PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
BONE DENSITY REGULATORS

Proposed Effective Date: January 1, 2020

Revisions are noted with a ~~strikethrough~~ for deletions and **bold and underline** for additions.

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

A. Revisions to Prescriptions That Require Prior Authorization

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

1. A non-preferred ~~Bone Resorption Suppression and Related Agent~~ **Bone Density Regulator**~~, regardless of the quantity prescribed~~. See the Preferred Drug List (PDL) for the list of preferred ~~Bone Resorption Suppression and Related Agents~~ **Bone Density Regulators** at: https://papdl.com/preferred-drug-list.

2. A ~~preferred Bone Resorption Suppression and Related Agent~~ **Bone Density Regulator** with a prescribed quantity that exceeds the quantity limit. ~~See Quantity Limits for the list of drugs with quantity limits at:~~ **The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:** http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Revisions to 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~~ **Bone Density Regulator**, the determination of whether the requested prescription is medically necessary will take into account ~~the following~~ **whether the beneficiary**:

1. **For a non-preferred Bone Density Regulator, all of the following:**

   a. **Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,**

   b. **Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,**

   c. **Does not have a history of a contraindication to the prescribed medication,**

   d. **For an osteoporosis related condition, 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),

i. ~~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**~~

b) ~~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**~~

c) ~~Has a documented history of therapeutic failure,~~[*] ~~intolerance, or contraindication to the preferred Bone Resorption Suppression and Related Agents indicated for the condition~~

~~**AND**~~

d) ~~For a parenteral bisphosphonate, has a documented history of contraindication or intolerance to oral bisphosphonates;~~

~~**AND**~~

e. For Forteo (teriparatide) and Tymlos (abaloparatide), ~~whether the beneficiary~~ **all of the following:**

i. **One of the following**:

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,[1] intolerance, or contraindication to bisphosphonates,

~~**AND**~~

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

~~**AND**~~

iii. Does not have a history of **any** of the following:

a) Paget's disease,
b) Bone metastases,
c) Skeletal malignancies,
d) Metabolic bone disease other than osteoporosis,
e) Hypercalcemic disorders,
f) Unexplained elevations of alkaline phosphatase,
g) Open epiphyses,
h) Prior external beam or implant radiation therapy involving the skeleton,

~~**AND**~~

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

~~**OR**~~

f. For Evista (raloxifene), ~~whether the beneficiary~~ **all of the following**:

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

~~**AND**~~

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

~~**AND**~~

iii. **One of the following**:

a) Is a postmenopausal woman **at high risk of fracture[2] and** high risk for invasive breast cancer as defined by **one** of the following:

(i) Prior biopsy with lobular carcinoma in situ (LCIS) or atypical hyperplasia,

(ii) One or more first degree relatives with breast cancer,
(iii) A 5-year predicted risk of breast cancer ≥ 1.66% (based on the modified Gail model), ~~**OR**~~
(iv) ~~Is a postmenopausal woman with osteopenia or osteoporosis (T- score < -1.0) and risk of breast cancer,~~

~~**OR**~~

b) Is a postmenopausal woman **at high risk of fracture**[2] with a history of therapeutic failure[1], intolerance, or contraindication to oral bisphosphonates;

~~**AND**~~

c) ~~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**~~

d) ~~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**~~

e) ~~Had a bone density test and the T-score is lower than - 2.5,~~

~~**OR**~~

f) ~~Has a history of low-trauma spine or hip fracture, regardless of bone density;~~

~~**OR**~~

g. For Xgeva (denosumab), ~~whether the beneficiary~~ **one of the following**:

i. Has a history of therapeutic failure, intolerance, or contraindication to the preferred zoledronic acid ~~**OR**~~
ii. Is being treated for giant cell tumor of the bone;

h. **For all other non-preferred Bone Density Regulators, all of the following:**

i. Is at high risk of fracture,[2]
ii. Has a documented history of therapeutic failure,[1] intolerance, or contraindication to the preferred Bone Density Regulators approved for the beneficiary's diagnosis,
iii. For a parenteral bisphosphonate, has a documented history of

contraindication or intolerance to oral bisphosphonates;

AND

2. ~~In addition~~, If a prescription for ~~either a preferred or non-preferred~~ ~~Bone Resorption Suppression and Related Agent~~ **a Bone Density Regulator** 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.~~

FOR RENEWALS OF PRESCRIPITONS FOR BONE DENSITY REGULATORS: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Bone Density Regulators that were previously approved will take into account whether the beneficiary:

1. **Based on the prescriber's assessment, continues to benefit from the prescribed Bone Density Regulator; AND**

2. **If a prescription for a Bone Density Regulator 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: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

[1] Therapeutic failure for an osteoporosis-related condition is defined as documented continued bone loss or fragility fracture after two (2) or more years despite treatment with a bisphosphonate.
[2] High risk is defined as one of the following: T-score between -1.0 and -2.5 and a history of fragility fracture of the proximal humerus, pelvis, or distal forearm; T-score between -1.0 and -2.5 at the femoral neck, total hip, or lumbar spine and a 10-year probability of a hip fracture ≥ 3% or a 10-year probability of a major osteoporosis-related fracture ≥ 20% based on the US-adapted World Health Organization (WHO) algorithm; T-score -2.5 or below at the femoral neck, total hip, or lumbar spine; OR history of low-trauma spine or hip fracture, regardless of bone density.

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~~ **Bone Density Regulator**. 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

Requests for prior authorization of Bone Density Regulators will be approved as follows:

1. **Initial and renewal requests for prior authorization of Bone Density Regulators will be approved for up to 12 months.**

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

E. References:

1. Eastell, R, Rosen, R.J, et.al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society* Clinical Practice Guideline. *Journal of Clinical Endocrinology and Metabolism*. (2019) 104:1595–1622.
2. Cosman, F, de Beur, S.J, et.al. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. *Osteoporosis International.* (2014) 25:2359–2381.
3. Buckley, L, Guyatt, G, et.al. 2017 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis & Rheumatology.* (2017) 69:1521-1537.
4. Forteo (teriparatide) Prescribing Information. Indianapolis, IN; Lilly; October 2016.
5. Tymlos (abaloparatide) Prescribing Information. Waltham, MA; Radius Health, Inc. October 2018.
6. Reclast (zoledronic acid) Prescribing Information. East Hanover, NJ; Novartis Pharmaceuticals Corporation; July 2017.
7. Zometa (zoledronic acid) Prescribing Information. East Hanover, NJ; Novartis Pharmaceuticals Corporation; December 2018.
8. Evista (raloxifene) Prescribing Information. Indianapolis, IN; Lilly; June 2018.
9. Xgeva (denosumab) Prescribing Information. Thousand Oaks, California; Amgen Inc; June 2018.
10. Rosen, C.J. Parathyroid hormone/parathyroid hormone-related protein analogs for osteoporosis. Up To Date. Accessed April 22, 2019.