



OTC Hearing Aids FAQs

What Are Over-the-Counter (OTC) Hearing Aids?

Over-the-counter hearing aids are devices that consumers can buy directly from traditional retailers and pharmacies without the need for a visit to a hearing health professional.

Why Are Hearing Aids Now Being Offered Over the Counter?

In 2017, Congress passed bipartisan legislation requiring the U.S. Food and Drug Administration (FDA) to create a category of OTC hearing aids, but it was not fully implemented until now, with OTC hearing aids available in traditional retail and drug stores as soon as October 17, 2022, when the rule took effect.

Who Is a Good Candidate for OTC Hearing Aids versus Prescription Hearing Aids?

OTC hearing aids are for adults 18 years of age or older who think they have mild-to-moderate hearing loss. You may have mild-to-moderate hearing loss if, for example:

- Sounds or speech seem quiet or muffled to you.
- You have difficulty hearing in a group setting, with background noise (e.g., restaurant), speaking on the phone, or need to face people when talking to understand them.
- You ask others to repeat themselves or speak more loudly.
- People complain that you turn up the TV or radio too high.

Can Children Use OTC Hearing Aids?

Currently, the FDA regulations state that OTC hearing aids are for adults (18 years of age or older). Children should see a hearing health professional for evaluation and obtaining a hearing aid.

What Are the Benefits and Concerns Associated with OTC Hearing Aids?

The primary benefit of OTC hearing aids is the lower cost and ease of purchase of these devices compared to hearing aids obtained from a hearing health professional. Concerns related to OTC hearing aids start with the most basic question: **Does the customer have hearing loss and is it the type for which OTC hearing aids are designed?** Additional consideration should be given if the individual's hearing loss comes from a medical problem that can be corrected (eliminating the need for a hearing aid) or addressed to prevent worsening the hearing loss or more serious problems. These conditions would be missed without an evaluation by a hearing health professional. Obtaining the best result and avoiding pain and infection depend on a properly fitting hearing aid. If your OTC hearing aid becomes painful to put in your ear, you should see an ENT (ear, nose, and throat) specialist, or otolaryngologist.

How Much Will OTC Hearing Aids Cost?

The cost of OTC hearing aids will depend on the complexity and features of the device as well as other provisions included in the sale, such as service, returns, and the degree of support the manufacturer provides. Companies that provide telephone-based help and remote programming of the devices charge approximately \$1,500 to \$3,000 for a pair of OTC hearing aids. Off-the-shelf devices that do not offer those services may cost approximately \$200 to \$800 for a pair of devices.

Will My Insurance, Medicare, and/or Medicaid Cover OTC Hearing Aids?

Medicare currently does not cover any hearing aids. Medicaid coverage for those over 18 years old will vary by state, and you have to check with your Medicaid program. Some private health insurance plans do not cover the cost of hearing aids, so you should check with your particular insurance regarding coverage for OTC hearing aids.

How Will I Know Which Kind of OTC Hearing Aid to Select? What Is the Return Policy?

The marketplace for OTC hearing aids has just opened (as of October 17, 2022) and identifying the right device for you may be challenging. As more devices become available, it may become easier to select the right device for you. You should also consider these issues:

- Is it waterproof?
- Does it block out background sound?
- Does it have Bluetooth capability?
- Is it compatible with your smart phone?
- Does it come with an app to help customize my individual hearing profile?
- How long does the battery last? Is it rechargeable?
- Does it have adequate and understandable sizing choices?

Manufacturers of OTC hearing aids are required by the FDA to report their return policy; however, OTC sales do not require a return policy, so [you should review that policy before buying an OTC hearing aid](#). Most reputable prescription hearing aid dispensers offer a one-month trial period, and you should look for something similar for your OTC hearing aids before purchasing them.

What Technological Issues Should I Consider?

Different OTC hearing aids will offer different features, may be programmable, and will likely be offered at different price points, but most OTC hearing aids will probably be compatible with other devices. If compatibility is important to you, be sure to check if your OTC hearing aids will work with your smart phone before purchasing them.

Are There Other Types of Hearing Devices I Should Consider?

For people with the type of hearing loss that would benefit from OTC hearing aids, there are additional options you may consider:

- A personal amplification device may be helpful and possibly less expensive than OTC hearing aids. These devices are typically a “boxy” receiver attached to headphones and are therefore bulkier than what you would expect from hearing aids. One example is a pocket talker.
- Personal sound amplification products (PSAPs) amplify sound for the user but are intended for people with normal hearing to amplify sounds in certain situations, such as recreational activities like birdwatching, according to the FDA. PSAPs are regulated as consumer electronics and not medical devices.
- Traditional prescription hearing aids from an ENT specialist or audiologist are a good choice if you are not getting the boost you would like from OTC hearing aids. OTC devices are not tuned to a hearing test, but prescription hearing aids are tuned to your exact level of hearing.

What Are FDA “Red Flag” Conditions and What Do They Mean?

The list below describes conditions that need medical attention to prevent additional problems and complications. You should see a doctor—preferably an ENT specialist—if you have any of these red flag conditions indicating that there is a medical condition causing your hearing loss, including:

- Your ear has a birth defect or an unusual shape or your ear was injured or deformed in an accident.
- You have had blood, pus, or fluid coming out of your ear during the past six months.
- Your ear feels painful or uncomfortable.
- You have a lot of ear wax, or you think something could be in your ear.
- You feel dizzy or have a feeling of spinning or swaying (called vertigo).
- Your hearing changed suddenly in the past six months.

- Your hearing gets worse then gets better again.
- You have worse hearing in one ear.
- You hear ringing or buzzing in only one ear.

Who Should I Talk to If I Have Questions About OTC Hearing Aids?

If you need help deciding if you have hearing loss, if OTC hearing aids are right for you, or if you need prescription strength hearing aids, a hearing specialist—ENT specialist or an audiologist—can help you. Tell them if you are experiencing any red flag conditions listed above. And be sure you know the return policy of the OTC hearing aid you are considering.

Are There Other Resources Available to Learn More About Hearing Loss?

<https://www.nia.nih.gov/health/hearing-loss-common-problem-older-adults>

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