

Over-the-Counter (OTC) hearing aids: What do consumers need to know?

By Vinaya Manchaiah, AuD, MBA, PhD; Cory Portnuff, AuD, PhD; Anu Sharma, PhD; and De Wet Swanepoel, PhD

Following the Food and Drug Administration (FDA) historic ruling on the over-the-counter (OTC) hearing aids in August 2022 (1), non-prescription OTC hearing aids went on sale in various outlets including pharmacies, supermarkets and consumer electronics retailers on October 17, 2022. The expectation from this new category of devices is that it will make it easier for people to purchase hearing aids and at a cheaper price point. This new category is meant to be for adults with perceived mild-to-moderate hearing loss. OTC hearing aids come in various types and form factors (e.g., behind the ear, in the ear) and are typically priced considerably cheaper than average prescription hearing aids.

Depending on who you talk to or what you read, you may find two extreme views on OTC hearing aids (2): either they provide affordable solutions (3), or they won't work at all and do more harm than good (4). Our aim is to present a balanced view on what is known about the OTC hearing aids from academic research as well as provide some tips for consumers (for hearing health care clients) on what to consider when considering these devices.

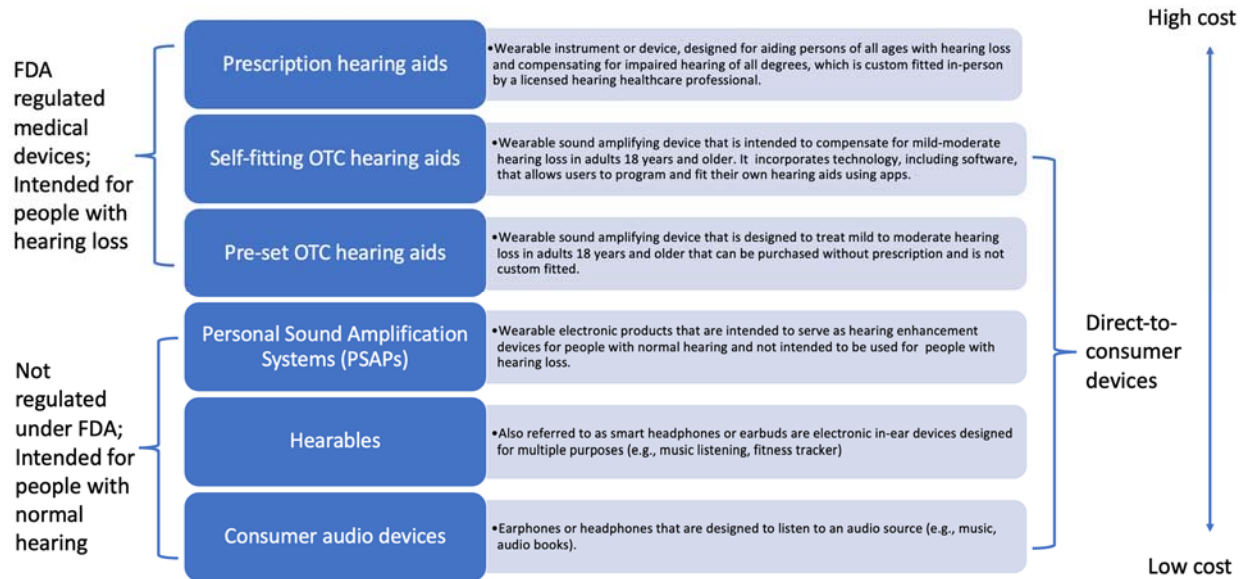
Hearing device categories

The new OTC hearing aid category adds to a range of existing hearing devices, including conventional prescription hearing aids (5), hearables, personal sound amplification products (PSAPs) and (6) consumer audio devices such as earphones with amplification features as illustrated in the image below. The OTC hearing aid category (7) supersedes direct-to-consumer (DTC) hearing aids which were previously available for purchase online (8). OTC hearing aids can now be purchased both in-store and online without the need for a prescription. Companies who have legally sold DTC prior to 16 October 2022 have until 14 April 2023 to comply with the labelling and packaging requirements set by the new OTC Hearing Aid Regulations (OTCHA).

