

PA Criteria	Criteria Details							
<p><b>Description</b></p>	<p>Denosumab is a RANK ligand (RANKL) inhibitor.</p> <p>Brand Name: Prolia<sup>®</sup>, Xgeva<sup>®</sup></p> <p>Biosimilars:</p> <ul style="list-style-type: none"> <li>• Bilprevda, Bildyos (denosumab-nxxp)</li> <li>• Bomynta, Connexence (denosumab-bnht)</li> <li>• Osenvelt, Stoboclo (denosumab-bmwo)</li> <li>• Jubbonti, Wyost (denosumab-bbdz)</li> <li>• Ospomyv (denosumab-dssb)</li> <li>• Bosaya, Aukelso (denosumab-kyqq)</li> </ul>							
<p><b>Covered Uses</b> (FDA approved indication)</p>	<p>Prolia (denosumab) is indicated:</p> <ul style="list-style-type: none"> <li>• <b>Postmenopausal osteoporosis (PMO):</b> For the treatment of postmenopausal women with osteoporosis at high risk for fracture*, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures.</li> <li>• <b>Male osteoporosis:</b> For the treatment to increase bone mass in men with osteoporosis at high risk for fracture*, or patients who have failed or are intolerant to other available osteoporosis therapy.</li> <li>• <b>Male osteoporosis - oncology:</b> For treatment to increase bone mass in men at high risk for fracture* receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures.</li> <li>• <b>Female osteoporosis - oncology:</b> For treatment to increase bone mass in women at high risk for fracture* receiving adjuvant aromatase inhibitor therapy for breast cancer.</li> <li>• <b>Glucocorticoid-induced osteoporosis (GIO):</b> For the treatment of GIO in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to <math>\geq 7.5</math> mg of prednisone and expected to remain on glucocorticoids for <math>\geq 6</math> months.</li> </ul> <p>Xgeva (denosumab) is indicated:</p> <ul style="list-style-type: none"> <li>• <b>Multiple myeloma (MM) and solid tumors:</b> For the prevention of skeletal-related events in patients with MM and in patients with bone metastases from solid tumors.</li> <li>• <b>Giant cell tumor of the bone:</b> For the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.</li> <li>• <b>Hypercalcemia of malignancy:</b> For the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.</li> </ul>							
<p><b>Dosing and Administration</b></p>	<table border="1" data-bbox="487 1732 1529 1911"> <thead> <tr> <th data-bbox="487 1732 1299 1774">Dosing Regimen</th> <th data-bbox="1299 1732 1529 1774">Maximum Dose</th> </tr> </thead> <tbody> <tr> <td data-bbox="487 1774 1299 1816">Prolia: 60 mg subcutaneous Q6 months</td> <td data-bbox="1299 1774 1529 1816">60 mg</td> </tr> <tr> <td data-bbox="487 1816 1299 1858">Xgeva: 120 mg subcutaneous Q4 weeks</td> <td data-bbox="1299 1816 1529 1858">120 mg</td> </tr> </tbody> </table> <p>Must be administered by healthcare professional.</p>		Dosing Regimen	Maximum Dose	Prolia: 60 mg subcutaneous Q6 months	60 mg	Xgeva: 120 mg subcutaneous Q4 weeks	120 mg
Dosing Regimen	Maximum Dose							
Prolia: 60 mg subcutaneous Q6 months	60 mg							
Xgeva: 120 mg subcutaneous Q4 weeks	120 mg							

**Billing and Coding Information**

	<b>10-digit NDC</b>	<b>11-digit NDC</b>
Aukelso	83257-030-11	83257-0030-11
Bilprevda	78206-195-01	78206-0195-01
Bildyos	78206-193-01	78206-0193-01
Bomynta	SDV: 65219-670-01 PFS: 65219-672-01	SDV: 65219-0670-01 PFS: 65219-0672-01
Bosaya	83257-029-41	83257-0029-41
Conexence	65219-668-01	65219-0668-01
Enoby	0143-9165-01	00143-9165-01
Jubbonti	61314-240-63	61314-0240-63
Osenvelt	72606-038-01	72606-0038-01
Ospomyv	83457-012-10	83457-0012-10
Stoboclo	72606-037-01	72606-0037-01
Wyost	61314-228-94	61314-0228-94
Xtrenbo	0143-9166-01	00143-9166-01

