RXADVANCE
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| **Clinical Policy Title:** | Abaloparatide (Tymlos) |
| **Policy Number:** | RxA.531 |
| **Drug(s) Applied:** | Abaloparatide (Tymlos®) |
| **Original Policy Date:** | 01/2020 |
| **Last Review Date:** | 05/05/2020 |
| **Line of Business Policy Applies to:** | Commercial, HIM, Medicaid |

## Background

Abaloparatide (Tymlos®) is a human parathyroid hormone (PTH)-related peptide analog. It 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.

## Dosing Information

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Abaloparatide (Tymlos) | Osteoporosis | 80 mcg SC QD | 80 mcg/day for up to 2 years cumulative use of PTH analogs per lifetime |

## Dosage Forms

- Single-patient-use prefilled pen: 3120 mcg/1.56 mL (30 daily doses of 80 mcg)

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

**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 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)**

## II. Continued Therapy

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy.
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)**

## III. Appendices

**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®) | Osteoporosis<br>10 mg PO QD or 70 mg PO q week<br><br>Glucocorticoid-induced osteoporosis<br>5 mg PO QD or 10 mg PO QD (in postmenopausal women not receiving estrogen)<br><br>Osteoporosis prophylaxis<br>5 mg PO QD or 35 mg PO q week | Osteoporosis<br>10 mg/day or 70 mg/week<br><br>Glucocorticoid-induced osteoporosis<br>5 mg/day or 10 mg/day (in postmenopausal women not receiving estrogen)<br><br>Osteoporosis prophylaxis<br>5 mg/day or 35 mg/week |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Fosamax® Plus D (alendronate/ cholecalciferol) | Osteoporosis<br>70 mg alendronate/2,800 units cholecalciferol or 70 mg alendronate/5,600 units cholecalciferol PO q week | Osteoporosis<br>70 mg alendronate/5,600 units cholecalciferol/week |
| risedronate (Actonel®, Atelvia®) | Osteoporosis (including prophylaxis)<br>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<br><br>Glucocorticoid-induced osteoporosis<br>5 mg PO QD | Osteoporosis (including prophylaxis)<br>5 mg/day or 35 mg/week or 75 mg/day for 2 days per month or 150 mg/month<br><br>Glucocorticoid-induced osteoporosis<br>5 mg/day |
| zoledronic acid (Reclast®) | Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid- induced osteoporosis<br>5 mg IV q year<br><br>Postmenopausal osteoporosis prophylaxis<br>5 mg IV q 2 years | Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid-induced osteoporosis<br>5 mg/year<br><br>Postmenopausal osteoporosis prophylaxis 5 mg/2 years |
| ibandronate (Boniva®) | Postmenopausal osteoporosis<br>150 mg PO q month or 3 mg IV every 3 months<br><br>Postmenopausal osteoporosis prophylaxis<br>150 mg PO q month | 150 mg/month or 3 mg/3 months |

*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 |

**References**

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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 May 1, 2020.
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| Review/Revision History | Review/Revised Date | P&T Approval Date |
|---|---|---|
| Policy was established | 01/2020 | 03/06/2020 |
| Policy was reviewed: rephrased Continued Therapy criteria A.1. to "currently receiving medication that has been authorized by RxAdvance benefit".<br>References were reviewed and updated | 05/2020 | 05/21/2020 |