Clinical Policy Title:	risedronate
Policy Number:	RxA.5
Drug(s) Applied:	Actonel® and Atelvia®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
risedronate (Actonel®)	treatment and prevention of postmenopausal osteoporosis	5 mg PO once daily or 35 mg PO once weekly or 75 mg PO ONCE DAILY taken on two consecutive days each month or150 mg PO once monthly	5 mg/day 35 mg/week 150 mg/month
	Male osteoporosis	35 mg PO once weekly	35 mg/week
	treatment and prevention of glucocorticoid induced osteoporosis	5 mg PO once daily	5 mg/day
	Paget's Disease	30 mg PO once daily for 2 months	30 mg once daily not to exceed 2 months
risedronate (Atelvia®)	PMO	35 mg PO once weekly	35 mg/week

Dosage Forms

- risedronate IR (Actonel®): Tablets: 5mg, 30 mg, 35 mg, 75 mg, 150 mg
- risedronate DR (Atelvia®): Delayed-release tablet: 35 mg

Clinical Policy

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

I. Initial Approval Criteria

A. Osteoporosis (must meet all):

1. Prescribed for the prevention or treatment of osteoporosis;
   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 12-month trial of alendronate at up to maximum indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed (a or b):
   a. Actonel®: 5 mg per day;
   b. Atelvia® (PMO only): 35 mg per week (1 tablet per week).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

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

1. Diagnosis of Paget's disease;
2. Request is for Actonel®;
3. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
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.

Approval Duration
Commercial: 2 months
Medicaid: 2 months

II. Continued Therapy Approval

A. Osteoporosis (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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 per day;
   b. Atelvia® (PMO only): 35 mg per week (1 tablet per week).

Approval Duration
Commercial: 12 months

Medicaid: 12 months

B. Paget's Disease (must meet all):
1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Two months has 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 per day.

Approval Duration
Commercial: 2 months
Medicaid: 2 months

III. Appendices

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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements

Drug Name	Dosing Regimen	Maximum Dose
alendronate (Fosamax®)	PMO/MO treatment: 10 mg PO once daily or 70 mg PO once weekly PMO prevention: 5 mg PO once daily or 35 mg PO once weekly Paget's disease: 40 mg PO once daily 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.

APPENDIX D: General Information
Not applicable

References

1. Actonel® Prescribing Information. Rockaway, NJ: Warner Chilcott, LLC; November 2019. Available at: https://www.actonel.com. Accessed January 28, 2021.
2. Atelvia® Prescribing Information. Rockaway, NJ: Warner Chilcott, LLC; August 2020. Available at: https://www.atelvia.com. Accessed January 28, 2021.
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 January 28, 2021.
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.
10. 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.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
2Q2020 P&T Review; Updates, references reviewed and updated - osteoporosis: closed epiphyses added if less than 18 yo; alendronate trial changed to 12-month trial; - Paget disease: closed epiphyses added if less than 18 yo, - continuation of therapy requirements removed for	4/2020	05/20/2020

individualization of therapy		
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business 3. Initial criteria IA.1 was updated by adding a. and b. 4. Initial criteria IA.4b was updated by including PMO 5. Continued therapy IIA.3b was updated by including PMO 6. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 7. Deleted HIM approval duration. 8. Appendix B standard verbiage has been changed and updated. 9. Reference was updated.	1/28/2021	03/09/2021