

Ministry of Health
Drugs and Devices Division

Executive Officer Notice: Funding of Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler as a Temporary Benefit on the Ontario Drug Benefit (ODB) Formulary.

May 21, 2020

Overview

The ministry recognizes the impact of drug shortages on patients, health care professionals and the health care system, and works with stakeholders to better prevent, mitigate and communicate shortages. Effective November 1, 2019, amendments were made to Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* to better enable the Ontario Drug Benefit (ODB) Program to respond to drug shortages. These amendments allow the ministry to provide short-term public funding of clinically-appropriate alternate drugs in response to a drug shortage.

In response to an ongoing shortage of Canadian marketed salbutamol metered dose inhalers as a result of the COVID-19 pandemic, effective **May 29, 2020**, Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler will be funded as a Temporary Benefit on the ODB Formulary.

http://www.health.gov.on.ca/en/pro/programs/drugs/odbf_eformulary.aspx

Health Canada is permitting the importation of Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler into Canada for subsequent sale.

Details regarding Health Canada's decision can be found on Health Canada's website at:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.html>

The following product identification number (PIN) has been assigned:

- Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler 100mcg/per metered dose: **PIN 09858115**. The Drug Benefit Price (DBP) is \$5.0000 per 200-dose inhaler.

The Temporary Benefit PIN for Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler must be used for online claims submitted through the Health Network System (HNS). Billing procedures are the same as the billing procedures for salbutamol products currently listed on the ODB Formulary, subject to any future changes which will be communicated to pharmacies via OneMail.

Pharmacies are eligible to be reimbursed for the DBP associated with the PIN, plus the applicable mark-up and the pharmacy's usual ODB dispensing fee, minus any applicable co-payment amount. The usual conditions for payment of a dispensing fee under the ODB program must be followed. For billing purposes, pharmacy documentation must be maintained in a readily available format for the purpose of post-payment verification for a minimum of 2 years. Overpayments due to inappropriate claim submissions are subject to recovery.

Pharmacies should continue to dispense salbutamol inhaler drug products listed as regular General Benefit (GB) on the ODB Formulary as long as they have supply in stock. Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler should only be dispensed if a regular GB salbutamol inhaler product is not available.

Questions and Answers

1. What is Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler?

Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler is a salbutamol (salbutamol sulfate) inhaler drug product manufactured by Teva and marketed in the UK. It is available in a 100 mcg /per metered dose strength and 200 metered dose pack size.

2. Why is the Ontario Public Drug Programs funding a foreign labelled drug product on the ODB Formulary?

Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler is funded on the ODB Formulary effective **May 29, 2020**, on a temporary basis to help facilitate access to salbutamol inhalers during the supply shortage of the Canadian marketed products reimbursed on the ODB formulary.

3. What is a Temporary Benefit?

A temporary benefit on the ODB Formulary is a clinically-appropriate alternate drug that is publicly funded on a short-term basis to facilitate the management of a drug shortage. Certain drug submission requirements are waived to allow for the short-term approval. If deemed necessary, the ministry may list a product under the “Temporary Benefit” status of the formulary for a limited period of time. The removal of a Temporary Benefit drug product from the formulary will be communicated in a future announcement.

4. Is Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler interchangeable with the other salbutamol inhaler products funded on the ODB Formulary as General Benefits?

No, Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler is not interchangeable with other salbutamol inhaler products funded on the ODB Formulary as General Benefits.

5. If I have a prescription for Ventolin or salbutamol, can I dispense Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler?

If the prescription authorizes the dispensing of a particular strength and dosage of salbutamol without specifying a specific brand or product name, then a pharmacist may dispense Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler, of the same strength and dosage noted in the prescription, if NO listed interchangeable version is available.

If the prescription directs the dispensing of a particular brand of salbutamol or if other listed interchangeable versions are available at the pharmacy, a new prescription would be required in order to dispense Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler. The new prescription would specifically authorize the dispensing of the Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler.

6. If I have to get a new prescription to dispense Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler, would it be an eligible billing through the Pharmaceutical Opinion Program?

No. Pharmacies cannot bill pharmaceutical opinions in regards to drug shortages and/or recalls. If the pharmacy does not have a prescribed drug in the pharmacy inventory and there is a need to replace it with a replacement drug – this process is not eligible for payment under the Pharmaceutical Opinion Program (POP).

7. If I still have stock of Salbutamol products that are listed on the ODB Formulary, can I still dispense Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler?

Pharmacies should continue to dispense salbutamol products reimbursed on the ODB Formulary as regular General Benefits if they are available. Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler should only be dispensed in situations where Salbutamol is required but unavailable due to shortages in the supply chain. See previous question above for details.

8. What are the differences between Salbutamol and Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler?

Please refer to the *Dear Healthcare Professional Letter* issued by Health Canada:

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73095a-eng.php>

9. The Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler product I received does not have the usual labelling required by Health Canada. Can I still dispense this product?

Yes, Health Canada has authorized the importation of Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler into the Canadian marketplace. This product may have different labeling as it was originally intended for sale in another country. Please refer to the *Dear Healthcare Professional Letter* issued by Health Canada for details.

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73095a-eng.php>

Additional Information:

For pharmacies:

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For all other Health Care Providers and the Public:

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282