



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

Over-the-Counter (OTC) Hearing Aid Glossary Terms:

Application (app): Software that is created for a mobile device (for example, smartphone, tablet, computer) and can be used to set up, operate, or adjust the settings of an OTC hearing aid. This is often referred to as an “app”.

Comprehensive hearing evaluation: An in-depth assessment of a person’s hearing done by a NC licensed hearing healthcare professional. The goal of the assessment is to determine the type and degree of hearing loss.

Conditions for sale: Refers to the requirements for the sale of an OTC hearing aid. For example: minimum age requirement. The OTC hearing aid conditions for sale can be found [here](#).

Customizable (hearing aid): Has basic features like volume control and preset programs that allow a user to control the device.

Dispenser: According to the FDA, this is any person engaged in the sale, lease, or rental of hearing aids. In North Carolina this is any non-licensed individual providing the sale of OTC hearing aids.

FDA: [U.S. Food and Drug Administration](#). The FDA regulates all hearing aids to ensure they are safe and effective. The FDA has established the new category of OTC hearing aids.

Hearing Aid: A small electronic medical device that makes some sounds louder so that a person with hearing loss can hear sounds and understand speech more clearly.

- There are several different styles of hearing aids such as: behind-the-ear (BTE), mini BTE, receiver in-the canal, in-the-ear (ITE), and completely-in-the-canal aids (CIC), to name a few.¹
- Some of the common features of hearing aids can be directional microphone(s), noise reduction, feedback suppression, telecoil switch, wireless connectivity, and direct audio input.¹
 - a) **Air conduction hearing aid:** Conducts sound to the ear through the air. Most hearing aids work by air conduction.
 - b) **Over-the-counter (OTC) hearing aid:** An air conduction hearing aid that is intended for people aged 18 or older who have mild to moderate hearing loss. The device is sold over the counter and does not require the involvement of a licensed person. These hearing aids can be purchased in stores, online, by mail, or from some licensed hearing healthcare professionals.
 - c) **Prescription hearing aid:** A hearing aid intended for people of any age and with any degree of hearing loss. These require a prescription and must be purchased from and fit by a NC licensed hearing health professional.

Hearing Screening: A simple assessment to see how well you hear varying tones. These assessments are not diagnostic and are pass or fail only. In NC, anyone can conduct a hearing screening if properly trained and supervised by a NC licensed Audiologist or Physician.



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

Licensed person: An individual who holds a license to diagnose, assess, treat, or dispense prescription hearing aids for hearing loss. In North Carolina, only a NC licensed hearing healthcare professional may perform these services for prescription hearing aids.

- **Hearing Aid Specialist:** A NC licensed hearing healthcare professional who conducts basic hearing tests and specializes in fitting prescription hearing aids.
- **Otolaryngologist:** A NC licensed medical physician who specializes in the ears, nose, and throat. These specialists are trained in medicine and surgery. These professionals are often called an ear, nose, and throat physician or ENT. This professional may work with you to diagnose hearing loss and offer treatment options. They may refer you to another hearing health professional to receive a hearing test and to be fit for a hearing aid.²
- **Audiologist:** A NC licensed hearing healthcare professional who provides non-medical evaluation, diagnoses, treatment, and management of hearing loss and balance disorders in individuals of all ages. These professionals are licensed to fit prescription hearing aids.

Perceived mild to moderate hearing loss: This is the term the FDA uses to describe the level of hearing loss for intended OTC hearing aid uses. By definition a mild hearing loss is between 25-40dB and a moderate loss is between 40-60dB. The FDA also describes mild-moderate hearing loss as “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.”

Personal Amplifiers: About the size of a cell phone, these devices increase volume levels and can reduce background noise for a listener. Some have directional microphones that can be pointed toward a speaker or other source of the sound. Features of these devices vary, with some including tone control and telecoil mode.

Personal Sound Amplification Product (PSAP): Electronic devices intended to amplify sounds for people with normal hearing but have been historically used by people to compensate for hearing loss and have been marketed for this use. PSAPs are not medical devices, are not hearing aids, and are not to be mistaken for OTC hearing aids.

Self-fitting (hearing aid): Has greater customization options than a “customizable OTC hearing aid”. The user may create a greater number of volume profiles that more closely resemble the fitting process done by a licensed hearing health professional.³

Telecoil (T-coil): A small coil of wire inside of hearing aids and cochlear implants that receives electromagnetic signals transmitted by compatible telephones, loops, and other devices so the sound is delivered directly to the user's ear. This helps overcome interference from background noise and can improve speech understanding.



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

Tools, tests, & software: Refers to the parts that may accompany an OTC hearing aid that would allow a user to control or customize the device to meet their hearing needs. For example, allowing the user to adjust the volume.

Works Cited

1. [Types of Hearing Aids](#)
2. [Who Can I Turn to for Help with My Hearing Loss?](#)
3. [Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids](#)

