SUBMISSION REQUIREMENTS CHECKLIST FOR BLOOD GLUCOSE TEST STRIP PRODUCTS TO THE BC MINISTRY OF HEALTH

BLOOD GLUCOSE TEST STRIP DOCUMENTS AND INFORMATION REQUIRED FOR PRODUCTS REVIEWED BY THE BC MINISTRY OF HEALTH

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

When submitting a request for coverage of blood glucose test strip products, submission sponsors must:

- Submit **one hard copy and one electronic copy** (e.g., CD, DVD, USB flash drive that is unlocked and fully executable) of their complete submission to the Ministry of Health
- Read and follow the checklist of required documents below to ensure the submission package is complete
- Send the complete submission package of blood glucose test strip documents to the courier address below:

Courier Packages to:

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

Regular Correspondence to:

Director, Formulary Management
Medical Beneficiary and Pharmaceutical Services Division
BC Ministry of Health
PO BOX 9652 STN PROV GOVT
Victoria BC V8W 9P4

Below is a detailed checklist of blood glucose test strip documents required by the Ministry of Health.

Note:

- Unless otherwise stated in the checklists (i.e., N/A), all documents must be printed on company letterhead, signed by an appropriate senior official, and submitted to the Ministry of Health as hard and electronic copies
- 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 that include all checklist documents will be reviewed

Checklist for required Blood Glucose Test Strip documents specific to the Ministry of Health	Criteria for submission documents		
General Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
Cover Letter The cover letter, printed on company letterhead and signed by an appropriate senior official, should describe the blood glucose test strip and identify: • the name of each vendor/associate company working on the submission • contact information for the primary and backup person who can be contacted regarding the submission under review.	❑	❑	❑
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.	**N/A**	❑	❑
Letter confirming that written notification of any future changes will be provided The letter should be printed on company letterhead and signed by an appropriate senior official.	❑	❑	❑
Letter confirming ability to supply for anticipated demand The letter should be printed on company letterhead and signed by an appropriate senior official.	❑	❑	❑
Health Canada Documentation	**Signature Required**	**Hard Copy**	**Electronic Copy**
Medical Device License	**N/A**	❑	❑
Pricing and Distribution Information	**Signature Required**	**Hard Copy**	**Electronic Copy**
Summary list and/or table on unit pricing information Include all package sizes to four decimal places.	**N/A**	❑	❑
Sharing of Information	**Signature Required**	**Hard Copy**	**Electronic Copy**
Letter of consent authorizing the unrestricted communication and sharing of information The letter, printed on company letterhead and signed by an appropriate senior official, authorizes the Ministry of Health to share information with respect to the drug product under review, with: • Health Canada • Other provinces and territories • CADTH/CDR (Canadian Agency for Drugs and Technologies in Health/Common Drug Review) • 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	**Signature Required**	**Hard Copy**	**Electronic Copy**
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	**N/A**	❑	❑

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 also submit any required electronic documentation in accordance with copyright permissions.