	<b>HCPCS Code</b>	<b>Description</b>
Aukelso	Q5161	Injection, denosumab-kyqq, biosimilar, 1 mg
Bilprevda	C9399 J3590	Unclassified drugs or biologicals Unclassified biologics
Bildyos	C9399 J3590	Unclassified drugs or biologicals Unclassified biologics
Bomynta	Q5158	Injection, denosumab-bnht, biosimilar, 1 mg
Bosaya	Q5161	Injection, denosumab-kyqq, biosimilar, 1 mg
Conexence	Q5158	Injection, denosumab-bnht, biosimilar, 1 mg
Enoby	C9399 J3590	Unclassified drugs or biologicals Unclassified biologics
Jubbonti	Q5136	Injection, denosumab-bbdz, biosimilar, 1 mg
Osenvelt	Q5157	Injection, denosumab-bmwo, biosimilar, 1 mg
Ospomyv	Q5159	Injection, denosumab-dssb, biosimilar, 1 mg
Stoboclo	Q5157	Injection, denosumab-bmwo, biosimilar, 1 mg
Wyost	Q5136	Injection, denosumab-bbdz, biosimilar, 1 mg
Xtrenbo	C9399 J3590	Unclassified drugs or biologicals Unclassified biologics

<b>CPT Procedural Codes</b>	<b>Description</b>
96372	Subcutaneous or IM injection administration (therapeutic)
96401	Chemotherapy administration, subcutaneous or IM

<p><b>Product Availability</b></p>	<p><i>Solution, Subcutaneous [preservative free]:</i></p> <ul style="list-style-type: none"> <li>• Aukelso: Denosumab-kyqq 120 mg/1.7 mL (1.7 mL)</li> <li>• Bilprevda: Denosumab-nxxp 120 mg/1.7 mL (1.7 mL)</li> <li>• Bomynta: Denosumab-bnht 120 mg/1.7 mL (1.7 mL)</li> <li>• Osenvelt: Denosumab-bmwo 120 mg/1.7 mL (1.7 mL)</li> <li>• Wyost: Denosumab-bbdz 120 mg/1.7 mL (1.7 mL)</li> <li>• Xgeva: 120 mg/1.7 mL (1.7 mL)</li> <li>• Xtrenbo: Denosumab-qbde 120 mg/1.7 mL (1.7 mL)</li> </ul> <p><i>Solution Prefilled Syringe, Subcutaneous [preservative free]:</i></p> <ul style="list-style-type: none"> <li>• Bildyos: Denosumab-nxxp 60 mg/mL (1 mL)</li> <li>• Bomynta: Denosumab-bnht 120 mg/1.7 mL (1.7 mL)</li> <li>• Bosaya: Denosumab-kyqq 60 mg/mL (1 mL)</li> <li>• Conexence: Denosumab-bnht 60 mg/mL (1 mL)</li> <li>• Enoby: Denosumab-qbde 60 mg/mL (1 mL)</li> <li>• Jubbonti: Denosumab-bbdz 60 mg/mL (1 mL)</li> <li>• Ospomyv: Denosumab-dssb 60 mg/mL (1 mL)</li> <li>• Prolia: 60 mg/mL (1 mL)</li> <li>• Stoboclo: Denosumab-bmwo 60 mg/mL (1 mL)</li> </ul>
<p><b>Contraindications</b></p>	<p>Hypersensitivity (systemic) to denosumab or any component of the formulation; preexisting hypocalcemia; pregnancy.</p>
<p><b>Recommended Medical Monitoring</b></p>	<p><b>BLACK BOX WARNING: Severe Hypocalcemia in patients with Advanced Kidney Disease -</b>      Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Denosumab administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported.</p> <p>Denosumab is also associated with:</p> <ol style="list-style-type: none"> <li>a. Hypocalcemia</li> <li>b. Hypersensitivity reactions</li> <li>c. Osteonecrosis of the jaw</li> <li>d. Atypical femoral fractures</li> <li>e. Multiple vertebral fractures</li> <li>f. Serious infections, including skin infections</li> <li>g. Dermatologic reactions</li> <li>h. Severe bone, joint, muscle pain</li> <li>i. Suppression of bone turnover</li> </ol>

