Reference number(s)
3361-A

STANDARD MEDICARE PART B MANAGEMENT

FORTEO (teriparatide)
BONSITY (teriparatide)
TERIPARATIDE (branded generic)
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 (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.
2. 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.
3. Treatment of men and women with osteoporosis associated with sustained systemic 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 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. Glucocorticoid-induced osteoporosis
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:
A. The member is currently receiving therapy with the requested drug
B. The requested drug is being used to treat an indication enumerated in Section II

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C. The member is receiving benefit from therapy.

IV. OTHER

The cumulative duration of parathyroid hormone analogs (teriparatide and abaloparatide) will not exceed a total of 24 months in the member's lifetime unless the member remains at or has returned to having a high risk for fracture.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Forteo, Bonsity, and teriparatide.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Forteo, Bonsity, and teriparatide are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCES

1. Forteo [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2021.
2. Bonsity [package insert]. San Diego, CA: Pfenex, Inc.; October 2019.
3. Teriparatide [package insert]. San Diego, CA: Alvogen, Inc.; November 2019.
4. Teriparatide [package insert]. Weston, FL: Apotex Corp.; December 2023.

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