

**Over-the-Counter Hearing Aids: CONSUMER FAQs  
As of August 31, 2022**

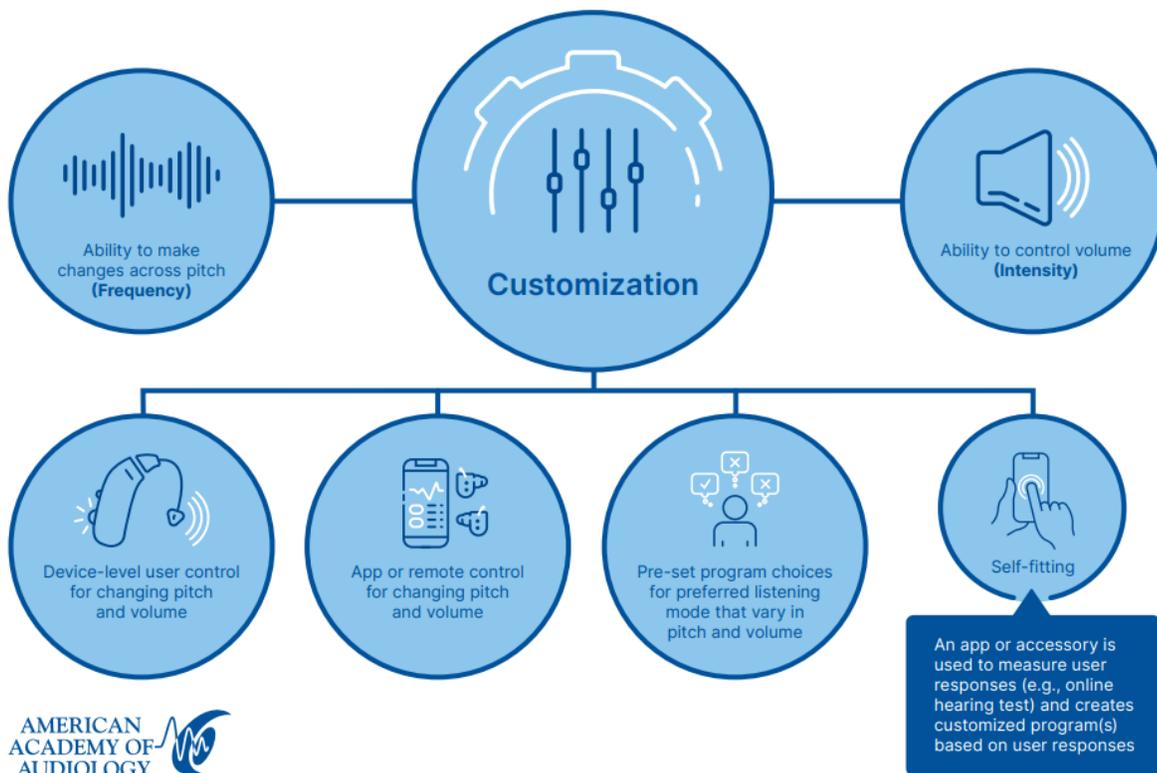
**If I Get an OTC Hearing Aid and It Does Not Meet My Needs, Can I Return It?**

The proposed regulations from the FDA do not require that OTC hearing aids be returnable but state that device packages need to include the return policy of a device. If you have not had a hearing test and are not sure that you are even a candidate for OTC hearing aids, you may want to select a device that can be returned in case you do not see a benefit from the device.

**Are OTC Hearing Aids Programmable?**

OTC hearing aids are considered “customizable,” which means that the consumer controls the settings and that no hearing-health-care professional must be involved. Devices must have the ability to make changes in pitch (e.g., bass versus treble) and must allow the user to change volume (e.g., louder or quieter). If the device is labeled “self-fitting”, then you can expect an app or accessory that creates a customized listening program based on your responses to some type of signals.

**Over-the-Counter (OTC) Hearing Aids**



### **If I Want to Try an OTC Hearing Aid, How Will I Know Which One to Select?**

A wide variety of OTC hearing aids are expected to come onto the market. You can get a hearing test with an audiologist and discuss possible OTC hearing aid solutions. The audiologist will be familiar with these products and can provide assistance.

Without the assistance of an audiologist, you will want to research the various options available and consider what you want from the product. You may find online reviews that are helpful as these products are used by other consumers and they report on their experience. You will want to look for a device that can be returned in case you find it does not meet your needs.

### **Where Would I Get an OTC Hearing Aid if I Want One?**

As of October 17, 2022, OTC hearing aids will be advertised and sold in audiology offices, local drug stores, big-box stores, online, and via mail.

### **How Much Will OTC Hearing Aids Cost?**

Manufacturers and distributors will set the price of any device, but OTC hearing aids are anticipated to be between \$300 and \$600 per device.

### **If I Get an OTC Hearing Aid and Cannot Figure Out How to Use It, Where Can I Get Help?**

Device manufacturers are required to provide information about how to handle repairs and they must include an email address and mailing address that you can use to contact them. Manufacturers of OTC devices are NOT required to provide customer service for OTC devices over the phone.

In addition to information from the manufacturer, an audiologist can provide general guidance and programming for OTC hearing aids. An audiologist can also perform a hearing evaluation and measure the output of an OTC hearing aid to determine if it is appropriate for you. You can [find an audiologist](#) in your area and ask if they offer these services.