<p><b>Approval Criteria</b></p>	<ul style="list-style-type: none"> <li>a. Physician administered; in-office or HOPD           <ul style="list-style-type: none"> <li>i. Cannot be self-administered</li> </ul> </li> <li>b. Osteoporosis (<b>must meet all</b>):           <ul style="list-style-type: none"> <li>i. Request is for Prolia or biosimilar</li> <li>ii. Diagnosis of PMO, GIO, or male osteoporosis and (i or ii):               <ul style="list-style-type: none"> <li>1. Member is at very high risk for fracture (1 or 2):                   <ul style="list-style-type: none"> <li>a. BMD T-score at hip or spine <math>\leq</math> -3.5</li> <li>b. BMD T-score at hip or spine <math>\leq</math> -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus)</li> </ul> </li> <li>2. Member has completed a three-year trial of bisphosphonate therapy (alendronate is preferred) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced to both IV and PO formulations</li> </ul> </li> <li>iii. Age <math>\geq</math> 18 years or documentation of closed epiphyses on x-ray;</li> <li>iv. Prolia is not prescribed concurrently with Xgeva</li> <li>v. Dose does not exceed 60 mg every six months.</li> </ul> </li> <li>c. Prostate/Breast Cancer – Fracture Prevention (must meet all):           <ul style="list-style-type: none"> <li>i. Request is for Prolia or biosimilar</li> <li>ii. One of the following diagnoses (i or ii):               <ul style="list-style-type: none"> <li>1. Prostate cancer and member is receiving ADT (e.g., leuprolide (Lupron<sup>®</sup>), bicalutamide (Casodex<sup>®</sup>) or Nilandron<sup>®</sup>)</li> <li>2. Breast cancer and member is receiving adjuvant endocrine therapy (e.g., tamoxifen or aromatase inhibitors such as anastrozole (Arimidex<sup>®</sup>), exemestane (Aromasin<sup>®</sup>) or letrozole (Femara<sup>®</sup>))</li> </ul> </li> <li>iii. Prescribed by or in consultation with an oncologist</li> <li>iv. Age <math>\geq</math> 18 years or documentation of closed epiphyses on x-ray</li> <li>v. Prolia is not prescribed concurrently with Xgeva</li> <li>vi. Dose does not exceed 60 mg every six months.</li> </ul> </li> <li>d. Multiple Myeloma or Solid Tumor (must meet all):           <ul style="list-style-type: none"> <li>i. Request is for Xgeva or biosimilar</li> <li>ii. Diagnosis of one of the following (i or ii):               <ul style="list-style-type: none"> <li>1. MM</li> <li>2. Bony metastasis from solid tumor (e.g., breast, kidney, lung, prostate, thyroid)</li> </ul> </li> <li>iii. Member is at risk for a skeletal-related event (e.g., pathologic fracture, radiation therapy or surgery to bone, spinal cord compression)</li> <li>iv. Prescribed by or in consultation with an oncologist</li> <li>v. Age <math>\geq</math> 18 years or documentation of closed epiphyses on x-ray</li> <li>vi. Xgeva is not prescribed concurrently with Prolia</li> <li>vii. Dose does not exceed 120 mg every four weeks.</li> </ul> </li> </ul>
---------------------------------	---

	<p>e. Giant Cell Tumor of Bone (must meet all):</p> <ul style="list-style-type: none"> <li>i. Request is for Xgeva or biosimilar</li> <li>ii. Diagnosis of giant cell tumor of bone (i or ii): <ul style="list-style-type: none"> <li>1. Metastatic or unresectable disease</li> <li>2. Localized disease and Xgeva is prescribed as a single agent or in combination with interfereon alfa or radiation therapy</li> </ul> </li> <li>iii. Prescribed by or in consultation with an oncologist</li> <li>iv. Age ≥ 18 years or documentation of closed epiphyses on x-ray</li> <li>v. Xgeva is not prescribed concurrently with Prolia</li> <li>vi. Dose does not exceed 120 mg every four weeks plus 120 mg on days eight and 15 of first month of therapy.</li> </ul> <p>f. Hypercalcemia of Malignancy (must meet all):</p> <ul style="list-style-type: none"> <li>i. Request is for Xgeva or biosimilar</li> <li>ii. Diagnosis of hypercalcemia of malignancy</li> <li>iii. Prescribed by or in consultation with an oncologist</li> <li>iv. Age ≥ 18 years or documentation of closed epiphyses on x-ray</li> <li>v. Albumin-corrected calcium &gt; 12.5 mg/dL despite IV bisphosphonate therapy in the last 30 days</li> <li>vi. Xgeva is not prescribed concurrently with Prolia</li> <li>vii. Dose does not exceed 120 mg every four weeks plus 120 mg on days eight and 15 of first month of therapy.</li> </ul>
<b>Age Restriction</b>	Age ≥ 18 years or documentation of closed epiphyses on x-ray.
<b>Coverage Duration</b>	<b>Initial:</b> 6 months. <b>Reauthorization:</b> 12 months.  Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
<b>Other Criteria (LCD, NCD, etc.)</b>	Must follow LCD <a href="#">L34648</a> Bisphosphonate Drug Therapy.
<b>Misc Info, Appendix Etc.</b>	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	1/16/26	1/16/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	2/12/26	Pharmacy & Therapeutics (P&T) Committee	2/12/26
Updated	4/9/26	N/A	Additions of Enoby, Xtrenbo, Bosaya and Aukelso biosimilars	4/9/26
Approved	N/A	5/14/26	Pharmacy & Therapeutics (P&T) Committee	5/14/26