified audiologists |
| <b>Reimbursement</b><br><br>Hearing aids and care subject to (Part B) deductible and 20% coinsurance<br><br>Medigap* or Medicaid could cover cost-sharing      | <b>Assignment</b><br><br>HCP prohibited from charging beneficiary more than the deductible and insurance based on approved Medicare fee      |
| <b>Channel</b><br><br>Hearing aids must be sold and fitted by licensed professional (audiologist or dispenser)   | <b>Two MAASA Items</b><br><br>Reclassification of audiologists to practitioners<br><br>Coverage of audiologist treatment services            |
| <b>Physician Order</b><br><br>Requires a written order by a physician, audiologist, or other practitioner<br><br>Categorizes hearing aids as prosthetic device | <b>Timing and Scope</b><br><br>Coverage begins in 2023<br><br>Medicare Advantage plans required to cover these benefits                      |

\*Medigap supplements Original Medicare benefits by paying the coinsurance, and for those eligible for Original Medicare before 2020, the deductible.

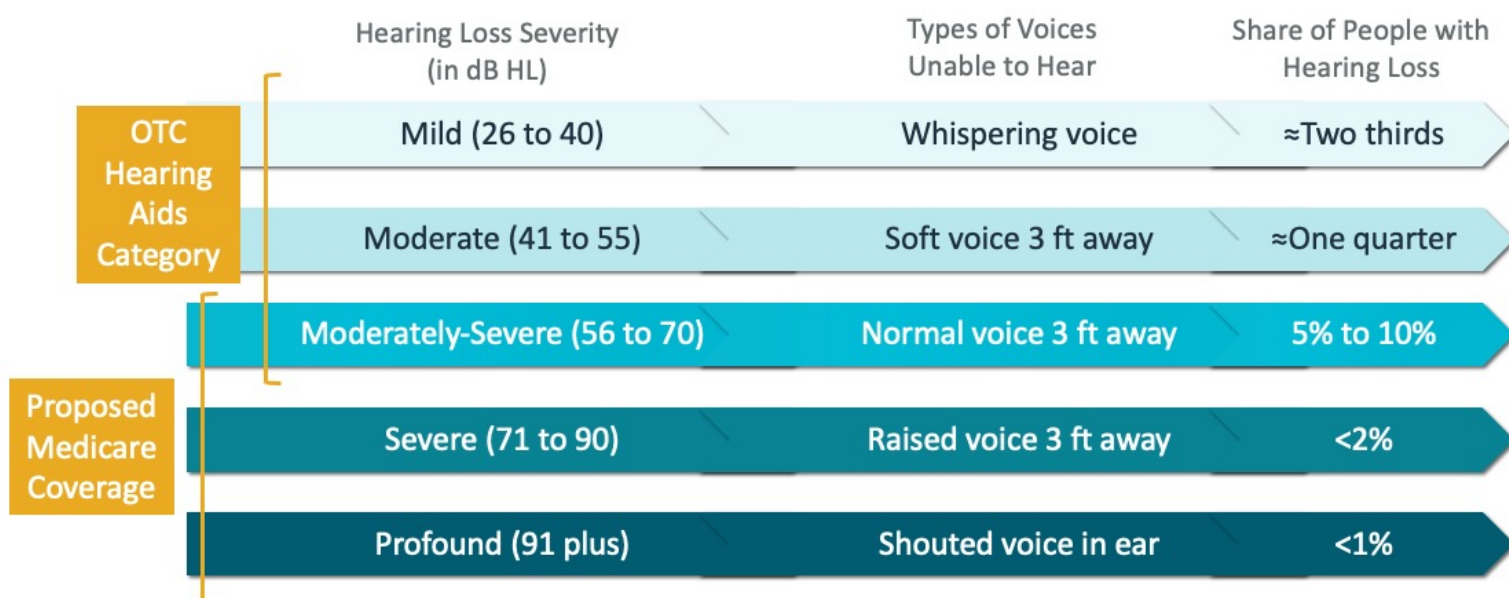
## OTC Hearing Aids Apply to Most of the Hearing Aid Market

Even accounting for the fact that hearing aid usage increases with severity, **the OTC category covers the lion's share of the people who regularly wear hearing aids today.**

The FDA proposed rule stipulates that adults with a “self-perceived mild-to-moderate hearing loss” are indicated for OTC hearing aids, without clearly defining whether ‘moderate’ includes the moderately-severe category. Given that the FDA’s stipulated maximum output level would address the needs of people with a moderately-severe loss, we include ‘moderately-severe’ in our defined OTC hearing aids category below.

