

Over the Counter (OTC) Hearing Aids: Frequently Asked Questions

What are OTC hearing aids?

Over-the-Counter Hearing Aid Act of 2017 laid the groundwork for OTC hearing aids to be sold directly to the consumer. FDA regulations for the sale of over-the-counter (OTC) hearing aids have been recently approved in the US for those adults (over the age of 18 years) with a perceived mild or moderate hearing loss. The FDA regulations are set to try to ensure that the hearing aids would be able meet the needs of the user while ensuring the safety of the consumer.

OTCs/PSAPs and prescription hearing aids: Oh My! What are the differences?

Personal Sound Amplification Products (PSAP) only have a basic volume control and are designed for adults with mostly normal hearing to amplify sound in certain environments. Over-The-Counter (OTC) hearing aids have minimal controls and adjustments to make sound louder for adults with a perceived mild or moderate hearing loss. Prescriptive hearing aids have multiple controls and adjustments that are custom fit by qualified and licensed professionals for any severity (mild, moderate, severe, or profound) or type (conductive, mixed, or sensorineural) of hearing loss and are available for individuals of any age.

Who are some of the professionals that would assist consumers with either OTC hearing aids or prescriptive hearing aids?

- OTC Hearing aids may be seen in retail stores that sell other consumer electronic devices. They would typically be set up by the user and device support would likely come from the device manufacturer.
- In New York State, prescriptive hearing aids are sold and serviced by NYS licensed Hearing Aid Dispensers or NYS licensed Audiologists who are also NYS licensed Hearing Aid Dispensers.
 - Audiologists are licensed professionals who have a master's or doctoral degree that includes specialized instruction in the evaluation of one's hearing and fitting and dispensing of amplification devices intended to improve communication of an individual with a hearing loss.
 - Hearing aid dispensers are state licensed professionals that have completed a 12-month training course and passed an examination in the area of hearing aid fitting and dispensing.
 - For more information on the difference between audiologists and hearing aid dispensers, please visit <https://www.asha.org/aud/otc-hearing-aid-toolkit/audiologist-and-hearing-aid-dispenser-what-is-the-difference/>

Why might I choose to purchase a hearing aid from a qualified professional?

Qualified professionals are there to assist consumers and help them make informed decisions regarding their amplification choices. They also provide support and follow-up care including fine tuning, repairs, maintenance, and troubleshooting of devices after the initial fitting.

How much do these different devices cost?

Costs can vary widely based on the type of amplification device. PSAPs are inexpensive devices with few controls and adjustments, and can cost between \$75-\$500 for a pair. OTC hearing aids have more controls and are expected to cost about \$1000 for a pair. Prescription hearing aids have many controls and individual adjustments, and can cost between \$3000-\$6000 a pair. Often times prescription hearing aids will come with relatively long warranty periods, and these devices can be repaired (sometimes in the office) and continually adjusted as your hearing loss changes over time.

Here are some questions that you can ask a provider about the hearing aids and associated services:

- What kinds of services are included? Will I be charged for follow-up visits, reprogramming the hearing aids, cleanings, and supplies?
- Where can I get hearing aid cleanings, services, and supplies? Where can I get the hearing aid repaired?
- Is there a warranty on the hearing devices and how long does it last? What is included in the warranty?

Does insurance cover any costs of the OTC hearing aid or prescriptive hearing aids?

There is little known at this time whether insurance providers will cover OTC hearing aids. Currently we do not know of any insurance provider that is planning on providing OTC hearing aid coverage. For prescriptive hearing aids, benefits can vary widely across insurance providers. Some will cover the entire cost, some will cover a percentage of the cost, while others may offer a fixed dollar amount towards the hearing aid cost with the remaining balance paid out of pocket. Some insurances will even contract with 3rd party providers and then dictate where those services are provided and the extent of services offered.

What if my hearing aids don't work like I hoped? Can I get a refund?

There are no FDA requirements for refunds of OTC hearing aids that you did not find to be helpful. A retailer or manufacturer may have their own return policy. Be sure to understand the condition of those policies before purchasing.

In New York State, prescriptive hearing aids are sold with a 45-day trial period. The prescriptive device(s) can be returned or exchanged within the trial period, but the dispenser may retain a small portion of the original fees for that trial and return process. The fee structure is dictated by state regulations.

Can I purchase an OTC hearing aid for my child under 18 years of age?

No. OTCs are NOT approved for the use with children under the age of 18. Those with hearing loss under the age of 18 must be evaluated by a NYS licensed professional.

Where can one purchase an OTC hearing aids?

It remains to be seen where OTCs can be purchased but some big-box stores, drug stores, and online retailers have already indicated that they may be selling these devices.

What else should I be cautious about when I purchase an OTC hearing aid?

You should consult a medical provider before purchasing an OTC hearing aid if you have any of the following conditions: ear malformation, drainage from the ear (fluid, pus, blood), hearing loss in only one ear or that is significantly worse in one ear, ringing (tinnitus) that occurs in only one ear, pain in the ear, excessive earwax, sudden, quickly worsening, or fluctuating hearing loss, vertigo or severe dizziness.

If I purchase an OTC hearing aid and I do not find it helpful, does that mean I cannot be helped with prescription hearing aids either?

If you feel the OTC hearing aids you purchased are not helpful, we recommend that you see a NYS licensed hearing aid professional for consultation. You will not know whether the OTC hearing aids are of poor quality, defective, or you have too much hearing loss to benefit from these lower-powered devices. Prescriptive hearing aids work to improve speech understanding based on your individual hearing needs and therefore may provide greater benefit than OTC devices.