

# STANDARD MEDICARE PART B MANAGEMENT

## FORTEO (teriparatide) BONSITY (teriparatide) 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.

##### 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 osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

##### A. Osteoporosis treatment

Authorization of 12 months may be granted for the treatment of osteoporosis in men or postmenopausal women at high risk for fracture.

##### B. Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture

Authorization of 12 months may be granted for the treatment of glucocorticoid-induced osteoporosis in members who are at high risk for fracture.

#### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with the requested drug
2. The requested drug is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy.

#### IV. OTHER

<b>Reference number(s)</b>
3361-A

The cumulative duration of parathyroid hormone analogs (teriparatide and abaloparatide) will not exceed a total of 24 months in the member's lifetime.

## V. REFERENCES

1. Forteo [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2020.
2. Bonsity [package insert]. San Diego, CA: Pfenex, Inc.; October 2019.
3. Teriparatide [package insert]. San Diego, CA: Pfenex, Inc.; October 2019.
4. Forteo. Micromedex Solutions. IBM Watson Health, Armonk, New York. Available at <https://www.micromedexsolutions.com>. Accessed October 4, 2020.