

Clinical Policy: Risedronate (Actonel, Atelvia)

Reference Number: CP.PMN.100

Effective Date: 03.01.18

Last Review Date: 02.19

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:

- Treatment and prevention of osteoporosis in postmenopausal women
- Treatment and prevention of glucocorticoid-induced osteoporosis
- Treatment to increase bone mass in men with osteoporosis
- Treatment of Paget's disease (PD)

Atelvia is indicated for the 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 the prevention or treatment of osteoporosis;
2. Age \geq 18 years;
3. Failure of alendronate at up to maximum indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed:
 - a. Actonel: 5 mg per day (1 tablet per day);
 - b. Atelvia: 35 mg per week (1 tablet per week).

Approval duration:

Medicaid/HIM – 12 months

Commercial – Length of Benefit

B. Paget’s Disease (must meet all):

1. Diagnosis of Paget’s disease;
2. Request is for Actonel;
3. Age \geq 18 years;
4. Failure of \geq 6 month trial of alendronate at maximum indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 30 mg per day (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. Actonel: 5 mg per day (1 tablet per day);
 - b. Atelvia: 35 mg per week (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 has elapsed since the completion of previous therapy with Actonel;
3. Disease has relapsed or progressed (e.g., increases in or failure to achieve normalization of serum ALP, radiographic progression of disease);
4. If request is for a dose increase, new dose does not exceed 30 mg per day (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

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 or 150 mg PO once monthly	5 mg/day 35 mg/week 150 mg/month
	MO	35 mg PO once weekly	35 mg/week
	GIO treatment and prevention	5 mg PO QD	5 mg/day
	PD	30 mg PO QD for 2 months	30 mg QD not to exceed 2 months
Risedronate (Atelvia)	PMO	35 mg PO once weekly	35 mg/week

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 November 5, 2018.
2. Atelvia Prescribing Information. Rockaway, NJ: Warner Chilcott, LLC; March 2015. Available at: <https://www.atelvia.com>. Accessed November 5, 2018.
3. National Osteoporosis Foundation-The Clinician’s Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: <https://cdn.nof.org/wp-content/uploads/2016/01/995.pdf> . Accessed November 5, 2018.
4. The North American Menopause Society. Management of postmenopausal osteoporosis: 2010 position statement of the North American Menopause Society. Menopause 2010; 7(1):22-54.
5. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract 2010; 16 (Suppl 3):1-37.
6. Grossman JM, Gordon R, Ranganath VK, et al. American College of Rheumatology 2010 recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis Care Res 2010; 62 (11):1515-1526.
7. American College of Physicians. Treatment of low bone density or osteoporosis to prevent fractures in men and women: a clinical practice guideline update from the American College of Physicians. Ann intern Med. 2017; 166: 818-839.
8. 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.

9. 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

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.

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