



Frequently asked questions for Over-the-Counter (OTC) Hearing Aids

Over-the-Counter Hearing Aids Frequently Asked Questions

Over 90% of people that develop hearing loss in adulthood can benefit from using hearing aids, however, only 16% have ever used them.³ Effective October 17, 2022, the U.S. Food and Drug Administration (FDA) established a new category of hearing aids called over-the-counter (OTC) hearing aids. These hearing aids can now be purchased in stores, online, by mail, or from some NC licensed hearing healthcare professionals. These OTC hearing aids are intended for adults 18 years and older with perceived mild to moderate hearing loss. Below you will find answers to common questions about OTC hearing aids. To better understand certain terms related to OTC hearing aids please see the related [glossary](#). The following interactive table of contents provides sections of guidance to assist with understanding more about OTC hearing aids:

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An Introduction to OTC Hearing Aids

1. Who is an Over-the-Counter (OTC) hearing aid for?

- OTC hearing aids are for adults 18 and over with perceived mild to moderate hearing loss.

2. Are OTC hearing aids safe and effective?

- According to the FDA, the requirements for OTC hearing aids will “protect public health by providing reasonable assurance of safety and effectiveness for hearing aids.”²
- Anyone considering the purchase of OTC hearing aids should be aware that these devices may be unnecessary or inappropriate if certain health conditions are present. These conditions include, but are not limited to, ear wax impaction, infections, ear drum damage, and tumors.



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- If your hearing loss exceeds the mild or moderate range, an OTC hearing aid may not be effective. Many of these issues may be identified through audiologic testing and an ear examination.

3. What should I expect from using any kind of hearing aid?

- You should first notice that your ability to hear others and understand speech should be easier when using your hearing aid in a variety of listening environments.
- While each person's experience with a hearing aid differs, you should expect a period of adjustment to a new device that may last weeks to a few months.
- A well-fit hearing aid should be comfortable in your ear.

4. Do hearing aids that are not OTC still exist?

- Yes, hearing aids are still available through NC licensed hearing healthcare professionals (audiologists and hearing aid specialists). These professionals will evaluate hearing and prescribe appropriate hearing technology if the customer would benefit.

5. What do I get when I purchase an OTC hearing aid vs. when I purchase a prescription hearing aid from a NC licensed hearing healthcare professional (such as an Audiologist, Hearing Aid Specialist or Ear, Nose and Throat Doctor)?

- Over-the-Counter hearing aids are designed for mild to moderate hearing loss and do not require the expertise or services of a NC licensed hearing healthcare professional. The consumer is responsible for determining their level of hearing loss, choosing a product that will meet their needs, choosing a customizable or a self-fitting OTC hearing aid, and performing maintenance on the device.
- Prescription hearing aids are required to be fit by a NC licensed hearing healthcare professional. These professionals confirm the patient's degree and develop a graph of the hearing loss using calibrated testing equipment and assess the patient's speech understanding.
- These professionals can take ear impressions which allows them to build custom fit hearing aids and ear molds when necessary.
- Prescription hearing aids can address mild to profound hearing loss. Hearing healthcare professionals often provide ongoing maintenance plans within the initial purchase cost of a hearing aid. They also provide rehabilitation focused on learning to hear better, counseling related to hearing loss, ongoing testing, and ensure that hearing aids are adjusted to a patient's precise hearing loss.



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6. How are OTC hearing aids different from hearing devices previously available in drugstores and online?

- The FDA has created requirements for OTC hearing aids which separate them from personal amplifiers and personal sound amplification products (PSAPs). OTC hearing aids are designed for adults with mild to moderate hearing loss. PSAPs are intended for people with normal hearing to amplify sounds in certain situations but have been previously used by some people with hearing loss. Personal sound amplification products (PSAPs) are not medical devices, can be used by people of any age and have no FDA requirements regarding conditions for sale.¹ Some online companies as well as drug stores have advertised PSAPs as hearing aids even though they are not.

Is an OTC Hearing Aid Right for You?

1. How does the FDA describe mild to moderate hearing loss?

- According to the FDA, symptoms of mild to moderate hearing loss are: “having trouble hearing speech in noisy places, finding it hard to follow speech in groups, having trouble hearing on the phone, listening makes you tired, you need to turn the volume up on the TV or radio, and other people complain it’s too loud.”²
 - The above symptoms are not all inclusive for mild to moderate hearing loss and can also be symptoms of a more severe loss.

