Clinical Policy Title:	risedronate
Policy Number:	RxA.005
Drug(s) Applied:	Atelvia®
Original Policy Date:	02/07/2020
Last Review Date:	01/17/2022
Line of Business Policy Applies to:	All lines of business

Background

Risedronate DR (Atelvia®) is an oral bisphosphonates and 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 DR (Atelvia®)	PMO	35 mg orally once weekly	35 mg/week

Dosage Forms

- 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Osteoporosis (must meet all):

1. Prescribed for the treatment of osteoporosis in post-menopausal women;
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 35 mg per week (1 tablet per week).

Approval Duration

Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Osteoporosis (must meet all):

1. Member is 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 35 mg per week (1 tablet per week).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
DR: delayed release
FDA: Food and Drug Administration
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 orally once daily or 70 mg orally once weekly PMO prevention: 5 mg orally once daily or 35 mg orally once weekly Paget's disease: 40 mg orally once daily for 6 months	40 mg/day 70 mg/week

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia;
  - Inability to stand/sit upright for at least 30 minutes;
  - Hypocalcemia;
  - Hypersensitivity.

- Boxed Warning(s):
  - None reported.

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

APPENDIX D: General Information
Not applicable.

References

1. Atelvia® Prescribing Information. Madison, NJ: Allergan USA, Inc; August 2020. Available at: https://www.atelvia.com. Accessed November 18, 2021.
2. 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 18, 2021.
3. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/21224201/. Accessed November 18, 2021.
4. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/20662044/. Accessed November 18, 2021.
5. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/28492856/. Accessed November 18, 2021.
6. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/25406796/. Accessed November 18, 2021.
7. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/30907953/. Accessed November 18, 2021.

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 1. Osteoporosis: closed epiphyses added if less than 18 yo; alendronate trial changed to 12-month trial; 2. Paget disease: closed epiphyses added if less than 18 yo, 3. Continuation of therapy requirements removed for individualization of therapy	4/2020	05/20/2020
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	1/28/2021	03/09/2021

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.		
Policy was reviewed: 1. Drugs Applied, Back ground, Dosing Information ,Dosage Forms, Clinical Policy, Appendix A , was update to remove information about Actonel® as it no longer requires PA. 2. Dosage Forms: Updated to remove discontinued dosage form, 30 mg, 75 mg. 3. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 4. Continued Therapy Approval Criteria II.A.1 and II.B.1 were rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. Appendix B: Updated: Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 6. Disclaimer about	11/18/2021	01/17/2022

contraindications," Contraindications listed reflect statements made in the manufacturer's package insert.." was added to Appendix C. 7. References were reviewed and updated.		