Office visit fees may apply as insurance does not always cover hearing aid services.

### **Is There Any Reason I Should Not Try OTC Hearing Aids?**

If you have significant hearing loss or have any of the symptoms listed below, you should not purchase an OTC hearing aid without first [seeing an audiologist](#) or ear, nose, and throat (ENT) physician.

The following symptoms are examples of medical issues that should be evaluated before considering OTC hearing aids:

- Malformed or misshapen ear at birth or due to trauma
- History of drainage from the ear within the previous 90 days

- History of sudden or rapidly progressive hearing loss within the previous 90 days
- Dizziness just experienced or experienced over a long time
- Hearing loss in only one ear or sudden or recent onset of hearing loss within the previous 90 days
- Significant ear wax accumulation or a foreign body in the ear canal
- Pain or discomfort in the ear

Seek medical advice if any of the above symptoms occur after using an OTC hearing aid.

### **If I am Thinking About Getting Help for My Hearing, Should I See an Audiologist?**

The most common hearing loss in adults comes on gradually. Individuals often do not identify the level of their hearing loss accurately because of these gradual changes over time. This makes it difficult to identify accurately if you are a candidate for OTC hearing aids (someone with a mild to moderate hearing loss). A hearing evaluation can help you be confident that you are a candidate. Hearing tests provided by an audiologist are typically covered by health insurers, but check your coverage specifically.

The audiologist uses information about your lifestyle and listening needs, as well as the results from your hearing test, to create the best treatment plan for you. This plan includes what type of devices are recommended. Choosing a hearing aid may seem straightforward, but a lot of information goes into making the best choice for an individual.

1. The degree of hearing loss, ear canal characteristics, and individual preferences will all impact the recommendation of style (what the hearing aid physically looks like).
2. The individual's lifestyle and communication demands will help determine the technology and features (how the hearing aid functions and how automatic it is) to select and program in the hearing aid fitting.

Because adult hearing loss comes on gradually, the individual's brain is used to listening through the hearing loss and considers that input "normal" even though sound is being filtered by the hearing loss. The brain thinks that is normal, and it is difficult for individuals to judge how much amplification is needed when they try hearing aids.

Typically, people have different amounts of hearing loss at different frequencies, which complicates the hearing aid selection process. In fitting a hearing aid, the audiologist puts a microphone in the person's ear canal to measure the amplification provided by the hearing aid for different types of sounds. This allows the hearing aid to be tuned correctly for the person's hearing loss and ear canal and ensures that loud sounds will not damage the user's hearing. On the first day of the hearing aid fitting, most patients indicate that sounds do not seem normal to them, and that is because the brain is not used to hearing many of the softer sounds. On average, it takes several weeks of full-time use (all waking hours) to adjust to a new hearing aid fitting because the brain must adapt to this new normal. Without these measurements, it is impossible to know if the amplification device has been set optimally for the individual.

If you go with an OTC hearing aid and do not feel that you are receiving the benefit you expected, you may want to see an audiologist who can make these measurements in the ear canal and provide you with advice about how to reset the device if it has controls on it for fine-tuning. You would expect to pay an office visit fee for these services, which are not typically covered by insurance.

Remember, if you are engaged in loud activities and are exposed to loud sounds over time, your hearing can be damaged. If you are concerned that your hearing has changed, you should see an audiologist for an updated hearing test.

### **Do I Need One or Two OTC Hearing Aids?**

Symmetrical hearing (hearing that is the same in both ears) allows for better localization of sound (knowing where sound is coming from) and improved hearing in noise. Therefore, if hearing loss is present in both ears, two hearing aids, OTC, or otherwise, are recommended in order to achieve best outcomes.

### **I've Heard the Term "Personal Sound Amplification Products." What Are These?**

While hearing aids are intended to *treat* impaired hearing, personal sound amplification products (PSAPs) are meant for individuals with normal hearing who want to amplify sounds in certain situations, for example, bird watching.

PSAPs are regulated the same as other consumer electronics and not as medical devices, so the quality can vary widely. The FDA does not regulate PSAPs for safety and effectiveness like it does hearing aids. You should be careful not to keep the device on if the sound is very loud because you could damage your hearing over time. PSAPs are usually low cost (less than \$100) and simple to operate.

### **I've Heard the Term "Hearables." What Are These?**

Hearables are worn in or on the ear (e.g., headset, earbuds) and wirelessly receive a sound signal from another device (e.g., phone, television, etc.). The headset may have a volume control or an app associated with it so users can turn the volume up or down to meet their listening needs. Hearables provide situation-specific listening solutions rather than a hearing solution for a listener's entire day of communication. Some hearables allow the user to adjust the pitch or loudness of the sound. The difference with professionally fit hearing aids is that they provide custom amplification to the signals being heard and are used throughout the day.

Hearables are usually priced between \$300 and \$500 for a headset or earbuds with good sound quality. Hearables are not regulated by the FDA for safety and effectiveness. You will want to be thoughtful about how loud you listen to sound. If you are concerned about the level of sound you are using, an audiologist can measure the output of your headset and let you know if you are in a safe listening range depending on how much time you spend listening at that level.

## **How Do I Report Concerns If I Feel Like I've Experienced Misleading Advertising or Practices Related to Obtaining OTC Hearing Aids?**

The Federal Trade Commission (FTC) is focused on consumer protection and encourages consumers to report any problems. [Report an issue here.](#)