

STEP THERAPY POLICY

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

REVIEW DATE: 10/26/2022

OVERVIEW

Alendronate tablets are indicated for the following uses:¹

- 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:^{5,6}

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

Ibandronate tablets are indicated for the treatment and prevention of **postmenopausal osteoporosis**.⁴

Risedronate tablets are indicated for the following uses:²

- 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**.³

Alendronate, risedronate, risedronate delayed-release tablets, and ibandronate tablets are orally administered bisphosphonates.¹⁻⁴ Fosamax Plus D contains alendronate plus vitamin D₃ in one tablet; both are available as single-entity products.⁵ Binosto provides alendronate in a 70 mg effervescent tablet for oral solution.⁶ 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.¹

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of the Step 2 Product, and the use of the Step 2 Product prior to the use of the 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.

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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 the Step 2 Product within the 130-day look-back period can receive the 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 criteria (A or B):
 - A) Patient has a gastrostomy tube (G-tube); OR
 - B) Patient cannot swallow or have difficulty swallowing tablets or capsules.
4. No other exceptions are recommended.

REFERENCES

1. Fosamax[®] tablets and oral solution [prescribing information]. Jersey City, NJ: Organon; June 2021.
2. Actonel[®] tablets [prescribing information]. Irvine, CA: Allergan; November 2019.
3. Atelvia[®] delayed-release tablets [prescribing information]. Madison, NJ: Allergan; August 2020.
4. Boniva[®] tablets [prescribing information]. South San Francisco, CA: Genentech/Roche; April 2020.
5. Fosamax[®] Plus D tablets [prescribing information]. Jersey City, NJ: Organon; August 2021.
6. Binosto[®] effervescent tablets for oral solution [prescribing information]. Herndon, VA: Ascend Therapeutics; October 2020.