Clinical Policy: Ibandronate Sodium (Boniva)

Reference Number: CP.PHAR.189
Effective Date: 03/16
Last Review Date: 03/17

Coding Implications
Revision Log

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for ibandronate sodium (Boniva®) intravenous injection.

Policy/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 postmenopausal osteoporosis evidenced by one of the following (a or b):
   a. T-score ≤ -2.5 [dual energy X-ray absorptiometry (DXA)] at the femoral neck, spine, or total hip;
   b. History of osteoporotic fracture confirmed by radiographic imaging;
2. Failure [decline in bone mineral density (BMD) of ≥ 5% or continued fractures] of both of the following (a and b), each trialed for one year unless contraindicated or clinically significant adverse effects are experienced:
   a. An oral bisphosphonate (e.g., alendronate, risedronate);
   b. Reclast* (zoledronic acid);
3. If member has received Reclast, it has been at least one year since the last administration of Reclast;
4. Recent (within the last 90 days) lab result confirms that member does not have hypocalcemia (serum calcium (Ca) or (albumin-corrected calcium (cCa) level must be within normal limit);
5. Prescribed dose of Boniva injection does not exceed 3 mg (1 syringe) every three months.

**Requires prior authorization*

Approval duration: 6 months (two injections)

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documentation of positive response to therapy;
3. Prescribed dose does not exceed 3 mg (1 syringe) every three months.

Approval duration: 12 months (four injections)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Ibandronate sodium is a nitrogen-containing bisphosphonate that inhibits osteoclast-mediated bone resorption. The action of ibandronate on bone tissue is based on its affinity for hydroxyapatite, which is part of the mineral matrix of bone. Ibandronate inhibits osteoclast activity and reduces bone resorption and turnover. In postmenopausal women, it reduces the elevated rate of bone turnover, leading to, on average, a net gain in bone mass.

Formulations:
Boniva injection is available as a single-use prefilled syringe containing 3 mg/mL solution.

FDA Approved Indication:

Boniva injection is a bisphosphonate/intravenous injectable indicated for:

- Treatment of osteoporosis in postmenopausal women. In postmenopausal women with osteoporosis, Boniva increases BMD and reduces the incidence of vertebral fractures.

Limitations 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.

Appendices

Appendix A: Abbreviation Key

BMD: bone mineral density
DXA: dual energy X-ray absorptiometry
Ca: Calcium
cCa: albumin-corrected calcium

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1740	Injection, ibandronate sodium, 1 mg

Reviews, Revisions, and Approvals	Date	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

References

1. Boniva Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; December 2016. Available at http://www.boniva.com. Accessed February 9, 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).

Important Reminder

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.