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.

Formulary claim copy

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.

Frequent Questions: Is the APS exempt from PAAB preclearance?

1. APS comprised only of "Drug X: Now on OBD formulary" not linked in any way to additional product messages or disease/corporate messages.
   Exempt per PAAB code s6.6 (iv). Do not include PAAB logo in absence of PAAB review.
2. APS comprised only of "Drug X: Now on OBD formulary (general benefit)" not linked in any way to additional product messages or disease/corporate messages.
   Exempt per PAAB code s6.6(iv). Do not include PAAB logo in absence of PAAB review.
3. APS comprised only of "Drug X: Now on OBD formulary (Limited use code required)" not linked in any way to additional product messages or disease/corporate messages.
   Exempt per PAAB code s6.6(iv). Do not include PAAB logo in absence of PAAB review.
4. APS comprised only of "Drug X: Now on OBD 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 s6.6(iv).
5. APS comprised only of "Drug X: Now on OBD 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 s6.6(iv).

Special Case. Changes to previously PAAB approved pieces:

Modification to existing formulary claims, and/or addition of formulary claims, in previously approved APS require 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. Multiple PAAB approved pieces may be included within a single submission provided **all** of the following factors are met:

- ☐ The APS modifications are submitted on the same day.
- ☐ Only files within the PAAB approval period are clumped together in this manner. The modified APS will retain the same acceptance period as the previously approved APS (i.e. a new acceptance number will not be issued).
- ☐ There are no changes to the APS other than the formulary claim.
- ☐ The formulary message does not include coverage criteria or codes.

Changes relating to coverage codes or criteria must be submitted as separate files.

Fees - Please refer to the fee schedule on our website http://www.paab.ca/fee-schedule-services.htm

Sample Message #1

"Now on ODB" to be placed on one or more previously approved APS:

All updated APS may be submitted within a single file if all provisions listed above are met (even if some of the APS refer to different provinces).

E.g. The text "Now on ODB" is to be added to some Detail aids, Shelf Talkers, and Journal ads which are currently in use in Ontario. The text "Now on BC Pharmacare" is to be added to the corresponding BC versions. These may all be submitted under the same eFile if all provisions listed above are met.

2 months later, the product is approved as a general benefit on the Alberta formulary. The modified APS would again be submitted together in a single new eFile (if all provisions listed above are still met).

Sample Message #2

"Now on ODB, (Special Authorization)" to be placed on one or more previously approved APS:Same as sample message 1.

Sample Message #3

"Now on ODB, Limited Use Code 290" to be placed on one or more previously approved APS:

Each updated APS is required to be submitted in a separate eFile. The first file will be assessed a full fee, subsequent related files submitted on the same day could be assessed a series fee.

Note that the manufacturer will be required to insert the coverage criteria in this case.

E.g. "Now on ODB, LU code 290" to be placed on a Detail Aid, a Shelf Talker, and a Journal Ad which are currently in use. These would be submitted as 3 separate eFiles submissions. If the three Manitoba versions of these APS were also to be updated, this would make for a total of 6 files.

Sample Message #4

"Now covered on ODB for condition X in patients who failed treatment of prior Y" placed on previously approved APS:

Same as sample message 3.