

American Academy of Audiology
Position Statement

**The Role of Audiologists with
Over-the-Counter Hearing Aids**

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RATIONALE

In 2017, Congress directed the U.S. Food and Drug Administration (FDA) to develop a new category of hearing aids that could be accessed by the consumer without the engagement of an audiologist or other hearing care provider. The rationale for this expanded category of hearing aids was to address the unmet needs of individuals with perceived mild to moderate hearing loss. Among the stated reasons for the law was that the cost of hearing aids (HAs) prevents some individuals from seeking treatment for this hearing loss, and that access to hearing care can be difficult.

In response to the law, the American Academy of Audiology (the Academy) developed a guide to assist audiologists in understanding the differences between existing hearing care products and over-the-counter (OTC) devices (The Audiologist's Guide to Hearing Aids, Personal Sound Amplification Products (PSAPS), Hearables, and OTC Devices, 2018) and was actively involved in providing feedback to the FDA regarding regulations, collaborating with other members of the hearing health community to draft consensus recommendations for this emerging class of devices.

POSITION STATEMENT

The Academy acknowledges consumer autonomy with respect to control over health-care decisions, including access to effective and safe hearing care. It is the position of the American Academy of Audiology that a primary role of audiologists is to optimize hearing health and communication, including the safe and effective use of OTC hearing aids. Audiologists should incorporate support of persons who pursue OTC hearing aid technologies, including offering supportive counseling on appropriate care and use, and developing educational and clinical practices to assist consumers in understanding the benefits and risks associated with use of OTC hearing aids. In light of consumers choosing OTC hearing aids, audiologists are encouraged to develop strategies to ensure patient care and safety remain paramount, including objective measurement of hearing aid benefit and functional outcomes.

It is also the position of the Academy that consumers are best served when they receive a comprehensive audiologic assessment prior to the use of any hearing aid. Additionally, hearing loss and auditory system deficits are best mitigated through the development of a safe and effective treatment plan that may or may not include OTC hearing aids or other devices.

DISCUSSION

The Academy recognizes that consumers have expanded device choices with OTC products compared to historical options, and that these hearing aids can be obtained without audiological evaluation, prescription, or verification. Audiologists should consider where OTC HAs fit into their patient care model including decisions related to (1) elements of the evaluation that might lead to an OTC HA recommendation, (2) integrating OTC HAs directly into the practice, (3) recommending OTC HAs separate from the practice, and (4) providing support to those who have purchased OTC HAs whether from the practice or elsewhere.

Integration of the OTC hearing aid class into clinical practice should remain consistent with the Academy's Code of Ethics Principle 5: "Members shall provide accurate information about the nature and management of communicative disorders and about the services and products offered."

Audiologists should consider developing educational materials that assist consumers to understand the difference between the ability to self-identify a communication difficulty versus self-diagnose a medical problem, and subsequently, to self-manage the difficulty versus self-treat the problem. The educational materials should include the advice that

consumers seek an evaluation by an audiologist when they notice any change in their hearing and/or they are not satisfied with an OTC hearing aid. Moreover, consumers with hearing loss who choose to use OTC hearing aid technologies should do so understanding that certain medical conditions might cause them to have adverse reaction to the OTC hearing aid (e.g., irritation, poor fit, untreated ear wax/cerumen).

Audiologists are educated and clinically trained during doctoral graduate programs to evaluate and recommend all types of hearing technology for the treatment of hearing loss. Therefore, there is no additional training needed for audiologists to deliver OTC hearing aid technologies beyond knowledge specific to the devices themselves. However, audiologists should familiarize themselves with the FDA regulations associated with the OTC class of hearing aids. Audiologists will continue to be a critical provider in the management of persons with hearing loss; therefore, they must remain vigilant to evolving hearing technologies, including OTC hearing aids. Furthermore, as best clinical practices emerge, audiologists must ensure their knowledge and skills are current in relation to these devices, which is consistent with the Academy's Code of Ethics principle 2f, "Individuals shall maintain professional competence, including participation in continuing education."