



NIDCD Fact Sheet | Hearing and Balance

Over-the-Counter Hearing Aids

What are over-the-counter (OTC) hearing aids?

Over-the-counter (OTC) hearing aids are a new category of hearing aids that consumers can buy directly, without visiting a hearing health professional (<https://www.nidcd.nih.gov/health/who-can-i-turn-help-my-hearing-loss>). These devices are intended to help adults with perceived mild to moderate hearing loss. Like prescription hearing aids (<https://www.nidcd.nih.gov/health/hearing-aids>), OTC hearing aids make sounds louder so that some adults with difficulty hearing are better able to listen, communicate, and participate fully in daily activities. In addition, OTC hearing aids are regulated as medical devices by the U.S. Food and Drug Administration (FDA).

OTC hearing aids are an alternative to prescription hearing aids, which are currently only available from hearing health professionals, such as audiologists, otolaryngologists (ear, nose, and throat doctors), and hearing aid specialists. The hearing health professional fits you for the hearing aid, adjusts the device based on your hearing loss, and provides other services.



OTC hearing aids may help adults with perceived mild to moderate hearing loss hear better by making sounds louder.

You can buy OTC hearing aids as soon as mid-October 2022 directly in stores and online, where prescription hearing aids are not available. You fit them yourself, and you may be able to control and adjust the devices in ways that users of prescription hearing aids cannot. Some OTC hearing aids might not look like prescription hearing aids at all.

OTC hearing aids are for adults with perceived mild to moderate hearing loss. They are not meant for children or for adults who have more severe hearing loss or significant difficulty hearing. If you have more severe hearing loss, OTC hearing aids might not be able to amplify sounds at high enough levels to help you.

The FDA has established regulations that manufacturers of OTC hearing aids need to follow. In general, these federal regulations:

- ▶ Ensure that the OTC devices are *safe* and *effective* for people with perceived mild to moderate hearing loss.
- ▶ Set standards for package labels to help buyers understand OTC hearing aids and who might benefit from them. The labels also include warnings and other information you should know before buying or when using the hearing aid, such as signs that indicate that you should see a doctor.

Personal sound amplification products (PSAPs) are another class of amplifying devices that you can purchase without a prescription or seeing a health care professional. PSAPs are for people without hearing loss. They boost the ability to hear certain sounds in specific situations, such as while bird-watching. While the FDA regulates OTC hearing aids as medical devices for adults for hearing loss, PSAPs are *not* regulated as medical devices by the FDA.

Who are OTC hearing aids for?

OTC hearing aids are for adults (18 and older) who believe they have mild to moderate hearing loss, even if they have not had a hearing exam. You might have mild to moderate hearing loss if, for example:

- ▶ Speech or other sounds seem muffled.
- ▶ You have trouble hearing when you're in a group, in a noisy area, on the phone, or when you can't see who is talking.

- ▶ You have to ask others to speak more slowly or clearly, to talk louder, or to repeat what they said.
- ▶ You turn up the volume higher than other people prefer when watching TV or listening to the radio or music.

If you have trouble hearing conversations in quiet settings—or have trouble hearing loud sounds, such as cars or trucks, noisy appliances, or loud music—consult a hearing health professional. These are signs that you might have more severe hearing loss and that OTC hearing aids won't work well for you. A hearing health professional can help you determine if a prescription hearing aid or other device can help you hear better.

Some ear problems need medical treatment. If you have any of the following, please see a licensed physician promptly:

- ▶ Fluid, pus, or blood coming out of your ear within the previous 6 months.
- ▶ Pain or discomfort in your ear.
- ▶ A history of excessive ear wax or suspicion that something is in your ear canal.
- ▶ Episodes of vertigo (severe dizziness) with hearing loss (<https://www.nidcd.nih.gov/health/balance-disorders>).
- ▶ Sudden hearing loss or quickly worsening hearing loss (<https://www.nidcd.nih.gov/health/sudden-deafness>).
- ▶ Hearing loss that has gotten more and then less severe within the last 6 months.
- ▶ Hearing loss or tinnitus (ringing) in only one ear (<https://www.nidcd.nih.gov/health/tinnitus>), or a noticeable difference in how well you can hear in each ear.

Why are some hearing aids available without a prescription?

Hearing loss significantly affects quality of life for tens of millions of adults in the United States and contributes to high health care costs. Untreated hearing loss can lead to isolation, and it has been associated with serious conditions such as depression, anxiety, low self-esteem, dementia, reduced mobility, and falls. Yet only one in four adults who could benefit from hearing aids has ever used them. Making hearing health care more accessible and affordable is a public health priority, especially as the number of older adults in the U.S. continues to grow.

Leading experts in science, technology, and hearing health care have been working with researchers, health professionals, and consumers to find safe and effective ways to improve access to hearing health care for adults. They suggested changing some regulations that studies showed were barriers to adults getting the hearing help they need. They also recommended that

the FDA create guidelines and quality standards for OTC hearing aids.

A law established as part of the FDA Reauthorization Act of 2017 directed the FDA to create a category of OTC hearing aids for adults with perceived mild to moderate hearing loss. As part of this process, in October 2021, the FDA formally proposed a rule to establish the new OTC hearing aids category. Finalized in August 2022 (<https://www.fda.gov/news-events/press-announcements/fda-finalizes-historic-rule-enabling-access-over-counter-hearing-aids-millions-americans>), the final rule (<https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids>) allows hearing aids within this category to be sold directly to consumers in stores or online without a medical exam or a fitting by an audiologist. Hearing aids for more severe hearing loss or for users younger than age 18 remain prescription devices.

OTC hearing aids are for adults (18 and older) who believe they have mild to moderate hearing loss, even if they have not had a hearing exam.



National Institute on
Deafness and Other
Communication Disorders

Where can I find more information about hearing loss and hearing aids?

The NIDCD maintains an online directory of organizations that provide information on the normal and disordered processes of hearing, balance, taste, smell, voice, speech, and language. Visit the NIDCD website at <https://www.nidcd.nih.gov> to search the directory.

To read more about hearing loss and hearing aids, visit:

- ▶ Age-Related Hearing Loss
- ▶ Hearing Aids
- ▶ Hearing Aids (FDA)

To learn more about research that the NIDCD supports to make hearing health care more accessible and affordable, visit <https://www.nidcd.nih.gov/research/improve-hearing-health-care>.

Visit the NIDCD website at <https://www.nidcd.nih.gov> to read, print, or download fact sheets.

For more information, contact us at:

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The NIDCD supports and conducts research and research training on the normal and disordered processes of hearing, balance, taste, smell, voice, speech, and language and provides health information, based upon scientific discovery, to the public.



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