

Executive Officer Notice: Funding of denosumab under Ontario Public Drug Programs

September 20, 2024

Jubbonti® (denosumab injection) was approved by Health Canada as a biosimilar version of Prolia® (denosumab injection) and Wyost® (denosumab injection) was approved by Health Canada as a biosimilar version of Xgeva® (denosumab injection). The funding of these products is being aligned with the funding of other biosimilars under the Ontario Drug Benefit (ODB) Program's new start policy, which requires recipients initiating treatment on a biologic drug to start on a biosimilar. Biosimilars have similar efficacy and safety as originator biologics and present an opportunity to achieve better value for money for biologic drugs that will help to support the long-term sustainability and accessibility of Ontario's public drug programs.

Details of the ministry's biosimilar policy can be found at https://www.ontario.ca/files/2024-07/moh-executive-officer-notice-en-2024-07-17.pdf

As of the August 2024 Formulary update (effective August 30, 2024), changes to the funding of denosumab under the ODB Program are as follows:

Jubbonti® (denosumab injection) is funded in accordance with the following Limited Use (LU) criteria:

LU code: 687

To increase the bone mass in postmenopausal females with osteoporosis who are at high risk* for fracture who have failed, had intolerance to, or are unable to take a bisphosphonate therapy.

*High risk of fracture based on a clinician's evaluation of the individual's risk of fractures that may include prior fragility fracture history and the Fracture Risk Assessment (FRAX) scores or another validated tool.

LU Authorization Period: Indefinite.



• LU code: 688

To increase the bone mass in males with osteoporosis who are at high risk* of fractures who have failed, had intolerance to, or are unable to take a bisphosphonate therapy.

*High risk of fracture based on a clinician's evaluation of the individual's risk of fractures that may include prior fragility fracture history and the Fracture Risk Assessment (FRAX) scores or another validated tool.

LU Authorization Period: Indefinite.

Wyost® (denosumab injection) is funded in accordance with the following LU criteria:

• LU code: 686

For the treatment of bony metastases for patients with hormone refractory prostate cancer as determined by an elevated PSA level, or evidence of progressive bony disease, despite castrate serum testosterone levels (less than 1.7nmol/L or less than 50ng/dL) or having undergone orchidectomy.

Dose: 120mg SC every 4 weeks.

LU Authorization Period: 1 year

Wyost® and Xgeva® are also funded through the ministry's New Drug Funding Program (NDFP), administered by Ontario Health - Cancer Care Ontario (OH-CCO). OH-CCO's Drug Formulary can be found on its website at https://www.cancercareontario.ca/en/cancer-treatments/chemotherapy/drug-formulary

Details of the above LU criteria have been posted in the August 2024 Formulary update, which can be found on the ministry's website at:





Formulary / Comparative Drug Index (CDI) Edition 43 | Ontario Drug Benefit (ODB) Formulary / Comparative Drug Index (CDI) and Monthly Formulary Updates | ontario.ca

Prescribers should be informed and stay current with official indications for drug products in accordance with Health Canada's approved product monograph.

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