Clinical Policy: Risedronate (Actonel, Atelvia)

Reference Number: PA.CP.PMN.100
Effective Date: 03.01.18
Last Review Date: 01.19

Revision Log

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 (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness 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 ≥ 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: 12 months

B. Paget's Disease (must meet all):
1. Diagnosis of Paget's disease;

2. Request is for Actonel;
3. Age ≥ 18 years;
4. Failure of ≥ 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 PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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: 12 months

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

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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 PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;**Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to PA.CP.PMN.53.

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 – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DR: delayed-release
FDA: Food and Drug Administration
GIO: glucocorticoid-induced osteoporosis
IR: immediate-release
MO: male osteoporosis
PD: Paget's disease
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	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.

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 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)	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
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.	01/19	