Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Denosumab - Hormone Refractory Prostate Cancer

(This form must 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 (comple question g)
○ 8-Modification due to supply interruption/drug shortage
○ Other (specify)

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

The patient must meet the following 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 (<1.7 nmol/L or 50ng/dL)

☐ Yes

3. Funded Dose

- Denosumab 120mg sc every 4 weeks

4. Notes

a. 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).

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

6. FAQs

1. 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. Supporting Documents

To ensure reimbursement of your claim, both the completed enrolment form and a copy of the required documentation (where applicable) must be submitted through CCO e-Claims.

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

Day ..... Month ..... Year .....