Clinical Policy Title:	abaloparatide
Policy Number:	RxA.531
Drug(s) Applied:	Tymlos®
Original Policy Date:	03/06/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Abaloparatide (Tymlos®) is a human parathyroid hormone (PTH)-related peptide analog. It is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos® reduces the risk of vertebral fractures and nonvertebral fractures.

Limitation(s) of use: Because of the unknown relevance of rodent osteosarcoma findings to humans, cumulative use of Tymlos® and PTH analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
abaloparatide (Tymlos®)	Postmenopausal women with osteoporosis at high risk for fracture	80 mcg SC once daily	80 mcg/day for up to 2 years cumulative use of PTH analogs per lifetime

Dosage Forms

- Single-patient-use prefilled pen: 3120 mcg/1.56 mL (30 daily doses of 80 mcg)

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. Diagnosis of osteoporosis;
2. Age ≥ 18 years or documentation of closed epiphyses (e.g., x-ray);
3. Member is a postmenopausal female;
4. Member meets one of the following (a or b):
   a. Prescribed by or in consultation with one of the following specialists: gynecologist, endocrinologist, rheumatologist, geriatrician, orthopaedist, or physiatrist;

b. Failure of a 12-month trial of a bisphosphonate (*alendronate is preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

5. Member has not received cumulative therapy on PTH analogs (e.g., Tymlos®, Forteo) that exceeds 2 years;
6. Dose does not exceed 80 mcg per day (1 pen every 30 days).

Approval Duration
Commercial: 6 months (limited to 2 years cumulative use of PTH analogs per lifetime)
Medicaid: 6 months (limited to 2 years cumulative use of PTH analogs per lifetime)

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;
2. Member is responding positively to therapy;
3. Member has not received cumulative therapy on PTH analogs (e.g., Tymlos®, Forteo) that exceeds 2 years;
4. If request is for a dose increase, dose does not exceed 80 mcg per day (1 pen every 30 days).

Approval Duration
Commercial: 6 months (limited to 2 years cumulative use of PTH analogs per lifetime)
Medicaid: 6 months (limited to 2 years cumulative use of PTH analogs per lifetime)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
BMD: Bone mineral density
FDA: Food and Drug Administration
PTH: Parathyroid hormone

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®)	Osteoporosis 10 mg PO once daily or 70 mg PO q week Glucocorticoid-induced osteoporosis 5 mg PO once daily or 10 mg PO once daily (in postmenopausal women not receiving estrogen) Osteoporosis prophylaxis 5 mg PO once daily or 35 mg PO q week	Osteoporosis 10 mg/day or 70 mg/week Glucocorticoid-induced osteoporosis 5 mg/day or 10 mg/day (in postmenopausal women not receiving estrogen) Osteoporosis prophylaxis 5 mg/day or 35 mg/week

Drug Name	Dosing Regimen	Maximum Dose
(alendronate/cholecalciferol) Fosamax® Plus D	Osteoporosis 70 mg alendronate/2,800 units cholecalciferol or 70 mg alendronate/5,600 units cholecalciferol PO q week	Osteoporosis 70 mg alendronate/5,600 units cholecalciferol/week
risedronate (Actonel®, Atelvia®)	Osteoporosis (including prophylaxis) 5 mg PO once daily or 35 mg PO q week or 75 mg PO once daily for 2 consecutive days for 2 doses/month or 150 mg PO q month Glucocorticoid-induced osteoporosis 5 mg PO once daily	Osteoporosis (including prophylaxis) 5 mg/day or 35 mg/week or 75 mg/day for 2 days per month or 150 mg/month Glucocorticoid-induced osteoporosis 5 mg/day
zoledronic acid (Reclast®)	Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid- induced osteoporosis 5 mg IV q year Postmenopausal osteoporosis prophylaxis 5 mg IV q 2 years	Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid-induced osteoporosis 5 mg/year Postmenopausal osteoporosis prophylaxis 5 mg/2 years
ibandronate (Boniva®)	Postmenopausal osteoporosis 150 mg PO q month or 3 mg IV every 3 months Postmenopausal osteoporosis prophylaxis 150 mg PO q month	150 mg/month or 3 mg/3 months

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity included anaphylaxis, dyspnea and urticaria

- Boxed Warning(s):

- risk of osteosarcoma

APPENDIX D: General Information

The World Health Organization uses the following classifications for osteoporosis and osteopenia:

Category	T-score
Normal	-1.0 or above
Low bone mass (osteopenia)	Between -1.0 and -2.5
Osteoporosis	-2.5 or below

References

1. Tymlos® Prescribing Information. Waltham, MA: Radius Health, Inc. October 2020. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=712143d9-e21e-4013-bb3b-3426a21060a8. Accessed Feb 04, 2021.
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3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/. Accessed Feb 04, 2021.
4. National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2015. Available at: https://my.nof.org/bone- source/education/clinicians-guide-to-the-prevention-and-treatment-of-osteoporosis. Accessed Feb 04, 2021.
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. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guidelines. J Clin Endocrinol Metab 2012;97(6):1802-1822.
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.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.
8. Richard Eastell, Clifford J Rosen, Dennis M Black, Angela M Cheung, M Hassan Murad, Dolores Shoback, Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
1. Policy was reviewed: rephrased Continued Therapy criteria A.1. to "currently receiving medication that has been authorized by RxAdvance benefit". 2. References were reviewed and updated	05/2020	05/21/2020
1. Policy title table was updated: Line of	02/04/2021	03/09/2021

business policy applies was updated to All lines of business. 2. Appendix B standard verbiage has been changed and updated. 3. Appendix C: Contraindications was updated. 4. References were reviewed and updated.		