The U.S. FDA has defined two hearing aid categories: prescription hearing aids and OTC hearing aids, which are both regulated as medical devices and intended for people with hearing loss. OTC hearing aids have two sub-categories, 1) OTC hearing aids with pre-set programs with a one-size-fits-all approach, and 2) self-fitting OTC hearing aids that can be customized and adjusted by the consumer to fit the individual users' hearing profile or preferences. The key difference between these two categories is that the self-fitting hearing aids require a more rigorous FDA 510(k) (Premarket Notification) clearance (9). Generally, the self-fitting OTC devices are at higher price point compared to pre-set OTC hearing aids.

The other three categories of devices (i.e., PSAPs, hearables, consumer audio devices) are not medical devices and are not regulated by the FDA. As technology advances,

many of these devices may appear and function similar to hearing aids. It is important to pay attention to labelling, so that OTC hearing aids are not confused with other device categories. It is not uncommon to see false advertising claims where potentially PSAPs are marketed as OTC hearing aids (10).



What do we know about DTC hearing devices from research?

In the absence of OTC hearing aid category in the United States prior to 2017-22, much of the research relevant to OTC hearing aids and service delivery models was performed on hearing devices (i.e., PSAPs, hearables, direct-mail hearing aids) that were available to consumers through various DTC channels. Hence, these devices can be categorized as early generation DTC hearing devices.

Based on our literature review (11), academic research on DTC hearing devices can be grouped into three key themes. First, several studies have looked at their acoustic characteristics (e.g., if the device has appropriate frequency response, low distortion and internal noise is within allowable limits) and have found mixed results. Some studies show that the DTC hearing devices do not have suitable acoustic characteristics (12), whereas the others show that some devices may be able to provide appropriate amplification for people with hearing loss (13). Moreover, higher priced devices seem to have much better acoustic quality (11, 14). These studies suggest that the selection of the device is important. Second, there are several large-scale consumer surveys in the United States (15) and Japan (16) suggesting that the DTC hearing devices such as PSAPs have lower benefit and satisfaction from users when compared to conventional hearing aids. Finally, there are several clinical trials measuring the self-fitting process (17) and outcomes of OTC hearing aid service delivery model (18) which have generally reported a positive outcome for OTC hearing aids for people with mild-to-moderate hearing loss. There are numerous ongoing clinical trials on OTC hearing aids (19) as well as more studies which are likely to occur in the next few years providing a wealth of information on this topic.

As the market matures, available OTC devices will change and may not be reflective of those which have been studied previously. Current research generally agrees that those who choose an appropriate OTC device and manage to personalize and use it well are likely to benefit from it (11). However, in our opinion, not all available OTC hearing aids will be of high quality. We hope that regulations and market competition will lead to improvements in the quality and reliability of OTC hearing devices.

Some aspects to consider when shopping for OTC hearing aids

Due to high media coverage of OTC hearing aids, many consumers are aware of these devices and are asking about them during clinical consultations. It is important to discuss them with your patients and also to provide a rationale on why (or why not) an individual is a good candidate for OTC hearing aids. Following a hearing aid consultation, if your patients like to peruse OTC hearing aids, following are some key points that you can share with them to facilitate their journey with OTC hearing aids. In addition, the FDA also offers some guidance to potential consumers on how to get hearing aids (20).

Brand, warranty and return period: There are a handful of companies offering OTC hearing aids currently. It is likely that many new companies will emerge in the coming months/years. Some of these companies may not remain in the OTC business for too long. Choose a brand with a good reputation that will stand behind their product and ensure that you can return the device if it does not work.

Features and functionalities: The look and feel of the device (e.g., traditional hearing aid looks vs consumer audio look), features and functionalities (i.e., ability to personalize the device through self-fitting methods, smartphone app compatibility, Bluetooth connectivity, rechargeability) may be important factors to consider when deciding which device to purchase.

Customer care and remote support: Some companies offering OTC hearing aids also offer customer service as well as remote clinical support. Certain consumers may need additional support to personalize their device and learn handling skills and remote support can be helpful for this.

