Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Denosumab (Biosimilar) - Hormone Refractory Prostate Cancer

(This form should be completed before the first dose is dispensed.)

1. Patient Profile

* Surname: _____

* Given Name: _____

* OHIN: _____ * Chart Number: _____

* Postal Code: _____

* Height (cm): _____ * Weight (kg): _____

* BSA (m^2): _____ * Gender: ○ Male ○ Female ○ Other

* Date of Birth: _____ _____ _____
Day Month Year

* Site:

* Attending Physician (MRP- Most Responsible Physician): _____

Requested Prior Approval ☐ Yes * Patient on Clinical Trial ○ Yes ○ No

Other (specify): _____

Specify Arm:
○ Standard of care arm ○ Experimental arm
○ Blinded / Unknown

Prior Approval Request

* Select the appropriate prior approval scenario:

- ○ 1-Unknown primary (submit pathology report and clinic note)
- ○ 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
- ○ 3-Regimen modification - schedule (complete questions a and b)
- ○ 4-Regimen modification - drug substitutions (complete questions a and c)
- ○ 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
- ○ 6-Maintenance therapy delay (submit clinic note)
- ○ 7-Prior systemic therapy clinical trials (complete question g)
- ○ 8-Modification due to supply interruption/drug shortage
- ○ Other (specify)

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All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.

a. Co-morbidities / toxicity / justification:

.....

b. Intended regimen schedule: .....

c. Intended regimen: .....

d. Drug(s) to be held: .....

e. Rationale for holding drug(s): .....

f. Intention to introduce drug at a later date? ☐ Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen): .....

h. Anticipated date of first treatment: ....
Day Month Year

i. Additional comments:

2. Eligibility Criteria

Denosumab will be used 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 1.7 nmol/L or 50 ng/dL). ☐ Yes

3. Baseline Information

a. Is the patient transitioning from a manufacturer's patient support program? ○ Yes ○ No

b. If yes to (a), please indicate the date of the last administered dose. _____ _____ _____
Day Month Year

4. Funded Dose

Denosumab 120 mg subcutaneously (SC) once every 4 weeks.

Treatment should continue until unacceptable toxicity.

[ST-QBP regimen code(s): DENO]

5. Notes

1. Evidence of progressive bony disease can be demonstrated by progressive changes in radionucleotide bone scan or clinical signs of disease progression (e.g., pathologic fracture or increasing bone pain).

2. Serum testosterone level does not apply for patients who have undergone orchidectomy.

6. FAQs

1. **My patient is currently receiving a denosumab biosimilar through non-publicly funded means (e.g., patient support program). Can my patient be transitioned to receive funding through the New Drug Funding Program (NDFP)?**

   Provided the eligibility criteria were met at the time of treatment initiation, your patient may be eligible for continued coverage of a denosumab biosimilar through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:
   - A clinic note outlining patient history, including bloodwork, from treatment initiation, AND
   - The most recent clinic note.

   Please note: Patients enrolled in the manufacturer's patient support program (PSP) are eligible to receive free drug through the PSP until November 23, 2024, inclusive. The hospital or cancer centre should coordinate the supply of PSP-supplied drug between the PSP and their respective sites, if not done so already.

   After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

3. **My patient is currently receiving denosumab (Xgeva). Can my patient stay on the reference biologic?**

   Yes, patients currently on the reference biologic or who initiated treatment on the reference biologic before **September 28, 2024** may continue with the reference biologic until their treatment course has ended.

   Patients who are continuing treatment with the reference biologic after September 27, 2024 must have an enrolment form and treatment claim(s) submitted in eClaims prior to September 28, 2024 to be eligible for continued reimbursement of the reference biologic.

4. **My patient is currently receiving denosumab (Xgeva). Can my patient be switched to a denosumab biosimilar for the remainder of their treatment course?**

   At the discretion of the treating physician or based on individual hospital policy, patients currently on the reference biologic may be switched to a denosumab biosimilar for the remainder of their treatment course.

   If the patient is already enrolled in an NDFP policy for denosumab (Xgeva), please re-enroll the patient in the new denosumab (biosimilar) enrolment form in order to submit treatment claims for a denosumab biosimilar.

   Note: Existing patients can switch from the reference biologic to a denosumab biosimilar; however, patients who switch to a denosumab biosimilar will not be funded for further treatments with the reference biologic.

5. **Will the reimbursement rate be the same for all denosumab biosimilars?**

   Reimbursement in eClaims will be adjudicated based on the Drug Identification Number (DIN) submitted and are unique to each denosumab biosimilar.

   Any incentives or promotions accepted by hospitals related to purchase and/or selection decisions of denosumab will be interpreted as lowering the local acquisition cost of denosumab and, consistent with other NDFP policies, are subject to recovery.

Supporting Documents

None required at time of enrolment.

In the event of an audit or upon request, the following should be available to document eligibility:

- Clinic notes outlining patient history, including bloodwork.

Signature of Attending Physician (MRP-Most Responsible Physician): _____

Day Month Year

Form 1060