Ontario

Ministry of Health

OHIP, Pharmaceuticals and Devices Division

Ontario Guidelines for Flash Glucose Monitoring

Submission Requirements and Review Process

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Introduction

The Ontario Public Drug Programs (OPDP) provides funding for a number of publicly funded drug programs. The largest program is the Ontario Drug Benefit (ODB) program and it funds eligible benefits (known as listed drug products and listed substances) designated on the ODB Formulary/Comparative Drug Index (the "Formulary"). Additional coverage may be provided for drug products through case by case review under the Exceptional Access Program (the "EAP").

The *Ontario Drug Benefit Act* (the "ODBA") defines "listed substance" to mean a substance, other than a drug, designated as a listed substance in the Formulary by the Executive Officer of the Ontario Public Drug Programs (the "Executive Officer"). Flash Glucose Monitoring (FGM) are listed substances reimbursed for ODB-eligible persons in certain circumstances.

A submission for an FGM undergoes a similar review process as a drug product, although the manufacturer must satisfy a different set of requirements to be considered for designation as a listed substance on the Formulary.

If an FGM product is listed on the Formulary, the FGM product would be eligible for reimbursement when it is prescribed for ODB-eligible recipients.

Objective

The objective of this document (the "Guidelines") is to provide guidance on submission requirements and the ministry's review process. The Guidelines are to be used in the preparation of an FGM submission provided to the Ministry of Health (ministry). The manufacturers, or those filing submissions on their behalf, are responsible for ensuring that all FGM submissions filed with the ministry contain sufficient information to satisfy the applicable requirements of the legislation and the Guidelines.

1. Checklists for Preparing Submissions

The manufacturer may use the below checklist to help ensure that all submission requirements have been included.

Requirement:	Included
Signed cover letter	☐
Table of contents	☐
Health Canada Documentation: Medical Device Licence; AND Medical Device Establishment Licence	 ☐ ☐
Letter of Consent	☐
Proposed price	☐
Ability to Supply Letter	☐
Certification of Providing No Rebates Letter	☐
A copy of the device label	☐
Evidence of safety and effectiveness	☐
ODB Financial Impact Information	☐
Pharmacoeconomic Evidence: Pharmacoeconomic Analysis (report and model); AND Pharmacoeconomic Analysis Summary	 ☐ ☐

2. Submission Requirements for Flash Glucose Monitoring

2.1 Cover Letter and Table of Contents

A cover letter and table of contents must accompany the submission. The cover letter must clearly state:

- The name of the FGM, including the various package sizes.
- Whether the manufacturer has any business agreements with any third party (e.g. consultant, cross-licensed, co-marketing, etc.) with respect to the FGM, and, if so, the name of the third party / third parties. See additional information in section 7.1 of these Guidelines.

2.2 Evidence of approval from Health Canada

- A copy of the Medical Device Licence for the FGM; and
- A copy of the Medical Device Establishment Licence of the manufacturer or distributor of the FGM, for the sale or importation of the product in Canada, as applicable.

2.3 Letter of Consent

A letter authorizing the Executive Officer to gain access to all information with respect to the FGM in the possession of Health Canada, the government of any province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health and authorizing the Executive Officer to disclose any information with respect to the FGM in the possession of the Ministry to Health Canada, the government of a province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health.

See Template Letter of Consent in section 6 below.

2.4 Proposed Price

Submit the following two prices:

- Manufacturer list price (price without mark-up): the lowest price per package size and per FGM to four decimal places sold to wholesalers or pharmacies (if direct distribution to pharmacies).

In cases where the cost per FGM is different from the cost per pack divided by the number of FGMs in each package, the lowest price will be used for any designation on the Formulary. If the price is accepted by the ministry and listed on the Formulary, it will apply to all pack sizes of the product.

2.5 Evidence Confirming Ability to Supply

Confirmation that the manufacturer is able to supply the FGM at the proposed list price in a quantity sufficient to meet the anticipated demand for the product.

See Template Letter of Ability to Supply in section 6 below.

2.6 Certification Confirming That No Rebates Were Provided

The manufacturer must certify in writing that no rebates were provided to persons listed in subsection 11.5(1) of the *Ontario Drug Benefit Act* (ODBA) with respect to the FGM from the time that Health Canada approved the product for sale in Canada.

See Template Letter Certification of Providing No Rebate in section 6 below.

2.7 A copy of the device label

2.8 Evidence of safety and effectiveness of the submitted product

- A copy of the completed, dated, and signed New Class II Medical Device Licence Application Form approved by Health Canada.
- A summary of objective evidence to establish that the submitted product is compliant with the safety and effectiveness requirements in accordance with section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the Medical Devices Regulations.

2.9 ODB Financial Impact Information

ODB market share penetration or impact analysis on ODB expenditure, including the underlying assumptions for the calculations.

2.10 Pharmacoeconomic Evidence

The manufacturer must prove the benefit of its proposed product in relation to the cost of the product and to alternative products.

- A completed Pharmacoeconomic Analysis (report and model).
- A completed Pharmacoeconomic Analysis Summary (see section 6 below).

3. Submission Review Process

3.1 Filing of Submissions

A manufacturer that wishes to have an FGM product considered for designation as a listed substance on the Formulary must file a submission with the ministry.

