



Over-the-Counter (OTC) Hearing Aid Landscape

MARCH 2026





Overview

The purpose of this is to explain today's hearing health landscape including the various ways consumers can access over-the-counter (OTC) hearing aids and to share important takeaways learned by the hearing health industry since the OTC Hearing Aid Act was enacted in late October 2022.¹ The insights and lessons gained from the content of this document are intended to provide a foundation for awareness and continued adoption of OTC hearing aids. Understanding today's landscape helps hearing-health companies improve education and support, increase adoption, and make OTC hearing aids a normal part of everyday care so consumers have more access and control.

¹ <https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids>

“Since the OTC hearing aid category took effect on October 17, 2022, the most powerful impacts have come from three priorities: setting clear, manufacturer-friendly standards, proving safety and effectiveness through FDA pathways, and meeting consumers where they already shop. As Chair of CTA’s OTC Hearing Aid Working Group, I’ve focused on collaborative, practical guidance so that manufacturers and retailers can deliver products with confidence, without sidelining audiology or consumer wearables best practices, and always with the consumer’s hearing benefit as the ultimate goal.

Marketing hearing health today succeeds when it blends medical credibility with consumer simplicity. The approaches that resonate include retail and e-commerce distribution across traditional and non-traditional channels with transparent pricing and generous trials; app-guided onboarding that takes minutes instead of weeks; lifestyle-driven designs (smart glasses, earbuds) that normalize amplification; and collaboration with audiologists, ENTs, and licensed hearing care professionals for escalation beyond mild-to-moderate hearing loss. Digital marketing along with traditional print advertising reaches all consumer age demographics where they consume their media. OTC hearing aids serve all consumers over 18 years of age with perceived

mild to moderate hearing loss. This is a broad demographic that requires investment, time, and very different approaches to have a return on the marketing investment. A new category isn’t born overnight and while the OTC hearing aid act made the product pathway available in the US in late 2022, as we have learned, consumer confidence and trust in self-care of their hearing is just now coming into focus for many companies and products and will require a few more years to become a mature market.

Lessons learned are clear: Don’t oversell gain or ‘cures’, focus on outcomes that matter, like speech-in-noise performance, comfort, and situational verses all-day wear solutions. Ensure labeling and self-fit experiences are unambiguous and fully aligned with FDA requirements. Treat customer service, support, warranty, returns, and software updates as essential features. Be patient with market maturity and consumer acceptance of OTC self-care. And keep the CTA Standards and OTC Hearing Aid Committee work at the center, in partnership with the FDA - it’s the quiet engine of trust that allows innovation to accelerate responsibly.”

**JOHN R. LUNA, CEO, Sound Business Consulting Services;
Strategic Advisor, EssilorLuxottica**



What is Hearing Health

In recent years, there has been a significant shift to individuals seeking to personalize their health management by leveraging technology and data to tailor their healthcare experience. There is increasing recognition that hearing health is not an isolated facet of a person's wellbeing, but rather an integral component of one's overall quality of life — much like vision health or brain health. Hearing loss is connected to conditions like dementia, depression, social isolation, and anxiety.² By taking a holistic view that places hearing health alongside other pillars of wellness, individuals receive better support, tools, and the community awareness needed to thrive at every stage of life.

There has been significant transformation with the emergence of OTC hearing aids,³ making solutions more affordable and accessible to consumers. Technological innovations like hearing enhancement

technology (e.g., adaptive sound processing) have also driven increased adoption. Additionally, there is a push to grow the emphasis on hearing protection and personalized care, empowering individuals to proactively manage their hearing health.

The promise of OTC hearing aids and other hearing health solutions is that by improved access to care, particularly for adults with mild to moderate hearing loss, there will be greater hearing health outcomes. These tools are critical in empowering consumers to take a more active role in managing their hearing health. This document will primarily focus on OTC hearing aids to better highlight options that can be more accessible to consumers based on situational opportunities. There is a wide breath of innovations in the hearing health space that expand beyond OTC hearing aids which represent a growing segment of entry points for improved access and awareness. Consumers, as used in this document, indicate a wide audience at different life stages.

² <https://www.nidcd.nih.gov/about/nidcd-director-message/fdas-new-category-hearing-aids-advances-hearing-health-care#:~:text=August%2016%2C%202022,an%20urgent%20public%20health%20issue>

³ Refers to the hearing device category for Over The Counter hearing aids, as defined in ANSI-CTA-2051-B.

Understanding and Personalizing Hearing Health

Enhanced personalization allows consumers the ability to monitor and understand their hearing health more effectively. This approach provides tailored solutions, encouraging proactive care and engagement in hearing well-being.

