



# Sound Source

Physician Newsletter | October 2022

## Over-The-Counter (OTC) Hearing Aids

In August 2022, the FDA issued the final rules and guidelines for over-the-counter (OTC) hearing aids. These rules established two categories for hearing devices: 1. Over-The-Counter - available directly to consumers with no need for audiological evaluation and programmed/managed by the patient, and 2. Prescriptive - available only through hearing care professionals and fit/programmed based on audiological evaluation.

OTCs provide additional choices and greater access to treatment for individuals with communication concerns. These devices are likely to be for sale in retail centers, online and through mail-order. The FDA did not establish a requirement for a trial period or a refund policy for OTCs. Consumers should look on the packaging for the terms of sale prior to purchase. Although these may be a good option for some individuals, they are not appropriate for everyone.

## Candidates for Over-The-Counter Hearing Aids

### 1) Mild to moderate hearing loss

Individuals who can understand speech in a quiet environment at typical volume but have difficulty understanding soft or distant speech may be candidates for OTCs. OTCs will not adequately address hearing losses that exceed a mild to moderate level.

### 2) Adults - age 18 and older

The FDA has long recommended children under 18 years of age are best fit by an audiologist who has specialized training in treating the unique needs of this population. It is critical that children and adolescents receive hearing aid fittings that are based on prescriptive formulas and verified to be accurate.

### 3) Is the patient physically and cognitively able to manipulate the devices?

The OTC rules were established to provide access to hearing devices without the services of a licensed audiologist or other professional. Individuals using these devices should have the ability to understand and physically manipulate technology.

# Contraindications for OTC Hearing Aids

Medical and audiological evaluation is recommended when individuals meet any of the following conditions:

- Under the age of 18
- Deformity of the ear(s)
- Hearing differently between ears
- Drainage from the ear
- Tinnitus
- Vertigo
- Pain in the ears
- History of infections







---

## Prescriptive Devices

### What to look for when referring to an Audiology Clinic

Audiologists can guide the patient in selecting appropriate prescriptive devices and will program those devices for speech audibility. Follow-up care will also help the patient to be successful and may include patient education regarding use and care of devices, aural rehabilitation, verification of the hearing aid fittings, and validation of patient benefit.

### Best Practices For Fitting Hearing Aids

-  A comprehensive audiologic evaluation, including lifestyle and needs assessment
-  Access to a variety of communication device choices for individualization of treatment
-  Objective testing to verify hearing aid fittings for proper output and function of devices
-  Aided speech testing to confirm benefit of devices
-  Follow-up care which addresses ongoing communication and hearing healthcare needs
-  Counseling and aural rehabilitation for ongoing communication support

---

**Did you know?:** Although OTCs do not require professional evaluation or fitting, if your patient has purchased an OTC and is not satisfied, an audiologist may be able to help by evaluating the device and its appropriateness for the individual's hearing needs, providing guidance on tuning or setting the device, and educating about use and care.

## Questions about hearing devices?

1966 Inwood Rd., Dallas, TX 75235  
972-883-3030

[Alexandra.Harris@utdallas.edu](mailto:Alexandra.Harris@utdallas.edu)

2895 Facilities Way, Richardson, TX 75080  
972-883-3630

[Shawna.Jackson@utdallas.edu](mailto:Shawna.Jackson@utdallas.edu)