3.2 Written/Verbal Communication

All written and verbal communication between the ministry and a manufacturer takes place through a single primary contact from the manufacturer. The ministry requires written notification in order to change a manufacturer's primary contact, or any other information related to contact information (e.g. address, telephone number, e-mail address etc.). It is the manufacturer's responsibility to keep this information current and accurate.

3.3 Submission Receipt and Review

FGM submissions are screened for compliance with applicable requirements in the legislation and these Guidelines by ministry staff in sequence, according to the date and time of receipt.

The targeted time frame for screening is approximately three weeks from the date the submission is received by the ministry.

Only products that are the subject of complete submissions (i.e. those that meet all applicable requirements) are eligible for review and consideration for designation as listed substances on the Formulary. The date that the ministry deems a submission complete, as well as the type of review (i.e. first review or reconsideration), determines the subsequent priority of the review of the product. The complete submission date refers to the date when the Notice of Drug Submission Status (NDSS) letter is sent.

3.4 Ministry Communication

Once a submission is screened by the ministry, an NDSS is issued to the manufacturer. Each submission is assigned a unique master file number, and each individual FGM within the same submission is assigned a unique FGM product file number. The NDSS will indicate the status of the submission (i.e. complete or incomplete) as well as the assigned file numbers. The NDSS for an incomplete submission will state the reasons why the submission was deemed incomplete.

3.5 Manufacturer's Response

A manufacturer must make reference to the FGM (product name), the master file number and the FGM file number(s) in all subsequent correspondence to the ministry. If a manufacturer receives an NDSS, which indicates that the submission was deemed incomplete, the manufacturer will be provided with 60 calendar days in which to provide the information required to complete the submission.

Manufacturers are encouraged to respond to requests for additional information in a timely manner to avoid delays in the submission review process.

3.6 Review by the Advisory Committee

Complete submissions undergo review by the ministry's expert advisory committee, the Committee to Evaluate Drugs (CED). The complete submission is sent to a reviewer who reviews the submission and prepares a written report. Submissions are reviewed by the committee members and/or by other reviewers drawn from an extensive roster of external clinical and pharmacoeconomic consultants. The targeted time frame for the completion of reviews is four to six weeks. The CED and the ministry may require additional time to review complex submissions. Occasionally, a panel or subcommittee of the CED may be requested to review a specific submission, which will extend the timeline for the review.

The CED discusses each submission, with input from reviewers, other expert external consultants, and the ministry as required. The FGM is evaluated for the comparative therapeutic efficacy and safety for ODB program recipients, cost-effectiveness in comparison to currently funded alternatives, patient value or input, and impact on other health services. This comprehensive evaluation contributes to the determination of value-for-money for OPDP.

3.7 Communication to Manufacturers

The CED recommendation letter is issued to a manufacturer after the committee's review. The recommendation letter is sent to the manufacturer generally within four to five weeks after the ratification of the committee's minutes. The recommendation letter will summarize the committee's recommendation and reason(s) for its recommendation.

4. Format and Organization of Submissions

The OHIP, Pharmaceuticals and Devices Division accepts e-mail submissions. The submissions must be well organized and indexed/tabbed with description. Manufacturers must not provide submission information in one continuous document. If the submission is too large to be sent by a single e-mail, the ministry will accept the whole submission via multiple e-mails. If the manufacturer is sending multiple e-mails for one submission, clearly identify that the e-mails belong to the same submission and how many total e-mails pertain to that particular submission.

The ministry expects manufacturers to follow the Guidelines when preparing submissions. The onus is on a manufacturer to provide the ministry with a submission that is complete, accurate and complies with applicable legislative and policy requirements. The ministry will not assume responsibility for advising manufacturers of the completeness of their submissions prior to the ministry screening and review. Also, the ministry reserves the right to request additional information at any time during the review process.

5. Filing of Submissions

All submissions and any additional related information must be sent to:
Senior Manager
Drug Benefits Management Unit
Drug Programs Policy and Strategy Branch
OHIP, Pharmaceuticals and Devices Division
Ministry of Health

Please send the submissions to email mailbox DrugSubmissions.MOH@ontario.ca

6. Templates and Checklist

Templates:

- Template Letter of Consent
- Template Letter Confirming Ability to Supply
- Template Letter Certification of Providing No Rebate
- Pharmacoeconomic Analysis Summary

The ministry's template letters and checklists are available on the ministry's website. All template letters must be prepared using the appropriate manufacturer's letterhead, dated and signed by the senior company official.

7. Additional Information

7.1 Third Party Involvement

Where a third party is involved with a submission, a letter must be submitted from each of the Medical Device Licence holder and the third party confirming the business arrangement between the submitting party and the Medical Device Licence holder, and the submitting party's authority to file and discuss the submission with the ministry, on behalf of the Medical Device Licence holder.

7.2 Notification of Change

The ministry must be notified of changes to the licence, ownership of the product, including any change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented where the changes may affect the quality or performance of the product. The manufacturer must provide evidence to support the change, including where applicable, evidence of Health Canada's approval.

7.3 Withdrawal Process

The submitting manufacturer may voluntarily withdraw a submission any time throughout the review process. A written request must be provided by the manufacturer to the ministry with an explanation to withdraw a submission.

List of Abbreviations

CED	Committee to Evaluate Drugs
EAP	Exceptional Access Program
FGM	Flash Glucose Monitoring
NDSS	Notice of Drug Submission Status
ODB	Ontario Drug Benefit
ODBA	Ontario Drug Benefit Act
OPDP	Ontario Public Drug Programs

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