Additionally, it is important to clarify that a person with any level of severity may choose to self-fit an OTC hearing aid. This flexibility may further expand the market for OTC hearing aids. For these reasons, we believe that the OTC category will play a bigger role in driving hearing aid adoption than the proposed Medicare benefit.

If a person with severe hearing loss chooses to forgo treatment with prescription hearing aids, either because of cost or access, then is it appropriate for that person to receive some amplification with an OTC hearing aid? We believe, from a public health perspective, that some amplification, particularly if it is customized as much as possible with a hearing test, is better than none.

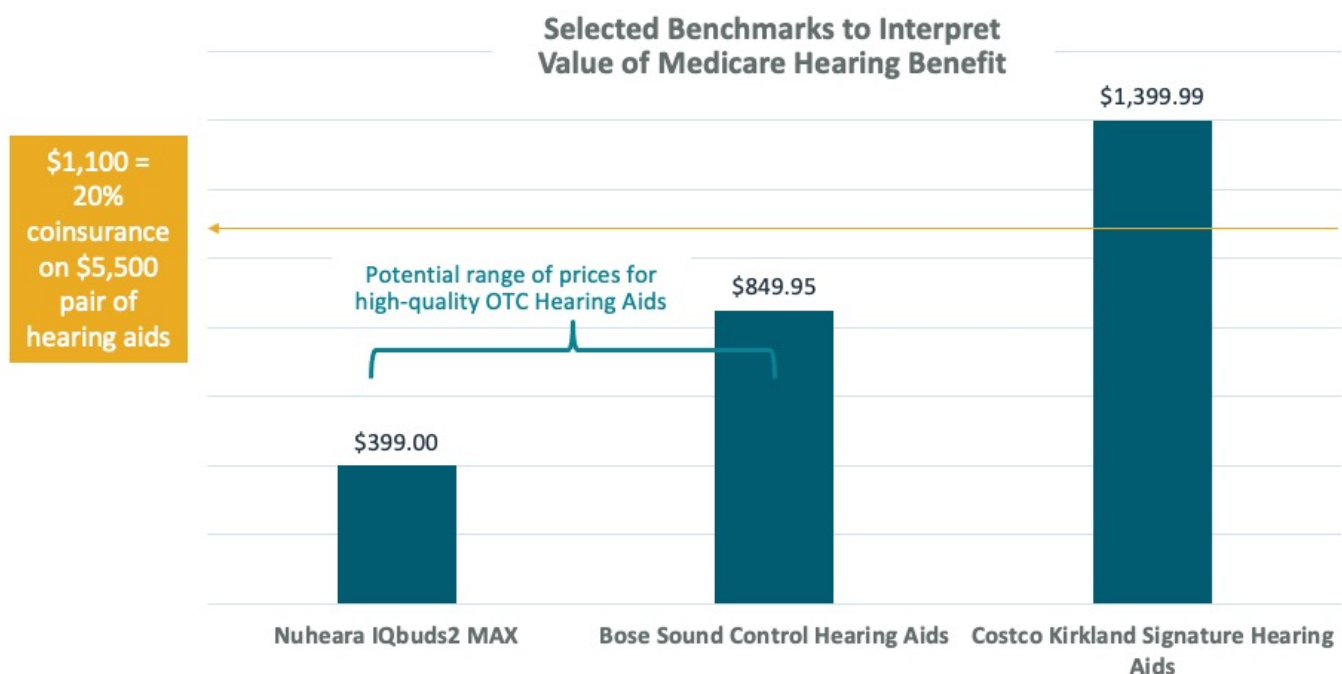


## Consumer Preference May Hinge on Relative Prices of OTC Hearing Aids versus Medicare Allowed Fee

Auditory Insight analysis shows that **price is the number one reason preventing consumers with hearing difficulties from seeking care**. Price-sensitive consumers would no doubt compare the price of high-quality OTC hearing aids with the coinsurance payment on Medicare-covered devices in the prescription channel.

