

Pharmacy Policy Bulletin

Title: New Jersey Abaloparatide (Tymlos™)/ teriparatide (Forteo®)

Policy #: Rx.01.242

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **abaloparatide (Tymlos™)** and **teriparatide (Forteo®)** as provided under the member's prescription drug benefit.

Description:

Parathyroid hormone (PTH) and calcitriol are the two major hormones that regulate calcium and phosphate homeostasis. PTH maintains serum ionized calcium concentrations in a narrow range by stimulating renal tubular calcium reabsorption and bone resorption. Chronic exposure to high PTH results in bone resorption, however intermittent administration of recombinant human PTH stimulates bone formation to a greater extent than resorption, at least over the first 12 months of therapy. While PTH is an effective treatment for osteoporosis, it is generally not a first line drug due to route of administration (subcutaneous), long-term safety concerns, and availability of other agents.

Teriparatide is recombinant human PTH. Abaloparatide is a human parathyroid hormone related peptide (PTHrP(1-34)).

Teriparatide (Forteo®) is indicated:

- A. For the treatment of postmenopausal women with osteoporosis who are at high risk for fracture. These include women with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant of previous osteoporosis therapy, based upon physician assessment.
- B. To increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture. These include men with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant to previous osteoporosis therapy, based upon physician assessment.
- C. For treatment of osteoporosis associated with sustained systemic glucocorticoid therapy at high risk fracture.

Abaloparatide (Tymlos™) is indicated for the treatment of postmenopausal women with osteoporosis at high risk of fracture.

Policy:

INITIAL CRITERIA: Teriparatide (Forteo®) is approved when ALL of the following inclusion criteria are met:

- A. The member is 18 years of age or older; and
- B. One of the following:
 1. Primary or hypogonadal osteoporosis in men; or
 2. Glucocorticoid-induced osteoporosis in men or women (daily dose greater than or equal to 5mg prednisone or equivalent for at least 3 months); and
- C. One of the following:

1. Member is high risk for fracture defined by ONE of the following:
 - i. History of osteoporotic fractures; or
 - ii. At least two risk factors for a fracture (e.g., endocrine disorders, gastrointestinal disorders, use of medications associated with low bone mass or bone loss such as corticosteroids); or
 - iii. Member has a T score of at least -2.5 standard deviations below the young adult mean (T-score \leq -2.5); or
 2. Inadequate response or inability to tolerate ONE of the following osteoporosis therapies:
 - i. Bisphosphonates; or
 - ii. Hormone replacement therapy; or
 - iii. Selective estrogen receptor modulators (SERMs); or
 - iv. Calcitonin salmon (Miacalcin); or
 - v. Denosumab (Prolia); and
- D. For Forteo® only, inadequate response or inability to tolerate Teriparatide® manufactured by Alvogen

Initial Authorization: 12 months

INITIAL CRITERIA: Abaloparatide (Tymlos™) or teriparatide (Forteo®) are approved when ALL of the following are met:

- A. The member is 18 years of age or older; and
- B. Diagnosis of postmenopausal osteoporosis; and
- C. One of the following:
 1. Member is high risk for fracture defined by ONE of the following:
 - i. Member has a T score of at least -2.5 standard deviation below the young adult mean (T-score \leq -2.5); or
 - ii. History of osteoporotic fractures; or
 - iii. At least two risk factors for a fracture (e.g., endocrine disorders, gastrointestinal disorders, use of medications associated with low bone mass or bone loss such as corticosteroids); or
 2. Inadequate response or inability to tolerate ONE of the following osteoporosis therapies:
 - i. bisphosphonates; or
 - ii. Hormone replacement therapy; or
 - iii. Selective-estrogen receptor modulators (SERMs); or
 - iv. Calcitonin-salmon (Miacalcin®); or
 - v. Denosumab (Prolia®); and
- D. For Forteo® only, inadequate response or inability to tolerate Teriparatide® manufactured by Alvogen

Initial Authorization: 12 months

REAUTHORIZATION CRITERIA: Abaloparatide (Tymlos™) or teriparatide (Forteo®) is reapproved when BOTH of the following are met:

- A. Documentation of positive clinical response; and
- B. ONE of the following:
 1. Cumulative lifetime therapy does not exceed 2 years; or
 2. For Forteo® only, member remains at or has returned to having a high risk for fracture despite a total of 24 months of use or parathyroid hormones

Reauthorization: 12 months

* Coverage duration of teriparatide and Tymlos™ is limited to 730-day supply max per lifetime. All other treatment durations are considered Experimental/Investigational.

**Osteoporosis defined as T score of the individual's bone mineral density (BMD) is at least -2.5 standard deviations below the young adult mean OR history of osteoporotic fracture (i.e. hip, spine, etc.)

Black Box Warning as shown in the drug Prescribing Information:

**Abaloparatide (Tymlos™):
RISK OF OSTEOSARCOMA**

In male and female rats, teriparatide caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. The effect was observed at systemic exposures to teriparatide ranging from 3 to 60 times the exposure in humans given a 20-mcg dose. Because of the uncertain relevance of the rat osteosarcoma finding to humans, prescribe teriparatide only for patients for whom the potential benefits are considered to outweigh the potential risk. Teriparatide should not be prescribed for patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton).

Abaloparatide caused a dose-dependent increased in the incidence of osteosarcoma, a malignant bone tumor, in male and female rats. It is unknown whether TYMLOS™ will cause osteosarcoma in humans. Use of TYMLOS™ is not recommended in patients at increased risk for osteosarcoma. Cumulative use of TYMLOS™ and parathyroid hormone analogs (e.g. teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Forteo® (teriparatide) [package insert]. Indianapolis, IN. Lilly USA, LLC. November 2020. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=aae667c5-381f-4f92-93df-2ed6158d07b0&type=display>. Accessed April 5, 2021.

Prolia® (denosumab) [package insert]. Thousand Oaks, CA. Amgen Inc. March 2020. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=49e5afe9-a0c7-40c4-af9f-f287a80c5c88&type=display>. Accessed April 5, 2021.

Rosen CJ. Parathyroid hormone therapy for osteoporosis. UpToDate. February 2021. Available at: https://www.uptodate.com/contents/parathyroid-hormone-therapy-for-osteoporosis?source=search_result&search=teriparatide&selectedTitle=4-150. Accessed April 5, 2021.

Tymlos™ (abaloparatide) [package insert]. Waltham, MA: Radius Health, Inc. October 2020. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=712143d9-e21e-4013-bb3b-3426a21060a8&type=display>. Accessed April 5, 2021.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Tymlos™	abaloparatide
Forteo®	teriparatide

Cross References:

Rx.01.33 Off-Label Use

Policy Version Number:	2.0
P&T Approval Date:	March 18, 2021
Policy Effective Date:	July 01, 2021
Next Required Review Date:	March 18, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

