

## **Clinical Policy: Abaloparatide (Tymlos)**

Reference Number: CP.PHAR.345

Effective Date: 07.17

Last Review Date: 02.19

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<sup>®</sup>) is a human parathyroid hormone (PTH)-related peptide analog.

### **FDA Approved Indication(s)**

Tymlos 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.

### **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<sup>®</sup> that Tymlos is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

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

1. Diagnosis of osteoporosis;
2. Age  $\geq$  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<sup>®</sup>) that exceeds 2 years;
6. Dose does not exceed 80 mcg per day (1 pen every 30 days).

**Approval duration: 6 months (limited to 2 years cumulative use of PTH analogs per 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 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: 12 months (limited to 2 years cumulative use of PTH analogs per 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

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
alendronate (Fosamax <sup>®</sup> )	<p>Osteoporosis 10 mg PO QD or 70 mg PO q week</p> <p>Glucocorticoid-induced osteoporosis 5 mg PO QD or 10 mg PO QD (in postmenopausal women not receiving estrogen)</p> <p>Osteoporosis prophylaxis 5 mg PO QD or 35 mg PO q week</p>	<p>Osteoporosis 10 mg/day or 70 mg/week</p> <p>Glucocorticoid-induced osteoporosis 5 mg/day or 10 mg/day (in postmenopausal women not receiving estrogen)</p> <p>Osteoporosis prophylaxis 5 mg/day or 35 mg/week</p>
Fosamax <sup>®</sup> Plus D (alendronate/cholecalciferol)	<p>Osteoporosis 70 mg alendronate/2,800 units cholecalciferol or 70 mg alendronate/5,600 units cholecalciferol PO q week</p>	<p>Osteoporosis 70 mg alendronate/5,600 units cholecalciferol/week</p>
risedronate (Actonel <sup>®</sup> , Atelvia <sup>®</sup> )	<p>Osteoporosis (including prophylaxis) 5 mg PO QD or 35 mg PO q week or 75 mg PO QD for 2 consecutive days for 2 doses/month or 150 mg PO q month</p> <p>Glucocorticoid-induced osteoporosis 5 mg PO QD</p>	<p>Osteoporosis (including prophylaxis) 5 mg/day or 35 mg/week or 75 mg/day for 2 days per month or 150 mg/month</p> <p>Glucocorticoid-induced osteoporosis 5 mg/day</p>
zoledronic acid (Reclast <sup>®</sup> )	<p>Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid-induced osteoporosis 5 mg IV q year</p> <p>Postmenopausal osteoporosis prophylaxis 5 mg IV q 2 years</p>	<p>Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid-induced osteoporosis 5 mg/year</p> <p>Postmenopausal osteoporosis prophylaxis 5 mg/2 years</p>
ibandronate (Boniva <sup>®</sup> )	<p>Postmenopausal osteoporosis 150 mg PO q month or 3 mg IV every 3 months</p> <p>Postmenopausal osteoporosis prophylaxis 150 mg PO q month</p>	<p>150 mg/month or 3 mg/3 months</p>

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: 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

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Osteoporosis	80 mcg SC QD	80 mcg/day for up to 2 years cumulative use of PTH analogs per 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/2018/208743s0031bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208743s0031bl.pdf). Accessed October 31, 2018.
2. Miller PD, Hattersley G, Riis BJ et al. Effect of abaloparatide vs placebo on new vertebral fractures in postmenopausal women with osteoporosis. JAMA 2016; 316 (7):722-733.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <http://www.clinicalpharmacology-ip.com/>.
4. National Osteoporosis Foundation Clinician’s Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: <https://my.nof.org/bone-source/education/clinicians-guide-to-the-prevention-and-treatment-of-osteoporosis>. Accessed October 31, 2018.
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.
8. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.17	07.17
1Q18 annual review: <ul style="list-style-type: none"> <li>• Combined Medicaid and commercial policies</li> <li>• New policy for HIM</li> <li>• Removed criteria for evidence of diagnosis</li> <li>• Modified age requirement to include pediatric members with closed epiphyses</li> <li>• Modified criteria to add specialist requirement or trial and failure to a bisphosphonate (alendronate is preferred).</li> <li>• Modified approval duration to 6 months (initial) and 12 months (continuation)</li> <li>• References reviewed and updated.</li> </ul>	11.15.17	02.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	10.31.18	02.19

**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.

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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.

**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.

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