Washington State Health Care Authority

Bone Density Regulators

Medical policy no. 30.04.00 Effective Date: October 1, 2019

Note:

- *For non-preferred agents in this class/category, patients must have had an inadequate response or have had a documented intolerance due to severe adverse reaction or contraindication to at least TWO* preferred agents.*
  **If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed*
- *If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria*

Background:

Osteoporosis is characterized by the deterioration of bone tissue and low bone mass. There are three categories of osteoporosis: postmenopausal, age-related, and secondary osteoporosis. Postmenopausal osteoporosis affects mainly trabecular bone in the decade after menopause as estrogen deficiency increases bone resorption more than bone formation. Age-related osteoporosis results from increased bone resorption that begins shortly after peak bone mass is obtained. Cortical and trabecular bone are both affected. Secondary osteoporosis is caused by medications (glucocorticoids, excess thyroid replacement, some antiepileptic drugs, and long-term heparin use) or diseases (hyperthyroidism, type 1 diabetes). Both types of bone are affected.

The primary goal of osteoporosis management is to reduce fracture risk. This can be done by reducing bone loss, increasing bone mass or improving bone architecture to maintain bone strength. Pharmacologic prevention and treatment focuses on limiting bone resorption.

Medical necessity

Drug	Medical Necessity
Bisphosphonates alendronate (Binosto / Fosamax) etidronate disodium ibandronate (Boniva) risedronate (Actonel / Atelvia) zoledronic acid (Reclast) **Calcitonins** calcitonin salmon **Parathyroid Hormone Analogs** abaloparatide (Tymlos) teriparatide (Forteo) **Rank Ligand (RankL) Inhibitors** denosumab (Prolia)	Bone Density Regulators may be considered medically necessary when used for the prevention and treatment of osteoporosis. • Non-preferred products require a trial of at least **TWO** preferred products • Requests for brand-name medications with a generic equivalent available must also meet the criteria described in the **Brands with Generic Equivalents** policy (Non-Clinical Policy No. 0001).

Selective Estrogen Receptor Modulators (SERM) raloxifene (Evista)	

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Abaloparatide (Tymlos)	Tymlos may be covered when **patients meet criteria 1 and either 2 or 3** of the following are met: 1. Total combined duration of parathyroid hormone analog (e.g., Tymlos, Forteo) use not to exceed 2 years 2. Diagnosis of osteoporosis in postmenopausal women with a high risk for fracture defined as **ALL** (both a and b) of the following: a. Patient meets criteria defined by **ONE** of the following: i. Bone mineral density (BMD) that is 2.5 or more standard deviations below that of a "young normal" adult (T score at or below -2.5 from the femoral neck, total hip, or lumbar spine); **OR** ii. The patient has osteopenia (T score between -1 and -2.5 from the femoral neck, total hip, or lumbar spine) and a history of previous fractures or glucocorticoid use for at least 3 months at a dose of 5 mg per day of prednisone (or equivalent); **AND** b. History of at least **ONE** of the following: i. History of contraindication, or intolerance to at least one oral bisphosphonates, zoledronic acid, and one selective estrogen receptor modulator (SERM) (e.g., raloxifene); **OR** ii. History of failure to a two (2) year trial of one (1) oral bisphosphonate and a two (2) year trial of zoledronic acid; **OR** iii. History of failure to a two (2) year trial of one selective estrogen receptor modulator (SERM) (e.g., raloxifene); **OR** 3. Diagnosis of severe osteoporosis in postmenopausal women (as defined by a T-score at or below -3.5) or in postmenopausal women (with a T-score at or below -2.5) with a recent fragility fracture in the spine or hips. If all the criteria are met, **approve for up to 12 months,** unless total combined duration of parathyroid hormone analog would exceed 2 years.

