Pharmacy Policy Bulletin: J-0681 Parathyroid Hormone Analogs – Commercial and Healthcare Reform	
Number: J-0681	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0681-014	**Original Date:** 11/08/2017
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Forteo (teriparatide) • Tymlos (abaloparatide)

FDA-Approved Indication(s):	• Forteo (teriparatide)
	  ○ Treatment of postmenopausal women with osteoporosis at high risk for fracture \ or who have failed or are intolerant to other available osteoporosis therapy.
	  ○ To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.
	  ○ Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.
	• Tymlos
	  ○ Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.
	  ○ Treatment to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

Background:

Class	Drug(s)
Antiresorptive Agents	
Bisphosphonates: bind to the surfaces of the bones and slows down the bone resorption action of the osteoclasts (bone-eroding cells). This allows the osteoblasts (bone-building cells) to work more effectively.	alendronate ibandronate risedronate zoledronic acid
RANK ligand (RANKL) inhibitor: inhibits the development and activation of osteoclasts (bone-eroding cells).	Prolia (denosumab)

Estrogen therapy or hormone therapy: prevents bone resorption	Estrogens, selective estrogen receptor modulators (SERMs), calcitonin
Anabolic Agents	
Sclerostin inhibitor: increases bone mineral density in the lumbar spine, total hip, trabecular, and cortical bone, leading to an increase in bone strength and reduced risk of fracture.	Evenity (romosozumab-aqqg)
Parathyroid hormone (PTH) analog: increases bone remodeling by activating osteoblast (bone-building) cells.	Forteo (teriparatide)
Parathyroid hormone-related protein (PTHrp) analog: binds to PTH receptors in the, bone promoting bone formation. Minimizes other functions of PTH, namely bone resorption, and calcium release.	Tymlos (abaloparatide)

- Bone mineral density (BMD) testing generates a T-score and is a powerful tool that diagnoses osteopenia and osteoporosis. A score T-score of -1 to greater than -2.5 indicates osteopenia, and a score of -2.5 or less indicates osteoporosis.
- Clinical risk factors also significantly influence fracture risk in individual patients. The Fracture Risk Assessment Tool (FRAX) tool incorporates multiple clinical risk factors that predict fracture risk, largely independent of BMD. Clinical risk factors in FRAX include age, sex, body mass index, smoking, alcohol use, prior fracture, parental history of hip fracture, use of glucocorticoids, rheumatoid arthritis, secondary osteoporosis, and femoral neck BMD, when available.
- The 2020 Endocrine Society guideline for Pharmacological Management of Osteoporosis in Postmenopausal Women defines fracture risk as follows:

Low Risk	Moderate Risk	High-Very High Risk
○ No prior hip or spine fractures, **and** ○ BMD T-score at the hip and spine both above −1.0, **and** ○ 10-year hip fracture risk < 3%, or major osteoporotic fractures < 20%	○ No prior hip or spine fractures, **and** ○ BMD T-score at the hip and spine both above −2.5, **and** ○ 10-year hip fracture risk < 3%, or major osteoporotic fractures < 20%	○ Prior spine or hip fracture, **or** ○ BMD T-score at the hip or spine of −2.5 or below, **or** ○ 10-year hip fracture risk ≥ 3%, or major osteoporotic fracture risk ≥ 20%

- Systemic glucocorticoid therapy is defined as a daily dosage equivalent to 5 mg or greater of prednisone.
- Prescribing Considerations:
    - Forteo: Use for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.
    - Tymlos: Use for more than 2 years during a patient's lifetime is not recommended.
    - Screening for underlying causes of secondary osteoporosis such as hyperthyroidism or hyperparathyroidism, hypogonadism, chronic estrogen deficiency state (e.g., menopause before age 45, bilateral oophorectomy), vitamin D deficiency, chronic liver disease or chronic kidney disease is recommended.
    - The member should not have an underlying hypercalcemic disorder such as hypercalcemia, hyperparathyroidism or hypoparathyroidism, or is at risk for osteosarcoma (e.g., Paget's disease, prior radiation therapy, bone metastases, open epiphyses).

	○ Postmenopausal females with osteopenia and risk factors are recommended to consider osteoporosis treatment. ○ It is recommended that the member is taking calcium and vitamin D supplements daily. ○ Bisphosphonates such as alendronate are indicated for treatment and prevention of osteoporosis. The American Association of Clinical Endocrinologists guidelines recommend oral therapy with bisphosphonates as initial therapy for most osteoporotic patients with high fracture risk. ○ Bisphosphonate therapy is contraindicated in patients with creatinine clearance less < 35 mL/min, hypocalcemia, esophageal ulcerations, esophageal stricture, Barrett's esophagus, and active ulcers. ○ Ligand's teriparatide (formerly known as Bonsity) is an authorized alternative to Eli Lilly's Forteo. Ligand has licensed teriparatide exclusively to Alvogen to commercialize. There are also true generics of teriparatide available on the market.

