IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Abaloparatide (Tymlos™) is a synthetic form of a human parathyroid hormone related protein, which is naturally found in the body. The synthetic hormone is given daily by subcutaneous injection for the treatment of osteoporosis.
Policy/Criteria

I. Most contracts require prior authorization approval of abaloparatide (Tymlos) prior to coverage. Abaloparatide (Tymlos) may be considered medically necessary when criteria A, B, and C below are met:

A. Diagnosis of postmenopausal osteoporosis.

AND

B. The patient is at high risk of fracture defined by meeting either criterion 1 or 2 below:
   1. The patient has a bone mineral density that is 2.5 or more standard deviations below that of a “young normal” adult (T score at or below -2.5).
   OR
   2. The patient has osteopenia (T score between -1 and -2.5) and a history of previous fractures or glucocorticoid use for at least 3 months at a dose of 5 mg per day of prednisone (or equivalent).

AND

C. Step therapy with lower-cost alternatives has been ineffective, not tolerated or contraindicated as defined by at least one of the following:
   1. At least one bisphosphonate or raloxifene is not effective after at least a 24-month treatment period based on objective documentation.
   OR
   2. Raloxifene and bisphosphonates (both oral and IV) are contraindicated based on current medical literature and objective documentation describing the contraindication is provided.
   OR
   3. Raloxifene or bisphosphonates (both oral and IV) are not tolerated due to documented clinical side effects.

II. Administration, Quantity Limitations, and Authorization Period

A. OmedaRx considers abaloparatide (Tymlos) to be a self-administered medication.

B. When prior authorization is approved, abaloparatide (Tymlos) may be authorized for a maximum of 2 years of therapy.

C. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

III. Abaloparatide (Tymlos) is considered investigational when used for all other conditions, including, but not limited to,

A. The prevention of osteoporosis.

B. To promote fracture healing.

C. To promote post-fusion healing.

D. Use in combination with denosumab (Prolia®).
Position Statement

Summary

- Abaloparatide (Tymlos) is approved for the treatment of osteoporosis in postmenopausal women at high risk for fracture. Patients in the pivotal trial of abaloparatide (Tymlos) in postmenopausal osteoporosis were required to have a T-score ≤ -2.5 and had a mean age of 68.8 years at baseline. [1]

- Data comparing of abaloparatide (Tymlos) to other therapies for the treatment of osteoporosis are lacking and abaloparatide (Tymlos) has not been shown to be more effective than other agents used for the treatment of osteoporosis.

- Alendronate, risedronate, raloxifene, and ibandronate have been shown to increase bone mineral density and reduce the incidence of fractures in patients with osteoporosis. [2-9] Risedronate and alendronate have been shown to be well-tolerated out to at least 5 years of therapy. [2,3]

- The 2014 National Osteoporosis Foundation (NOF) Guidelines are based mainly on evidence from randomized, controlled clinical trials, and attempts to help identify who will benefit from treatment. Treatment decisions should be based on clinical information as well as intervention thresholds. [4]

- A T-score lower than -2.5 is diagnostic of osteoporosis. However, a nontraumatic fracture (fragility fracture), is considered osteoporosis regardless of T-score. [4]

- The World Health Organization (WHO) algorithm (FRAX®) was developed to calculate the 10-yr probability of a hip fracture and the 10-yr probability of any major osteoporotic fracture (defined as vertebral, hip, forearm, or humerus fracture) taking into account femoral neck BMD and the clinical risk factors. The WHO algorithm pertains only to previously untreated patients. [4]

- There are no large, randomized, double-blind, comparative trials that have demonstrated superior health outcomes (such as clinically significant fractures) with abaloparatide (Tymlos) as compared to bisphosphonates or other therapies.

- There is no evidence to support the use of abaloparatide (Tymlos) for the prevention of postmenopausal osteoporosis.

- There is no evidence to support the use of abaloparatide (Tymlos) for bone healing.

Clinical Efficacy

- The efficacy of abaloparatide (Tymlos) was demonstrated in a randomized controlled trial that compared abaloparatide to placebo, as well as open-label teriparatide, for 18 months of treatment in postmenopausal women. [1]

  * Abaloparatide (Tymlos) decreased the absolute risk of new vertebral fractures by 3.6% compared to placebo. New vertebral fractures occurred in 0.58% of participants in the abaloparatide group and in 4.22% of those in the placebo group.[1,5]

  * Although considered an exploratory endpoint, new vertebral fractures occurred in 0.84% of participants treated with teriparatide. [1]
- Abaloparatide (Tymlos) has been shown to reduce the risk of vertebral and non-vertebral fractures; however, it is unknown if abaloparatide (Tymlos) protects against hip fracture. Abaloparatide (Tymlos) has also been shown to increase bone mineral density (BMD) in the spine and hip. [1]

- There are no direct comparative trials with fracture as a primary outcome comparing abaloparatide (Tymlos) to other therapies for the treatment of osteoporosis.

**Investigational Uses**

- There is no evidence to support the use of abaloparatide (Tymlos) for the prevention of postmenopausal osteoporosis.

- There are no clinical trials to support the use of abaloparatide (Tymlos) for bone healing.

**Safety**

- Due to the potential risk of osteosarcoma, cumulative use of abaloparatide (Tymlos) and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years is not recommended. [10]

- Like teriparatide, abaloparatide (Tymlos) has a boxed warning stating that an increase in the incidence of osteosarcoma, dependent on dose and treatment duration, was observed in rats. Abaloparatide (Tymlos) should not be prescribed to patients at increased risk for osteosarcoma including those with Paget’s disease of bone, patients with previous radiation therapy, and patients with bone metastases or skeletal malignancies. [10]

- There is no reliable evidence that abaloparatide (Tymlos) is safer than teriparatide (Forteo).

<table>
<thead>
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<th>Cross References</th>
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<tbody>
<tr>
<td>risedronate-containing medications (generic, Actonel®, Atelvia™, generic risedronate delayed-release), Medication Policy Manual, Policy No dru155</td>
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<tr>
<td>Forteo®, teriparatide, Medication Policy Manual, Policy No dru085</td>
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<td>Prolia®, denosumab, Medication Policy Manual, Policy No dru223</td>
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<tr>
<td>Xgeva™, denosumab, Medication Policy Manual, Policy No dru393</td>
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<td>Bone Density Studies rad2, Medical Policy Manual, TRGMPM – Radiology</td>
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## Codes

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<td>J3110</td>
<td>Injection, teriparatide, 10mcg</td>
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<td>HCPCS</td>
<td>J0897</td>
<td>Injection, denosumab 1 mg</td>
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<td>J3488</td>
<td>Injection, zoledronic acid (Reclast), 1 mg (Reclast 5 MG/100ML SOLN)</td>
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## References


## Revision History

<table>
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<tr>
<th>Revision Date</th>
<th>Revision Summary</th>
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<tbody>
<tr>
<td>08/11/2017</td>
<td>New policy (effective 8/11/17)</td>
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