Teriparatide Frequently Asked Questions

1. What is the difference between Osnuvo®, Forteo® and Teva-teriparatide?

Osnuvo® (teriparatide), Forteo® (teriparatide) and Teva-teriparatide are all Health Canada-approved versions of teriparatide products manufactured by different drug manufacturers. Teriparatide is a drug that is used to treat osteoporosis in patients with a high risk of fracture. Forteo® is the brand innovator product, Teva-teriparatide is a generic interchangeable version of Forteo®, and Osnuvo® is a biosimilar of Forteo®. Osnuvo® has not been designated as interchangeable with Forteo® or Teva-teriparatide.

2. What was the previous funding status of Osnuvo®, Forteo® and Teva-teriparatide, and how have they changed as of the May 2024 Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary) Update?

Prior to the May 2024 Formulary update, Teva-teriparatide and Forteo® were designated as interchangeable with each other and reimbursed upon meeting specified criteria through the Exceptional Access Program (EAP). Osnuvo® is listed on the Formulary as a Limited Use (LU) benefit.

As of the May 2024 Formulary update (effective May 31, 2024), the funding status of Forteo® and Teva-teriparatide has transitioned from the EAP to the Formulary as LU benefits. Teva-teriparatide remains designated as interchangeable with Forteo®.

ODB-eligible patients with existing EAP approvals of Teva-teriparatide or Forteo® will continue to be provided coverage of Teva-teriparatide or Forteo® in accordance with the authorization period for the patient's EAP approval and EAP's generic substitution policies.

3. What are the Limited Use Criteria for Forteo® and Teva-teriparatide?

The Reason for Use (RFU) Codes and their associated reimbursement criteria for Forteo® and Teva-teriparatide are set out below. Please refer to the e-Formulary for the most up-to-date information (as of the May 2024 Formulary update effective May 31, 2024).

Osteoporosis (RFU Code 676)

For the treatment of osteoporosis in patients at a high risk of fragility fractures who meet ALL the following criteria:

- 65 years of age or older; AND
- Has a documented bone mineral density [BMD] T-score of less than or equal to 3; AND
- Has a history of prior fragility fracture(s); AND
- Has used an anti-resorptive agent for osteoporosis which resulted in osteonecrosis of the jaw and/or an atypical femur fracture.

Note: The maximum lifetime exposure to teriparatide for an individual patient is 24 months

LU Authorization Period: 2 years

4. Is the Ministry requiring patients to switch from Osnuvo® to Forteo® or Teva-teriparatide?

No. There will not be any requirements for patients currently using Osnuvo® to switch to Forteo® or Teva-teriparatide. Patients currently using Osnuvo® in accordance with the LU criteria on the Formulary may continue to do so.

Pharmacists can help ODB-eligible patients meeting LU criteria and wishing to "switch" between Osnuvo, Teva-teriparatide and Forteo® by discussing with the prescriber and dispensing the appropriate product, in accordance with the *Drug Interchangeability and Dispensing Fee Act* (DIDFA) and the *Ontario Drug Benefit Act* (ODBA). In some cases, a new prescription may be required.

5. Will the ministry consider new requests for Forteo® (teriparatide) or Teva-teriparatide reimbursement under the Exceptional Access Program (EAP)?

No. As of the May 2024 Formulary update (effective May 31, 2024), the funding status of Forteo® and Teva-teriparatide has transitioned from the EAP to the Formulary as LU benefits. Teva-teriparatide remains designated as interchangeable with Forteo® (see Q2 above).

6. How should pharmacies submit claims for Forteo® (teriparatide) or Teva-teriparatide?

Pharmacies should submit claims using the drug/product identification number (DIN/PIN) of the product and the applicable Reason for Use code (see Q3 above).

7. How will these changes impact patients?

As of the May 2024 Formulary update (effective May 31, 2024), the funding status of Forteo® and Teva-teriparatide has transitioned from the EAP to the Formulary as LU benefits. New ODB-eligible patients starting treatment on teriparatide may start on Osnuvo®, Forteo® or Teva-teriparatide depending on their prescription upon meeting the LU criteria, subject to generic substitution rules under the ODBA and DIDFA (see Q8 below).

Patients with existing EAP approvals for Forteo® or Teva-teriparatide may continue to receive coverage for their established therapy, in accordance with the authorization period for the patient's EAP approval and EAP's generic substitution policies.

