Clinical Policy: Abaloparatide (Tymlos)

Reference Number: CP.PHAR.345
Effective Date: 07/17
Last Review Date: 07/17
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 an analog of human parathyroid hormone related peptide (PTHrP).

FDA approved indication

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.

Limitations of Use: Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) 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 osteoporosis evidenced by one of the following (a or b):
   a. T-score ≤ -2.5 (DXA) at the femoral, neck, spine or total hip;
   b. History of osteoporotic fracture confirmed by radiographic imaging;
2. Postmenopausal female;
3. Failure (decline in BMD of ≥ 5% or continued fractures) of both of the following (a and b), each trialed for one year unless contraindicated or clinically significant adverse effects are experienced:
   a. An oral bisphosphonate (e.g., alendronate, risedronate);
   b. Zoledronic acid (Reclast);
      **Prior authorization is required for zoledronic acid*;
4. If member has received zoledronic acid (Reclast), it has been at least one year since the last administration of zoledronic acid (Reclast);
5. Member has not received teriparatide (Forteo) for up to 2 years;
6. Dose does not exceed 80 mcg per day.

Approval duration: 6 months

**Lifetime limit of 2 years total on parathyroid hormone analogs (e.g.: teriparatide (Forteo) and Tymlos).*

B. Other diagnoses/indications:
1. Refer to CP.PHAR.57 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 Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. Prescribed dose does not exceed 80 mcg per day;
4. Member has not used Tymlos and teriparatide (Forteo) for ≥ 2 years.

Approval duration: 6 months

**Lifetime limit of 2 years total on parathyroid hormone analogs (e.g.: teriparatide (Forteo) and Tymlos).*

B. Other diagnoses/indications (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 CP.PHAR.57 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 – CP.PHAR.57 evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BMD: bone mineral density
DXA: dual energy X-ray absorptiometry

Appendix B: General Information
The 2010 North American Menopause Society position statement for the management of osteoporosis in postmenopausal women recommend bisphosphonates as first-line drugs as a result of the demonstrated reduction in risk of vertebral and non-vertebral fracture, including hip fracture.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Osteoporosis	80 mcg subcutaneously once daily	80 mcg/day subcutaneously

VI. Product Availability

Injection: 3120 mcg/1.56 mL in a single-patient-use prefilled pen (to deliver 30 doses of 80 mcg/dose).

VII. References

1. Tymlos Prescribing Information. Waltham, MA: Radius Health. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208743lbl.pdf
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. Tymlos Drug Monograph. Clinical Pharmacology. Accessed May 2017. http://www.clinicalpharmacology-ip.com/.
5. National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis. Available at: https://my.nof.org/bone-source/education/clinicians-guide-to-the-prevention-and-treatment-of-osteoporosis. Accessed May 15, 2017.
6. Management of osteoporosis in postmenopausal women: 2010 position statement of The North American Menopause Society. Menopause 2010. 17 (1): 23-54.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	06/17	07/17

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.