Drug Name: Prolia or Xgeva (denosumab)

Date: 9-2017
Last Revision date: 5-2019
Scope: Medicaid & Exchange

Drug Name:	**Prolia (denosumab)**
Required Medical Information:	• **Osteoporosis in Postmenopausal Women** Authorization of 12 months may be granted to postmenopausal female members when ANY of the following criteria are met: o Member has a history of fragility fractures o Member has a pre-treatment T-score of < -2.5 OR member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria: ▪ Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores, or increased fall risk) ▪ Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo]) ▪ Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A) • **Osteoporosis in Men** Authorization of 12 months may be granted to male members with osteoporosis when ANY of the following criteria are met: o Member has a history of an osteoporotic vertebral or hip fracture o Member has a pre-treatment T-score of < -2.5 o Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) • **Breast Cancer** Authorization of 12 months may be granted to members who are receiving adjuvant aromatase inhibitor therapy for breast cancer. • **Prostate Cancer** Authorization of 12 months may be granted to members who are receiving androgen deprivation therapy for prostate cancer.

	• **Glucocorticoid-induced Osteoporosis** Authorization of 12 months may be granted to members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met: o Member is currently receiving or will be initiating glucocorticoid therapy o Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A) o Member meets ANY of the following criteria: ▪ Member has a history of a fragility fracture ▪ Member has a pre-treatment T-score of ≤ -2.5 ▪ Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)
Renewal Critiera:	All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.
Appendix:	Appendix A. <u>Clinical reasons to avoid oral bisphosphonate therapy</u> • Esophageal abnormality that delays emptying such as stricture of achalasia • Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers) • Inability to stand or sit upright for at least 30 to 60 minutes • Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day • Renal insufficiency (creatinine clearance < 35mL/min) • History of intolerance to an oral bisphosphonate Appendix B. <u>WHO Fracture Risk Assessment Tool</u> • High FRAX fracture probability: 10 year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%. • 10-year probability; calculation tool available at: http://www.shef.ac.uk/FRAX/tool.jsp

Drug Name:	Xgeva (denosumab)
Required Medical Information:	• **Being used for the prevention of skeletal-related events in patients with multiple myeloma OR bone metastases from solid tumors** †; AND o Patient is at least 18 years of age; AND o Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Zoledronic Acid; OR o Patient has metastatic breast cancer or metastatic castration-resistant prostate cancer • **Being used for Giant Cell Tumor of the Bone †** o Patient must be an adult or at least 13 years of age and skeletally mature; AND ▪ Disease is unresectable or surgical resection is likely to result in severe morbidity; OR ▪ For metastatic disease ‡; AND • Used as a single agent; OR ▪ For localized disease ‡; AND • Used as a single agent; OR • In combination with interferon alpha or radiation therapy • **Being used for Hypercalcemia of malignancy** † o Patient is at least 18 years of age; AND o Patient must have a diagnosis of cancer (malignancy); AND ▪ Patient must have a diagnosis of refractory hypercalcemia of malignancy defined as an albumin-corrected calcium of >12.5 mg/dL (3.1 mmol/L) despite treatment with a minimum seven day trial on previous therapy with intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid; OR ▪ Patient has a documented contraindication or intolerance to intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid † FDA Approved Indication(s); ‡ Compendia recommended indication(s)

Renewal Criteria:	All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.
Approval duration:	12 months

Drug Name: Prolia or Xgeva (denosumab)

Date: 9-2017
Last Revision date: 5-2019
Scope: Integrity

Drug Name:	**Prolia (denosumab)**
Required Medical Information:	• **Osteoporosis in Postmenopausal Women** Authorization of 12 months may be granted to postmenopausal female members when ANY of the following criteria are met: o Member has a history of fragility fractures o Member has a pre-treatment T-score of < -2.5 OR member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria: ▪ Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores, or increased fall risk) ▪ Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo]) OR oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A) • **Osteoporosis in Men** Authorization of 12 months may be granted to male members with osteoporosis when ANY of the following criteria are met: o Member has a history of an osteoporotic vertebral or hip fracture o Member has a pre-treatment T-score of < -2.5

- Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)

- **Breast Cancer**
  Authorization of 12 months may be granted to members who are receiving adjuvant aromatase inhibitor therapy for breast cancer.

- **Prostate Cancer**
  Authorization of 12 months may be granted to members who are receiving androgen deprivation therapy for prostate cancer.

- **Glucocorticoid-induced Osteoporosis** Authorization of 12 months may be granted to members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:
  - Member is currently receiving or will be initiating glucocorticoid therapy
  - Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)
  - Member meets ANY of the following criteria:
    - Member has a history of a fragility fracture
    - Member has a pre-treatment T-score of ≤ -2.5
    - Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)

Renewal Critiera:

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Appendix:

Appendix A. Clinical reasons to avoid oral bisphosphonate therapy

- Esophageal abnormality that delays emptying such as stricture of achalasia
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance < 35mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B. WHO Fracture Risk Assessment Tool

	• High FRAX fracture probability: 10 year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%. • 10-year probability; calculation tool available at: http://www.shef.ac.uk/FRAX/tool.jsp
Drug Name:	Xgeva (denosumab)

Required Medical Information:	• **Being used for prevention of skeletal-related events in patients with multiple myeloma OR bone metastases from solid tumors**; AND
	  ○ Patient is at least 18 years of age
	• **Being used for Giant Cell Tumor of the Bone**
	  ○ Patient must be an adult or at least 13 years of age and skeletally mature; AND
	  ○ Disease is unresectable or surgical resection is likely to result in severe morbidity;
	• **Being used for Hypercalcemia of malignancy**
	  ○ Patient is at least 18 years of age; AND
	  ○ Patient must have a diagnosis of cancer (malignancy); AND
	  ▪ Patient must have a diagnosis of refractory hypercalcemia with previous therapy with bisphosphonates such as ibandronate or zoledronic acid; OR
	  ▪ Patient has a documented contraindication or intolerance to bisphosphonates such as ibandronate or zoledronic acid.

Renewal Criteria:	All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.
Approval duration:	12 months