Clinical Policy: Abaloparatide (Tymlos)

Reference Number: PA.CP.PHAR.345
Effective Date: 07/17
Last Review Date: 07/18
Line of Business: Medicaid

Revision Log

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 Pennsylvania Health and Wellness® 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 ≥ 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 parathyroid hormone (PTH) analogs (e.g., Tymlos, Forteo) 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 PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. Member has not received cumulative therapy on parathyroid hormone (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 (1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

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 – PA.CP.PMN.53 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, Inc. April 2017. Available at https://www.radiuspharm.com/wp-content/uploads/tymlos/tymlos-prescribing-information.pdf. Accessed November 10, 2017.

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. Available at: https://my.nof.org/bone-source/education/clinicians-guide-to-the-prevention-and-treatment-of-osteoporosis. Accessed November 10, 2017.
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.

Reviews, Revisions, and Approvals	Date	Approval Date
.09.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.	02/18	