pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
July 23, 2018	July 23, 2018	*See below

SUBJECT

Prior Authorization of Bone Resorption Suppression and Related Agents - Pharmacy Services

BY

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Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Bone Resorption Suppression and Related Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services under the MA managed care delivery system should address any questions related to Bone Resorption Suppression and Related Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make

*01-18-19	09-18-20	27-18-18	33-18-19
02-18-14	11-18-14	30-18-14	
03-18-14	14-18-15	31-18-20	
08-18-21	24-18-15	32-18-14	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

recommendations relating to the following:

- New drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to the PDL; and
- Guidelines to determine medical necessity.

DISCUSSION:

During the May 16, 2018, meeting, the P&T Committee recommended the following changes:

- Removal of the provision for grandfathering of Evista (raloxifene). The Committee recommended that the determination of medical necessity of Evista should be subject to, and consistent with, the same safety guidelines as other drugs within this class.
- The addition of a guideline for therapeutic failure, intolerance, or contraindication to Forteo (teriparatide) for Tymlos (abaloparatide).

The recommended changes were subject to public review and comment, and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Bone Resorption Suppression and Related Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Bone Resorption Suppression and Related Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Bone Resorption Suppression and Related Agents

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 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: https://papdl.com/preferred-drug-list.

2. 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.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

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. For a diagnosis of an osteoporosis-related condition, whether the beneficiary:

   a. Had a bone density test and the T-score is between -1.0 and -2.5 and a history of fragility fracture of the proximal humerus, pelvis, or distal forearm

   OR

   b. 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 ≥ 3% or a 10-year probability of a major osteoporosis-related fracture ≥ 20% based on the US-adapted World Health Organization (WHO) algorithm

   OR

c. Had a bone density test and the T-score is -2.5 or below

OR

d. Has a history of low-trauma spine or hip fracture, regardless of bone density.

AND

e. 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

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

AND

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

AND

2. For Forteo (teriparatide) and Tymlos (abaloparatide), whether the beneficiary:

a. Has a T-score of -3.5 or below or a T-score of -2.5 or below and a history of fragility fracture

OR

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

AND

c. Has not been receiving cumulative treatment duration with parathyroid hormone analogs for more than 2 years.

AND

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

AND

e. For Tymlos (abaloparatide) whether the beneficiary has a documented history of therapeutic failure, intolerance, or contraindication to Forteo (teriparatide).

OR

3. For Evista (raloxifene), whether the beneficiary:

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 beneficiary 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 ≥ 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 the T-score is between -1.0 and - 2.5 and a history of fragility fracture of the proximal humerus, pelvis, or distal forearm

OR

b) Had a bone density test and T-score between -1.0 and -2.5 and a 10-year probability of a hip fracture is ≥ 3% or a 10-year probability of a major osteoporosis-related fracture ≥ 20% based on the US-adapted WHO algorithm

OR

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

OR

d) Has a history of low-trauma spine or hip fracture, regardless of bone density.

OR

4. For Xgeva (denosumab), whether the beneficiary:

a. Has a history of therapeutic failure, intolerance, or contraindication to preferred zoledronic acid

OR

b. Is being treated for giant cell tumor of the bone.

5. 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.

NOTE: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit guidelines listed above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

* 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 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 beneficiary.

D. Dose and Duration of Therapy

The Department will limit authorization of Forteo (teriparatide) and Tymlos (abaloparatide) to 2 years cumulative duration of treatment.

E. References:

1. Forteo (package insert). Indianapolis, IN; Lilly; October 2016.
2. Overview of the management of osteoporosis in postmenopausal women. Up To Date. Accessed August 2, 2017.
3. Tymlos (package insert). Waltham, MA; Radius Health, Inc. April 2017.