

Over the Counter Hearing Aids

Clay Smith

10/18/2022



Before October 17th, in order to attain hearing aids, individuals had to receive a prescription from an audiologist. Now, with hearing aids becoming available to purchase over the counter (OTC), adults with perceived mild to moderate hearing loss can get hearing aids from retailers at significantly lower costs.

This cost reduction will affect the Utah Assistive Technology Program's financing efforts as well, since it pushes the cost of some hearing aids below the \$500 threshold for UATP's small grants. This means clients who fall within our income guidelines – and who would otherwise not be able to afford the technology – may receive hearing aids for free (after applying for the grant, of course). For hearing aids that cost more than \$1000, UATP's reduced-interest loan program would still apply. Anyone can apply for an AT loan, regardless of their income. However, UATP's financial aid applies only to the device, not the cost of receiving medical services from a provider.

Under the prescription system – the device itself and diagnosis, fittings, and check-ups that came with it – consumers ended up paying more than \$5,000. Unfortunately, insurance coverage is limited, and Medicare only pays for diagnostic evaluations. The time and money spent getting devices that may or may not be the right solution for individual hearing issues can be quite costly. Indeed, a large number of UATP's reduced-interest loans for assistive technology typically went toward purchasing hearing aids prior to October 17th. Bora Lee, director of the Utah Assistive Technology Program, said, "We hope that

more consumers utilize our resources when looking into the purchase of OTC hearing aids, particularly minority, underserved communities not previously aware of our services."

The FDA's new category of hearing aids was finalized in August of 2022 as part of the FDA Reauthorization Act of 2017. Federal officers expect an average savings of around \$2,800 for the cost of a pair of hearing aids, not to mention the time and money saved from no longer needing to visit an audiologist for diagnostics and fittings. Hearing aids are no longer the bulky, ringing piece of plastic hanging off the back of your ears. Many are now currently outfitted with modern technology, automatically performing multiple adjustments every second. Some even come with apps that can allow for adjustments directly from the phone. Prices today at retailers range from \$200 to just over \$1000 per pair.

OTC hearing aids will likely be widely accessible and at a much lower cost, although they are not for everyone. According to the rule by the FDA, with input from audiologists and other professionals, OTC hearing aids should only be used for individuals 18 years of age and older with perceived mild to moderate hearing loss. Children and anyone experiencing more severe hearing loss should visit their physician, especially those with ringing in the ear, discharge, or pain from the ear. It is important children with hearing impairments do not use OTC hearing aids, as the connection between the ear and brain are still developing. Additionally, they require special guidance from audiologists, especially children with additional disabilities. It is highly discouraged that individuals with more severe hearing loss purchase OTC hearing aids as a means to escape the pricing of visits and prescription aids.

When individuals lose their hearing as a result of age, damage, or other causes, certain parts of the brain associated with different noises are no longer stimulated.

Hearing aids are assistive technology devices used to make some sounds louder and clearer for a person with hearing impairments. The aid magnifies sound vibrations entering the ears that are then converted into signals that are passed along to the brain. Preserving or re-establishing these connections by use of the hearing aids are important and can take a long time. Many people compare hearing aids to glasses, taking them on and off for different environments, activities, and scenarios. However, hearing aids must be worn regularly. Dr. Tiffany Shelton, a licensed audiologist and clinical assistant professor at the Utah State University Hearing and Balance Clinic, said, "Hearing aids are not an event, they are a process. It takes time adjusting to them, and

it takes a lot of time testing them.” Adjusting to the aids often depends on the circumstances and individual. While receiving a prescription from audiologists will not be necessary for OTC hearing aids, audiologists continue to be a valuable resource for more severe cases, evaluations, and guidance on devices.

Dr. Shelton strongly encourages everyone to receive a hearing evaluation. Therefore, in the future, if experiencing hearing impairment, there is a baseline at which to compare the hearing loss.

When finalizing the new category of OTC hearing aids, the FDA took into account over 1,000 comments from a variety of stakeholders, including consumers, health care professionals, hearing aid manufacturers, and more. The comments resulted in several changes for the devices: (1) lowering the maximum sound output to reduce the risk to hearing loss from over-amplification of sound, (2) shortening the insertion depth into the ear canal, (3) requiring a user-adjustable volume control, and (4) simplifying the labels and instructions on and for the devices to be easily understood by consumers and professionals alike.

Additionally, packaging indicates warning signs the device may not be for you, as well as signs the user should seek out their physician. The FDA and many audiologists have assured the safety and effectiveness of the upcoming OTC hearing aids.

It is important to distinguish hearing aids from other devices, such as PSAPs, (personal sound amplification products). Dr. Shelton shared she has many patients come in with PSAPs they received ads for in the mail. They were looking for guidance because the PSAPs are not fixing their hearing. The devices are often a fraction of the price of hearing aids and are supposedly recommended by physicians, but PSAPs are distinctly different from hearing aids. They only make sounds louder, not necessarily clearer. Many people use them for hunting or birdwatching. There are many devices marketed to work as hearing aids and while the price may be enticing, they typically do not work effectively, and can sometimes be damaging to the ear.

In the upcoming days, as the accessibility to receive OTC hearing aids becomes available, millions of Americans will have the ability to hear their loved ones again. The FDA and audiologists hope that as accessibility grows, the stigma surrounding hearing aids will disappear and people will become proactive about their hearing and solutions. Additionally, there are expectations that with more hearing aids in the market, innovation and competition will drive

prices down and increase technology in the industry. Nonetheless, this legislation is a huge step toward prioritizing affordable and safe healthcare in the United States.