2. How do I KNOW if I have mild to moderate or severe to profound hearing loss?

- The only way to know the severity of your hearing loss is to have your hearing evaluated by a NC licensed hearing healthcare professional; however, the FDA stance is that such evaluation is not necessary for assurance of safety and effectiveness of OTC aids.²

3. What do I do if I have concerns that I may have a medical condition that is causing my hearing loss?

- You can discuss medical concerns with your primary healthcare provider. You can also consult with an otolaryngologist (ear, nose, and throat doctor) to rule out an underlying medical condition that may be treatable without hearing aids.
 - Check with your Medicare, Medicaid, or private insurance to see if costs for such a consultation are covered.
- The FDA states that the following are signs that professional services are needed: you can’t hear speech even if the room is quiet, you don’t hear loud sounds well, for example, you don’t hear loud music, power tools, or other very noisy things. The FDA states that, “If your hearing loss makes it hard to hear loud noises, an OTC hearing aid may not be your best choice without help from a professional. If this



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OTC hearing aid does not help you enough, ask for help from a hearing healthcare professional.”²

4. How do I know if I am comfortable enough with technology to set up an OTC hearing aid?

- The OTC hearing aid may require you to set up the hearing aid without the help of an on-site hearing healthcare professional.
- You should read the outside of the package labeling carefully first to determine what is needed to set up the device. You may need a specific type of smartphone, laptop or tablet to effectively set up the device.
- Reading the instructions for device set up should help you determine whether you are comfortable enough with the technology required to set up the OTC hearing aid. You may be able to download instructions from the device manufacturer website before purchasing.

5. Do I have a computer, smart device or the technology needed to set up the OTC Hearing Aid?

- The FDA requires that the outside package labeling of the OTC hearing aid state whether a separate device, such as a smartphone, personal computer or tablet is required for set-up. The labeling must also include how to connect the separate device to the hearing aid (for example, Bluetooth or USB-C cable).

Shopping for an OTC Hearing Aid

1. How much do OTC hearing aids cost?

- Experts are reporting different costs and price ranges may vary depending on where you are shopping for OTC hearing aids. Results from an online search of about nine of the most popular OTC brands displayed a range of costs from \$149-\$2,950 per pair.

2. Where can I purchase OTC hearing aids?

- Some places where OTC hearing aids can be purchased are, retail stores, pharmacies, internet retail sites, by mail, and some NC licensed hearing healthcare providers to name a few.

3. How do I determine if the device I am looking at is an OTC hearing aid regulated by the FDA?

- The packaging of an OTC hearing aid must use bold print to display the words “OTC” and “hearing aid”.



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4. What are important things to consider when determining whether to buy an OTC hearing aid?

- OTC hearing aids are intended for use by adults with perceived mild to moderate hearing loss. Ask yourself the following questions to help determine if an OTC hearing aid is right for you:
 1. Do I feel comfortable adjusting certain features of my OTC hearing aids by hand or by using a computer or smart device application (app)?
 2. Do I feel comfortable learning to use an OTC hearing aid by reading or watching video instructions listed on the package or internet, or by talking to a person via phone or online?
 3. Do I have family, friends, or professional support that would help me to operate and maintain these electronic devices?
 4. Do I feel comfortable mailing in my OTC hearing aids for repair and replacing parts such as batteries, ear tips, wax guards and microphone filters myself?
 5. Do I feel comfortable comparing different OTC hearing aids to determine which would be beneficial to me?
 6. If you answered “no”, to any of these questions, you may want to consider if you would prefer to buy prescription hearing aids or OTC hearing aids from a NC licensed hearing healthcare professional who will provide in-person care after the purchase.

5. There are many OTC hearing aids on the market, below is a list of questions to consider when choosing which device is right for you.

- Is there a free trial period or money-back return policy?
- Does the OTC hearing aid need a smartphone, application (app) or computer to install, operate and customize to my needs?
- Is it compatible with cellphones or smartphones to hear calls?
- Will it connect via Bluetooth or telecoil to a smartphone, computer or listening system?
- What sort of assistance does the seller provide for the initial set-up of the hearing aid and accessories?
- How long is customer support provided after purchase?
- How long is the battery life? Can it be recharged?
- If the hearing aid uses a rechargeable battery, how much will it cost to replace the original battery when it stops functioning?
- Is it water or sweat resistant?
- How does it control, reduce, or block out background noise?



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6. Will an OTC hearing aid be programmed and customized to fit my specific hearing loss?

- While some OTC hearing aids will have customizable sound settings, others will not be programmed specifically to fit your hearing loss for the following two reasons:
 1. A formal audiogram used to measure degree and type of hearing loss is not needed to purchase an OTC hearing aid.
 2. A NC licensed hearing healthcare professional who is trained to program and customize hearing aids specific to hearing losses is not required to be involved in the purchase.
- Some OTC hearing aids will be more customizable than others.

7. How do I know if everything I need to get started is in the box?

- See the questions below regarding what information you can find on the outside and inside of the box. The outside labeling will include a weblink of where the user instructional brochure can be found so you can learn more about what is included before you make a purchase.

