BREAKING NEWS

FEBRUARY 1, 2024

PHARMACY CAPSULE

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Barrie and Community Family Health Team

OZEMPIC: NEW LU CODES

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Ontario Drug Benefit (ODB) Change to Ozempic Coverage

As of January 31, 2024, all ODB recipients using Ozempic require an LU code for diabetes ONLY (if METFORMIN insufficient or intolerable). No coverage for any other indication. No longer a general benefit.

For the treatment of adult patients with type 2 diabetes when adequate glycemic control is not achieved on the maximum tolerated dose of metformin or where metformin is contraindicated or inappropriate.

Semaglutide is not funded in combination with another glucagon-like peptide-1 receptor agonist (GLP-1 RA) or dipeptidyl peptidase-4 (DPP-4) inhibitor.

Injectable semaglutide is not funded in combination with oral semaglutide.

Coverage is only provided for one dosage format. Reimbursed dose: As per the product monograph

LU Authorization Period: Indefinite

Patients on Ozempic and ODB Who Meet Criteria

What LU code do I use?

The exceptions for Ozempic persist.

ODB has listed different LU codes for Ozempic, based on package size, NOT by dose, making it less obvious which code to use.

• HIGH DOSE PEN: (1 mg dose provided as 1.34 mg semaglutide/mL; 3 mL total = 4 mg semaglutide in the pen; LU CODE = 665)

• LOW DOSE PEN: (0.25 mg, 0.5 mg doses provided as 0.68 mg semaglutide/mL; 3 mL total = 2 mg semaglutide in the pen; LU CODE = 667).

• **ANOTHER LOW DOSE PEN DOSE: currently being phased out** (0.25 mg, 0.5 mg doses provided as a 1.34 mg semaglutide/mL; 1.5 mL total = 2 mg semaglutide in the pen; **LU CODE = 666**).



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BREAKING NEWS

Make it Make Sense!

DIN/ PIN/ NPN	Generic Name	Brand Name, Strength & Dosage Form	MFR	Drug Benefit Price or Unit Price	Amount MOH Pays	Inter- change- able	Limited Use	Therapeutic Notes
02540258	SEMAGLUTIDE	Ozempic 0.68mg/mL Inj Sol - Pref Pen 3mL Pk "low dose pen" i.e. weekly dose is 0.25 mg or 0.5 mg	NOO	210.8700	210.8700	NO	YES LU = 667	NO
02471477	-SEMAGLUTIDE- [Disregard - product being removed from market]	- Ozempic- -1.34mg/mL Inj- -Sol-Pref Pen- -1.5mL Pk-	NOO	210.8700	210.8700	NO	YES LU = 666	NO
02471469	SEMAGLUTIDE	Ozempic 1.34mg/mL Inj Sol-Pref Pen 3mL Pk "high dose pen" i.e. weekly dose is 1 mg or 2 mg	NOO	210.8700	210.8700	NO	YES LU = 665	NO

Patients on Ozempic and ODB Who Do Not Meet Criteria

Can I apply for exceptional access?

No.

"Patients who do not meet the new LU criteria for Ozempic will not be considered for other conditions through EAP. Effective on January 31st, 2024"

What are my options for patients using Ozempic for obesity?

• Patient still has option to pay out of pocket for Ozempic (approx. \$280/month if using 1 mg/week)

• If stopping Ozempic, please encourage patients to titrate their dose. Rate of taper will depend on how much drug they have available to them with the aim of the taper extending as long as possible.

- If they are using any non-standard (fractional dosing), they need to buy additional needle tips (some plans will cover with prescription)
 - On a high dose pen (1 mg dose provided as 1.34 mg semaglutide/mL; 3 mL total = 4 mg semaglutide in the pen)
 - 19 clicks = 0.25mg;
 - 38 clicks = 0.5mg;
 - 76 clicks = 1mg

• If appropriate, consider referral to the following FHT IHPs: Pharmacist to facilitate patient taper, Registered Dietitian to support increased hunger and weight loss goals, Mental Health for coping and behavioural change

BREAKING NEWS

What are my options for patients using Ozempic for obesity? Continued...