Price point: Current OTC hearing aids are typically priced between \$200 to \$1000 but may go as high as \$2950. This offers a range of products for consumers with different price points. Lower cost devices are typically pre-set OTC hearing aids without a self-fitting option. Self-fitting devices that we are familiar with and can recommend run around \$800-\$1200 for a pair, although it's possible that the lower cost devices could provide some benefit. Prescription hearing aids have a wide range of costs from \$1000-\$6000+ per pair. Higher-end OTC devices may be similar in cost to lower-end prescription hearing aids. It's important to compare the features, customization, and support from an OTC hearing aids to professionally-fit prescription hearing aids. OTC costs are likely to change over time, so it is important to know what you're getting for the

price. Some OTC companies also offer financing options so that consumers can pay for it with monthly installment which can be an attractive option for some consumers.

Online reviews: Looking at the online consumer reviews (21) can also be a way to determine the quality of the products. Reviews for OTC devices are helpful resources to guide consumers along with App-store reviews for the accompanying apps in the case of self-fitting devices. It may be worth reading both device and app reviews if you are interested in knowing the user-friendliness of the app in addition to the device. Reviews can support consumers with information on the benefits or issues previous users reported about a specific product and/or company.

Hearing loss and ear disorders: Current OTC labeling indicates that OTC hearing aids are intended for perceived mild-to-moderate hearing loss. Self-perceived hearing loss (or disability) (22) is an important factor although its relation to measured hearing ability is poor. In other words, people are not great at estimating their hearing levels (23), and tend to underestimate the severity of their hearing loss. Since OTC devices only work well for mild to moderate hearing loss, if you underestimate your hearing loss, they may not provide adequate amplification. In addition, some people may have hearing problems due to treatable ear conditions, like earwax impactions. We recommend consumers consider getting a hearing test from an audiologist before purchasing an OTC hearing aid. Alternatively a free online hearing test (e.g., [hearWHO](#)) as well tools like the Consumer Ear Disease Risk Assessment (CEDRA) can help screen for hearing loss and risk of an ear disorder (24).

Labelling and marketing claims: Pay attention to labelling. Due to the fast-changing marketplace, it is easy to mix one device category with another as highlighted earlier. There are also false marketing claims that consumers need to be aware of. If you do come across such false claims or are affected by such a claim, you can report these to the FDA, Federal Trades Commission (FTC), and non-profit organizations such as Truth in Advertising.

What if you don't find benefit? If you are benefiting from the OTC hearing aids with hearing and communication, that is great news. This means that you have chosen an appropriate device, managed to customize it to your hearing, and learned how to handle the device. However, if you are not experiencing optimal benefit from the OTC hearing aids, it is important to consider potential reasons (25). Are the devices working? Are they fitted properly and producing adequate amplification? Do you have problem with adjusting or handling

Questions to consider when purchasing an OTC hearing aid:

- Is this a quality brand and device?
- What features and functionalities does it have that are important to me?
- How is the device programmed or fitted and does it offer the level of customer support that I need?
- What is the warranty?
- How can I get the device fixed if it breaks?
- What is the return policy?
- How much does it cost? How long is it likely to last?
- Will this be appropriate for my hearing loss?
- What's my next step if this doesn't work for me?

these devices? You may want to consider seeking services from hearing healthcare professionals. Alternatively, you may have the option to return the devices within their specified return period.

Final note

We expect that OTC hearing aids will force competition among manufacturers and result in better products at a cheaper price point. This will be a significant improvement in affordability and access for individuals and families with hearing loss. Academic literature suggests that choosing a good device as well as learning how to use it is key in determining whether or not someone will benefit from OTC hearing aids.

Nevertheless, it's important to help our patients to be a responsible consumer and to choose the device and services that is best for them. It remains to be seen whether hearing healthcare professionals will incorporate dispensing OTC hearing aids into their practices. However, hearing healthcare professionals can play an active role in facilitating our patients journey with OTC hearing aids by educating them during clinical consultations as well as through creation and distribution of patient education materials.

