# Step Therapy
# Bisphosphonates (Oral) Enhanced

## Table of Contents



## Product Identifier(s)

**Effective 1/1/23 to 3/21/23:** 109528, 111675

**Effective 3/22/23:** 14758, 14760

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## National Formulary Medical Necessity

Drugs Affected

- Actonel® (risedronate tablets – [5, 30, 35 mg and 150 mg, generic])
- Atelvia® (risedronate delayed-release tablets – generic)
- Binosto® (alendronate effervescent tablets for oral use)
- Boniva® (ibandronate tablets – generic)
- Fosamax® (alendronate tablets – generic)
- Fosamax® Plus D (alendronate/cholecalciferol tablets)

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.

**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

**Cigna covers Step 2 and Step 3 agents as medically necessary when the following criteria are met:**

1. If the individual has tried one Step 1 Product, approve a Step 2 Product.

2. If the individual has tried one Step 1 Product and one Step 2 Product , approve a Step 3 Product.

3. Approve Binosto if the individual meets one the following criteria (A or B):
   **A)** Individual has a gastrostomy tube (G-tube); OR
   **B)** Individual cannot swallow or has difficulty swallowing tablets

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

**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 $D_3$ 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]

## 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.


## Revision History

| Type of Revision | Summary of Changes | Approval Date |
|---|---|---|
| Annual Revision | No criteria changes. | 10/26/2022 |