8. How do I know if there is a return policy or what the return policy is?

- The outside of the package labeling is required to include a statement of the return policy or absence of a return policy.²

9. What should I consider when deciding whether a return policy is sufficient or not?

- OTC hearing aids are not required to have a return policy. If having such a policy is important to you, making sure there is one at all should be the first step.
- A period of adjustment to an OTC hearing aid may last weeks to a few months. Consider how long you have to return the device after purchase.
- One may also want to consider whether or not you can return an open box/used device, and if you will receive your money back vs. store credit, etc.

10. Are retail store and website customer service staff trained to answer my OTC Hearing Aid questions?

- The FDA does not require training for sellers of OTC hearing aids so you may experience varying levels of knowledge. You may consider doing some research on your own and checking reviews from reputable sources.

11. How do I find information on the batteries used in OTC hearing aids and how long will they last?

- The FDA requires the labeling on the outside of the package to include the battery type, number of batteries and whether they are included in the box.² The inside of the package labeling is required by the FDA to indicate the expected battery life.²



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12. What information can I find on the label of an OTC hearing aid?

- The outside of the package labeling must include the following:²
 - The words “OTC” and “hearing aid” so non-OTC hearing aids or non-hearing aids will not be confused with OTC hearing aids.
 - A warning for people under age 18 not to use OTC hearing aid(s).
 - A [list of symptoms](#) suggesting perceived mild to moderate hearing loss.
 - Information on how to know if you should seek help from a professional
 - A list of “red flag” conditions (find the FDA list [here](#))
 - A weblink and additional contact information for the company
 - A statement of the manufacturer’s return policy or absence of return policy
 - A statement indicating if the OTC hearing aid is used or rebuilt
 - Information about the type and number of batteries required and if they are included.
 - Whether a mobile phone or other device not included is needed to control the OTC hearing aid(s) and how this device will connect to the aid(s)

13. What information will I find inside the box?

- Inside the package must include: ²
 - User instructional brochure
 - Warnings:
 - Against use by people younger than 18
 - [When to see a doctor](#)
 - Potential pain from device placement
 - Cautions:
 - Stating that the device is not intended for hearing protection
 - Sound output from the device should not be uncomfortable or painful
 - What to do if a piece gets stuck in your ear
 - Additional guidance:
 - About [when to seek professional services](#)
 - [User expectations](#)
 - [Reporting negative events to the FDA](#)
 - An illustration of the OTC hearing aid noting the different parts
 - Description of accessories included (including but not limited to wax guards and accessories for use with a computer, television, or telephone.)
 - Specific instructions for:
 - Sizing and inserting the ear tip(s)
 - Using the accompanying tools and/or included software
 - Use of the OTC hearing aid
 - Use of any accompanying accessories



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- Maintenance and care
- Information regarding the battery
- Identification of any known side effects
- The technical specifications of the OTC hearing aid
- A description of common, avoidable events that could negatively affect or damage the OTC hearing aid
- Information on how or where to obtain repair service or replacement parts
- A summary of clinical or non-clinical studies if conducted
- “If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.”²

What Happens Following the Purchase of an OTC Hearing Aid?

1. Will the OTC hearing aid require maintenance?

- Any hearing aid, whether it be OTC or prescription, will require maintenance. For proper performance of hearing aids, there are certain parts that may need to be changed and replaced periodically, such as hearing aid batteries, wax filters, microphone covers, ear molds, ear mold tubes, and earbuds. It is also best to [dehumidify](#) your hearing aids. Devices should also be cleaned regularly to disinfect. This will help prevent outer ear canal infections, and it will also help the hearing aid components last longer which should result in better hearing aid performance.
- The FDA requires the inside of the box labeling to include information on the maintenance and care of the OTC hearing aid. This information must explain how you “can clean, disinfect, and replace parts or how to seek replacements, as well as how to store the hearing aid when it will not be used for an extended period of time.”²

2. How do I get help with my OTC hearing aid or repairs after my purchase?

- Review the instruction manual for your OTC hearing aid for performing required maintenance, reprogramming or adjustments, and troubleshooting information.
- Check your instructions to see if there is a customer service department that you can contact for help or recommendations.
- The FDA states, “If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.”²
- The inside package labeling includes “information on how and where to obtain repair service or replacements, with at least one specific address where the user can go or send the OTC hearing aid to obtain such repair service or replacements.”²



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- 3. Do any of the manufactures or distributors of OTC hearing aids offer hearing aid adjustments?**
 - Some brands do offer remote hearing aid adjustments, but the support varies between companies; it is best to look at the manufacturer’s website for details and ask questions to clarify.