Authors Bio

Dr. Vinaya Manchaiah, AuD, MBA, PhD serves as the Professor of Otolaryngology-Head & Neck Surgery at the University of Colorado School of Medicine and as the Director of Audiology at the University of Colorado Hospital (UCHealth).

Dr. Cory Portnuff, AuD, PhD is the Clinical Audiologist at the University of Colorado Hospital (UCHealth) and Assistant Clinical Professor at the University of Colorado School of Medicine.

Dr. Anu Sharma, PhD is a Professor in the Department of Speech Language and Hearing Science, Fellow at the Center for Neuroscience and Institute of Cognitive Science at the University of Colorado Boulder.

Dr. De Wet Swanepoel, Ph.D. is Professor of Audiology at the University of Pretoria, South Africa, and Editor-in-Chief of the International Journal of Audiology. He is also founder of a digital health company called the hearX group.

References

1. Food and Drug Administration (2022). FDA Finalizes Historic Rule Enabling Access to Over-the-Counter Hearing Aids for Millions of Americans. Retrieved from: <https://www.fda.gov/news-events/press-announcements/fda-finalizes-historic-rule-enabling-access-over-counter-hearing-aids-millions-americans> (accessed on November 02, 2022).
2. Badri, R. (2022). OTC hearing aids: The good, bad and the ugly. Retrieved from: <https://hearinghealthfoundation.org/blogs/otc-hearing-aids-the-good-the-bad-and-the-ugly> (accessed on November 02, 2022).
3. Dragan, L. (2022). Over-the-Counter Hearing Aids Could Finally Give People an Affordable, Convenient Hearing Solution. Retrieved from:

- <https://www.nytimes.com/wirecutter/blog/over-the-counter-hearing-aids/> (accessed on November 02, 2022).
4. Gianoli, G. (2017). Sen. Warren's not listening: OTC hearing aids will do more harm than good. Retrieved from: <https://thehill.com/blogs/pundits-blog/healthcare/333943-sen-warrens-not-listening-otc-hearing-aids-will-do-more-harm-than-good/> (accessed on November 02, 2022).
 5. Food and Drug Administration (2022). Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS) - Guidance for Industry and FDA. Retrieved from: <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-guidance-document-transcutaneous-air-conduction-hearing-aid-system-tachas> (accessed on November 02, 2022).
 6. Food and Drug Administration (2022). Hearing Aids and Personal Sound Amplification Products: What to Know. Retrieved from: <https://www.fda.gov/consumers/consumer-updates/hearing-aids-and-personal-sound-amplification-products-what-know> (accessed on November 02, 2022).
 7. Food and Drug Administration (2022). Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids. Retrieved from: <https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids> (accessed on November 02, 2022).
 8. Food and Drug Administration (2022). Medical Devices; Ear, Nose, and Throat Devices; Classification of the Self-Fitting Air-Conduction Hearing Aid. Retrieved from: <https://www.federalregister.gov/documents/2019/10/28/2019-23464/medical-devices-ear-nose-and-throat-devices-classification-of-the-self-fitting-air-conduction> (accessed on November 02, 2022).
 9. Food and Drug Administration (2022). 510(K) clearance. Retrieved from: <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances> (accessed on November 02, 2022).
 10. Federal Trade Commission (1995). FTC Settles on False Advertising Charges Against Maker of "Miracle-Ear"... Retrieved from: <https://www.ftc.gov/news-events/news/press-releases/1995/11/ftc-settles-false-advertising-charges-against-maker-miracle-ear> (accessed on November 02, 2022).
 11. Manchaiah V, Taylor B, Dockens AL, Tran NR, Lane K, Castle M, Grover V. Applications of direct-to-consumer hearing devices for adults with hearing loss: a review. *Clin Interv Aging*. 2017 May 18;12:859-871. doi: 10.2147/CIA.S135390.
 12. Chan ZY, McPherson B. Over-the-Counter Hearing Aids: A Lost Decade for Change. *Biomed Res Int*. 2015;2015:827463. doi: 10.1155/2015/827463.
 13. Reed NS, Betz J, Lin FR, Mamo SK. Pilot Electroacoustic Analyses of a Sample of Direct-to-Consumer Amplification Products. *Otol Neurotol*. 2017 Jul;38(6):804-808. doi: 10.1097/MAO.0000000000001414.
 14. Almufarrij I, Munro KJ, Dawes P, Stone MA, Dillon H. Direct-to-Consumer Hearing Devices: Capabilities, Costs, and Cosmetics. *Trends Hear*. 2019 Jan-Dec;23:2331216519858301. doi: 10.1177/2331216519858301.
 15. Kochkin, S. (2010). MarkeTrak VIII: Utilization of PSAPs and Direct-Mail Hearing Aids by People with Hearing Impairment. *The Hearing Review*. Retrieved from:

