Clinical Policy: Abaloparatide (Tymlos)

Reference Number: IL.PHAR.345
Effective Date: 07.17
Last Review Date: 8.8.23
Line of Business: 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.
- Male osteoporosis: To increase bone density in men with osteoporosis at high risk for fracture* or patients who have failed or are intolerant to other available osteoporosis therapy.

**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.

It is the policy of health plans affiliated with Centene Corporation® that Tymlos is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of PMO or male osteoporosis and (a or b):
   a. Member is at very high risk for fracture as evidenced by one of the following (i, ii, or iii):
      - i. Recent osteoporotic fracture (within the past 12 months);
      - ii. Bone mineral density (BMD) T-score at hip or spine ≤ -3.0;

      iii. 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 (see Appendix B; alendronate is preferred) at up to maximally indicated doses, unless one of the following (i-v):
   i. All bisphosphonates are contraindicated;
   ii. Clinically significant adverse effects are experienced to both IV and PO formulations (see Appendix D)
   iii. Member has experienced a loss of BMD while receiving bisphosphonate therapy;
   iv. Member has experienced a lack of BMD increase after ≥ 12 months of bisphosphonate therapy;
   v. Member experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy*

**Prior authorization may be required for bisphosphonates*

2. Age ≥ 18 years or documentation of closed epiphyses (e.g., x-ray);
3. Member has not received ≥ 2 years cumulative abaloparatide therapy;
4. Dose does not exceed 80 mcg per day (1 pen every 30 days).

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

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
1. Member is responding positively to therapy;
2. Member has not received ≥ 2 years cumulative abaloparatide therapy;
3. 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 abaloparatide use lifetime)

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMD: bone mineral density
FDA: Food and Drug Administration
PTH: parathyroid hormone
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 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®)	Treatment/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:	

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Treatment/prevention: PMO, GIO Treatment: male osteoporosis Treatment: Paget disease Atelvia: Treatment: PMO *See prescribing information for dose.*	
ibandronate (Boniva®)	Treatment/prevention: PMO *See prescribing information for dose.*	

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to Tymlos
- Boxed warning(s): none reported

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, male osteoporosis	80 mcg SC QD	80 mcg/day up to 2 years cumulative PTH analog use lifetime

VI. Product Availability

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

VII. References

1. Tymlos Prescribing Information. Waltham, MA: Radius Health, Inc. December 2021. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208743s003lbl.pdf. Accessed April 18, 2022.
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. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2020 update. Endocr Pract. 2020;26(1):1-46.
6. National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: https://cdn.nof.org/wpcontent/uploads/2016/01/995.pdf. Accessed November 05, 2021.
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	06.17	07.17
1Q18 annual review: • Combined Medicaid and commercial policies • New policy for HIM • Removed criteria for evidence of diagnosis	11.15.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
• Modified age requirement to include pediatric members with closed epiphyses • Modified criteria to add specialist requirement or trial and failure to a bisphosphonate (alendronate is preferred). • Modified approval duration to 6 months (initial) and 12 months (continuation) • References reviewed and updated.		
1Q 2019 annual review: no significant changes; references reviewed and updated.	10.31.18	02.19
Revised preferred product verbiage in compliance with HFS PDL migration. Removed references to HIM, Medicaid policy only. Removed appendix B.	12.6.19	
3Q 2021 Annual Review: Add BMD T-Score to diagnosis of PMO; Added 3-year bisphosphonate trial with required contraindication to both PO/IV formulations; Removed criteria for member is a postmenopausal female;; Removed specialist; updated FDA approve indication; Reviewed and updated references	7.1.21	
2Q 2022 Annual Review: Added option (in addition to contraindications or adverse effects) to bypass bisphosphonate trial if member has experienced a loss of BMD, lack of BMD increase, or has had an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy; clarified use is limited to ≤ 2 years cumulative abaloparatide therapy (rather than reference PTH analogs generally, as Forteo label was updated to allow use beyond 2 years); removed osteosarcoma black box warning from Appendix B. References reviewed and updated.	7.22.22	
2Q 2023 Annual Review: Template changes applied to other diagnoses/indications and continued therapy section. RT4: added newly approved indication of male osteoporosis to criteria;added appendices b, c, and d, updated section V, references reviewed and updated.	8.8.23	

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.