SmartPA Criteria Proposal

Drug/Drug Class:	Bone Ossification Agents PDL Edit
First Implementation Date:	December 16, 2004
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: The bisphosphonates act primarily on bone through inhibition of normal and abnormal bone resorption. This group of agents has an affinity for hydroxyapatite crystals in bone and induces the inhibition of osteoclast activity. They also decrease the number of available osteoclasts by inhibiting enzymes in the mevalonate pathway, which then prevents the prenylation of proteins that are necessary for osteoclast formation. Studies have demonstrated the ability of these agents to decrease bone resorption without impairing bone mineralization or interfering with bone formation. Bisphosphonates administered orally have been associated with dysphagia, esophagitis, and esophageal or gastric ulcers. Therefore, these agents should not be given to participants with any active upper GI disease and should be discontinued in those who develop symptoms of esophagitis. Bisphosphonates are most commonly used for the treatment and prevention of osteoporosis in postmenopausal women. Prior to treatment with bisphosphonates, participants should be tested for other possible contributors to osteoporosis such as hypocalcemia, vitamin D deficiency, and renal impairment. Bisphosphonates are also used to treat hypercalcemia, Paget disease, and malignancies including multiple myeloma, breast cancer, and prostate cancer. There are both intravenous and orally available formulations of bisphosphonates. An adverse effect specific with the intravenous route are flu-like symptoms. Some adverse effects that may occur with both intravenous and oral routes are hypocalcemia, musculoskeletal pain, renal, ocular side effects, atrial fibrillation, osteonecrosis of the jaw, and atypical femur fractures.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	• Alendronate Tabs • Ibandronate	• Actonel® • Alendronate Soln • Atelvia® • Binosto® • Boniva® • Calcitonin Salmon Nasal Spray • Etidronate • Fosamax Plus D® • Fosamax® • Risedronate • Risedronate DR

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☐ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Bone Ossification Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
BINOSTO 70 MG	ALENDRONATE	1 tablet per week
FOSAMAX 5 MG	ALENDRONATE	1 tablet per day
FOSAMAX 10 MG	ALENDRONATE	1 tablet per day
FOSAMAX 35 MG	ALENDRONATE	1 tablet per week
FOSAMAX 40 MG	ALENDRONATE	1 tablet per day
FOSAMAX 70 MG	ALENDRONATE	1 tablet per week
FOSAMAX 70 MG/75 ML	ALENDRONATE	75ml per week
FOSAMAX PLUS D 70 MG/2,800 IU	ALENDRONATE/VITAMIN D3	1 tablet per week
FOSAMAX PLUS D 70 MG/5,600 IU	ALENDRONATE/VITAMIN D3	1 tablet per week

Required Documentation

Laboratory Results: ☐ Progress Notes: ☐
MedWatch Form: ☐ Other: ☐

SmartPA PDL Proposal Form

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Evidence-Based Medicine and Fiscal Analysis: “Bone Deossification Suppression Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; May 2020.
2. Evidence-Based Medicine Analysis: “Bone Deossification Suppression Agents (Including Calcitonin)”, UMKC-DIC; March 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
6. Binosto [package insert]. Herndon, VA: Ascent Therapeutics; 2019.
7. Fosamax [package insert]. Whitehouse Station, NJ: Merch & Co Inc; 2019.
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9. Etidronate Disodium [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; 2010.
10. Boniva [package insert]. South San Francisco, CA: Genentech USA, Inc.; 2016.
11. Actonel [package insert]. Irvine, CA: Allergan; 2019.
12. Atelvia [package insert]. Rockaway, NJ: Warner Chilcott; 2015.
13. Calcitonin salmon nasal spray [package insert]. Weston, FL: Apotex Inc.; 2017.