

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Bone Resorption Suppression and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Bone Resorption Suppression and Related Agents that meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Bone Resorption Suppression and Related Agent, regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of preferred Bone Resorption Suppression and Related Agents at:
www.providersynergies.com/services/documents/PAM_PDL.pdf
2. A prescription for a preferred Bone Resorption Suppression and Related Agent with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at:
<http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm>

GRANDFATHER PROVISION – The Department will grandfather prescriptions for Evista when the PROMISe Point-Of-Sale On-Line Claims Adjudication System verifies that the recipient has a record of a paid claim for Evista within the past 90 days from the date of service of the new claim. If there is a record of a paid claim for Evista, a prescription or a refill for Evista will be automatically approved.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Bone Resorption Suppression and Related Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. Whether the recipient:
 - a. Had a bone density test and the T-score is between -1.0 and -2.5 and a 10-year probability of a hip fracture is $\geq 3\%$ or a 10-year probability of a major osteoporosis-related fracture $\geq 20\%$ based on the US-adapted World Health Organization (WHO) algorithm

OR

- b. Had a bone density test and the T-score is lower than -2.5

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

AND

- c. Was evaluated for secondary causes of osteoporosis including complete blood count (CBC), Vitamin D, Ionized Calcium, Phosphorus, Albumin, Total Protein, Creatinine, Liver enzymes (specifically Alkaline Phosphatase), Intact Parathyroid Hormone (PTH), Thyroid-Stimulating Hormone (TSH), Urinary Calcium Excretion, and Testosterone (if a male)

AND

- d. Has a documented history of therapeutic failure*, intolerance, or contraindication to the preferred Bone Resorption Suppression and Related Agents indicated for the condition.

AND

- e. For a parenteral Bisphosphonate, has a documented history of contraindication or intolerance to oral Bisphosphonates.

AND

- 2. For Forteo – Whether the recipient:

- a. Has a history of therapeutic failure*, intolerance, or contraindication to the Bisphosphonates

AND

- b. Has not been receiving this medication for more than 2 years

AND

- c. Does not have a history of any of the following:
 - i. Paget's Disease
 - ii. Bone metastases
 - iii. Skeletal malignancies
 - iv. Metabolic bone disease other than osteoporosis
 - v. Hypercalcemic disorders
 - vi. Unexplained elevations of alkaline phosphatase
 - vii. Open epiphyses

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- viii. Prior external beam or implant radiation therapy involving the skeleton

OR

3. For Evista, whether the recipient:

- a. Does not have a documented history of venous thromboembolic events or breast cancer

AND

- b. For women with a risk factor for stroke (such as: prior stroke or transient ischemic attack (TIA), atrial fibrillation, hypertension, or cigarette smoking), the risk of death due to stroke has been discussed with the recipient and documented by the prescriber

AND

- i. Is a postmenopausal woman at high risk for invasive breast cancer as defined by one of the following:
 - a) Prior biopsy with lobular carcinoma in situ (LCIS) or atypical hyperplasia
 - b) One or more first degree relatives with breast cancer
 - c) A 5 year predicted risk of breast cancer $\geq 1.66\%$ (based on the modified Gail model)

OR

- ii. Is a postmenopausal woman with osteopenia or osteoporosis (T-score < -1.0) and risk of breast cancer

OR

- iii. Is a postmenopausal woman with a history of therapeutic failure*, intolerance, or contraindication to the oral Bisphosphonates AND
 - a) Had a bone density test and T-score between -1.0 and -2.5 and a 10-year probability of a hip fracture is $\geq 3\%$ or a 10-year probability of a major osteoporosis-related fracture $\geq 20\%$ based on the US-adapted WHO algorithm

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

OR

- b) Had a bone density test and the T-score is lower than -2.5

OR

- 4. For Xgeva, whether the recipient has a history of therapeutic failure, intolerance, or contraindication to preferred Zometa

OR

- 5. For all non-preferred Bone Resorption Suppression and Related Agents, whether the recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

In addition, if a prescription for either a preferred or non-preferred Bone Resorption Suppression and Related Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

* Therapeutic failure is defined as documented continued bone loss or fragility fracture after two (2) or more years despite treatment with a Bisphosphonate.

C . Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for a Bone Resorption Suppression and Related Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

The Department will limit authorization of Forteo to 2 years cumulative duration of treatment.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

References:

1. Forteo (package insert). Indianapolis, IN; Lilly; January 2010. .