8. How will these changes impact prescribers and dispensers?

Osnuvo® has not been designated as interchangeable with either Forteo® or Teva-teriparatide. However, Teva-teriparatide is designated as interchangeable with Forteo®.

As of the May 2024 Formulary update (effective May 24, 2024), new ODB-eligible patients starting treatment on teriparatide may start on Osnuvo® Forteo® or Teva-teriparatide depending on their prescription upon meeting the LU criteria, subject to generic substitution rules under the ODBA and DIDFA.

The following is applicable to both teriparatide-naïve and teriparatide-experienced patients:

i. If a prescription directs “Forteo” to be dispensed to an ODB-eligible patient meeting LU criteria with no substitution (i.e., “NO SUB”), the pharmacist shall dispense Forteo. The ministry would pay the drug benefit price of Teva-teriparatide and the applicable mark-up on that price, unless the patient has a documented adverse reaction to Teva-teriparatide, in which case the drug benefit price of Forteo and applicable mark-up on that price would be paid. If the ministry does not pay the drug benefit price and mark-up for Forteo, then the patient can be charged the difference in the amount of the drug benefit price and mark-up for Forteo® and Teva-teriparatide.

ii. If a prescription directs “Forteo” to be dispensed to an ODB-eligible patient meeting LU criteria but is silent on whether it can be substituted with an interchangeable product (e.g., prescription says “Forteo” but does not say “NO SUB”), the pharmacist may dispense Teva-teriperatide, unless the ODB eligible patient or person presenting the prescription specifically requests Forteo®. The ministry would pay the drug benefit price of Teva-teriparatide and the applicable mark-up on that price, regardless of whether Forteo® or Teva-teriparatide is dispensed. If Forteo® is dispensed at the request of the patient or the person presenting the prescription, then they could be charged the difference in the amount of the drug benefit price and mark-up for Forteo and Teva-teriparatide.

iii. If a prescription directs “Teva-teriparatide” to be dispensed to an ODB eligible patient meeting LU criteria but is silent on whether it can be substituted with an interchangeable product (e.g., prescription says “Teva-teriparatide” but does not say “NO SUB”), the pharmacist may dispense Teva-teriparatide, unless the ODB eligible patient or person presenting the prescription specifically requests Forteo®. The ministry would pay the drug benefit price of Teva-teriparatide and the applicable mark-up on that price. If Forteo® is dispensed at the request of the patient or person presenting the prescription, then they could be charged

the difference in the amount of the drug benefit price and mark-up for Forteo® and Teva-teriparatide.

iv. If a prescription directs “Osnuvo” to be dispensed to an ODB eligible patient meeting LU criteria with no substitution (i.e., with “NO SUB”), the pharmacist shall dispense Osnuvo; the pharmacist could not dispense either Teva-teriparatide or Forteo® unless the patient receives a new prescription.

v. If a prescription directs “Osnuvo” to be dispensed to an ODB eligible patient meeting LU criteria but does not specify no substitutions (e.g., prescription says “Osnuvo” but does not say “NO SUB”), the pharmacist may dispense Teva-teriparatide or Forteo®.

Although Osnuvo is a biosimilar and has not been designated as interchangeable with either Forteo® or Teva-teriparatide, the pharmacist may still dispense Teva-teriparatide or Forteo® in its place in such a scenario because Teva-teriparatide and Forteo® have been designated as interchangeable products and contain teriparatide in the same amounts of the same active ingredients in the same dosage form as Osnuvo. In accordance with subsection 4(5) of DIDFA, pharmacists are permitted to select Teva-teriparatide or Forteo® in such a scenario but are not required to. Pharmacists should use their professional judgment when selecting the product to dispense and may wish to consider consulting with the patient’s prescriber for clarification. This situation applies to teriparatide as the innovator biologic (Forteo®) has both an interchangeable generic and a biosimilar product. See Q10 and Q11 below.