Personalizing hearing health is an ongoing journey that evolves throughout an individual's life, intersecting with overall well-being and daily functioning. By tailoring hearing solutions to individual needs, preferences, and lifestyles — whether through the latest technology, regular monitoring, or professional support — people can proactively address changes in their hearing health.

“Now more than ever people are taking health into their own hands. And hearing health is no different. Therefore it's vital for companies to provide safe, simple, highly effective devices along with an effortless onboarding and ongoing support experience. It's also important to have this entire product and support experience customized to the individual and their unique circumstances and needs. While people are seeking value, they still expect premium product performance and support.”

BRIAN MAGUIRE, CCO, LXE Hearing



Channels To Hearing Health Accessibility And Awareness

Accessing OTC hearing aids has become more diverse, with retailers and manufacturers offering multiple pathways to meet consumer needs. From professional guidance to direct-to-consumer options, these channels cater to varying preferences, budgets, and levels of accessibility, striving to increase awareness and engagement in hearing health.

An element that intersects across channels is when consumers turn to online forums, platforms, and other proactive digital touchpoints to seek information, share personal experiences, and ask questions about hearing health solutions. These online communities and high-touch support avenues often provide resources or suggested products to consumers who are exploring hearing health options. High-touch support points may include manufacturer websites for direct-to-consumer interaction, retailer platforms, telehealth services, and public-private entity managed community forums.

In-person engagement with consumers typically occur in clinics, hearing centers, or retail environments offering consultations and product demonstrations while virtual engagement may include video consultations, app-based onboarding, and moderated online communities that provide peer-to-peer advice and professional input. Both online and in-person touch points can be leveraged as greater high-touch support for better access and awareness.



Hearing Health Professional

In this model, the consumer has coordinated with a healthcare professional like an ENT (ear-nose-throat-doctor), audiologist, or other qualified hearing health professional and based on a medical and audiological exam, it is recommended that the consumer would benefit from hearing technology. The healthcare professional may suggest specific prescriptive brands for the consumer to explore, but there are also OTC options a healthcare professional can recommend serving as point of sale for OTC hearing aid devices.

Additional FDA guidance and resources for consumers considering a hearing health professional are available.⁴

Benefits:

- Hearing healthcare professionals are trained to perform comprehensive hearing evaluations and

inform consumers of their suitability for various types of hearing technologies reaching new audiences and shifting access.

- Consumers value professional guidance before purchasing hearing technology.
- Allows for qualified Hearing health professional in-person pre/post purchase support.

Opportunities for Growth:

- A consumer may not be aware of the range of hearing solutions if only offered prescriptive options. OTC Hearing Aids and/or wearable hearing solutions may not be presented to consumers.
- A consumer may prioritize advice from social media or peer-to-peer interactions over professionals resulting in unsatisfied purchases.

⁴ <https://www.fda.gov/medical-devices/hearing-aids/how-get-hearing-aids#:~:text=your%20hearing%20aids.-,Should%20I%20consult%20a%20hearing%20health%20care%20professional%20before%20I,%2C%20in%20rare%20cases%2C%20tumors.>

Direct-to-Consumer

The direct-to-consumer model centers on streamlining the process by which OTC hearing aids and related products reach the consumer. Rather than relying exclusively on retailers, manufacturers leverage digital platforms, online forums, direct retail locations, and more to connect with consumers more efficiently.

Benefits:

- Direct- to-consumer models streamlines and simplifies access for increased product satisfaction.
- By enabling direct feedback loops and support, direct to consumer channels enhances rapid dissemination of product information.
- Manufacturers meet consumers where they are in their hearing health journey – product options are available for what the consumer is comfortable with.
- Direct-to-consumer models may offer pre-purchase and post-purchase support allowing for a more flexible experience to increase consumer satisfaction.

Opportunities for Growth:

- Consumers may be hesitant due to the need to verify advice with credible sources or healthcare professionals to avoid potential pitfalls.

“Hearing health is marketed on TV and via email during promotional periods. QVC & HSN adhere to specific legal requirements and have approved video assets showing simulations of before and after using the hearing aids, along with live testimonials from customers. QVC & HSN typically have monthly promotions and support larger stories like National Hearing Month. Our biggest success comes from TV promotions.

Lessons Learned: The return rate is high in this category, but by partnering with vendors, we have lowered the return rate through better packaging and customer service. For large promotions, we send customized post-purchase emails to follow up with customers, providing information on what to expect and how to reach out with any questions.”

