“The leading factor that would influence adults’ purchasing decisions on an OTC hearing aid would be a recommendation from a medical professional: 42% report that this would play the largest role in product selection, with cost being a distant second (18%).”

“About 40% of dementia cases, we believe, result from so-called modifiable risk factors—things like diet, physical activity levels, and, prominently, hearing.”

Bret Rutherford, Columbia University psychiatrist and researcher, September 2021 ASHA Voices podcast

In October 2021, the Food and Drug Administration (FDA) released proposed guidelines for over-the-counter (OTC) hearing aids.

As a primary care physician, you know that patients look for your guidance in managing their overall health and wellness. Although OTC hearing aids are appropriate for individuals with perceived mild to moderate hearing loss, they are not appropriate for those with greater degrees of hearing loss or certain medical conditions. Purchasing OTC hearing aids will not require a formal hearing evaluation by an audiologist, so, in many cases, patients will be tasked with trying to self-diagnose their levels of hearing. This can be difficult to do accurately. Licensed audiologists—who will have either a master’s degree or a doctorate and 1,800+ hours of clinical training—are the experts for assessing each patient’s hearing loss needs.

Quick Facts About Hearing Loss

- Approximately 15% of American adults (37.5 million) aged 18 and older report having some trouble hearing, and 91% of those with hearing loss are aged 50 or older (Blackwell et al., 2014).³
- The average time from when an individual first suspects hearing loss to when they seek evaluation and treatment is 7 years.
- Although many treatments for hearing loss exist, the National Institute on Deafness and Other Communication Disorders (NIDCD) estimates that only 16% of individuals aged 20–69 and 30% aged 70 and older who could benefit from hearing loss treatment pursue hearing aids.⁴
Quick Facts About Hearing Loss (cont’d)

- As with other conditions, such as high blood pressure and diabetes, hearing loss is more effectively treated before it becomes a severe problem. **Untreated hearing loss has been linked to several comorbidities—increased fall risk, diabetes, loneliness, depression, and cognitive decline or dementia, to name a few.**

Quick Facts About OTC Hearing Aids

- OTC hearing aids are meant for individuals with perceived mild to moderate hearing loss.
- OTC hearing aids are intended for individuals aged 18 and older.
- The purchase of OTC hearing aids does not require a hearing evaluation.
- Devices have a “one-size-fits-most” design.
- Devices may come with either “self-fitting” options or preset programs; the FDA has not yet decided upon this regulation.
- OTC hearing aids may reduce barriers to hearing health care, such as the requirement to see an audiologist and the costs associated with prescription hearing aids (which insurance often does not cover).
- Currently, there are no FDA proposed requirements for return policy.

Costs

Prescription hearing aids range greatly in cost, from approximately $1,500 to $7,000 per pair. Costs vary due to

- speech processing features and fine-tuning capabilities;
- technology for hearing assistance in difficult listening environments;
- warranty of the devices;
- miniaturization and customizable features, including less visible design options;
- types of services; and
- whether audiological follow-up care is included.
### Pros and Cons of OTC Hearing Aids

#### Pros

- An individual can purchase OTC hearing aids without visiting a medical professional.
- Cost will likely be lower; current estimates show that a pair of OTC hearing aids will cost under $1,000.
- Accessibility and cost may entice more people with hearing loss to explore options for treatment.
- OTC devices can be good “starter hearing aids” for adults with a mild to moderate level of perceived hearing loss.

#### Cons

- Based on hearing loss that is perceived rather than hearing loss that is measured by an audiologist, there is the potential for over- or under-amplification.
- No formal assessment or medical evaluation is needed to obtain the devices; thus, there is risk of an ear disorder going undiagnosed (e.g., cholesteatoma or acoustic neuroma).
- OTC devices come with no follow-up care plan or rehabilitation.
- No professional will be monitoring hearing levels over time or troubleshooting OTC device issues.
- There is no use of verification or best practices for hearing aid fitting and follow-up.
- Few customizable options are available—thus, limited opportunities for person-centered care.

### Patients Who Should NOT Use OTC Hearing Aids

- Individuals under the age of 18
- Individuals with aural drainage, pain in the ears, or a history of ear infections and/or individuals with deformity of one or both ears
- Individuals with vertigo and/or tinnitus that have not been medically evaluated

Please visit ASHA.ORG/OTC-HEARING-AID-TOOLKIT for more information.
Patients Who Should NOT Use OTC Hearing Aids (cont’d)

- Individuals with sudden onset of hearing loss
- Individuals who have unilateral hearing loss that has not been medically evaluated
- Individuals with tinnitus, especially if pulsatile or in one ear

Summary

Although access to hearing aids is important for those with hearing loss, the implementation of OTC hearing aids should not lead to the false assumption that medical professionals, such as audiologists, are not extremely important to hearing health care.

As a primary care physician, you can encourage patients to seek a hearing assessment by an audiologist. Additionally, an easily accessible hearing screening tool allows physician offices to provide in-office screenings utilizing a smart device and a pair of headphones called hearWHO. This screening tool is an easy and quick option (screening takes about 3 minutes) that anyone can utilize to screen for hearing loss. A failed hearing screening should prompt a referral to an audiologist for a comprehensive audiological evaluation.

The popularity of direct-to-consumer and Internet sales have made it easier for consumers to access potentially useful medical treatment. For the safety of individuals seeking hearing treatment—including OTC hearing aids—please encourage them to seek a hearing evaluation by an audiologist for appropriate guidance and hearing health care.

References

Resources


Hearing Aid Project. (n.d.). Hearing aid resources. https://hearingaiddonations.org/resources