	Criteria (Reauthorization) 1. Patient has not suffered a fragility fracture while on treatment with this medication during the previous 6 months 2. Patient continues to meet all initial authorization criteria, absence of contraindications, and is able to tolerate and be compliant with the medication 3. Total combined duration of parathyroid hormone analog (e.g. Tymlos, Forteo) use not to exceed 2 years If all the criteria are met, **approve for up to 12 months,** unless total combined duration of parathyroid hormone analog would exceed 2 years
Drug	**Clinical Criteria (Initial Approval)**
Denosumab (Prolia)	Prolia may be covered when ALL of the following are met: 1. **ONE** of the following: a. Treatment of postmenopausal women or men with osteoporosis at high risk for fracture , defined as a T-score ≤ –2.5 at the femoral neck, total hip, or lumbar spine b. Treatment of glucocorticoid-induced osteoporosis who are at high risk for fracture, defined as a T-score ≤ –2.5 at the femoral neck, total hip, or lumbar spine c. Treatment to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy (ADT) for non-metastatic prostate cancer d. Treatment to increase bone mass in patients at high risk for fracture receiving adjuvant aromatase inhibitor (AI) therapy for breast cancer 2. History of failure, contraindication, or intolerance to at least one (1) oral bisphosphonate and IV zolendronic acid 3. **NONE** of the following: a. Uncorrected pre-existing hypocalcemia b. Currently pregnant c. Currently receiving XGEVA (denosumab) If all the criteria are met, **approve for 12 months** **Criteria (Reauthorization)** 1. Patient has not suffered a fragility fracture while on treatment with this medication during the previous 6 months 2. Patient continues to meet all initial authorization criteria, absence of contraindications, and is able to tolerate and be compliant with the medication If all the criteria are met, **approve for 12 months**

Drug	Clinical Criteria (Initial Approval)
Teriparatide (Forteo)	Forteo may be covered when **patients meet criteria 1 and either 2 or 3** of the following are met: 1. Total combined duration of parathyroid hormone analog (e.g., Tymlos, Forteo) use not to exceed 2 years 2. Diagnosis of osteoporosis in postmenopausal women with a high risk for fracture defined as **ALL** (a, b, c, and d) of the following: a. Greater than or equal to (≥) 18 years of age with closed epiphyses b. Diagnosis of **ONE** of the following: i. Treatment of postmenopausal osteoporosis at high risk for fracture ii. Treatment of primary or hypogonadal osteoporosis at high risk for fracture iii. Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture c. Patient meets criteria defined by **ONE** of the following: i. Bone mineral density (BMD) that is 2.5 or more standard deviations below that of a "young normal" adult (T score at or below -2.5 from the femoral neck, total hip, or lumbar spine); **OR** ii. The patient has osteopenia (T score between -1 and -2.5 from the femoral neck, total hip, or lumbar spine) and a history of previous fractures or glucocorticoid use for at least 3 months at a dose of 5 mg per day of prednisone (or equivalent); **AND** d. History of at least **ONE** of the following: i. History of contraindication, or intolerance to at least one oral bisphosphonates, zoledronic acid, and one selective estrogen receptor modulator (SERM) (e.g., raloxifene); **OR** ii. History of failure to a two (2) year trial of one (1) oral bisphosphonate and a two (2) year trial of zoledronic acid; **OR** iii. History of failure to a two (2) year trial of one selective estrogen receptor modulator (SERM) (e.g., raloxifene); **OR** 3. Diagnosis of severe osteoporosis in postmenopausal women (as defined by a T-score at or below -3.5) or in postmenopausal women (with a T-score at or below -2.5) with a recent fragility fracture in the spine or hips. If all the criteria are met, **approve for up to 12 months,** unless total combined duration of parathyroid hormone analog would exceed 2 years

	Criteria (Reauthorization)
	1. Patient has not suffered a fragility fracture while on treatment with this medication during the previous 6 months 2. Patient continues to meet all initial authorization criteria, absence of contraindications, and is able to tolerate and be compliant with the medication 3. Total combined duration of parathyroid hormone analog (e.g., Tymlos, Forteo) use not to exceed 2 years If all the criteria are met, **approve for up to 12 months,** unless total combined duration of parathyroid hormone analog would exceed 2 years

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
abaloparatide (Tymlos)	80mcg once daily
denosumab (Prolia)	60mg once every 6 months
teriparatide (Forteo)	20mcg once daily

Coding:

HCPCS Code	Description
J0897	Injection, denosumab 1 mg
J2430	Injection, pamidronate disodium, per 30 mg
J3489	Injection, zoledronic acid, 1 mg

References

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History

Date	Action and Summary of Changes
07.31.2019	Updated abaloparatide, teriparatide criteria
05.31.2019	Updated abaloparatide, teriparatide, and densoumab reauthrozation criteria
04.01.2019	Added Brands with Generic Equivalents policy; updated abaloparatide and teriparatide clinical policies
04.18.2018	New Policy