

|                                                                             |
|-----------------------------------------------------------------------------|
| Effective Date: 11/1/2020                                                   |
| Last Reviewed: 7/2020, 4/2021,<br>3/2022, 6/2023, 4/2024, 4/2025,<br>6/2026 |
| Scope: Medicaid                                                             |

# Teriparatide

## POLICY

### 1. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indication

- A. Treatment of postmenopausal women with osteoporosis at high risk for fracture (defined herein as having a history of osteoporotic fracture or multiple risk factors for fracture) or who have failed or are intolerant to other available osteoporosis therapy.
- B. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.
- C. Treatment of men and women with osteoporosis associated with sustained glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.

All other indications are considered experimental/investigational and are not a covered benefit.

### 2. CRITERIA FOR INITIAL APPROVAL

#### **A. Postmenopausal osteoporosis**

Authorization of 12 months may be granted to postmenopausal members with osteoporosis when ANY of the following criteria are met:

- 1. Documentation that the member has a history of fragility fractures
- 2. Documentation that the member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria (documentation provided):
  - a. The member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3.5], or increased fall risk)
  - b. The member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], denosumab biosimilar)
  - c. The member has had an oral bisphosphonate trial of at least 1-year duration or there is a contraindication to treatment with an oral bisphosphonate (See Appendix A)

|                                                                             |
|-----------------------------------------------------------------------------|
| Effective Date: 11/1/2020                                                   |
| Last Reviewed: 7/2020, 4/2021,<br>3/2022, 6/2023, 4/2024, 4/2025,<br>6/2026 |
| Scope: Medicaid                                                             |

## **B. Primary or hypogonadal osteoporosis in men**

Authorization of 12 months may be granted to male members with primary or hypogonadal osteoporosis when ANY of the following criteria are met:

1. Documentation that the member has a history of an osteoporotic vertebral or hip fracture
2. Documentation that the member meets criteria BOTH of the following criteria:
  - a. The member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (See Appendix B)
  - b. The member has had an oral OR injectable bisphosphonate trial of at least 1-year duration OR there is a contraindication to treatment with an oral bisphosphonate (See Appendix A)

## **C. Glucocorticoid-induced Osteoporosis**

Authorization of 12 months for parathyroid may be granted for members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:

1. Documentation that the member has had an oral OR injectable bisphosphonate trial of at least 1-year duration OR there is a contraindication to treatment with an oral bisphosphonate (See Appendix A)
2. Documentation that the member is currently receiving or will be initiating glucocorticoid therapy at an equivalent dose of  $\geq 2.5\text{mg/day}$  for  $\geq 3$  months
3. Documentation that the member meets ANY of the following criteria:
  - a. The member has a history of a fragility fracture;
  - b. The member has a pre-treatment T-score less than or equal to -2.5;
  - c. The member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (See Appendix B)

## **3. CONTINUATION OF THERAPY**

Authorization of up to 12 months may be granted for continuation of teriparatide when all the following criteria are met:

1. If member has not been approved for this drug by Neighborhood in the past, clinician must submit documentation that initial criteria is met.
2. Documentation that the member has not yet received more than 24 months of parathyroid hormone analog therapy in their lifetime

## **4. APPENDIX**

### Appendix A. Contraindications and precautions to oral bisphosphonate therapy

- Esophageal abnormality that delays emptying such as stricture of achalasia
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)

|                                                                             |
|-----------------------------------------------------------------------------|
| Effective Date: 11/1/2020                                                   |
| Last Reviewed: 7/2020, 4/2021,<br>3/2022, 6/2023, 4/2024, 4/2025,<br>6/2026 |
| Scope: Medicaid                                                             |

- Presence of documented or potential gastrointestinal malabsorption (e.g, gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance < 35 mL/min)
- History of intolerance to an oral bisphosphonate

#### Appendix B. WHO Fracture Risk Assessment Tool

- High FRAX fracture probability: 10 year major osteoporotic fracture risk  $\geq 20\%$  or hip fracture risk  $\geq 3\%$ .
- 10-year probability; calculation tool available at: <https://www.sheffield.ac.uk/FRAX/>
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day.

## 5. REFERENCES

1. Teriparatide [package insert]. San Diego, CA: Pfenex, Inc.; December 2025. Accessed May 2026.
2. Bisphosphonates. *Drug Facts and Comparisons*. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; March 21, 2019. Accessed April 10, 2019.
3. 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.
4. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. *Am Fam Physician*. 2015;92(4):261-268.
5. 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*. 2016;22 (Suppl 4):1-42.
6. ACOG Practice Bulletin Number 129: Osteoporosis. *Obstet Gynecol*. 2012;120(3):718-734.
7. National Institute for Health and Care Excellence. Osteoporosis Overview. Last updated February 2018. Available at: <http://pathways.nice.org.uk/pathways/osteoporosis>. Accessed April 10, 2019.
8. Treatment to prevent osteoporotic fractures: an update. Department of Health and Human Services, Agency for Healthcare Research and Quality. 2012; Publication No. 12-EHC023-EF. Available at [www.effectivehealthcare.ahrq.gov/lbd.cfm](http://www.effectivehealthcare.ahrq.gov/lbd.cfm).
9. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men : an Endocrine Society clinical practice guideline. *J Clin Endocr Metab*. 2012;97(6):1802-1822.
10. Fink HA, Gordon G, Buckley L, et al. 2017 American College of Rheumatology Guidelines for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Care Res*. 2017;69:1521-1537.
11. FRAX® WHO fracture risk assessment tool. © World Health Organization Collaborating Centre for Metabolic Bone Diseases: University of Sheffield, UK. Available at: <https://www.sheffield.ac.uk/FRAX/>. Accessed April 10, 2019.
12. Ensrud KE, Crandall CJ. Osteoporosis. *Ann Intern Med* 2017;167(03):ITC17–ITC32