If Osnuvo® is dispensed in this scenario, the ministry would pay the drug benefit price of Osnuvo® and the applicable mark-up on that price. If Teva-teriparatide is dispensed, the ministry would pay the drug benefit price of Teva-teriparatide and the applicable mark-up on that price. If Foreto® is dispensed, the ministry would pay the drug benefit price of Teva-teriparatide and the applicable mark-up on that price, unless the patient has a documented adverse reaction to Teva-teriparatide, in

which case the drug benefit price of Forteo® and applicable mark-up on that price would be paid. If the ministry does not pay the drug benefit price and mark-up for Forteo®, then the patient can be charged the difference in the amount of the drug benefit price and mark-up for Forteo® and Teva-teriparatide.

vi. If a prescription directs "teriparatide" to be dispensed without identifying a specific product name or manufacturer, the pharmacist shall dispense Teva-teriparatide, in accordance with section 5 of DIDFA. If a pharmacist has concerns about whether Forteo® or Osnuvo® should be dispensed instead of Teva-teriparatide in this scenario, then the pharmacist may consult the prescriber and obtain a new prescription to dispense the intended therapy, if necessary.

Note: If there is any discrepancy between the information in this response and the ODBA or DIDFA, the legislation prevails. If pharmacists have questions about their professional obligations, they should consult the Ontario College of Pharmacists (OCP) for further guidance.

For dispensers: For patients with existing and valid EAP approvals for Forteo® or Teva-teriparatide, pharmacies/pharmacists can continue to submit claims for Forteo® and Teva-teriparatide, as applicable, using the appropriate DIN/PINs:

Table 1

DIN	Brand Name	Generic Name	Strength & Dosage Form	MFR
09857535	Forteo®	teriparatide	250mcg/ml, 2.4 mL prefilled inj pen	Eli Lilly Canada Inc.
02486423	Teva-teriparatide	teriparatide	250mcg/ml, 2.4 mL prefilled inj pen	Teva Canada Ltd.

There will not be any requirements for patients currently using Osnuvo® to switch to Forteo® or Teva-teriparatide. Patients currently using Osnuvo® in accordance with the LU criteria on the Formulary may continue to do so.

Pharmacists can help ODB-eligible patients meeting LU criteria and wishing to "switch" between Osnuvo®, Teva-teriparatide and Forteo® by discussing with the prescriber and dispensing the appropriate product, in accordance with DIDFA and ODBA. In some cases, a new prescription may be required.

9. What is the difference between a biosimilar and generic product?

Generic products are smaller molecules that can be synthesized chemically and contain the same medicinal ingredients to the reference, innovator products.

Biosimilars, also referred to as subsequent entry biologics or follow-on biologics, are biologics that are similar to an originator biologic, and would enter the market after the patents or data protection rights for an originator biologic have expired. Biologics contain molecules that are often much larger than generic drugs and their original reference product. They are made in living cells, so while they are highly similar, they are not identical.

Both generics and biosimilars undergo extensive Health Canada evaluations to confirm that there are no clinically meaningful differences in safety and efficacy between them and their original reference products., However, due to differences in manufacturing and the complexity of biologics, biosimilars are not designated as interchangeable with the innovator reference biologic.

10. Why does Forteo® (teriparatide) have both a generic and biosimilar on the market?

Forteo® (teriparatide) is a much smaller, less complex product compared to newer biologics. As a result, it can be chemically synthesized to be identical (generic) or produced using living cells (biologic).

Please refer to Health Canada's Biosimilar biologic drugs in Canada: Fact Sheet for more information.

11. Do the dispensing scenarios described in Q8 apply to all other innovator biologics and biosimilars?

No. As noted in Q10 above, Forteo® (teriparatide) is a drug product with a generic version and biosimilar version. The dispensing scenarios described in Q8 reflect rules in DIDFA that apply because Forteo® and the generic (Teva-teriparatide) have been designated as interchangeable with each other, but not with a biosimilar (Osnuvo®).

For other biologics without interchangeable generic options, biologics and biosimilars are not designated as interchangeable products. The prescription for these products should specify the brand name along with the active ingredient name throughout the medication use process to ensure clarity about which product has been directed for dispensing by the prescriber. For these biologics without a generic interchangeable version, the prescription directing the dispensing of a specific brand (e.g., the innovator biologic) cannot be used to dispense another brand (e.g., the biosimilar version).

Resources are available from Health Canada and the Ontario College of Pharmacists (OCP) on best practices on prescribing/dispensing biologics and biosimilars:

- Originator and Biosimilar Biologic Medications: Understanding the Changes to ODB Coverage in Ontario and How to Support Patients - Pharmacy Connection
- Notice to Stakeholders - Policy Statement on the Naming of Biologic Drugs - Canada.ca

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