

## STEP THERAPY POLICY

- POLICY:** Bisphosphonates (Oral) Enhanced Step Therapy Policy
- Actonel® (risedronate tablets – Abbvie [5, 30, 35 mg and 150 mg, generic])
  - Atelvia® (risedronate delayed-release tablets – Abbvie, generic)
  - Binosto® (alendronate effervescent tablets for oral use – Ascend)
  - Boniva® (ibandronate tablets – Genentech/Roche, generic)
  - Fosamax® (alendronate tablets – Organon, generic)
  - Fosamax® Plus D (alendronate/cholecalciferol tablets – Organon)

**REVIEW DATE:** 11/08/2023

---

### OVERVIEW

**Alendronate tablets** are indicated for the following uses:<sup>1</sup>

- Treatment and prevention of **postmenopausal osteoporosis**.
- Treatment of **glucocorticoid-induced osteoporosis** in men and women.
- Treatment of **Paget's disease** in men and women.
- Increase **bone mass** in men with osteoporosis.

**Binosto** and **Fosamax Plus D** tablets are indicated for the following uses:<sup>5,6</sup>

- Treatment of **postmenopausal osteoporosis**.
- Increase **bone mass** in men with osteoporosis.

**Ibandronate tablets** are indicated for the treatment and prevention of **postmenopausal osteoporosis**.<sup>4</sup>

**Risedronate tablets** are indicated for the following uses:<sup>2</sup>

- Treatment and prevention of **postmenopausal osteoporosis**.
- Treatment and prevention of **glucocorticoid-induced osteoporosis** in men and women.
- Treatment of **Paget's disease** in men and women.
- Increase **bone mass** in men with osteoporosis.

**Risedronate delayed-release tablets** are indicated for the treatment of **postmenopausal osteoporosis**.<sup>3</sup>

Alendronate, risedronate, risedronate delayed-release tablets, and ibandronate tablets are orally administered bisphosphonates.<sup>1-4</sup> Fosamax Plus D contains alendronate plus vitamin D<sub>3</sub> in one tablet; both are available as single-entity products.<sup>5</sup> Binosto provides alendronate in a 70 mg effervescent tablet for oral solution.<sup>6</sup> 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.<sup>1</sup>

### POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product, and the use of a Step 2 Product prior to the use of a Step 3 Product. If the Step Therapy rule is not met for the Step 2 Product or the Step 3 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Note: Generic alendronate oral solution (70 mg/75 mL) is not included in this policy.

11/08/2023

© 2023. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

**Automation:** A patient with a history of one Step 1 Product within the 130-day look-back period can receive the Step 2 Product. A patient with a of one Step 1 Product and a Step 2 Product within the 130-day look-back period can receive a Step 3 Product.

**Step 1:** alendronate 5, 10, 35, 40 and 70 mg tablets, ibandronate 150 mg tablets, risedronate 5, 30, 35, and 150 mg tablets, risedronate 35 mg delayed-release tablets

**Step 2:** Atelvia delayed-release tablets

**Step 3:** Actonel tablets, Binosto effervescent tablets, Boniva tablets, Fosamax tablets, Fosamax Plus D tablets

## CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient has tried one Step 1 Product and one Step 2 Product, approve a Step 3 Product.
3. Approve Binosto if the patient meets one the following (A or B):
  - A) Patient has a gastrostomy tube (G-tube); OR
  - B) Patient cannot swallow or has difficulty swallowing tablets or capsules.
4. No other exceptions are recommended.

## REFERENCES

1. Fosamax<sup>®</sup> tablets and oral solution [prescribing information]. Jersey City, NJ: Organon; June 2021.
2. Actonel<sup>®</sup> tablets [prescribing information]. North Chicago, IL: Abbvie; October 2023.
3. Atelvia<sup>®</sup> delayed-release tablets [prescribing information]. North Chicago, IL: Abbvie; October 2023.
4. Boniva<sup>®</sup> tablets [prescribing information]. South San Francisco, CA: Genentech/Roche; April 2020.
5. Fosamax<sup>®</sup> Plus D tablets [prescribing information]. Jersey City, NJ: Organon; August 2021.
6. Binosto<sup>®</sup> effervescent tablets for oral solution [prescribing information]. Herndon, VA: Ascend; October 2020.