Clinical Policy: Abaloparatide (Tymlos)

Reference Number: ERX.SPA.152
Effective Date: 09.01.17
Last Review Date: 02.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Abaloparatide (Tymlos®) is a human parathyroid hormone (PTH)-related peptide analog.

FDA Approved Indication(s)
Tymlos is indicated:

- Postmenopausal osteoporosis (PMO): For the treatment of postmenopausal women with osteoporosis at high risk for fracture.* In postmenopausal women with osteoporosis, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures.

**High risk of fracture is 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.*

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.

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Tymlos is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of PMO and (a or b):
   a. Member is at very high risk for fracture (i or ii):
      i. BMD T-score at hip or spine ≤ -3.5;
      ii. BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus);
   b. Member has completed a 3-year trial of bisphosphonate therapy *(alendronate is preferred)* at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced to both IV and PO formulations (*see Appendices B and D*);
      **Prior authorization may be required for bisphosphonates*
2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
3. Member has not received ≥ 2 years cumulative PTH analog therapy (e.g., Forteo®, Tymlos);
4. Dose does not exceed 80 mcg per day (1 pen every 30 days).

Approval duration: 6 months (2 years cumulative PTH analog use lifetime)

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member has not received ≥ 2 years cumulative PTH analog therapy (e.g., Forteo, Tymlos);
4. If request is for a dose increase, dose does not exceed 80 mcg per day (1 pen every 30 days).

Approval duration: 12 months (2 years cumulative PTH analog use lifetime)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMD: bone mineral density
FDA: Food and Drug Administration
PMO: postmenopausal osteoporosis
PTH: parathyroid hormone

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit Maximum Dose
IV bisphosphonates		
ibandronate (Boniva®)	Treatment: PMO *See prescribing information for dose.*	Varies
zoledronic acid (Reclast®)	Teatment/prevention: PMO, GIO Treatment: male osteoporosis Treatment: Paget disease *See prescribing information for dose.*	
Oral bisphosphonates		
alendronate (Fosamax®)	Treatment/prevention: PMO Treatment: GIO, male osteoporosis Treatment: Paget disease *See prescribing information for dose.*	Varies
Fosamax® Plus D (alendronate / cholecalciferol)	Treatment: PMO, male osteoporosis *See prescribing information for dose.*	
risedronate (Actonel®, Atelvia®)	Actonel: Treatment/prevention: PMO, GIO Treatment: male osteoporosis Treatment: Paget disease Atelvia: Treatment: PMO *See prescribing information for dose.*	

Drug Name	Dosing Regimen	Dose Limit Maximum Dose
ibandronate (Boniva)	Treatment/prevention: PMO *See prescribing information for dose.*	

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): none reported
- Boxed warning(s): risk of osteosarcoma

Appendix D: IV/PO Bisphosphonates: Examples of Contraindications and Adverse Effects

Bisphosphonates	Oral Formulations	IV Formulations
Contraindications		
Hypocalcemia	X	X
Increased risk of aspiration	X	-
Hypersensitivity to product component	X	X
Inability to stand/sit upright for at least 30 minutes	X	-
Creatinine clearance < 35 mL/min or evidence of acute renal impairment	-	X
Esophagus abnormalities which delay emptying such as stricture or achalasia	X	-
Clinically significant warnings or adverse side effects		
Pregnancy	X	X
Eye inflammation	X	X
Acute renal failure	X	X
Osteonecrosis of the jaw	X	X
Atypical femoral shaft fracture	X	X
Drug interactions (product-specific)	X	X
Severe or incapacitating musculoskeletal pain	X	X

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PMO	80 mcg SC QD	80 mcg/day up to 2 years cumulative PTH analog use lifetime

VI. Product Availability

Single-patient-use prefilled pen: 3,120 mcg/1.56 mL (30 daily doses of 80 mcg)

VII. References

1. Tymlos Prescribing Information. Waltham, MA: Radius Health, Inc. October 2018. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208743s003lbl.pdf. Accessed October 14, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/.

Osteoporosis Diagnosis, Fracture Risk, and Treatment

3. Shoback D, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an endocrine society guideline update. J Clin Endocrinol Metab; March 2020, 105(3): 587-594.
4. 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.
5. 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.
6. National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: http://nof.org/files/nof/public/content/file/2791/upload/919.pdf. Accessed October 31, 2018.
7. Siris ES, Adler R, Bilezikian J, et al. The clinical diagnosis of osteoporosis: a position statement from the National Bone Health Alliance Working Group. Osteoporos Int (2014) 25:1439–1443. DOI 10.1007/s00198-014-2655-z.
8. Hodsman AB, Bauder DC, Dempster DW, et al. Parathyroid hormone and teriparatide for the treatment of osteoporosis: a review of the evidence and suggested guidelines for its use. Endocr Rev. 2005 Aug;26(5):688-703. Epub 2005 Mar 15.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.17	08.17
1Q18 annual review: Converted to new template. Added complete FDA approved indication and limitation of use. Removed requirements for evidence of diagnosis (T-score, history of fracture). Age requirement modified to include pediatric members with closed epiphyses. Modified criteria to add specialist requirement or trial and failure agent to a bisphosphonate (alendronate is preferred). Removed definition of treatment failure. Removed requirements regarding admin of last doses of Reclast and injectable ibandronate. Shortened approval duration for continuation treatment under other diagnoses/indications to 6 months per specialty drugs. Added Appendix C: General Information section. Updated Therapeutic Alternatives section.	11.10.17	02.18
1Q 2019 annual review: no significant changes; added geriatrician prescriber option; revised continued therapy approval duration to 12 months; references reviewed and updated.	10.31.18	02.19
1Q 2020 annual review: very high fracture risk or 3-year bisphosphonate trial added with required contraindication to both PO/IV formulations; specialists removed; age 18 or closed epiphyses added per PI; references reviewed and updated.	11.19.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.26.20	02.21

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..

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.