

What constitutes current medical opinion & practice?

PAAB code s3.2 requires that claims be consistent with current Canadian medical opinion/practice. PAAB considers a claim's alignment with authoritative Canadian consensus guidelines as evidence of consistency with current Canadian medical opinion/practice. This is based on the fact that consensus guidelines are widely recognized to be useful aids in clinical decision making.

Dispelling myths regarding peer-review & the word "guideline"

Myth 1: It's published and peer-reviewed so it must satisfy s3.2

Myth 2: The document title says "guideline" so it must satisfy s3.2

Publication and peer-review does not necessarily indicate that a document is reflective of Canadian medical opinion/practice. Nor does the presence of the word "guideline" in the document's title. In fact, a wide spectrum of published documents are sometimes referred to as "guidelines" including review papers, systematic analyses, and single sponsored papers describing an invited panel's therapeutic opinions/recommendations.

Also note that while some documents are created through appropriate consensus development methods, they might not be endorsed or recognized by an authoritative medical body and therefore may not be reflective of current medical practice (thus falling short of meeting the requirements of PAAB code s3.2).

For PAAB approval of drug claims based on guidelines, the document must be endorsed and/or recognized by a **national authoritative medical body**. This is true whether the document is the original guideline or an update to the guideline. Typically, this recognition is evidenced by mention of endorsement from the medical body within the guideline. PAAB would also consider appearance of the document on the authoritative body's website as evidence of recognition. If need be, PAAB could also accept a letter from the authoritative body (on official letterhead) as evidence of endorsement. Such letter must be framed so as to express the position of the organization as a whole, not the position of an individual.

Which claims can be supported by authoritative Canadian consensus guidelines?

Note that content from Canadian consensus guidelines is not automatically accepted in APS. All PAAB code provisions must be considered and adhered to. For example, all claims must be within the limitations of the Terms of Market Authorization and must meet the evidentiary standards outlined throughout the PAAB code.

Canadian consensus guidelines can be used to support product claims relating to place in therapy.

Example 1: "[Proprietary drug name] is recommended as a first line agent in the treatment of xyz."

*Example 2: "**Guideline ABC** recommends [non-proprietary drug name] as a first line agent in the treatment of xyz"*

They can also be used to support claims of special status.

Example 3: “[Proprietary drug name] is a cornerstone in the treatment of xyz”

PAAB has received requests from consensus groups to ensure that the proprietary drug name is not included within a claim directly referring to the guideline **if** the guideline recommendation only cites the non-proprietary drug name. See ‘example 2’ above.

To learn about the types of references required for various types of claims, visit the June 2015 tip document “Marketing benefit claims: What are they and what level of support do they require?”

Uh-oh! There are no Canadian consensus guidelines.

U.S. guidelines can be considered when there are **no** Canadian consensus guidelines within the corresponding therapeutic area. Guidelines from jurisdictions outside North America are only considered as the primary¹ support for a claim when they are explicitly recognized/endorsed by a Canadian authoritative medical body as being reflective of current medical practice/opinion in Canada. This is typically evidenced by a letter from the relevant Canadian authoritative medical body on official letterhead.

Using guidelines from other jurisdictions as additional support for content from Canadian guidelines

Valid published guidelines from other jurisdictions can generally be used to add further weight to acceptable recommendations from the Canadian consensus guidelines. In such cases, the APS presentation may only convey areas of alignment between Canada and the other region(s).

¹ If Canadian guidelines are available, advertisers can consider citing non-Canadian guidelines as secondary/additional support for messages supported by those Canadian guidelines. This is explained in the last paragraph of this document.