PAAB ADVISORY
Provincial Formulary Coverage Statements

Reference(s)

Only submissions which include one of the following references will be considered for review:

- Formulary listing (or equivalent provincial document)
- Letter signed by a TMA holder senior official (i.e. director level or higher) stating that the product coverage is expected to be unrestricted **OR** stating the restriction wording expected to be approved by the province. Final PAAB acceptance will not be provided until the final provincially approved formulary listing has been received and reviewed by the PAAB. For products that are being reimbursed according to criteria that are not publicly posted, please consult the PAAB for case-by-case consideration.

Formulary claim copy

Formulary coverage statements should be intended to be informational. They should not be positioned as a benefit of the product or as an endorsement from formulary bodies. Ensure they are positioned in a claim neutral manner and separate and distinct from clinical claims.

In cases where coverage is restricted (e.g., limited use, exceptional coverage):
The APS presentation must indicate that restrictions exist (in prominent body copy within the claim or proximal to it).

While different provincial formularies often use different terminology to refer to their coverage status (e.g. Exception Drug Status, Special Authorization, etc.), it is acceptable to use an accurate blanket statement such as "Covered on provincial formulary (special authorization)".

If the manufacturer elects to include coverage codes within the APS, the codes must be accompanied by the corresponding coverage criteria (e.g. inclusion/exclusion criteria), definitions, and notes where applicable. These elements may be included in a footnote.

Please also refer to the section Advisory regarding use of RAMQ in APS below for additional guidance on Quebec provincial formulary claims.

NEW!

When a product used as indicated would be covered, the sponsor can include the formulary coverage **even if the criteria is broader than the indication** (e.g., the indication is for moderate to severe condition X and the criteria is for condition X), provided that the i**ndication is presented prominently directly before the criteria to establish the context.** The indication should reflect the same condition as the criteria and, at a bare minimum, the font size should be 75% of the size of the criteria. This is similar to treatment guidance used for fair balance.

Note: This applies even if the indication is already included elsewhere in the APS.

There should also be **NO undue emphasis** on the broader condition or criteria, (e.g., bolding, callout, headline, etc.,) such that it appears as off-label promotion.

Reminder: When applying the above provisions, overt off-label criteria continue not to be acceptable in drug advertising per code section 3.1.

Frequent Questions: Is the APS exempt from PAAB preclearance?

1. APS comprised only of "Drug X: Now on ODB formulary" not linked in any way to additional product messages or disease/corporate messages.

   Exempt per PAAB code s1.5.D.ii. Do not include PAAB logo in absence of PAAB review.

2. APS comprised only of "Drug X: Now on ODB formulary (general benefit)" not linked in any way to additional product messages or disease/corporate messages.

   Exempt per PAAB code s1.5.D.ii. Do not include PAAB logo in absence of PAAB review.

3. APS comprised only of "Drug X: Now on ODB formulary (Limited use code required)" not linked in any way to additional product messages or disease/corporate messages.

   Exempt per PAAB code s1.5.D.ii. Do not include PAAB logo in absence of PAAB review.

4. APS comprised only of "Drug X: Now on ODB formulary (LU 493)" not linked in any way to additional product messages or disease/corporate messages.

   The APS requires inclusion of the coverage criteria and thus does not meet the PAAB code exemption s1.5.D.ii.

5. APS comprised only of "Drug X: Now on ODB formulary for condition X in patients who failed prior treatment of A, B and C" not linked in any way to additional product messages or disease/corporate messages.

   An APS containing the coverage criteria would not meet the PAAB code exemption s1.5.D.ii.

Updating formulary claims in previously PAAB approved pieces:

Modification of existing formulary claims and/or addition of formulary claims to previously approved APS requires PAAB review. These changes do not qualify as "FYIs". Note that the reference requirements on page 1 apply. Additionally, PAAB requires the previous eFile number(s) and updated layout(s) for assessment.

We acknowledge that manufacturers may need to update multiple PAAB approved pieces in order to inform healthcare professionals about formulary changes. Messages that would otherwise be considered exempt (e.g., Now on ODB) may also be added to existing, approved APS and be accepted as a "Minor Update", even if it is a new presentation. This is not applicable to added copy that includes the coverage criteria (as a separate formulary announcement containing the criteria would not be exempt from preclearance). The addition of copy which includes the coverage criteria could qualify for an ARO submission as "little new content" if it has <2 pages of new content. This allows for the coverage to be added to pieces in a timely manner. Note that the APS maintains its original approval window.

