SPECIALTY GUIDELINE MANAGEMENT

FORTEO (teriparatide)

POLICY

I. 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.

A. FDA-Approved Indications
1. Treatment of postmenopausal women with osteoporosis at high risk for fracture
2. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
3. Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture

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

II. CRITERIA FOR INITIAL APPROVAL

A. Osteoporosis in Postmenopausal Women

Authorization of a lifetime total of 24 months may be granted to postmenopausal female members when ANY of the following criteria are met:
1. Member has a history of fragility fractures
2. Member has a pre-treatment T-score of ≤ -2.5 OR member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria:
    a. Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores, or increased fall risk)
    b. Member has failed prior treatment with or is intolerant to previous osteoporosis therapy (i.e., oral bisphosphonates or injectable antiresorptive agents)

B. Primary or Hypogonadal Osteoporosis in Men

Authorization of a lifetime total of 24 months may be granted to male members with primary or hypogonadal osteoporosis when ANY of the following criteria are met:
1. Member has a history of an osteoporotic vertebral or hip fracture
2. Member has a pre-treatment T-score of ≤ -2.5
3. Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)

C. Glucocorticoid-induced Osteoporosis

Authorization of a lifetime total of 24 months may be granted for members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:
1. Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)
2. Member is currently receiving or will be initiating glucocorticoid therapy
3. Member meets ANY of the following criteria:
    a. Member has a history of a fragility fracture
    b. Member has a pre-treatment T-score of ≤ -2.5
    c. Member has osteopenia with a high pre-treatment FRAX fracture probability (See Appendix B)

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria AND has received less than 24 months of total lifetime therapy with Forteo.[1]

IV. APPENDIX

Appendix A. Clinical reasons to avoid 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 < 30 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: http://www.shef.ac.uk/FRAX/tool.jsp

V. REFERENCES

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