

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 will soon be able to 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 people with perceived mild-to-moderate hearing loss. Like traditional hearing aids (<https://www.nidcd.nih.gov/health/hearing-aids>), OTC hearing aids will make sounds louder so that some people with difficulty hearing are better able to listen, communicate, and participate fully in daily activities. In addition, OTC hearing aids will be regulated as medical devices by the U.S. Food and Drug Administration (FDA).

OTC hearing aids will be an alternative to today's FDA-regulated 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.

When OTC hearing aids are available, you will be able to buy them directly in stores and online, where today's hearing aids are not available. You will fit them yourself, and you may be able to control and adjust the devices in ways that users of today's hearing aids cannot. Some OTC hearing aids might not look like today's hearing aids at all.



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

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

The FDA is establishing regulations that manufacturers of OTC hearing aids will need to follow. In general, these federal regulations will:

- ▶ Ensure that the OTC devices are *safe* and *effective* for people with 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 will 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 your primary care provider or other health care professional.

Currently, hearing devices that you can buy directly (without seeing a health care professional first) are not intended for people with hearing loss. Importantly, these devices, known as personal sound amplification products (PSAPs), are for people without hearing loss to boost their ability to hear certain sounds in certain situations, such as while hunting. While the FDA will regulate OTC hearing aids as medical devices for adults for hearing loss, PSAPs are *not* regulated as medical devices by the FDA. In October 2021, the FDA released a draft guidance document (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products>) intended to describe hearing aids, PSAPs, their respective intended uses, and regulatory requirements that apply to both types of products.

Who are OTC hearing aids for?

OTC hearing aids will be for adults 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 find a hearing aid or other device to 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 six 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 six 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.

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.

Why are some hearing aids becoming 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 (<https://www.fda.gov/news-events/press-announcements/fda-issues-landmark-proposal-improve-access-hearing-aid-technology-millions-americans>) to establish the new OTC hearing aids category. When finalized, the rule would allow 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 severe hearing loss or for users younger than age 18 would remain prescription devices.

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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 <http://www.nidcd.nih.gov> to search the directory.

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

- ▶ Hearing Loss and Older Adults
- ▶ Hearing Aids
- ▶ Hearing Aids (FDA)

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.

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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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