Clinical Policy: Oral Bisphosphonates
Reference Number: HIM.PA.51
Effective Date: 12/14
Last Review Date: 08/17 Revision Log
Line of Business: Health Insurance Marketplace

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

Description
The following are oral bisphosphonates requiring prior authorization: alendronate/cholecalciferol (Fosamax® Plus D), risedronate (Actonel®, Atelvia®).

FDA approved indication
Fosamax Plus D is indicated:
- For the treatment of osteoporosis in postmenopausal women
- For the treatment to increase bone mass in men with osteoporosis

Limitation of use: Fosamax Plus D alone should not be used to treat vitamin D deficiency. The optimal duration of use has not been determined. The safety and effectiveness of Fosamax Plus D for the treatment of osteoporosis are based on clinical data of four years duration. 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.

Actonel is indicated:
- For the treatment and prevention of postmenopausal osteoporosis
- For the treatment to increase bone mass in men with osteoporosis
- For the treatment and prevention of glucocorticoid-induced osteoporosis
- For the treatment of Paget's disease

Limitation of use: The optimal duration of use has not been determined. Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use.

Atelvia is indicated:
- For the treatment of postmenopausal osteoporosis

Limitation of use: The optimal duration of use has not been determined. Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria
A. Osteoporosis (must meet all)**:**
1. Diagnosis of osteoporosis or prophylaxis of osteoporosis;
2. Age ≥ 18 years;
3. Member meets one of the following (a or b):

a. Failure of alendronate as evidenced by a documented history of fracture while on therapy;
b. Failure of ≥ 12 month trial of alendronate at up to maximally indicated doses as evidenced by a lack of improvement in baseline bone mineral density, unless contraindicated or clinically significant adverse effects are experienced;

4. Concurrent use of calcium and vitamin D;
5. Dose does not exceed the following (a, b, or c):
   a. Fosamax Plus D: 70 mg/week;
   b. Actonel: 5 mg/day, 150 mg/month, 35 mg/week;
   c. Atelvia: 35 mg/week.

Approval duration: 12 months

B. Paget's Disease (must meet all)**:**

1. Diagnosis of Paget's disease;
2. Age ≥ 18 years;
3. Failure of ≥ 6 month trial of alendronate at up to maximally indicated doses as evidenced by the inability to achieve normal serum alkaline phosphate levels, unless contraindicated or clinically significant adverse effects are experienced;
4. Concurrent use of calcium and vitamin D;
5. Request is for Actonel;
6. Dose does not exceed 30 mg/day (1 tablet/day).

Approval duration: 2 months

C. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed the following (a, b, or c):
   a. Fosamax Plus D: 70 mg/week;
   b. Actonel: 5 mg/day, 150 mg/month, 35 mg/week;
   c. Atelvia: 35 mg/week.

Approval duration: 12 months

B. Paget's Disease (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member has evidence of relapse (increase in bone turnover) or failure to normalize serum alkaline phosphate;
3. Member has had a medication-free period of 60 days;
4. If request is for a dose increase, new dose does not exceed 30 mg/day (1 tablet/day).

Approval duration: 2 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 policy – HIM.PA.21.## or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration

V. References

1. Actonel® drug monograph. Clinical Pharmacology. Accessed May 2016. http://clinicalpharmacology-ip.com
2. Fosamax Plus D®. Clinical Pharmacology. Accessed May 2016. http://clinicalpharmacology-ip.com
3. AACE Osteoporosis Guidelines – American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice For the Prevention and Treatment of Postmenopausal Osteoporosis. Endocrine Practice Vol. 16 (supplement) November/December 2010. Accessed May 2016 https://www.aace.com/files/osteo-guidelines-2010.pdf
4. Fosamax Plus D Prescribing Information. Whitehouse Station, NJ: Merck & Co.,Inc; November 2015. Available at accessdata.fda.gov. Accessed April 13, 2017.
5. Actonel Prescribing Information. Manati, Puerto Rico: Warner Chilcott Company, LLC: April 2015. Available at accessdata.fda.gov. Accessed April 13, 2017.
6. Atelvia Prescribing Information. North Norwich, NY; Norwich Pharmaceuticals, Inc: April 2015. Available at accessdata.fda.gov. Accessed April 13, 2017.
7. Camacho PM, Petak SM, Brinkley N et al. AACE/ACE Guidelines- American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocrine Practice Vol 22 (suppl 4) September 2016.
8. Singer FR, Bone HG, Hosking DJ et al. Paget's disease of bone: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014 Dec;99(12):4408-22. doi: 10.1210/jc.2014-2910.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guideline to new format.	08/16	08/16
Converted to new template	04/17	08/17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Osteoporosis: removed requirement for alendronate plus vitamin D, member must be unable to take alendronate and vitamin D as 2 separate tablets. If this is the medication prescribed, the member should be able to receive it if all other criteria are met. Paget's disease continued therapy: added that member has had a medication-free period of 60 days per Actonel PI. Added member has evidence of relapse or failure to normalize serum alkaline phosphate per PI. Paget's disease changed approval duration to 2 months per Actonel PI.		

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.