Approval Criteria

I. Approval Criteria

A. Forteo (teriparatide)

When a benefit, coverage of Forteo (teriparatide) may be approved when all of the following criteria are met **(1. through 6.)**:

1. The member is at high risk for a fracture as defined by one (1) of the following criteria **(a., b., or c.)**:
- **a.** The member has a history of a previous hip (ICD-10: M84.35) or vertebral fracture (ICD-10: S22.0).
- **b.** The member has a diagnosis of osteoporosis (ICD-10: M80-M81), defined as a T-score ≤ -2.5.
- **c.** The member has a diagnosis of osteopenia (no ICD-10 code), defined as a T-score between -1.0 and -2.5 and meets one (1) of the following criteria **(i., ii., or iii.)**:
  - **i.** The 10-year risk of major osteoporotic fracture is ≥ 20% using the FRAX calculator.
  - **ii.** The 10-year risk of hip fracture is ≥ 3% using the FRAX calculator.
  - **iii.** The member meets both of the following criteria **(A) and B))**:
    - **A)** The member is 40 years of age or older.
    - **B)** The member has a history of glucocorticoid use at a dose of 5 mg per day or more of prednisone (or equivalent) for at least 3 months.

2. The member has experienced therapeutic failure or intolerance to one (1) bisphosphonate, or all bisphosphonates are contraindicated.

3. If the request is for brand Forteo, the member has experienced therapeutic failure or intolerance to generic teriparatide.

4. If the member is a male or postmenopausal female at high risk for fracture, the member meets one (1) of the following **(a. or b)**:
- **a.** The member has experienced therapeutic failure, contraindication, or intolerance to plan-preferred Tymlos.
- **b.** The member is requesting Forteo (teriparatide) for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy.

5. The member meets one (1) of the following criteria **(a. or b.)**:
- **a.** The total cumulative duration of therapy with Forteo (teriparatide) does not exceed 24 months.
- **b.** The prescriber attests that the member remains at or has returned to having a high risk for fracture.

6. The member is not receiving Forteo (teriparatide) in combination with other parathyroid hormone analogs, RANKL inhibitors, or sclerostin inhibitors.

B. Tymlos

When a benefit, coverage of Tymlos may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is at high risk for a fracture as defined by one (1) of the following criteria **(a., b., or c.)**:
   - **a.** The member has a history of a previous hip (ICD-10: M84.35) or vertebral fracture (ICD-10: S22.0).
   - **b.** The member has a diagnosis of osteoporosis (ICD-10: M80-M81), defined as a T-score ≤ -2.5.
   - **c.** The member has a diagnosis of osteopenia (no ICD-10 code) defined as a T-score between -1.0 and -2.5 and meets one (1) of the following criteria **(i. or ii.)**:
     - **i.** The 10-year risk of major osteoporotic fracture is ≥ 20% using the FRAX calculator.
     - **ii.** The 10-year risk of hip fracture is ≥ 3% using the FRAX calculator.
2. The member has experienced therapeutic failure or intolerance to one (1) bisphosphonate, or all bisphosphonates are contraindicated.
3. The total cumulative duration of therapy with Tymlos does not exceed 24 months.
4. The member is not receiving Tymlos in combination with other parathyroid hormone analogs, RANKL inhibitors, or sclerostin inhibitors.

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 24 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Forteo [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2021.
2. Tymlos [package insert]. Waltham, MA: Radius Health, Inc.; December 2023.
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment Of Postmenopausal Osteoporosis - 2020 Update Executive Summary. *Endocr Pract*. 2020 May;26(5):564-570.
4. Buckley L, Guyatt G, Fink H, et al. 2017 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Rheumatol*. 2017;69:1521-37.
5. American Family Physician. Osteoporosis in Men. *Am Fam Physician.* 2010;82(5):503-508. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. *Osteoporos Int*. 2014;25(10):2359–2381.

6. Watts NB, Bilezikian, JP, Camacho PM, et al. American Association of Clinical Endocrinologists Medical Guidelines For Clinical Practice For The Diagnosis And Treatment of Postmenopausal Osteoporosis. *Endocr Pract*. 2010;16(3):1-37.
7. National Osteoporosis Foundation. The Hows and Whys of Osteoporosis Medications. Available at: https://www.nof.org/patients/treatment/medicationadherence/. Accessed October 08, 2021.