For pieces intended to be province-specific, sponsors may submit each province within the same submission as an "Iterative Submission" if the formulary coverage is the only difference across the pieces. Please see the Guidance on Submission Process and Format Requirement document for further clarification.

Fees - Please refer to the fee schedule on our website.

Examples:

Case 1

A product was approved as "special authorization" in Ontario – initial submission of APS 12345, 12346, 12347 and 12348. Two months later, the product is approved as a general benefit on the Ontario formulary.

> "Now on ODB formulary" *(to be placed on one or more previously approved APS)*

The modified APS could each be submitted as minor updates* as this is a modification to an existing formulary presentation.

Case 2

> "Now on ODB formulary (Special Authorization)" *(to be placed on one or more previously approved APS which did not previously contain formulary coverage claim)*

This could also be considered as a minor update*. Note that while the piece did not previously contain a formulary claim, the claim "Now on ODB (Special Authorization)" as a stand-alone message would have been considered an exempt message.

Case 3

The formulary coverage claim and limited use criteria are approved in eFile 19000. Since PAAB approval, the criteria have changed and the manufacturer wants to revise to state the new coverage (see highlights below).

Previously Accepted Presentation eFile 19000	**New Presentation**
PABTORA is covered on ODB (Special Authorization) PABTORA has coverage for the treatment of ulcerative colitis in patients who meet the following criteria: **Moderate disease** a) A Mayo score of 7 to 10 AND b) Endoscopic subscore of 2 AND c) Failed 2 weeks of oral prednisone at daily doses of >40 mg OR d) Stabilized with 2 weeks of oral prednisone at daily doses >40 mg	PABTORA is covered on ODB (Special Authorization) PABTORA has coverage for the treatment of ulcerative colitis in patients who meet the following criteria: **Moderate disease** A) A Mayo score of 7 to 10 AND B) Endoscopic subscore of 2 AND C) Failed 2 weeks of oral prednisone at daily doses of >40 mg OR D) Stabilized with 2 weeks of oral prednisone at daily doses >40 mg **Severe Disease** a) Mayo score >10 AND b) Endoscopy subscore of >2 AND c) Failed 2 weeks of oral prednisone at daily doses >40 mg OR d) Stabilized with 2 weeks of oral prednisone at daily doses >40 mg.

As the formulary presentation already exists in the APS and is simply being updated, this could be considered a minor update* if you have the ability and desire to maintain the existing expiry date for eFile 19000.

Case 4:

> Covered by Alberta Health Drug Benefit List (with special criteria)
>
> Drug X is indicated for metastatic breast cancer
>
> Special Criteria for Coverage: Drug X for locally advanced and metastatic breast cancer

A product was approved for coverage for locally advanced and metastatic breast cancer. The product is indicated for metastatic breast cancer. The indication must appear in close proximity and in proportional body copy. If this is being added to an existing APS, it can be considered for ARO if it has <2 pages of new content.

* *Note that the APS maintains its original approval window.*

Use of Régie de l'assurance maladie du Québec (RAMQ) in APS

RAMQ has informed PAAB that:

- All pieces including the copy "RAMQ" must acknowledge that this is the "Official Mark of the Régie de l'assurance maladie du Québec". This acknowledgment may appear as a footnote on the same page. The acknowledgement may alternatively appear within a reference list presented in the piece.
- Coverage claims must be accompanied by reimbursement criteria (if applicable to the indications promoted in the piece). The criteria may appear in a footnote on the same page. When the criteria are presented elsewhere, a prominent statement near the claim must direct the reader to their location within the piece. Additionally, the layout must not suggest that the authorized Federal indication is the reimbursement criteria (except where this is indeed the case).

Reminder: When applying the above provisions, overt off-label criteria continue not to be acceptable in drug advertising per code section 3.1.

Additional consideration: RAMQ prefers that a URL linked to the RAMQ webpage containing the PDF "Liste des médicaments", along with the date of access, also be presented somewhere within the piece (e.g. reference list).

**Note that requirements outlined in this subsection apply only to RAMQ and is supplemental to the general provisions that proceed it on this page.