- Saxenda falls off patent 2026.
- Advocacy resources for patients to request drug coverage for these medications available here: https://obesitycanada.ca/resources/ tools-accessing-health-care/
- Switch to Saxenda (not covered by ODB)
 - 1 mg semaglutide/Ozempic SC Q7d = 1.2-1.8 mg liraglutide/Saxenda SC daily, which means cost could be comparable to Ozempic if this dose is not adjusted to standard dosing (no guarantee)
 - \$450/month if using 3 mg/week
 - Company provides one time discount of 50% off 5 pens when patients registers at www.saxenda.ca
- Switch to Contrave (not covered by ODB)
 - No direct switch. Start Contrave at least on day Ozempic would usually be administered.
 - \$350/month
 - Company provides first month free, 25% off cost indefinitely when patients registers at www.contrave.ca
- Switch to Mounjaro (not covered by ODB)

*off-label. Mounjaro is to Ozempic what Zepbound will be to Wegovy

- 1 mg semaglutide/Ozempic SC Q7d = 5 mg tirzepatide/Mounjaro SC Q7days but usual taper/starting recommended with 2.5 mg SC Q7days x4 doses as drug is different and has GIP activity, unlike Ozempic.
- \$360/month

If patients is taking medications that cause weight gain (i.e. antipsychotics), Adult Obesity Management Guidelines recommend starting metformin to mitigate risk (dose not specified)

Helpful Resources:

FAQ for Ozempic from the Ministry of Health (attached)

Executive Officer Notice: Update to Ozempic Listing - Change in Status to Limited Use Benefit from the Ministry of Health (attached)

Diabetes Canada Clinical Practice Guideline:

https://guidelines.diabetes.ca/cpg

Obesity Canada Advocacy Tools for Accessing Health Care: https://obesitycanada.ca/resources/tools-accessing-health-care/

Obesity in Adults: A Clinical Practice Guideline – CMAJ (notice: this was published before tirzepatide available): https://obesitycanada.ca/guidelines/chapters/



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Questions and Answers Regarding Ozempic Funding Status Change

1. What is the funding status of Ozempic and is it reimbursed under the Ontario Drug Benefit (ODB) Program?

As of January 31, 2024, Ozempic's listing status is changed to a Limited Use (LU) benefit in the ODB formulary, which means that patients must meet the new Limited Use criteria established for Ozempic in order to receive coverage under the ODB program. If a patient is an ODB-eligible recipient and the prescriber determines that the patient meets all of the Limited Use criteria for Ozempic, then Ozempic will be covered for that patient under the ODB program.

As such, as of January 31, 2024, all ODB recipients using Ozempic therapy must meet the LU criteria. Any prescription issued after January 31, 2024 must include the appropriate LU code if applicable. For patients who were receiving Ozempic through General Benefit prior to January 31, 2024, confirmation that the patient meets the LU criteria is required and the LU code must be documented on the next prescription at the time of filling. For patients with prior funding of Ozempic as a general benefit where the LU criteria cannot be confirmed with the prescriber, pharmacists may use the temporary LU code 279 when filling the prescription to avoid interruptions in therapy. This code will only be available for 3 months.

Ozempic is not funded for ODB program recipients who do not meet the LU criteria on the Formulary. Claims for payment for dispensing Ozempic for ODB program recipients who do not meet the LU requirement will be subject to recovery. Claims for payment for Ozempic must be supported by a prescription that includes the applicable Reason for Use (RFU) code, as described further in the Ontario Drug Programs Reference Manual.

2. Has the Ministry of Health established the funding criteria for Ozempic under the ODB program?

Yes. Ozempic is listed as a Limited Use (LU) benefit on the ODB formulary for Ontario Drug Benefit (ODB) recipients, effective January 31, 2024.



The LU criteria for Ozempic are as follows:

- For the treatment of adult patients with type 2 diabetes when adequate glycemic control is not achieved on the maximum tolerated dose of metformin or where metformin is contraindicated or inappropriate.
- Semaglutide is not funded in combination with another glucagon-like peptide-1 receptor agonist (GLP-1 RA) or dipeptidyl peptidase-4 (DPP-4) inhibitor.
- Injectable semaglutide is not funded in combination with oral semaglutide. Coverage is only provided for one dosage format.

Reimbursed dose: As per the product monograph

LU Authorization Period: Indefinite

Only ODB-eligible patients who meet the LU criteria and who have a valid prescription with the appropriate LU code will be eligible for funding under the ODB program.

3. A patient has been receiving Ozempic for the last year and is scheduled to receive the next refill in a month. The patient would like to know if they are covered by the ODB program for their future refills?

ODB-eligible patients will continue to be covered for Ozempic by the ODB program if they meet the Limited Use criteria. As of January 31, 2024, the prescriber must confirm each patient's eligibility by acknowledging on the prescription that the patient meets the new LU criteria for funding of Ozempic. For prior prescriptions for Ozempic that were funded as general benefits, the temporary LU code 279 may be used if the pharmacy is unable to reach the prescriber to obtain a new prescription and/or to confirm the patient's eligibility under the LU criteria. This option will only be available until April 30, 2024.

