

Clinical Policy: Risedronate (Actonel, Atelvia)

Reference Number: CP.PMN.100

Effective Date: 03.01.18

Last Review Date: 02.18

Line of Business: Commercial, Health Insurance Marketplace, 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 requiring prior authorization.

FDA Approved Indication(s)

Actonel is indicated:

- For the treatment and prevention of osteoporosis in postmenopausal women
- For the treatment and prevention of glucocorticoid-induced osteoporosis
- For the treatment to increase bone mass in men with osteoporosis
- For the 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 (including 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 diagnosis 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 30 mg/day (1 tablet/day);
 - b. Atelvia 35 mg/week (1 tablet/week).

Approval duration:

Medicaid/Health Insurance Marketplace - 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. Current (within the last 30 days) lab shows elevated (outside the upper limit of normal) serum alkaline phosphatase;
6. Dose does not exceed 30 mg/day (1 tablet/day).

Approval duration: 2 months

A. 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):

2. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed:
 - a. Actonel 30 mg/day (1 tablet/day);
 - b. Atelvia 35 mg/week (1 tablet/week).

Approval duration:

Medicaid/Health Insurance Marketplace - 12 months
Commercial - Length of Benefit

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

1. Previously received 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. Current (within the last 30 days) lab shows elevated (outside the upper limit of normal) serum alkaline phosphatase;
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 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.

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

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|--|----------------------------------|
| DR: delayed-release | MO: male osteoporosis |
| FDA: Food and Drug Administration | PD: Paget’s disease |
| GIO: glucocorticoid-induced osteoporosis | PMO: postmenopausal osteoporosis |
| IR: immediate-release | |

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	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax [®])	PMO/MO treatment: 10 mg PO QD or 70 mg PO once weekly PMO Prevention: 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.

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	Availability
Risedronate (Actonel)	5mg, 30 mg, 35 mg, 75 mg, 150 mg
Risedronate (Atelvia)	35 mg

VII. References

1. Actonel Prescribing Information. Rockaway, NJ: Warner Chilcott, LLC; March 2015. Available at: <https://www.actonel.com>. Accessed December 1, 2017.
2. Atelvia Prescribing Information. Rockaway, NJ: Warner Chilcott, LLC; March 2015. Available at: <https://www.atelvia.com>. Accessed December 1, 2017.
3. National Osteoporosis Foundation-The Clinician`s Guide to Prevention and Treatment of Osteoporosis. Available at: <https://cdn.nof.org/wp-content/uploads/2016/01/995.pdf> . Accessed December 1, 2017.
4. The North American Menopause Society. Management of postmenopausal osteoporosis: 2010 position statement of the North American Menopause Society. Menopause 2010; 17(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.

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

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.

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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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