Our analysis of selected price benchmarks below indicates that a pair of high-quality OTC hearing aids could retail from between \$400 to \$850 per pair. In contrast, Medicare's 20% coinsurance on a \$5,500 pair of hearing aids (currently the [average price for hearing aids sold](#) in the independent audiologist and ENT channel) would be over \$1,000.

Many **other important factors would drive consumers' ultimate decisions**, such as whether they have Medigap for coinsurance and the extent to which they value the personal attention of a licensed professional. Rehabilitation services, in which the audiologist works with the patient to maximize the benefits of hearing aids and ensure usage, would be covered services. However, at this point, it is unclear how much growth in new users the Medicare hearing benefit would drive in the prescription market.





## Medicare Coverage Would Provide Audiologists With Revenue Stream Independent Of Bundled Hearing Aid Sales

A fundamental aspect of the proposed Medicare hearing benefit is incorporation of two components from the Medicare Audiologist Access and Services (MAASA) Act.

**Audiologists would be reclassified as practitioners and would be reimbursed for all existing Medicare-covered services that audiologists are licensed to provide in their state.** Examples of treatment services could be aural rehabilitation to help patients integrate hearing aids into their personal and professional lives, as well as cerumen (earwax) removal and vestibular (balance) rehabilitation.

The Build Back Better Act would not eliminate, however, the requirement of a physician order for audiology care.



The MAASA Act was originally introduced in both the US Senate and House in May 2021, with bipartisan support. The three US audiology associations, shown above, came together to champion the legislation.

Under the legislation, **audiologists would gain a revenue stream independent of hearing aid sales, creating more flexibility in the scope of their practice.** Today about two-thirds of audiologists bundle hearing aids and fitting services into one charge. In contrast, some audiologists could **choose to add an OTC component to their practice, charging separately for add-on services**, such as determining suitability for an OTC device and helping patients who require extra assistance with self-fitting hearing aids.

## OTC Hearing Aids More Significant for Market Development Than Medicare Coverage

We continue to see the new OTC category (assuming few changes in the FDA proposed rule) as the primary driving force in hearing aids market development, with four primary impacts:

- **Innovation** in hearing aid form factors, sound quality, fitting technologies, and add-on services
- Considerably lower hearing aid prices, with a pair of OTC hearing aids retailing for about \$500 on average, compared to \$5,500 for a pair of traditional hearing aids from audiology and ENT hearing aid clinics today
- An increase in the overall adoption rate from the 15% of people who regularly use a hearing aid today (assuming innovation, greater awareness, and lower prices)
- An OTC category potentially characterized by **higher volume** than the prescription hearing aid category, with the economics of the entire hearing aid industry potentially very different than today.

To realize its potential, this new category will require sustained investment to create awareness and acceptance among consumers and primary care professionals. As we have noted, when prescription categories go OTC, the main brake on development is inertia in behavior. In the case of hearing aids, an important component of developing acceptance is addressing stigma.

Our forthcoming Q1 2022 Research Note will identify and profile the companies likely to create awareness and lead market development with OTC hearing aids.

Photo by [Tirza van Dijk](#) on [Unsplash](#)

## About the Author

A strategic advisor and thought-leader on transforming hearing healthcare, Nancy M. Williams is Founder and President of Auditory Insight.

## Advising Leaders on Transforming Hearing Healthcare

Auditory Insight partners with senior leaders of device and pharma companies to develop successful commercialization strategies. The firm also advises growth equity and private equity firms to create portfolio value in hearing healthcare. Auditory Insight has deep insight into consumer needs and experience, a practical understanding of clinical behaviors of audiologists and ENTs, and unique viewpoints on how hearing healthcare is evolving.



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