

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** Osteoporosis Medications Policy

**Drug(s):** AREDIA (pamidronate), BONIVA IV (ibandronate), FORTEO (teriparatide)

**Covered Uses:** Teriparatide is indicated for the treatment of postmenopausal women with osteoporosis who are at high risk for fracture and to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture. Ibandronate Injection is indicated for the treatment of osteoporosis in postmenopausal women. Pamidronate is indicated for hypercalcemia of malignancy, Paget's disease, osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma. Zoledronic injection is indicated for the treatment of osteoporosis in postmenopausal women and the treatment of Paget's disease of bone in men and women. All criteria in "other criteria" section must be met for coverage

**Required Medical Information:** Radiologic reports, bone mineral density reports

**Age Restrictions:** Restricted to 18 years of age or older

**Prescriber Restrictions:** NA

**Other Criteria:**

- Risk factors identified by the National Osteoporosis Foundation include, but are not limited to, advanced age, current smokers, low body weight (less than 127 lbs), history of fragility fractures in first-degree relatives, use of oral corticosteroids for greater than 3 months or personal history of a fracture after age 50.
- Treatment failure prior to teriparatide therapy is defined as continued bone loss despite two or more years of bisphosphonate therapy in either sex, or SERM therapy in females, as documented using BMD testing or evidence of new fractures despite at least 6 months of bisphosphonate therapy in either sex, or SERM therapy in females.
- Members should be screened for remedial, reversible causes of secondary osteoporosis

The use of **teriparatide** may be medically necessary for the treatment of osteoporosis:

1. In a postmenopausal woman at high risk of fracture if either a) or b) are met:
  - a) the member has a BMD T score of at least -2.5 standard deviations from the mean AND the member has documented failure, based on objective evidence, of at least a 2 year treatment period of bisphosphonate, or SERM therapy except if the member has a documented contraindication and/or intolerance to at least two bisphosphonates and SERM therapy

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- b) the member has a fragility fracture despite at least 6 months of bisphosphonate or SERM therapy.
2. In men with primary or hypogonadal osteoporosis at high risk of fracture if either a) or b) are met:
- a) the member has a BMD T score of at least -2.5 standard deviations from the mean AND the member has documented failure based on objective evidence of at least a 2 year treatment period of bisphosphonate therapy except if the member has a documented contraindication and/or intolerance to at least two bisphosphonates.
  - b) the member has a fragility fracture despite at least 6 months of bisphosphonate therapy.

Continued therapy may be authorized in members who demonstrate an increase in BMD of the lumbar spine, femoral neck, or whole body.

Use beyond two years has not been established in the literature.

The use of injectable **bisphosphonates** may be medically necessary for the treatment of osteoporosis if the member has a BMD T score of at least -2.5 standard deviations from the mean **AND**

- Unable to sit upright for 30 min **OR**
- Objective documentation (radiologic reports) supporting active or recurrent peptic ulcer disease, or esophageal stricture **OR**
- Significant intolerance to SERM therapy and at least two oral bisphosphonates

Continued therapy may be authorized in members who demonstrate maintenance or increase in BMD and continue to meet the above criteria.

**Exclusion Criteria:**

- Doses exceeding package labeling are not covered.
- Teriparatide is not a covered benefit in the following situations:
  - members who do not meet above criteria;
  - member is less than 18 years of age or in whom epiphyses have not yet closed;
  - prevention of osteoporosis in men and women;
  - members with Paget's disease or unexplained elevations of alkaline phosphatase;
  - members with a history of bone metastases, skeletal malignancies and/or metabolic bone disease other than osteoporosis;
  - members with hypercalcemia;
  - in combination with a bisphosphonate.
- Teriparatide is not covered after two years of treatment.

Claims when billed with HCPCS code J3110 are excluded.

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- Injectable bisphosphonates are not a covered benefit in the following situations:
  - prevention of osteoporosis,
  - uncorrected hypocalcemia,
  - use in men for osteoporosis unless osteoporosis is secondary complication of a transplant;
  - failure of oral bisphosphonates,
- dose and/or frequency exceeding package label

**Coverage Duration:** 12 months