- 4. What do I do if I have a complaint about the company or experience an adverse event?**
 - The FDA, states that adverse events while using the OTC hearing aid could include “skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.”²
 - The inside of the package labeling should include the manufacturer’s contact information, if you want to notify them, and is required to include a note to report to the FDA about injuries, malfunctions, or other adverse events and gives examples of what those may be.
 - Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or you may call 1-800-FDA-1088. You can also download a form to mail to FDA.²

- 5. Will I be able to take an OTC hearing aid to a NC licensed hearing healthcare professional and have them program or fix it if it breaks?**
 - According to the FDA, “A licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.”² You will have to reach out to NC licensed hearing healthcare professionals to see if they can program or fix OTC hearing aids and what the cost may be as it can vary.
 - The FDA also “recommends consulting licensed persons in several circumstances, including for the diagnosis, fitting and continued use of OTC hearing aids when consumers choose to seek such services.”²

- 6. What do I do if I think my hearing has changed after I already purchased an OTC hearing aid?**
 - There are several things you can do, including but not limited to:
 - Review the instruction manual for your OTC hearing aid and ensure you have been performing required maintenance, see if it may need to be reprogrammed or adjusted, and follow any troubleshooting information available.
 - Check your instructions to see if there is a customer service department that you can contact for help or recommendations.
 - Contact the FDA with issues if you are unable to get assistance from the manufacturer’s customer service.



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- If you feel that your hearing might have become worse you can contact an Audiologist, Hearing Aid Specialist or Otolaryngologist to see if your hearing loss is more severe than mild to moderate and/or if there is a medical reason behind the loss.
 - The FDA states, “If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.”²

Available Resources

1. What are low cost or no cost resources for people here in North Carolina to obtain hearing aids?

- In North Carolina there are certain no cost and low-cost programs offered to people with hearing loss. Some of these programs are dependent on criteria such as the degree of hearing loss, necessity for hearing aids to fulfill a job requirement, and one’s income level. Please see this comprehensive [list](#).

2. What can my North Carolina Division of Services for the Deaf and Hard of Hearing regional center help me with?

- By contacting a North Carolina Division of Services for the Deaf and Hard of Hearing Regional Center you can connect with a Hard of Hearing Services Specialist who is a knowledgeable staff member and a resource for information on hearing loss. The specialist can answer questions you may have about hearing loss, equipment, technology, your rights, and more. The staff can also help you connect with other organizations that provide resources and/or support for hearing loss.

Hearing Healthcare Professionals

1. What is meant by the term hearing healthcare professional?

- A hearing healthcare professional is an individual that has completed advanced education and received certification/licensure to provide care to individuals with hearing related disabilities. The following individuals are generally considered hearing healthcare professionals and carry NC licensure:
 - Ear Nose and Throat physicians, also known as otolaryngologists
 - Audiologists
 - Hearing Aid Specialists



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- 2. Are there still hearing healthcare professionals such as licensed Audiologists, Hearing Aid Specialists, and Ear Nose and Throat Doctors, where I can get hearing aids?**
- Yes, in North Carolina prescription hearing aids can be fit by either a Medical Doctor, Audiologist, or Hearing Aid Specialist who is licensed and qualified to do so.
 - A licensed person is not required for consumers to access OTC hearing aids; however, “a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.”²

Other Important Questions

- 1. Will the NC Division of Services for the Deaf and Hard of Hearing continue to provide updates and important information about OTC hearing aids?**
- The Division of Services for the Deaf and Hard of Hearing (DSDHH) is committed to helping North Carolinians understand their rights and resources as a person with hearing loss. DSDHH will continue to navigate the landscape of OTC hearing aids and share information that will help consumers make informed decisions.
 - As new beneficial resources are discovered or information changes, this website will be updated.
- 2. What other resources are available to assist North Carolinians with understanding OTC Hearing Aids?**
- American Academy of Otolaryngology-Head and Neck Surgery: [FDA Over-The-Counter Hearing Aids Final Rule](#)
 - Centers for Disease Control and Prevention: [What If I Already Have Hearing Loss?](#)
 - DSDHH: [An Introduction to Hearing Aids](#)
 - FDA: [Hearing Aids](#)
 - FDA: [OTC Hearing Aids: What You Should Know](#)
 - FDA: [Types of Hearing Aids](#)
 - Hearing Industries Association: [Over-the-Counter Hearing Aids](#)
 - Hearing Loss Association of America: [Over-the-Counter Hearing Aids](#)
 - National Council on Aging: [How to Avoid Over-the-Counter Hearing Aid Scams in 2023](#)
 - National Institute on Deafness and Other Communication Disorders: [Over-the-Counter Hearing Aids](#)

The above links may help you to learn more about hearing, hearing aids, and OTC hearing aids. Many are links outside of NC DHHS and the NC Division of Services for the Deaf and Hard of Hearing does not control the content on these pages.



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Works Cited

1. [Hearing Aids and Personal Sound Amplification Products: What to Know](#)
2. [Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids](#)
3. [National Institute on Deafness and Other Communication Disorders: Quick Statistics About Hearing](#)