RICH YOEGEL, VP GMM Home, QVC & HSN

- Direct-to-consumer models need investment in robust support systems to maintain trust and deliver reliable information.
- Manufacturers do not always have the ability to scale to meet consumer needs.
- Consumers may not be aware of direct-to-consumer options from manufacturers and may not be able to determine the brand needed to meet their needs.

Retail

In the retail model, OTC hearing aids can be distributed through various channels including health retailers, pharmacies, mass retailers, online, and in-store retail environments. In-store locations can provide personalized consultations, product demonstrations, and on-the-spot fittings, which help demystify the use of hearing aids and related technologies for consumers. Big-box retailers, through different experiences and approaches to the product, further democratize access by stocking OTC devices, making hearing health products more visible and approachable for wider audiences (e.g., personalized consultations, informal displays). E-commerce platforms, empower consumers with convenience, privacy, and the ability to compare products and reviews, broadening the reach of hearing health resources beyond geographic limitations. These efforts, combined with targeted promotional campaigns including interactive displays and partnerships with hearing care professionals, may help reduce barriers to adoption, encourage proactive hearing health management, and foster a culture of inclusivity for those experiencing hearing loss.

Benefits:

- Consumers are likely to engage with retail and specific brands if there is trust in the location.
 - This can reduce returns and follow up visits through proper onboarding of the product. Also fosters an opportunity to better understand returns to help address consume needs and appropriate next steps.

- Retail allows for consumers to discover and choose from a variety solutions and brands that fit their needs. The consumer likely assumes that brands have already been vetted by the retailer, reducing the overwhelming choice to help for easier decisions.
- Retail helps to increase awareness and reduce barriers to adoption, encourage proactive hearing health management, and foster a culture of inclusivity for those experiencing hearing loss.

Opportunities for Growth:

- Retail may not provide customer support during and after the sale depending on company staff and resource availability or retail service model.
- Retail may have inconsistent product quality or lack of clear guidance due to variability in staff knowledge across outlets.
- Some retailers are limited by time constraints and the availability of trained professionals, which may impede thorough fittings or follow-up consultations.
- Retailers may not always offer comprehensive information about ongoing care and maintenance.
- Medical professionals may not refer patients to products at retailers if unaware of lower cost options.
- Retailers may not have opportunities for consumers to experience the product prior to purchase, like a demo experience.

Public or Private Non-Profit Entity

This model encompasses a diverse range of organizations, including rehabilitation centers, government agencies, and community-based groups dedicated to providing services like hearing health. Such entities often serve as access points for individuals seeking assessment, treatment, and ongoing support for hearing loss. They may offer subsidized or free hearing aids, counseling, rehabilitation services, and educational outreach, ensuring broad access regardless of income or background. By collaborating with healthcare professionals, insurers, and advocacy groups, these models can help bridge gaps in service delivery and promote inclusive, comprehensive hearing health solutions within the community.

Benefits:

- Public or private non-profit models prioritize community well-being to provide affordable or free care to underserved populations.
- This model may leverage government funding, insurance partnerships, and philanthropic support to reduce financial barriers for great access.
- Includes additional services like counseling, rehabilitation, and ongoing education. This can increase customer satisfaction in a product. Community based platforms also decrease the stigma associated with hearing loss.

- Based on model priorities, these models tend to foster greater collaboration across sectors, working alongside manufacturers, medical professionals, advocacy groups, and policy makers.

Opportunities for Growth:

- A challenge when working within this model could be limitations in funding, which may impact the consistency of services and access provided.
- With limited resources and services often in high demand there may be delays in accessing services.
- Outreach and education efforts to increase awareness of products and services may not reach all segments of the population, particularly in rural or underserved communities.
- Fragmented care coordination and the challenge of integrating services could impact awareness and access to products like OTC hearing aids supplied when manufacturers and medical professionals partner with public or private non-profit entities.
- In some cases, regulatory and policy barriers hinder access to products and services, like OTC hearing aids.
- There are many priorities in the health space, public or private non-profit models may not be in the position to prioritize hearing as a health service.



Hearing Benefit Provider or Plans

Health payers may provide services to the consumer and play a role in facilitating access to hearing health solutions, shaping both the availability of services and the adoption of assistive technologies. This model may include coverage options or partial reimbursement for hearing aids and other assistive or rehabilitative devices.

Health benefit providers and insurance plans are beginning to include options that help consumers manage their hearing health through programs like Flexible Spending Accounts (FSA), Health Savings Accounts (HSA), and flex cards. These programs improve affordability, bring awareness to the products available, and encourage proactive adoption of hearing solutions and OTC hearing aids. Employers who offer health benefits are also starting to include hearing coverage like vision or dental as a part of overall health benefit packages.

