

## Notice from the Executive Officer: Availability and Funding of AUVI-Q® (Epinephrine Auto-Injectors) as a Result of the Shortage of EpiPen® Products.

**Updated October 11, 2018**

This is an update to the original notice dated September 10, 2018.

This notice is to provide information to pharmacies and dispensers on an update in the interim funding of AUVI-Q® epinephrine auto-injectors.

### Overview

In response to ongoing shortages of EpiPen® (0.3mg) and EpiPen Jr.® (0.15mg), Health Canada has approved through an Interim Order (IO) the importation into Canada of AUVI-Q® epinephrine auto-injectors.

In addition to the temporary interim funding of the AUVI-Q® 0.3mg auto-injector announced in the Executive Officer notice of **September 10, 2018**, **the AUVI-Q® 0.15mg format is now also approved for Ontario Drug Benefit (ODB) recipients through the Allergen Program.**

Health Canada has assigned the following temporary product identification number (PIN):

- AUVI-Q® 0.3mg – 02480379
- AUVI-Q® 0.15mg – 02480360

The temporary PINs for the AUVI-Q® products must be used for online claims submission through the Health Network System (HNS). Billing procedures are the same as the billing procedures for EpiPen® products. Reimbursement for both strengths of AUVI-Q® are set at \$170.00 per auto-injector (plus ODB mark-up and dispensing fee).

Temporary interim funding of the AUVI-Q® is now approved for ODB recipients through the Allergen Program for patients, where EpiPen® products are not available due to supply shortage, in discussion with their healthcare provider / prescriber.

Under the Allergen Program, pharmacies should continue to dispense EpiPen® products as long as they have supply in stock and an AUVI-Q® should only be dispensed if an EpiPen® product is not available.

**There is no co-payment or deductible required for products under the Allergen Program.**

Only an AUVI-Q® supplied to an ODB eligible recipient with a valid prescription for an AUVI-Q® will be reimbursed. EpiPen® and AUVI-Q® are not interchangeable products. Pharmacists should be working within their professional capacity with patients and prescribers to help prevent any gaps in therapy and provide alternative drug therapies as applicable.

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). For more information regarding the POP, please refer to page 69 of The Professional Pharmacy Services Guidebook 3.0 or:

<http://www.health.gov.on.ca/en/pro/programs/drugs/medscheck/docs/guidebook.pdf>

The ministry continues to monitor drug shortages and we thank you for your support as partners in health.

**Background on the Allergen Program**

The Allergen Program provides first dollar coverage for eligible ODB program recipients for certain drug products used to treat allergies and allergic reactions.

Allergen extract products reimbursed through the Allergen Program may be provided by an authorized allergen extract supplier or through an accredited retail pharmacy.

**Frequently Asked Questions**

**Is the AUVI-Q® auto-injector being funded in Ontario?**

Yes, AUVI-Q® is being added to Ontario's Allergen Program on a temporary basis to help facilitate access to epinephrine auto-injectors during the supply shortage of EpiPen® products.

**Will an allergen form be required for AUVI-Q®?**

No, an allergen form will not be required. As of December 1, 2017, all ODB-eligible individuals will no longer require a Special Authorization (Allergen) form for an epinephrine auto-injector to be reimbursed through the Allergen Program.

**If I have a prescription for an EpiPen® product, can I get an AUVI-Q®?**

No, EpiPen® and AUVI-Q® are not interchangeable products. Pharmacists and prescribers should be working in their capacity to switch patients from EpiPen® to AUVI-Q® as required to ensure product is available for those patients in need. Pharmacists should use their professional judgment to determine which product to dispense for any prescriptions that may not indicate a specific epinephrine product (e.g. “epinephrine auto-injector”).

**If I still have stock of EpiPen® products, can I still dispense AUVI-Q®?**

Pharmacies should continue to dispense EpiPen® products if they are available. AUVI-Q® should only be dispensed in situations where an EpiPen® product is required but unavailable due to shortages in the supply chain.

**What are the differences between EpiPen® and AUVI-Q® products?**

Both EpiPen® and AUVI-Q® products deliver the same labelled dose of epinephrine. Unlike EpiPen® products, AUVI-Q® has a retractable needle as well as an electronic voice instruction system. The AUVI-Q® is supplied as two auto-injectors plus one trainer in one box.

**AUVI-Q® comes packaged with two auto-injectors; do I dispense both auto-injectors?**

Pharmacists should use their discretion to conserve supply. A box of AUVI-Q® product can be opened to dispense single auto-injectors as necessary. The reimbursement amount of \$170 is per auto-injector.

**Can I dispense AUVI-Q® the same way I dispense any other product?**

In order to dispense this product, AUVI-Q® will need to be accompanied by the U.S. approved patient information, available in French and English on Health Canada’s website.

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/AUVI-q-patient-information.html>

Otherwise, the same usual dispensing requirements remain the same. Claims through the HNS remain unchanged and should be billed using the supplied temporary PIN:

- AUVI-Q® 0.3mg – 02480379
- AUVI-Q® 0.15mg – 02480360

**Can an AUVI-Q® product be sold without a prescription?**

Yes, an AUVI-Q® can be sold without a prescription similar to EpiPen® products, although for funding through the Allergen Program, a prescription is required.

**Can AUVI-Q® be administered in place of an EpiPen® product if a patient has an adverse reaction as part of the Universal Influenza Immunization Program (UIIP)?**

Direction regarding the use of AUVI-Q® as an alternative to EpiPen® product during an adverse reaction to the influenza vaccine will be available when the UIIP launches for the 2018/2019 season.

**The AUVI-Q® product I received does not have the usual labelling required by Health Canada. Can I still dispense this product?**

Yes, Health Canada has provided an interim order to supply AUVI-Q® product to the Canadian marketplace. This product may have different labeling as it was originally intended for sale in another country.

<https://www.canada.ca/en/health-canada/news/2018/08/health-minister-announces-access-to-a-us-approved-epinephrine-auto-injector.html>

**Additional Resources**

News Release - Health Minister announces access to a U.S. approved epinephrine auto-injector

<https://www.canada.ca/en/health-canada/news/2018/08/health-minister-announces-access-to-a-us-approved-epinephrine-auto-injector.html>

Interim Order Respecting Epinephrine Auto-Injectors

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-epinephrine-auto-injectors.html>

Explanatory Note: Epinephrine

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/explanatory-note-epinephrine.html>

Dear Healthcare Professional Letter

<https://healthy Canadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67658a-eng.php>

Patient Information – AUVI-Q® (epinephrine injection) Auto-Injector For Allergic Emergencies (Anaphylaxis)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/AUVI-q-patient-information.html>

**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.