Position Statement: OTC Hearing Aids

The National Association of Specialty Health Organizations (NASHO) is one of the nation's only organizations solely focused on fully integrating specialty health into the healthcare reimbursement model. It has served as a successful industry advocate for carriers and networks focused on hearing, vision, dental, physical medicine and integrative medicine to other ancillary service organizations for more than 15 years. NASHO's affiliate organization, the Hearing Network Alliance (HNA), works to broaden access to hearing health benefits and services for all Americans.

KEY TAKEAWAYS

Hearing care is essential healthcare. Hearing loss is a recognized medical condition that is best diagnosed and treated by a licensed healthcare provider.

Over-the-counter (OTC) hearing aids must be as safe and effective as traditional hearing aids, and have package labeling that clearly communicates safety and efficacy information, cautions against self-diagnosis and product selection, and identifies potential adverse events from use.

We strongly encourage Americans to take charge of their hearing health. As a first step, they should discuss if and how an OTC hearing aid fits into their long-term treatment for hearing loss with a licensed hearing healthcare provider prior to purchasing an OTC product.

BACKGROUND

On August 19, 2017, the President of the United States signed into law the Food and Drug Administration Reauthorization Act (FDARA) of 2017. The FDARA included the Over the Counter (OTC) Hearing Aid Act. That act enables greater accessibility to and affordability for OTC hearing aids for people with "perceived" mild-to-moderate hearing loss. It also allows individuals to self-determine which of the OTC hearing aids they should use. The products can be purchased and used without the guidance of an audiologist, hearing aid specialist or other healthcare professional. In fact, the act includes language that requires the U.S. Food and Drug Administration (FDA) to set requirements that would allow the sale of OTC hearing aids without a prescription.

FDA is required to promulgate regulations to establish this OTC category that includes methods to help individuals self-determine their hearing loss. The agency is still in the pre-rulemaking stage. The FDA also is required to issue guidance on the "Regualtory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAP), " often falsely compared as the hearing equivalent to "reader" eyeglasses, which will clarify which products meet the definition of PSAPs. FDA is charged with creating regulations and guidelines to assist consumers in selecting an appropriate OTC hearing aid device within 36 months; the guidelines are due approximately August 2020.

NASHO/HNA Position: OTC hearing aids should be as safe and effective as traditional prescription hearing aids and only purchased after consulting with a hearing healthcare professional to ensure proper fitting and use.

NASHO and HNA hold that hearing care is essential healthcare. Individuals should take hearing loss just as seriously as failing vision, dental issues or chronic disease. Therefore, we believe that hearing loss is a medical condition best diagnosed and treated by a licensed hearing healthcare professional. Self-selecting an OTC hearing aid without the guidance of a healthcare professional is potentially risky, may exacerbate an individual's hearing loss by delaying proper diagnosis and treatment, and ultimately, increase an individual's treatment costs in the long run. **NASHO and HNA recommend a hearing assessment by a licensed hearing**

Position Statement: OTC Hearing Aids

professional or other FDA-approved evaluation prior to purchase of OTC hearing aids.
With that said, NASHO and HNA encourage all Americans to take charge of their hearing health. OTC hearing aids approved by FDA that meet certification and treatment standards for mild-to-moderate hearing loss can be a good initial step in hearing care treatment. We believe that consumers should only consider purchasing FDA-approved devices that meet the same rigid standards as prescription hearing aids.

Meet Industry Performance Standards -- Recommend proposed association (HIA, AAA, ASHA) output standard of 105dB.

Meet Prescription Hearing Aid Manufacturing Standards – Specifications (output, physical fit); either 510(k) "exempt" or 510(k) "approved" (built to specifications of a hearing aid; medical-grade components; hypo-allergenic).

Demonstrate Safety and Efficacy Through Labeling – Labeling should:

- Reflect red-flag conditions; not intended for use by children; state that it is in an individual's best health interest to seek the advice of a licensed hearing healthcare professional prior to purchase.
- Require OTC hearing aid product manufacturers to clearly communicate testing and certification specific to each product on the packaging and in written and online user manuals or through other information channels.
- Require labeling that cautions consumers about self-diagnosis of hearing loss and product selection without consulting an audiologist or other licensed healthcare professional.
- Identify potential adverse events from OTC product use and facilitate and encourage the reporting of all consumer adverse events to FDA.
- Clearly explain the differences between FDA-approved traditional prescription or OTC hearing aids and PSAPs.

Trial Period Allowance – All OTC hearing aids should provide consumers a 30-trial period (suggested by FDA) to determine if the product works for the individual and a full refund if the consumer determines it does not.

In addition:

Proof of a Simple Hearing Test at Point of Purchase -- FDA should require that a simple hearing test is available at the OTC hearing aid point of purchase to guide consumers in self-diagnosing their hearing loss. This could be accomplished through an in-store station, such as those that measure blood pressure, or a downloadable app. Consumers should be required to present proof of their hearing test results at the time of OTC hearing aid purchase.