

## Bisphosphonates (Oral)

**Policy # 00364**

Original Effective Date: 10/16/2013

Current Effective Date: 10/01/2026

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.*

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider brand name oral bisphosphonates (including, but not limited to Fosamax<sup>®</sup> [alendronate tablets], Fosamax Plus D<sup>®</sup> [alendronate/cholecalciferol tablets], Actonel<sup>®</sup> [risedronate tablets], Atelvia<sup>®</sup> [risedronate delayed-release tablets], and Binosto<sup>®</sup> [alendronate effervescent tablets])<sup>†</sup> to be **eligible for coverage\*\*** when one of the below patient selection criteria is met:

#### Patient Selection Criteria

Coverage eligibility will be considered for brand name oral bisphosphonates when ONE of the following criteria is met:

- For **ALL brand name oral bisphosphonates**: Patient has tried and failed generic alendronate, ibandronate, or risedronate tablets OR there is clinical evidence or patient history that suggests that the generically available products will be ineffective or cause an adverse reaction to the patient; OR
- For **Binosto**: Patient has a gastrostomy tube OR patient cannot swallow or has difficulty swallowing tablets.

### When Services Are Considered Not Medically Necessary

Based on review on available data, the Company considers the use of brand name oral bisphosphonates when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.\*\***

### Background/Overview

Bisphosphonates are inhibitors of osteoclast-mediated bone resorption. Package insert indications vary depending on the chosen bisphosphonate, but indications include treatment and/or prevention of postmenopausal osteoporosis, treatment of Paget's disease, treatment and/or prevention of glucocorticoid induced osteoporosis, as well as increasing bone mass in men with osteoporosis.

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### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient. This policy also takes into account whether or not the patient has a gastrostomy tube, as well as the patient's ability to swallow a tablet. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand name oral bisphosphonate over the available generic bisphosphonate products. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

### **References**

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### **Policy History**

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|            |                                                                                                                                                                                                              |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/03/2013 | Medical Policy Committee review                                                                                                                                                                              |
| 10/16/2013 | Medical Policy Implementation Committee approval. New Pharmacy step therapy policy.                                                                                                                          |
| 10/02/2014 | Medical Policy Committee review                                                                                                                                                                              |
| 10/15/2014 | Medical Policy Implementation Committee approval. Added risedronate as a generic option in the criteria to get a brand product. Removed mention of Fosamax Oral Solution since it is no longer manufactured. |
| 10/08/2015 | Medical Policy Committee review                                                                                                                                                                              |
| 10/21/2015 | Medical Policy Implementation Committee approval. Removed the exception for Paget's disease since all products are now generically available.                                                                |
| 10/06/2016 | Medical Policy Committee review                                                                                                                                                                              |
| 10/19/2016 | Medical Policy Implementation Committee approval. No change to coverage.                                                                                                                                     |
| 10/05/2017 | Medical Policy Committee review                                                                                                                                                                              |
| 10/18/2017 | Medical Policy Implementation Committee approval. No change to coverage.                                                                                                                                     |
| 10/04/2018 | Medical Policy Committee review                                                                                                                                                                              |
| 10/17/2018 | Medical Policy Implementation Committee approval. No change to coverage.                                                                                                                                     |
| 10/03/2019 | Medical Policy Committee review                                                                                                                                                                              |
| 10/09/2019 | Medical Policy Implementation Committee approval. No change to coverage.                                                                                                                                     |
| 10/01/2020 | Medical Policy Committee review                                                                                                                                                                              |
| 10/07/2020 | Medical Policy Implementation Committee approval. No change to coverage.                                                                                                                                     |
| 10/07/2021 | Medical Policy Committee review                                                                                                                                                                              |
| 10/13/2021 | Medical Policy Implementation Committee approval. No change to coverage.                                                                                                                                     |
| 10/06/2022 | Medical Policy Committee review                                                                                                                                                                              |
| 10/11/2022 | Medical Policy Implementation Committee approval. No change to coverage.                                                                                                                                     |
| 10/05/2023 | Medical Policy Committee review                                                                                                                                                                              |
| 10/11/2023 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.                                                                                                                            |
| 10/03/2024 | Medical Policy Committee review                                                                                                                                                                              |
| 10/08/2024 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.                                                                                                                            |
| 10/02/2025 | Medical Policy Committee review                                                                                                                                                                              |
| 10/08/2025 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.                                                                                                                            |
| 09/09/2026 | Pre Pharmacy & Therapeutics Committee review                                                                                                                                                                 |
| 09/16/2026 | Pharmacy & Therapeutics Committee review approval. Removed discontinued product, Boniva tablets, from the policy. Coverage eligibility of remaining products unchanged.                                      |

Next Scheduled Review Date: 09/2027

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**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

**NOTICE:** If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.