Effective Date: 11/1/2020
Last Reviewed: 7/2020, 4/2021, 3/2022, 6/2023, 4/2024, 4/2025 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

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 [Prolia])
    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)

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 ≥ 2.5mg/day for ≥ 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)
- Prescence 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 ≥ 20% or hip fracture risk ≥ 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 (prednsione equivalent) per day.

5. REFERENCES

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