SmartPA Criteria Proposal

Drug/Drug Class:	Bone Ossification Agents PDL Edit
First Implementation Date:	December 16, 2004
Proposed Date:	September 15, 2022
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 gastrointestinal 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. The adverse effect of flu-like symptoms is specific to the intravenous route of administration. 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® • Boniva® • Calcitonin Salmon Nasal Spray • Etidronate • Fosamax®

	• Fosamax Plus D® • 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 all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
ACTONEL 5 MG TABLET	RISEDRONATE	1 tablet per day
ACTONEL 30 MG TABLET	RISEDRONATE	1 tablet per day
ACTONEL 35 MG TABLET	RISEDRONATE	1 tablet per week
ACTONEL 150 MG TABELT	RISEDRONATE	1 tablet per month
ATELVIA DR 35 MG TABLET	RISEDRONATE	1 tablet per week
BINOSTO 70 MG	ALENDRONATE	1 tablet per week
BONIVA 150 MG TABLET	IBANDRONATE	1 tablet per month
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	75 mL 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: ☐

Disposition of Edit

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

Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: “Bone Deossification Suppression Agents (Including Calcitonin)”, UMKC-DIC; April 2022.
- Evidence-Based Medicine and Fiscal Analysis: “Bone Deossification Suppression Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.