Bone Density Regulators

WA.PHAR.45 Bone Density Regulators

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
Abaloparatide (TYMLOS) Alendronate (BINOSTO) Alendronate (FOSAMAX) Calcitonin Salmon Denosumab (PROLIA) Etidronate Disodium Ibandronate (BONIVA) Raloxifene (EVISTA) Risedronate (ACTONEL) Risedronate (ATELVIA) Teriparatide (FORTEO)	Bone Density Regulators may be considered medically necessary when: Used for the prevention and treatment of osteoporosis. • Preferred products do not require a prior authorization • Non-preferred products require a trial of **TWO** preferred products • Brand name agents with a generic available require clinical justification why cannot use generic

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Abaloparatide (**TYMLOS**)	Tymlos may be covered when **ALL** of the following are met: 1. Diagnosis of osteoporosis in postmenopausal women with a high risk for fracture defined by **ONE** of the following: a. 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). b. 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). 2. History of at least **ONE** of the following:

	a. History of contraindication, or intolerance to at least two oral bisphosphonates and one selective estrogen receptor modulator (SERM) (e.g. raloxifene) b. History of failure to a two (2) year trial of one oral bisphosphonate OR one selective receptor modulator (SERM) (e.g.raloxifene) 3. Total combined duration of parathyroid hormone analog (e.g. Tymlos, Forteo) use not to exceed 2 years **Approve for up to 24-months ONLY**
Denosumab (**PROLIA**)	Prolia may be covered when ALL of the following are met: 1. **ONE** of the following: a. Patient is a man or postmenopausal woman and is diagnosed with osteoporosis, defined as a T-score ≤ –2.5 at the femoral neck, total hip, or lumbar spine b. Patient is a man who is receiving androgen deprivation therapy (ADT) for non-metastatic prostate cancer c. Patient is a woman who is 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. Prescribed for the prevention of osteoporosis or for the prevention or treatment of glucocorticoid-induced osteoporosis b. Uncorrected pre-existing hypocalcemia c. Currently pregnant d. Currently receiving XGEVA (denosumab) **Approve for 12 months**
	Criteria (Reauthorization)
	Documentation of positive clinical benefit **Approve for 12 months**
Teriparatide (**FORTEO**)	Forteo may be covered when **ALL** of the following are met: 1. Diagnosis of **ONE** of the following: a. Treatment of postmenopausal women with osteoporosis at high risk for fracture b. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture c. Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture 2. High risk for fracture defined by either of the following:

	a. 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). b. 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). 3. History of at least **ONE** of the following: a. History of contraindication, or intolerance to at least two oral bisphosphonates and one selective estrogen receptor modulator (SERM) (e.g. raloxifene) b. History of failure to a two (2) year trial of one oral bisphosphonate OR one selective receptor modulator (SERM) (e.g.raloxifene) 4. Greater than or equal to (≥) 18 years of age with closed epiphyses 5. Total combined duration of parathyroid hormone analog (e.g. Forteo, Tymlos) use not to exceed 2 years **Approve for up to 24-months ONLY**

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
J3487	Injection, zoledronic acid (Zometa), 1 mg
J3488	Injection, zoledronic acid (Reclast), 1 mg (Reclast 5 MG/100ML SOLN)

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