Benefits:

- Some providers or plans do clarify that OTC hearing aids are a benefit, allowing for great adoption and awareness.

Opportunities for Growth:

- Not all payers integrate OTC hearing aids as covered assistive technology. Criteria for eligible technologies can vary across plans limiting access and adoption of certain hearing health technologies.
- Provider or plan online information (e.g., peer advice and testimonials) could be inaccurate to a specific product, leading to the potential spread of misinformation.
- The timeframe for implementation in health plans is long (12-24 months), which could impact access to hearing health technologies.

Technical Innovations and Example Solutions Driving Adoption

While OTC hearing aids have played a pivotal role in expanding access and affordability for individuals with mild to moderate hearing loss, they represent only one part of a much larger ecosystem of hearing health solutions. To fully understand the opportunities and challenges in this space, it is essential to landscape OTC hearing devices as well as other hearing health solutions and the advancements propelling the category forward. This can include technological advancements like the incorporation of accessibility features. These innovations enhance functionality but also increase adoption by integrating hearing solutions more broadly.

The following provide hearing health solution examples that explore the broader landscape:

- The availability of hearing aids without prescription has reshaped the landscape of hearing health. OTC hearing aids leverage self-fitting algorithms, smartphone integration, and adaptive sound processing to deliver accessible, affordable hearing solutions without requiring a prescription. This technology enables some consumers to access hearing solutions more conveniently, removing barriers associated with medical visits (e.g., travel distance and costs, multiple visits, scheduling/rescheduling, waiting times, taking time off work, hearing aid availability/limiting options). OTC hearing aids may also provide an affordable alternative to prescriptive products and help those who may be hesitant to engage with traditional hearing aid purchase pathways.
 - Headphones and earbuds with air-conduction hearing assistance features:
 - Innovations in hearing aids can integrate with speech-to-text mechanisms, enhancing translation and hearing in large venues. There is also the

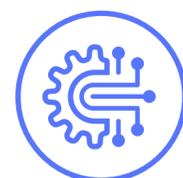
capability of connecting with smartphones or smart TVs. Integration with technologies could enhance day-to-day activities (e.g., museum visits, travel, movies).

- Protective measures are a vital component of overall hearing health. Emphasis on the importance of safeguarding hearing from environmental hazards is an important driver to greater adoption. Long-term hearing preservation can be driven by educating consumers about noise exposure and promoting protective gear.
 - Noise cancellation features are being integrated into consumer products like earbuds and headphones as well as being developed into multifunctional devices that combine hearing enhancements with noise cancellation. This can normalize hearing devices and appeal to younger populations as a means to protect hearing, expanding the market. Bone conduction wearable solutions that do not rely on air-conduction of sound, but instead deliver bone conduction hearing ability.
- Other wearable technologies are integrating new features (e.g., Artificial intelligence (AI) and combining the core functionality of hearing aid or hearing enhancement systems. These devices are designed to support hearing health while providing additional biometric and assistive capabilities (e.g., blood oxygen, speech clarity, activity level).
 - Smart glasses are starting to merge the divide between hearing health and other domains like vision health. These technologies integrate software, air-conduction audio and sometimes hardware sensor technology into eyewear. Features include noise filtering, personalized sound amplification, directional microphones for speech, AI assistants, real-time transcription and language translation abilities, etc.



Combating Stigma

To accelerate adoption and trust in OTC hearing aids and other hearing health solutions, industry stakeholders should consider the following:



Leverage Technology Integration - Explore avenues and high-level connections between hearing solutions and other technologies (e.g., speech comprehension technologies) to show the appeal and accessibility for hearing health solutions across domains.



Collaborate Across Sections - Identify diverse opportunities and environments (e.g., travel, wedding planners, health systems to improve workflow, restaurants) that could bring new consumers to use hearing solutions.



Measure and Share Outcomes - Collect stronger evidence that helps the industry better understand, ongoing adoption and returns for continuous improvement and next steps.



Enhance Consumer Education - Establish a collective industry campaign or awareness campaign on hearing health (e.g., “Hearing Number” or Better Hearing Month, or World Hearing Day (WHO)) to align and drive better consumer awareness of self-care, normalize general hearing health, and reduce stigma around the use of hearing technologies.



Consumer Technology Association, producer of CES®

1919 S. Eads St., Arlington, VA 22202

CTA.tech | CES.tech