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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

Teriparatide is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, and treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

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

##### 2. DOCUMENTATION

The following documentation will need to be provided for the prior authorization to be reviewed:

1. History of fractures
2. T-score
3. FRAX fracture probability

##### 3. 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. The member has a history of fragility fractures
2. 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:
  - 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. The member has a history of an osteoporotic vertebral or hip fracture
2. 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. 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. The member is currently receiving or will be initiating glucocorticoid therapy
3. 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)

## **4. 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. The member has not yet received more than 24 months of parathyroid hormone analog therapy in their lifetime

## **5. 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)
- 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 per day.

## 6. REFERENCES

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