MEDICAL MUTUAL®

Drug Policy

Policy:	Bisphosphonates (Oral Agents) Preferred Step Therapy Policy	Annual Review Date: 07/20/2023 Last Revised Date: 07/20/2023

OVERVIEW

Alendronate, Actonel, Atelvia and ibandronate tablets are orally-administered bisphosphonates. Fosamax Plus D contains alendronate plus vitamin D_3 in one tablet; both are available as single-entity products. Binosto provides alendronate in a 70 mg effervescent tablet for oral solution. Fosamax oral solution, Actonel with Calcium, the 2.5-mg tablet strength of Boniva, and the 75-mg tablet strength of Actonel are all discontinued products. Generic alendronate oral solution (70 mg/75 mL) is not included in this policy. The prescribing information for Fosamax notes that although an oral solution of alendronate may be available in the marketplace, Fosamax oral solution is no longer marketed.

Alendronate tablets, risedronate, and ibandronate tablets are all indicated for the treatment and prevention of postmenopausal osteoporosis (PMO). Alendronate tablets and risedronate are also indicated for the treatment of Paget's disease and for the treatment of glucocorticoid-induced osteoporosis (GIO) in men and women. Risedronate is also indicated for the prevention of GIO. Alendronate tablets and risedronate are also indicated to increase bone mass in men with osteoporosis. Fosamax Plus D tablets are indicated for the treatment of PMO and to increase bone mass in men with osteoporosis. Risedronate delayed-release tablets are indicated for the treatment of PMO. Binosto is indicated for the treatment of osteoporosis in postmenopausal women and as a treatment to increase bone mass in men with osteoporosis.

POLICY STATEMENT

A step therapy program has been developed to encourage use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one preferred drug within the 130-day look-back period are excluded from step therapy.

Preferred Medications

- Generic alendronate
- Generic ibandronate
- Generic risedronate
- Generic risedronate delayed-release tablets

Non-Preferred Medications

- Actonel® (risedronate tablets)
- Atelvia® (risedronate delayed-release tablets)

- Binosto® (alendronate effervescent tablets)
- Boniva® (ibandronate tablets)
- Fosamax® (alendronate tablets)
- Fosamax® Plus D (alendronate/cholecalciferol tablets)

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried, experienced intolerance, OR has a contraindication to at least one preferred bisphosphonate then authorization for a non-preferred bisphosphonate may be given.

2. Exceptions for Binosto can be made if the patient meets the following criteria (a or b):
    a. The patient has a gastrostomy tube (G-tube); OR
    b. The patient cannot swallow or has difficulty swallowing tablets or capsules.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent

available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Fosamax® tablets and oral solution [prescribing information]. Whitehouse Station, NJ: Merck & Co. Inc.; March 2016.
2. Actonel® tablets [prescribing information]. Irvine, CA: Allergan; January 2018.
3. Atelvia® extended-release tablets [prescribing information]. Rockaway, NJ: Warner Chilcott; April 2015.
4. Boniva® tablets [prescribing information]. South San Francisco, CA: Genentech/Roche; December 2016.
5. Fosamax® Plus D tablets [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2016.
6. Binosto® effervescent tablets for oral solution [prescribing information]. San Antonio, TX: Mission Pharmacal; July 2016.