



**RCASLPNB**

Regulatory College of  
Audiologists & Speech-  
Language Pathologists of  
New Brunswick

**OAONB**

Ordre des  
audiologistes &  
orthophonistes du  
Nouveau-Brunswick

## PRACTICE ADVICE – Audiology/Speech-Language Pathology

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### OVER-THE-COUNTER (OTC) AND OTHER NON-PRESCRIBED HEARING AIDS

**DATE:** April 30, 2025

#### PURPOSE



This Practice Advisory Statement provides guidance to RCASLPNB regulated audiologists and speech-language pathologists regarding Non-Prescribed Hearing Aids (NPHAs). With emerging developments in hearing aid technology and access models, audiologists and speech-language pathologists in New Brunswick may be approached by the public with questions, support needs, or requests related to the prescribing, fitting, or adjustment of these devices.

#### WHAT ARE NPHAS?



Non-Prescribed Hearing Aids (NPHAs) are hearing aids acquired without a formal audiological assessment or prescription. This category includes devices:

- Purchased over-the-counter (OTC) or online.
- Obtained second-hand or through donation.
- Acquired as a gift.

## Context and Developments in the USA



In the United States, the Over-the-Counter Hearing Aid Act (2017) established a new class of hearing aids regulated by the Food and Drug Administration (FDA), making them available directly to consumers. As of October 17, 2022, the FDA regulates these devices, which are available to adult consumers with perceived mild to moderate hearing loss, without the need for involvement from a health professional.

## Context and Developments in Canada



RCASLPNB is aware that Health Canada approved the Apple hearing test and hearing aid features in December of 2024, along with the approval of several Jinghao-branded over-the-counter (OTC) hearing aids.

As of **March 2025**, the Apple features remain **inaccessible to Canadian consumers**. Apple has indicated that these features classified as “regulated health features” and require further government authorization before being offered to the Canadian public.

RCASLPNB anticipates additional government-level decisions will be necessary for these Apple features to become accessible to Canadian consumers.

## PRACTICE GUIDANCE FOR RCASLPNB REGISTRANTS

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**What should I tell my patients/clients and members of the public who ask about Apple’s hearing health features or other OTC hearing aids?**

Audiologists and Speech-Language Pathologists may inform the public that:

- Apple’s hearing features are not currently available in Canada, and further government decisions are likely required before these features can be made accessible.
- This hearing technology is intended only for adults aged 18+ with perceived mild to moderate hearing loss.

- These devices are **not suitable** for infants, children, or individuals with more complex hearing or medical concerns.
- Potential risks include limited customization, reduced support for complex hearing needs, and minimal data on long-term efficacy.
- There is **limited research** on the effectiveness of this technology in addressing hearing issues.
- It is important to seek guidance from a regulated health professional if there is a complex medical history related to hearing, or if symptoms such as bothersome tinnitus, dizziness, or ear pain occur, or if the use of the OTC device is not providing benefit.

This list is not exhaustive. **Registrants are encouraged to use their professional judgment** to provide additional relevant information as needed.

Audiologists should also **educate the public on the benefits and limitations** of these technologies and offer guidance on appropriate hearing care.

## 2 Am I prescribing hearing aids if I support a patient/client using their own NPHA?

No. Supporting a patient/client who presents with their own hearing aid does **not** constitute prescribing.

Audiologists should:

- ✓ Assess the patient/client’s hearing and communication needs.
- ✓ Determine whether the existing device offers appropriate benefit.
- ✓ Educate the patient/client and their support system about expectations, limitations, risks, and recommended next steps.
- ✓ Recommend prescription-based alternatives if NPHAs are not effective or appropriate.

Audiologists’ professional responsibilities under **RCASLPNB’s Code of Ethics** and the **National Clinical Competencies** remain applicable. This includes:

- Using evidence-informed practice.
- Conducting hearing aid candidacy assessments.
- Verifying and validating hearing aid performance when feasible.
- Providing education, counseling, and follow-up care.
- Meeting documentation, regulatory and ethical obligations.

### **3 What if the NPHA is not appropriate or cannot be adequately adjusted?**

If it is difficult to work with the hearing aids the patient/client has acquired, explain the reasons clearly and discuss alternative options. While NPHAs, such as OTC devices, may be suitable for some, many patients/clients may not be aware of their limitations or potential drawbacks.

For example, it is important to inform patients/clients of the risks associated with using NPHAs to address:

- Complex or severe hearing loss
- Hearing loss in infants or children
- Hearing concerns related to broader medical conditions

Many members of the public may also be unfamiliar with:

- The rehabilitative support audiologists provide to help patients/clients acclimatize to hearing aids
- Patient-centered strategies for managing the impacts of hearing loss
- The professional process followed when prescribing hearing aids

Use these situations as educational opportunities to support informed decision-making.

If the device is unsuitable, audiologists should:

- ✓ Clearly explain the limitations
- ✓ Provide recommendations for more appropriate treatment options.
- ✓ Educate the patient/client on the audiological process, including the benefits of a prescription-based approach and professional hearing rehabilitation.

The public may not fully understand the rehabilitative role of audiologists or the scope of professional services beyond amplification.

#### **4 Am I required to provide services to someone using an NPHA?**

While you are not required by RCASLPNB to provide services for patients/clients using non-prescribed hearing aids, it protects the public to see a qualified and regulated health care professional with the knowledge, skills, and judgement to assist.

#### **5 Can audiologists order and sell OTC hearing aids as part of practice?**

No, this is not currently recommended. RCASLPNB understands that while some devices, such as the Apple hearing health features, have received medical device licenses from Health Canada, there remain regulatory and access-related barriers that limit their availability to Canadian consumers. Until this is better understood, RCASLPNB does not recommend that audiologists act as providers, dispensers, or sellers of these devices.

The practice advice in this document is meant to apply when an audiologist is approached by a member of the public who already has already acquired an OTC hearing aid or similar device elsewhere.

Audiologists are expected to be a source of reliable information for the public about OTC hearing aids and other hearing-related technologies. Inform the public of the benefits, risks, limitations, and alternative options available. While members of the public may independently choose to obtain OTC hearing aids or other devices as they become accessible, audiologists will provide support or service in alignment with the professional guidance outlined in this advisory.



For further clarification or questions, please contact RCASLPNB at [info@rcaslpnb.ca](mailto:info@rcaslpnb.ca).

#### Resources:



- [OTC Hearing Aids: What You Should Know | FDA](#)
- [FDA Authorizes First Over-the-Counter Hearing Aid Software | FDA](#)