Bisphosphonates (Oral)

Policy # 00364
Original Effective Date: 10/16/2013
Current Effective Date: 10/17/2018

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.

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® [alendronate tablets], Fosamax Plus D® [alendronate/cholecalciferol tablets], Actonel® [risedronate tablets], Atelvia® [risedronate delayed-release tablets], Boniva® [ibandronate tablets], and Binosto® [alendronate effervescent tablets])‡ 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.

Rationale/Source
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

Original Effective Date: 10/16/2013
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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.

Next Scheduled Review Date: 10/2019

**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.

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.