# Clinical Policy: Abaloparatide (Tymlos)

Reference Number: CP.PHAR.345
Effective Date: 07.17
Last Review Date: 02.21
Line of Business: Commercial, HIM, 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.*

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 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 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. 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 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): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for 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. 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 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): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and 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.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

| | |
|---|---|
| BMD: bone mineral density | PMO: postmenopausal osteoporosis |
| FDA: Food and Drug Administration | 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<br>*See prescribing information for dose.* | Varies |
| zoledronic acid (Reclast®) | Teatment/prevention: PMO, GIO<br>Treatment: male osteoporosis<br>Treatment: Paget disease<br>*See prescribing information for dose.* | |
| ***Oral bisphosphonates*** | | |
| alendronate (Fosamax®) | Treatment/prevention: PMO<br>Treatment: GIO, male osteoporosis<br>Treatment: Paget disease<br>*See prescribing information for dose.* | Varies |
| Fosamax® Plus D (alendronate / cholecalciferol) | Treatment: PMO, male osteoporosis<br>*See prescribing information for dose.* | |
| risedronate (Actonel®, Atelvia®) | Actonel:<br>Treatment/prevention: PMO, GIO<br>Treatment: male osteoporosis<br>Treatment: Paget disease<br>Atelvia:<br>Treatment: PMO<br>*See prescribing information for dose.* | |
| ibandronate (Boniva®) | Treatment/prevention: PMO<br>*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 |

| Bisphosphonates | Oral Formulations | IV Formulations |
|---|---|---|
| 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: 3120 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.
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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.

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| 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; 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. | 11.15.17 | 02.18 |
| 1Q 2019 annual review: no significant changes; references reviewed and updated. | 10.31.18 | 02.19 |
| 1Q 2020 annual review: removed HIM disclaimer for HIM NF drugs; 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. 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.

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**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.