Parathyroid Hormones: teriparatide (Forteo®), abaloparatide (Tymlos®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO146

Description

Teriparatide (Forteo) and abaloparatide (Tymlos) are human parathyroid hormone related peptide [PTHrP (1-34)] analogs.

Length of Authorization

- Initial: 12 months
- Renewal: up to 12 months (only **one** renewal allowed)
  - **Forteo**: a maximum of **26 fills total**
  - **Tymlos**: a maximum of **24 fills total**

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
teriparatide (Forteo)	250 mcg/mL	Primary Osteoporosis/Hypogonadal-related Osteoporosis in Men Post-Menopausal Osteoporosis in Women Glucocorticoid-induced Osteoporosis	1 syringe/28 days
abaloparatide (Tymlos)	2000 mcg/mL	Post-Menopausal Osteoporosis in Women	1 syringe/30 days

Initial Evaluation

I. Abaloparatide (Tymlos) and teriparatide (Forteo) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Member will not have received treatment with a parathyroid hormone for more than two years during their lifetime; **AND**
   C. Use not in combination with other osteoporotic agents [e.g., denosumab (Prolia), bisphosphonates (alendronate, risedronate, ibandronate, zoledronic acid injection), calcitonin nasal spray, or raloxifene]; **AND**
   D. One of the following is met:
      1. Member has severe osteoporosis (T-score ≤ -3.5 in the absence of fracture or T-score ≤ -2.5 with fragility fracture); **OR**
      2. Member has a high risk of fracture defined as:

i. History of osteoporotic fracture (fractures of spine, hip, wrist or humerus); **OR**
ii. Multiple risk factors for fracture; **AND**

E. Treatment with ONE of the following: bisphosphonates (e.g., alendronate, ibandronate, zoledronic acid injection), raloxifene, or calcitonin (Fortical) has been ineffective, not tolerated, or ALL are contraindicated; **AND**
F. For teriparatide (Forteo):
1. A diagnosis of one of the following:
i. **Post-Menopausal Osteoporosis in Women**; **AND**
a. Treatment with abaloparatide (Tymlos) has been ineffective, not tolerated or contraindicated; **OR**
ii. **Primary Osteoporosis/Hypogonadal-related Osteoporosis in Men; OR**
iii. **Glucocorticoid-induced Osteoporosis; AND**
a. Member is taking ≥ 5 mg prednisone or its equivalent daily with an anticipated duration of ≥ 3 months; **OR**
G. For abaloparatide (Tymlos):
1. A diagnosis of post-menopausal osteoporosis in women.

II. Parathyroid hormones are considered investigational when used for all other conditions, including but not limited to:
A. Osteoporosis prophylaxis
B. Promote fracture healing
C. Promote post-fusion healing; **AND**
D. The use of abaloparatide (Tymlos) is considered investigational when use for:
1. Primary Osteoporosis/Hypogonadal-related Osteoporosis; OR
2. Glucocorticoid-induced Osteoporosis.
E. The use of parathyroid hormones [abaloparatide (Tymlos) and/or teriparatide (Forteo)] for >2 years.

Renewal Evaluation

I. Member has not been established on therapy by the use of free samples, manufacturer coupons, or otherwise; **AND**
II. Member has received a previous prior authorization approval for this agent; **AND**
III. Member has not received treatment with parathyroid hormone for more than a total of **two** years (i.e., the maximum treatment duration is two years during a lifetime); **AND**
IV. Not used in combination with other osteoporotic agents [e.g., denosumab (Prolia), bisphosphonates (alendronate, risedronate, ibandronate, zoledronic acid injection), calcitonin nasal spray, or raloxifene]; **AND**

V. Member has demonstrated clinical improvement [e.g. improved bone mineral density, reduction in fracture(s)] with parathyroid hormone therapy.

Supporting Evidence

I. Maximum duration of use is based on the dose dependent increase in the incidence of osteosarcoma. Cumulative use of parathyroid analogs for more than 2 years during a patient's lifetime is not recommended.

