Clinical Policy: Risedronate (Actonel, Atelvia)

Reference Number: CP.PMN.100
Effective Date: 03.01.18
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

Risedronate IR (Actonel®) and risedronate DR (Atelvia®) are oral bisphosphonates.

FDA Approved Indication(s)

Actonel is indicated for:

- Postmenopausal osteoporosis (PMO): Treatment and prevention of osteoporosis in postmenopausal women.
- Glucocorticoid-induced osteoporosis (GIO): Treatment and prevention of GIO.
- Male osteoporosis: Treatment to increase bone mass in men with osteoporosis.
- Paget disease: Treatment of Paget's disease of bone.

Atelvia is indicated for:

- PMO: Treatment of osteoporosis in postmenopausal women.

Limitation of use: The optimal duration of use for bisphosphonates has not been determined. The safety and effectiveness of bisphosphonates for the treatment of osteoporosis are based on clinical data of one to 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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

I. Initial Approval Criteria

A. Osteoporosis (must meet all):

1. Prescribed for one of the following (a or b):
   a. Treatment or prevention of PMO or GIO;
   b. Treatment of male osteoporosis;
2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
3. Failure of a 12-month trial of alendronate at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Request meets one of the following (a or b):
   a. Actonel: Dose does not exceed 5 mg (1 tablet) per day;

b. Atelvia *(PMO treatment only)*: Dose does not exceed 35 mg (1 tablet) per week.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Paget's Disease (must meet all):
1. Request is for Actonel;
2. Diagnosis of Paget's disease of the bone;
3. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
4. Failure of ≥ 6-month trial of alendronate at maximumally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 30 mg (1 tablet) per day.

Approval duration: 2 months

C. 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;
3. If request is for a dose increase, new dose does not exceed (a or b):
   a. Actonel: 5 mg (1 tablet) per day;
   b. Atelvia *(PMO treatment only)*: 35 mg (1 tablet) per week.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Paget's Disease (must meet all)**:**
1. Currently receiving Actonel via Centene benefit or member has previously met initial approval criteria;
2. Two months have elapsed since the completion of previous therapy with Actonel;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 30 mg (1 tablet) per day.

Approval duration: 2 months

C. 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 12 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 or evidence of coverage documents.

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 minderal density
FDA: Food and Drug Administration
GIO: glucocorticoid-induced osteoporosis
PMO: postmenopausal osteoporosis

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax®)	• Treatment: PMO, male osteoporosis 10 mg PO QD or 70 mg PO once weekly • Treatment: GIO 5 mg PO QD or 10 mg PO QD in postmenopausal women not receiving estrogen • Prevention: PMO 5 mg PO QD or 35 mg PO once weekly • Paget's disease: 40 mg PO QD for 6 months	40 mg/day 70 mg/week

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.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): abnormalities of the esophagus which delay esophageal emtyping such as stricture or achalasia; inability to stand/sit upright for at least 30 minutes; hypocalcemia; hypersensitivity
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Risedronate (Actonel)	PMO treatment and prevention	5 mg PO QD or 35 mg PO once weekly or 75 mg PO QD taken on two consecutive days each month or150 mg PO once monthly	5 mg/day 35 mg/week 150 mg/month

Drug Name	Indication	Dosing Regimen	Maximum Dose
	Male osteoporosis treatment	35 mg PO once weekly	35 mg/week
	GIO treatment and prevention	5 mg PO QD	5 mg/day
	Paget disease	30 mg PO QD for 2 months	30 mg QD not to exceed 2 months
Risedronate (Atelvia)	PMO treatment	35 mg PO once weekly	35 mg/week

VI.

VI. Product Availability

Drug Name	Availability
Risedronate (Actonel)	Tablets: 5mg, 30 mg, 35 mg, 75 mg, 150 mg
Risedronate (Atelvia)	Delayed-release tablet: 35 mg

VII. References

1. Actonel Prescribing Information. Rockaway, NJ: Warner Chilcott, LLC; January 2018. Available at: https://www.actonel.com. Accessed October 22, 2019.
2. Atelvia Prescribing Information. Rockaway, NJ: Warner Chilcott, LLC; April 2015. Available at: dailymed.nlm.nih,.gov. Accessed November 5, 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. URL: http://www.clinicalpharmacology.com.

Osteoporosis Diagnosis, Fracture Risk, and Treatment

4. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab; 2019, 104: 1595–1622.
5. 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.
6. National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: http://nof.org/files/nof/public/content/file/2791/upload/919.pdf. Accessed October 31, 2018.
7. Siris ES, Adler R, Bilezikian J, et al. The clinical diagnosis of osteoporosis: a position statement from the National Bone Health Alliance Working Group. Osteoporos Int (2014) 25:1439–1443. DOI 10.1007/s00198-014-2655-z.
8. Hodsman AB, Bauder DC, Dempster DW, et al. Parathyroid hormone and teriparatide for the treatment of osteoporosis: a review of the evidence and suggested guidelines for its use. Endocr Rev. 2005 Aug;26(5):688-703. Epub 2005 Mar 15.

Male Osteoporosis

9. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guidelines. J Clin Endocrinol Metab 2012;97(6):1802-1822.

Glucocorticoid-Induced Osteoporosis

10. Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis Rheumatol. 2017; 69(8): 1521-1537.

Paget Disease
11. Singer FR, Bone HG, Hosking DJ, et al. Paget's disease of the bone: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99(12): 4480-4422.
12. Singer FR, Bone HG, Hosking DJ, et al. Paget's disease of the bone: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99(12): 4480-4422.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created Policy split from existing oral bisphosphonate policy for all lines for business - no significant change from previous corporate approved policy. Combined policy for Medicaid, market place and commercial lines of business. References reviewed and updated.	12.01.17	02.18
1Q 2019 annual review: Paget's disease – removed alkaline phosphate requirement, to align with other oral bisphosphonates, modified continuation of therapy requirement to state "Disease has relapsed or progressed (e.g., increases in or failure to achieve normalization of serum ALP, radiographic progression of disease)"; references reviewed and updated.	11.05.18	02.19
1Q 2020 annual review: removed HIM disclaimer for HIM NF drugs; osteoporosis: closed epiphyses added if less than 18 yo; alendronate trial changed to 12-month trial; Paget disease: age added, continuation of therapy requirements removed for individualization of therapy; references reviewed and updated.	11.19.19	02.20

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.