Clinical Policy: Ibandronate Injection (Boniva)

Reference Number: CP.PHAR.189
Effective Date: 11.15.17
Last Review Date: 02.18
Line of Business: Commercial, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ibandronate injection (Boniva®) is a bisphosphonate.

FDA Approved Indication(s)

Boniva is indicated for the treatment of osteoporosis in postmenopausal women.

Limitation of use: The safety and effectiveness of Boniva for the treatment of osteoporosis are based on clinical data of one year duration. The optimal duration of use has not been determined. All patients on bisphosphonate therapy should have the need for continued therapy re-evaluated on a periodic basis. Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use. Patients who discontinue therapy should have their risk for fracture re-evaluated periodically.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Boniva injection is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Osteoporosis (must meet all)**:**

1. Diagnosis of osteoporosis;
2. Member is a postmenopausal female;
3. Failure (decline in bone mineral density [BMD] of ≥ 5% or continued fractures) of a 12 month trial of an oral bisphosphonate (*alendronate is preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 3 mg every 3 months (1 syringe/3 months).

Approval duration:
Medicaid – 6 months
Commercial – Length of benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is

NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Osteoporosis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., decline in BMD < 5%, no new or continued fractures);
3. If request is for a dose increase, new dose does not exceed 3 mg every 3 months (1 syringe/3 months).

Approval duration:
Medicaid – 12 months
Commercial – Length of benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BMD: bone mineral density
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax®)	Osteoporosis 10 mg PO QD or 70 mg PO q week	Osteoporosis 10 mg/day or 70 mg/week Glucocorticoid-induced osteoporosis

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Glucocorticoid-induced osteoporosis 5 mg PO QD or 10 mg PO QD (in postmenopausal women not receiving estrogen) Osteoporosis prophylaxis 5 mg PO QD or 35 mg PO q week	5 mg/day or 10 mg/day (in postmenopausal women not receiving estrogen) Osteoporosis prophylaxis 5 mg/day or 35 mg/week
Fosamax® Plus D (alendronate/ cholecalciferol)	Osteoporosis 70 mg alendronate/2,800 units cholecalciferol or 70 mg alendronate/5,600 units cholecalciferol PO q week	70 mg alendronate/5,600 units cholecalciferol/week
risedronate (Actonel®, Atelvia®)	Osteoporosis (including prophylaxis) 5 mg PO QD or 35 mg PO q week or 75 mg PO QD for 2 consecutive days for 2 doses/month or 150 mg PO q month Glucocorticoid-induced osteoporosis 5 mg PO QD	Osteoporosis (including prophylaxis) 5 mg/day or 35 mg/week or 75 mg/day for 2 days per month or 150 mg/month Glucocorticoid-induced osteoporosis 5 mg/day
ibandronate (Boniva®)	Osteoporosis (including prophylaxis) 150 mg PO q month	150 mg/month

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Osteoporosis	3 mg IV every 3 months	3 mg/3 months

VI. Product Availability

Single-use prefilled syringe: 3 mg/3 mL

VII. References

1. Boniva Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; December 2016. Available at https://www.gene.com/download/pdf/boniva_injection_prescribing.pdf. Accessed November 14, 2017.
2. Cosman F, de Beur SJ, LeBoff MS, et al. Position paper: clinician's guide to prevention and treatment of osteoporosis. Osteoporosis Int. 2014; 25(10): 2359-2381.
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology practice guidelines for the

diagnosis and treatment of postmenopausal osteoporosis – 2016. Endocrin Pract. 2016; 22(Suppl 4).

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.20.Osteoporosis Injection Therapy and converted to new template. Criteria: Added "at femoral neck or spine" to T score. Removed requirement that must be over 50 in cases where the osteoporosis diagnosis relies on history of an osteoporotic fracture. Added definition of bisphosphonate trial failure and, if contraindication/ intolerance, that it be to one of the two oral drugs listed and to Reclast. Calcium/vitamin D requirement language edited to be less specific. Approval period changed to 6 and 12 months.	02.16	03.16
Removed age restriction. Added "at total hip" to T score. Added that osteoporotic fracture should be confirmed by radiographic imaging. Certain conditions representing potential contraindications to therapy and other safety criteria removed. Removed requirement for administration of calcium/vitamin D if dietary intake is inadequate. Added dose to continued therapy. Added requirement for positive response to therapy	03.17	03.17
1Q18 annual review: - Policies combined for commercial and Medicaid - Removed criteria for evidence of diagnosis - Modified trial and failure requirements to a bisphosphonate - Removed requirement regarding admin of last dose of Reclast - Removed hypocalcemia monitoring requirement - Added definition for positive response to therapy - References reviewed and updated.	11.15.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.