II. For the treatment of osteoporosis in postmenopausal women:
   A. The safety and efficacy of once-daily teriparatide (Forteo), median exposure of 19 months, was examined in a double-blind, multicenter, placebo-controlled clinical study of 1637 postmenopausal women with osteoporosis (FORTEO 20 mcg, n=541). The absolute risk reduction for new fracture in favor of teriparatide (Forteo) was a 9.3% reduction in vertebral fracture; 95% CI (5.5 – 13.1).
   B. The safety and efficacy of abaloparatide (Tymlos) was evaluated in an 18-month, randomized, multicenter, double-blind, placebo-controlled clinical trial in postmenopausal women aged 49 to 86 years (mean age of 69) who were randomized to receive abaloparatide (Tymlos) 80 mcg (N = 824) or placebo (N = 821). The absolute risk reduction for fractures in favor of abaloparatide (Tymlos) was 3.6% reduction in vertebral fractures; 95% CI (2.1 – 5.4).

III. For the treatment of men with primary or hypogonadal osteoporosis:
   A. The safety and efficacy of once-daily teriparatide (Forteo) was examined in a double-blind, multicenter, placebo-controlled clinical study of 437 men with either primary (idiopathic) or hypogonadal osteoporosis (n=151) for a median exposure of 10 months. The results of that study were reported as the following: increased lumbar spine bone mass density (BMD) from baseline in 94% of men treated. Fifty-three percent of patients treated with teriparatide (Forteo) achieved at least a 5% increase in spine BMD, and fourteen percent of patients gained ≥10% in spine BMD.

IV. For the treatment of glucocorticoid-induced osteoporosis:
   A. The efficacy of teriparatide (Forteo) was assessed in a randomized, double blind, active-controlled trial of 428 patients (19% men, 81% women) aged 22 to 89 years (mean 57 years) treated with ≥ 5 mg/day prednisone or equivalent for a minimum of 3 months. The duration of the trial was 18 months with 214 patients exposed to teriparatide (Forteo). In patients treated with teriparatide (Forteo), the mean percent change in BMD from baseline to endpoint was 7.2% at the lumbar spine, 3.6% at the total hip, and 3.7% at the femoral neck ($p<0.001$ all sites).

Investigational or Not Medically Necessary Uses

I. Osteoporosis Prophylaxis
   A. There is currently no evidence to support the use of parathyroid hormones for the prevention of postmenopausal osteoporosis.

II. Promote fracture healing and/or post fusion healing
   A. There is limited safety and efficacy evidence to support the use of parathyroid hormones in the setting of fracture healing and/or post fusion healing.

III. Abaloparatide (Tymlos) is only FDA-approved for the treatment of postmenopausal osteoporosis; there is currently a lack of sufficient evidence regarding safety and efficacy in other settings.

References

1. Forteo [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. October 2019.
2. Tymlos [Prescribing Information]. Waltham, MA: Radius Health, Inc. April 2017.
3. Camacho PM, Petak SM, Binkley N, et al. American Association Of Clinical Endocrinologists And American College Of Endocrinology Clinical Practice Guidelines For The Diagnosis And Treatment Of Postmenopausal Osteoporosis. September 2016. Available at: https://doi.org/10.4158/EP161435.GL.
4. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in Men: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 97, Issue 6, June 2012, Pages 1802–1822. Available at: https://doi.org/10.1210/jc.2011-3045
5. Buckley L, Guyatt G, Fink HA, et al. American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. American College of Rheumatology, Volume 69, Issue 8, August 2017, Pages 1521-1537. Available at: https://www.rheumatology.org/Portals/0/Files/Guideline-for-the-Prevention-and-Treatment-of-GIOP.pdf

Policy Implementation/Update:

Action and Summary of Changes	Date
Added detail around maximum duration of approval [26 (monthly) fills] in order to provide more clarity around fill history. Addition of supporting evidence regarding maximum two year treatment duration	04/2020
Added in fill count to renewal duration, as well as updated to reflect a 28-day supply instead of 30-days in the Forteo QL table	02/2020
Criteria transitioned into policy format with the following additions: supporting evidence, investigational section, and a list of drugs that should not be used in combination with parathyroid hormones. Guidelines reviewed, and the following updates were made: differentiate between T-scores without fragility fracture and with fragility fracture, defined high risk fractures, and provided inclusion criteria for glucocorticoid-induced osteoporosis.	12/2019
Update criteria to include abaloparatide (Tymlos)	08/2017
Reviewed	10/2005, 01/2007, 12/2008, 06/2013, 02/2016,

	06/2017, 12/2019
Date effective	03/2016
Policy created	09/2005