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Have You Heard? Hearing Aids Are Now Available Over The Counter

by [Brian Bossetta](#)

US consumers have OTC access a year after FDA proposed category. While OTC category is limited to devices designed for mild to moderate hearing loss and not more severe hearing impairment, it covers vast majority of consumers with hearing loss.

As of Monday 17 October, American adults with mild to moderate hearing loss will be able to walk into their local drugstore and pick up a pair of hearing aids without a prescription or prior medical exam.

This is the first time the devices will be available for direct over-the-counter purchase at retail outlets such as Walgreens, which recently announced the devices will be on shelves at locations nationwide.

\While the OTC category will only apply to devices designed for mild to moderate hearing loss and not more severe hearing impairment, the category will cover the vast majority of those with difficulty hearing.

Roughly 94% of Americans with trouble hearing a have mild to moderate case, Christian Gormsen, the CEO of hearing aid manufacturer Eargo, told Medtech Insight in July. (Also see "[Eargo CEO 'Enthusiastic' About Pending OTC Hearing Aid Sales](#)" - Medtech Insight, 15 Jul, 2022.)

Nearly 25% of American adults struggle with hearing loss to some degree, research from seniorliving.org shows. That increases after age 55 – and of the 62 million Americans with hearing loss, about a third have not addressed the problem.

Making hearing aids available for purchase over the counter in stores and online has been in the works for a while. The idea dates back to 2016 when the National Academies of Sciences, Engineering, and Medicine (NASEM) proposed the new classification for the devices. Congress

followed up in 2017 by passing bipartisan legislation that required the FDA to establish an OTC category and giving the agency until 2020 to issue guidance on it.

“The only way you can get more people to hear better is to improve access and affordability.” – Christian Gormsen

However, the FDA failed to meet the legislation's timeline. The initiative stalled until it was revived in July 2021 when President Joe Biden signed an executive order calling for the category's establishment. (Also see "[Sweeping Executive Order Puts Hearing Aids Over The Counter; Cracks Down On Internet Providers](#)" - Medtech Insight, 9 Jul, 2021.)

One of the goals of the new category is not only providing more convenient access to hearing aids, but also making them more affordable. A pair of hearing aids with a professional exam and fitting can run as much as \$4,000 to \$6,000 – and since they are not covered under Medicare, many who need them most either cannot afford them or choose to go without.

As an example of the potential cost savings, Walgreens also announced the chain will carry Lexie Lumen hearing aids for \$799 and will also offer them online through Walgreens Find Care for \$39 per month for 24 months. Each purchase includes a pair of hearing aids, batteries, and accessories.

As Gormsen noted, price and the hassle of prior audiological exams are often the biggest impediments to getting hearing aids.

“The only way you can get more people to hear better is to improve access and affordability,” Gormsen said.

But while the new category is intended to make purchasing hearing aids easier as well as less expensive, experts say it shouldn't be viewed as simple as picking up a pair of eyeglasses next to the pharmacy counter. And though a prior exam is not required, most experts recommend consulting with an audiologist before purchase to ensure getting the most appropriate device based upon the degree of hearing loss.

According to the FDA, a high output can be unsafe and further impair hearing. However, too low an output reduces device effectiveness and can lead to poor device performance, including clipping and distortion.

Audiologists are trained to find the right balance of sound based upon an individual's hearing impairment, which is why many experts still advise consulting one before purchasing the devices.

But as Gormsen noted, his devices have user-friendly volume controls and allow the wearer to make adjustments without having to go to a clinic, which, he said, turns the “patient into a consumer.”