Page last updated: November 26, 2019

COVERAGE STATUS MODIFICATION CHECKLIST

Drug submission sponsors may request a Modification of Current Coverage Status from the Ministry of Health to change the current coverage of a drug. Requests to modify the coverage status of a drug generally apply to non-Common Drug Review (CDR) drugs when new and relevant clinical information has become available.

To request a Modification of Current Coverage Status:

- submit **one copy** of the complete submission requirements on a USB flash drive to the Ministry of Health;

Note: The USB flash drive should be unlocked and fully executable. Hard/paper copies of drug submissions are not accepted.

- read and follow the checklist of required documents below to ensure the submission package is complete; and
- send the complete submission package to the courier address:

  Director, Formulary Management
  Pharmaceutical Services Division
  BC Ministry of Health
  1515 Blanshard Street
  Victoria BC V8W 3C8

Note:

- All letters submitted to the Ministry of Health, unless otherwise stated in the checklist, must be prepared on company letterhead, signed by an appropriate senior official, and submitted as an electronic copy. (Documents may be signed using an e-signature. When printing hard copies to sign and scan, use blue ink).
- Documents required by the Ministry of Health (e.g., letters) should be addressed to the Director of Formulary Management at the Ministry of Health
- Only complete drug submission packages that include all checklist documents below will be reviewed.
- If you have any questions about specific drug submissions, or the drug submission process, send an email to the Ministry of Health Formulary Management team at: DrugReviewProcess@gov.bc.ca

BC Ministry of Health Documentation

- ❑ **Cover letter *Signature Required***

- ❑ **Drug Product Request Form for Patented Drug Products**

Applies to Non-Common Drug Review (CDR) Submissions Only
Access and complete the Ministry of Health Drug Product Request Form for non-CDR Submissions (DOCX) as a Word document. In the template, include the following:

- Each indication, strength and the Drug Identification Number (DIN) to be reviewed.
- The name of the drug manufacturer and each vendor/associate company working on the submission.
- Contact information for the primary and backup person who can be contacted regarding the submission.
- A high-level executive summary describing the submission.

- ❑ **Product monograph**

- A copy of the most recent product monograph approved by Health Canada with the company, drug brand, and non-proprietary names that correspond to the Notice of Compliance (NOC).
- A copy of the clean and dated product monograph approved by Health Canada.

- ❑ **Letter confirming that written notification of any future changes will be provided *Signature Required***

- ❑ **Letter confirming the availability of the drug pre-NOC *Signature Required***

- ❑ **Letter confirming ability to supply for anticipated demand *Signature Required***

Patents Documentation

- ❑ **Summary list of the drug product's associated patents and the patent expiry dates as documented on Health Canada Patent Register**

Health Canada Documentation
❑ **NOC or Notice of Compliance with Conditions (NOC/c)**
❑ **Drug Identification Number(s) (DIN)**

Efficacy, Effectiveness, and Safety Documentation (including supplementary appendixes)
❑ **Supporting clinical evidence**
❑ **Pharmacoeconomic evidence**
❑ **All other information the drug submission sponsor would like the Ministry of Health to consider**
❑ **Reference list of key clinical studies and errata**
❑ **Copies of key clinical studies and errata**
❑ **Reference list of editorial articles (or statement that there are no editorials)**
❑ **Copies of editorial articles**
❑ **Literature search strategies**
❑ **Reference list of studies included in the submission**
❑ **Copies of studies included in the submission**
❑ **Letter declaring that all known unpublished studies have been disclosed *Signature Required***

- ❑ **Table of all known ongoing trials for indications that are different than the indication being submitted for review**

Budget Impact Analysis (BIA)

- ❑ **A Provincial Budget Impact Analysis (BIA) for BC that is consistent with the** standards published by the Patented Medicines Prices Review Board (PMPRB)

Pricing and Distribution Information

- ❑ **Summary list and/or table on unit pricing information**

Include all dosage forms, strengths and package sizes, to four decimal places.

- ❑ **Method of distribution**

Provide all available information on how the drug will be distributed.

- ❑ **Letter of commitment to honour the submitted price *Signature Required***

Sharing of Information

- ❑ **Letter of consent authorizing the unrestricted communication and sharing of information *Signature Required***

The letter authorizes the Ministry of Health to share information with respect to the drug product under review, with:

- Health Canada
- Other provinces and territories
- Canadian Agency for Drugs and Technologies in Health/Common Drug Review (CADTH/CDR)
- PMPRB
- Health authorities including regional health authorities
- Contracted third party reviewers who are subject to a signed confidentiality agreement.

Communications Documentation

- ❑ **All Pharmaceutical Advertising Advisory Board (PAAB)-approved promotional materials or draft copies of materials submitted to PAAB**

If the materials are not available at the time of submission, the drug submission sponsor should submit a letter indicating the reason for the delay and when the materials are expected to be available. Once available, the drug submission sponsor should provide them to the Ministry of Health to complete the submission.

If a drug submission sponsor does not intend to produce and use promotional materials for the product, they may submit a letter that includes:

- a request to waive the use of promotional materials
- the rationale for not using promotional materials
- the period during which no promotional materials will be used (from start month and year to end month and year).

Periodic Safety Update Report

- ❑ **Letter of consent to release Periodic Safety Update Reports as submitted to Health Canada *Signature Required***

The letter should state that all data on harm as submitted to Health Canada, related to the drug submission under review, including harm and safety issues that may arise while the submission is under review, will be submitted to the Ministry of Health.

Important: The Ministry of Health reserves the right to ask for additional information as required. The drug submission sponsor must submit any required electronic documentation in accordance with copyright permissions.