- <https://hearingreview.com/hearing-products/marketrak-viii-utilization-of-psaps-and-direct-mail-hearing-aids-by-people-with-hearing-impairment> (accessed on November 02, 2022).
16. EHIMA (2022). Results – Japan Trak 2015. The Hearing Review. Retrieved from: <https://www.ehima.com/surveys/> (accessed on November 02, 2022).
 17. Sabin AT, Van Tasell DJ, Rabinowitz B, Dhar S. Validation of a Self-Fitting Method for Over-the-Counter Hearing Aids. *Trends Hear.* 2020 Jan-Dec;24:2331216519900589. doi: 10.1177/2331216519900589.
 18. Humes LE, Rogers SE, Quigley TM, Main AK, Kinney DL, Herring C. The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. *Am J Audiol.* 2017 Mar 1;26(1):53-79. doi: 10.1044/2017_AJA-16-0111. Erratum in: *Am J Audiol.* 2019 Sep 13;28(3):730.
 19. Clinical Trials (2022). OTC hearing aid. Retrieved from: <https://clinicaltrials.gov/ct2/results?cond=Hearing+Loss%2C+Sensorineural&term=OTC+hearing+aid&cntry=&state=&city=&dist=> (accessed on November 02, 2022).
 20. Food and Drug Administration (2022). How to get hearing aids. Retrieved from: https://www.fda.gov/medical-devices/hearing-aids/how-get-hearing-aids?utm_source=hearingtracker.com&utm_medium=newsletter (accessed on November 22, 2022).
 21. Manchaiah V, Amlani AM, Bricker CM, Whitfield CT, Ratinaud P. Benefits and Shortcomings of Direct-to-Consumer Hearing Devices: Analysis of Large Secondary Data Generated From Amazon Customer Reviews. *J Speech Lang Hear Res.* 2019 May 21;62(5):1506-1516. doi: 10.1044/2018_JSLHR-H-18-0370.
 22. Knudsen LV, Oberg M, Nielsen C, Naylor G, Kramer SE. Factors influencing help seeking, hearing aid uptake, hearing aid use and satisfaction with hearing aids: a review of the literature. *Trends Amplif.* 2010 Sep;14(3):127-54. doi: 10.1177/1084713810385712. \
 23. Tsimpida D, Kontopantelis E, Ashcroft D, Panagioti M. Comparison of Self-reported Measures of Hearing With an Objective Audiometric Measure in Adults in the English Longitudinal Study of Ageing. *JAMA Netw Open.* 2020 Aug 3;3(8):e2015009. doi: 10.1001/jamanetworkopen.2020.15009.
 24. Klyn NAM, Kleindienst Robler S, Bogle J, Alfakir R, Nielsen DW, Griffith JW, Carlson DL, Lundy L, Dhar S, Zapala DA. CEDRA: A Tool to Help Consumers Assess Risk for Ear Disease. *Ear Hear.* 2019 Nov-Dec;40(6):1261-1266. doi: 10.1097/AUD.0000000000000731.
 25. Hearing Loss Association of America. (2022). Over-the-Counter (OTC) hearing aids. Retrieved from: <https://www.hearingloss.org/hearing-help/technology/otc-hearing-devices/otc-hearing-aids/> (accessed on November 02, 2022).