CSASK

# Over-the-Counter Hearing Aids Practice Guideline

Effective: December 2025

## Introduction and Background

### *Definition of Over-the-Counter Hearing Aids*

Unlike prescription hearing aids, Over-the-Counter Hearing aids (OTC) are intended for self-guided use and can be obtained without a professional assessment, recommendation or fitting. These devices are intended for adults with perceived mild to moderate hearing loss. In general, OTC hearing aids may be more affordable, but offer less customization, professional fitting and support than can be achieved with prescription hearing aids.

### *Regulation of Over-the-Counter Hearing Aids*

In 2022, the United States Food and Drug Administration (FDA) published a final rule establishing a regulatory category for OTC hearing aids aimed to increase public access to hearing aids for adults (18+) with perceived mild to moderate hearing loss. FDA regulations detail: intended uses of the devices, and labeling requirements that must appear on the external packaging (ex. warning not to be used if under 18 years of age, symptoms suggestive of perceived mild- moderate hearing loss, red flag conditions, etc.).

Health Canada regulates the sale, advertising for sale and importation for sale of medical devices through the *Medical Devices Regulations* (the Regulations) made pursuant to the authority of the *Food and Drugs Act*. Under the Regulations, Health Canada ensures that medical devices sold in Canada meet regulatory requirements with respect to safety, effectiveness, and quality. The Regulations classify medical devices into one of four classes, where Class I represents the lowest risk and Class IV the highest. Hearing aids are classified as Class II medical devices, and they require a medical device licence for import or sale in Canada. In December 2024, Health Canada issued Class II medical device licences for the following Apple features:

- Air Pods Pro Firmware Module; and
- Hearing Aid Feature iPhone App.

Although approved by Health Canada via the issuance of Class II medical device licences, the features are not yet available for use in Canada.

**Access to medical devices is overseen by the provinces and territories in Canada, as a result the provincial and territorial governments have primary jurisdiction in the administration and delivery of health care services.**

## CSASK's Mandate and Position Related to Over-the-Counter Hearing Aids

### *CSASK mandate*

The *College of Speech-Language Pathologists and Audiologists of Saskatchewan (CSASK)* is the provincial regulatory body for audiologists and speech-language pathologists. The College's mandate is to license and regulate the competent, safe and ethical practice of the two professions in Saskatchewan. CSASK registrants are required to abide by relevant legislation and key College documents such as the Code of Ethics and practice guidelines. Currently the legislation which governs CSASK is *The Speech-Language Pathologists and Audiologists Act (The Act).*

*The Act* does **not:**

- provide for scope of practice protection.
- grant CSASK the authority to regulate OTC hearing aids or regulate the sale of any devices (i.e. restricting or granting access to devices).
- delegate any restricted activities (such as prescribing, dispensing or fitting a wearable hearing instrument or inserting or removing an instrument or a device into the external ear canal).
- grant CSASK with the authority to regulate hearing instrument practitioners in Saskatchewan.

Under *The Hearing Aid Sales and Services Act and Regulations,* private hearing aid businesses in Saskatchewan must be licensed to operate and provide hearing aid services. They are required to provide safe and appropriate care to customers/clients. The Ministry of Health is responsible for issuing licenses to businesses, monitoring compliance with the legislation and investigating complaints.[i] Hearing instrument practitioners, as individual practitioners, are not members or registrants of a regulated profession in Saskatchewan.

## *CSASK's Position:*

In general, CSASK supports increasing public access to high-quality hearing devices and technology, while also recognizing the important role regulated health professionals play in supporting the public in making informed decisions. Audiologists use their professional judgement, knowledge, clinical skills and training to educate the public, conduct audiological assessments, identify hearing loss and provide treatment options or referrals to other healthcare professionals. It is important to note that OTC hearing aids are not intended for pediatric clients and may not be suitable for adults with medically complex cases or more severe hearing loss. Audiological assessments from regulated health professionals provide members of the public with an opportunity to gain insight into the type and degree of their hearing loss, identify possible sources of funding available, and seek guidance on the potential limitations, risks and benefits of these devices.

Audiologists **shall** support members of the public by:

- counselling on appropriate amplification options;
- advising users on the potential risks and contraindications of devices; and
- identifying device options to best suit the client's needs and/or provide alternate device options.

In alignment with the CSASK Code of Ethics, audiologists **shall not**:

- provide unnecessary or futile services/products where benefit or continued benefit cannot be reasonably expected. This does not preclude a member from providing a period of trial therapy or product trial to determine if benefit could occur.
- guarantee the results of services or products directly, or by implication. This does not rule out members providing a reasonable statement of prognosis, nor does it rule out manufacturers providing a product guarantee.
- submit a false or misleading account or charge for a service or product provided to a client.

This document serves as a reference to all CSASK registrants, including speech-language pathologists, when supporting the Saskatchewan public in receiving access to comprehensive hearing care.

In alignment with the CSASK Code of Ethics, all registrants **shall:**

- where indicated seek advice from, and/or refer clients to, another qualified colleague for diagnostic or intervention services.
- utilize resources that they and the client deem appropriate. This includes recommending and/or making referrals to other persons and agencies whose knowledge and services may contribute to the diagnosis, assessment and/or intervention of clients.
- promptly provide the client with information regarding other appropriate sources of assistance if unable to assess or provide the necessary services or if wait time may jeopardize client care.

CSASK will continue to engage with the provincial government to follow the regulation of these devices in Saskatchewan. Members of the public:

- who experience issues or adverse effects and wish to report medical device problems may contact Health Canada.
- with concerns related to the services received from a regulated audiologist or speech-language pathologist in Saskatchewan may contact CSASK.

## OTC Hearing Aid Related Resources

- Speech-Language & Audiology Canada: Health Canada Approves Apple AirPods Pro Firmware Module Upgrades: Implications for Hearing Health. 2025 - https://www.sac-oac.ca/health-canada-approves-apple-airpods-pro-firmware-module-upgrades-implications-for-hearing-health/
- Canadian Academy of Audiology Position Statement on Over-the-Counter Hearing Aids and Sound Amplifying Products. 2025 - https://canadianaudiology.ca/wp-content/uploads/2025/04/Canadian-Academy-of-Audiology-Position-Statement-on-Over-The-Counter-devices-and-Sound-Amplifying-Products.pdf
- Health Canada: Class II Medical Devices. 2025 - https://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/page-2.html#h-1021513
- FDA US Food and Drug - OTC Hearing Aids: What you should know. 2023 - https://www.fda.gov/medical-devices/hearing-aids/otc-hearing-aids-what-you-should-know
- The Hearing Aid Sales and Services Act: Chapter H-2.01 - https://pubsaskdev.blob.core.windows.net/pubsask-prod/17298/H2-01.pdf
- The Hearing Aid Sales and Services Regulations: Chapter H-2.01 Reg1 - https://publications.saskatchewan.ca/#/products/11664
- SAC Position Paper on Over the Counter Hearing Aids in Canada – July 2025 - https://www.sac-oac.ca/wp-content/uploads/2025/07/2025-PP-AUD-OTC-Hearing-Aids-in-Canada-FINAL-EN.pdf

[i] Government of Saskatchewan: Audiology and Hearing Services - https://www.saskatchewan.ca/residents/health/accessing-health-care-services/audiology-and-hearing-services