

SPECIALTY GUIDELINE MANAGEMENT

TYMLOS™ (abaloparatide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Tymlos is indicated for the treatment postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

Osteoporosis in Postmenopausal women

Authorization of a lifetime total of 24 months for parathyroid hormone analogs (e.g., abaloparatide or teriparatide) may be granted to postmenopausal members with osteoporosis when ANY of the following criteria are met:

1. Member has a history of fragility fractures, OR
2. Member has a pre-treatment T-score of ≤ -2.5 and meets ANY of the following criteria:
 - a. Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores, or increased fall risk), OR
 - b. Member has failed prior treatment with or is intolerant to previous osteoporosis therapy (i.e., oral bisphosphonates or injectable antiresorptive agents)

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Tymlos [package insert]. Waltham, MA: Radius Health, Inc. April 2017.
2. Miller PD, Hattersley G, Riis BJ, et al. Effect of Abaloparatide Vs Placebo on New Vertebral Fractures in Postmenopausal Women with Osteoporosis: A Randomized Clinical Trial. *JAMA*. 2016; 316 (7): 722:733.
3. 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*. 2016;22 (Suppl 4):1-42.