4. Is Ozempic funded under ODB after January 31, 2024 for patients who do not meet the LU criteria for Ozempic?

No. The LU criteria for Ozempic are consistent with the previous therapeutic notes and with the Health Canada-approved indication of type 2 diabetes. Ozempic is not funded for ODB program recipients who do not meet the LU criteria on the Formulary. Claims for payment for dispensing Ozempic for ODB program recipients who do not meet the LU requirement will be subject to recovery. Claims for payment



for Ozempic must be supported by a prescription that includes the applicable Reason for Use (RFU) code, as described further in the Ontario Drug Programs Reference Manual.

Between January 31, 2024 to April 30, 2024, pharmacists can use LU Code 279 to submit a claim for Ozempic (DINs 02471469, 02471477, 02540258) if they are unable to contact a patient's prescriber to obtain a new prescription with the LU criteria. This will ensure patients do not go without their drug until they are able to contact their prescriber. The rules regarding the use of LU code 279 are set out in the Ontario Drug Programs Reference Manual. Please refer to the Executive Officer Notice for more information.

5. Can patients who do not meet the LU criteria request coverage for other conditions for Ozempic through the Exceptional Access Program (EAP)?

Patients who do not meet the new LU criteria for Ozempic will not be considered for other conditions through the EAP. Effective on January 31, 2024, ODB-eligible recipients will only receive funding for Ozempic upon meeting the new LU criteria.

6. My patient is currently on Rybelsus (oral semaglutide) and was switched from Ozempic (injectable semaglutide) when it was not available. Can my patient be switched back to Ozempic injectable?

Rybelsus oral tablets and Ozempic injection are both Limited Use (LU) benefits in the ODB formulary with similar criteria. Switching is permitted for ODB patients upon meeting the LU criteria for each product, which specifies that injectable semaglutide is not funded in combination with oral semaglutide and that coverage is only provided for one dosage format.



Executive Officer Notice: Update to Ozempic Listing – Change in Status to Limited Use Benefit

January 26, 2024

Effective January 31, 2024, Ozempic injectables are listed as Limited Use (LU) benefits on the Ontario Drug Benefit (ODB) formulary. The LU criteria for Ozempic are consistent with the previous therapeutic notes and with the Health Canada-approved indication, and are as follows for each of the three Ozempic products that will be listed with LU 665, 666, 667:

- For the treatment of adult patients with type 2 diabetes when adequate glycemic control is not achieved on the maximum tolerated dose of metformin or where metformin is contraindicated or inappropriate.
- Semaglutide is not funded in combination with another glucagon-like peptide-1 receptor agonist (GLP-1 RA) or dipeptidyl peptidase-4 (DPP-4) inhibitor.
- Injectable semaglutide is not funded in combination with oral semaglutide. Coverage is only provided for one dosage format.

Reimbursed dose: As per the product monograph

LU Authorization Period: indefinite

As of January 31, 2024, ODB-eligible patients requesting funding of Ozempic under the ODB program must meet the LU criteria for funding. The prescriber should ensure that prescriptions include the appropriate LU code. For ODB-eligible patients currently receiving Ozempic through General Benefit, confirmation by the prescriber that the patient meets the LU criteria is required and the LU code must be documented with the prescription.

Ozempic is not funded for ODB program recipients who do not meet the LU criteria on the Formulary. Claims for payment for dispensing Ozempic for ODB program recipients who do not meet the LU requirement will be subject to recovery. Claims for payment for Ozempic must be supported by a prescription that includes the applicable Reason for Use (RFU) code, as described further in the Ontario Drug Programs Reference Manual.



Please note that for transition, Reason for use (RFU) code 279 will be activated for Ozempic to help transition patients to the new LU code and criteria. This transition code may be submitted for a claim for a period of three (3) months after the change, between January 31, 2024 and April 30, 2024. It is expected that after three (3) months, all patients with type 2 diabetes requiring funding of Ozempic under the ODB program and who meet the LU criteria, will have an updated prescription with the correct LU Code. The transition code RFU 279 will be effective for three (3) months and deactivated with the April 2024 Formulary update. The rules regarding the use of LU code 279 are set out in the Ontario Drug Programs Reference Manual.

Details of the changes to the funding of Ozempic will also be posted in the January 2024 Formulary update which can be found on the ministry's website at:

http://www.health.gov.on.ca/en/pro/programs/drugs/edition_43.aspx

To further inform healthcare providers and patients, we have also included a Frequently Asked Questions (FAQs) document for reference purposes.

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.