Page last updated: November 26, 2019

BLOOD GLUCOSE TEST STRIP SUBMISSION CHECKLISTS

Submission sponsors may request that the Ministry of Health cover their blood glucose test strip products.

To submit a request for coverage:

- read and follow the checklist of required documents below to ensure the submission package is complete;
- submit **one copy** of the complete submission requirements on a USB flash drive to the Ministry of Health; and

Note: The USB flash drive should be unlocked and fully executable. Hard/paper copies of drug submissions are no longer accepted.

- Send the complete submission package of blood glucose test strip documents 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 specifically 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 submission packages that follow the checklist criteria and include all checklist documents 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

Checklist of required Blood Glucose Test Strip product documents

BC Ministry of Health Documents
❑ **Cover Letter *Signature Required***
❑ **Drug Product Request Form for Patented Drug Products and Biosimilars** ***Applies to Non-Common Drug Review (CDR) Submissions Only*** Access and complete the Ministry of Health Drug Product Request Form for non-CDR Submissions as a Word document. • The name of the 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.
❑ **Summary of specifications of the blood glucose test strip product including information submitted to Health Canada for approval:** • enzyme system • sample size • time to test • any other relevant information.
❑ **Letter confirming that written notification of any future changes will be provided *Signature Required***
❑ **Letter confirming ability to supply for anticipated demand *Signature Required***

Health Canada Documentation
❑ **Medical Device License**

Pricing and Distribution Information
❑ **Summary list and/or table on unit pricing information** Include pricing to four decimal places on all package sizes.

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)
- Patented Medicines Prices Review Board (PMPRB)
- Health authorities including regional health authorities
- Contracted third party reviewers who are subject to a signed confidentiality agreement.

Communications Documentation

- ❑ **All promotional materials**

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

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