Clinical Policy: Abaloparatide (Tymlos)

Reference Number: AZ.CP.PHAR.345
Effective Date: 02.15.21
Last Review Date: 02.22
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) 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.

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st 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, ii, or iii):
      i. Recent osteoporotic fracture (within the past 12 months);
      ii. 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 *(alendronate is preferred)* at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced to both IV and PO formulations (*see Appendix D*);
      **Prior authorization may be required for bisphosphonates*
2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;

3. Failure of Forteo® at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Forteo*
4. Member has not received ≥ 2 years cumulative PTH analog therapy (e.g., Forteo®, Tymlos);
5. 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. History of failure of Forteo® at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Forteo*
4. Member has not received ≥ 2 years cumulative PTH analog therapy (e.g., Forteo, Tymlos);
5. 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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona 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 – AZ.CP.PMN.53 for Arizona Medicaid 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
PTH analog therapy		
Forteo (teriparatide)	Treatment:PMO, GIO, male osteoporosis 20 mcg SC QD	20 mcg/day up to 2 years cumulative PTH analog use lifetime
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.*	
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): known hypersensitivity to Tymlos
- 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 November 05, 2021.
2. Forteo Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2021. Available at http://www.forteo.com. Accessed September 16, 2021.

3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/.

Osteoporosis Diagnosis, Fracture Risk, and Treatment

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6. 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.
7. 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.
8. 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.
9. 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 to align with AZ Medicaid preferred product (Forteo).	01.30.21	02.21
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21
1Q 2022 annual review: updated definition of very high risk for fracture per 2020 AACE/ACE PMO guidelines; updated Appendix C; references reviewed and updated.	01.29.22	02.22

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.

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.