Effective Date **4/1/2024**
Next Review Date… **4/1/2025**
Coverage Policy Number **IP0329**

Abaloparatide

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for abaloparatide subcutaneous injection (**Tymlos®**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Abaloparatide (Tymlos) is considered medically necessary when ONE of the following is met:

1. **Osteoporosis Treatment for a Postmenopausal Woman.** Individual meets **ALL** of the following criteria:
    A. Meets **ONE** of the following conditions:
        i. Has had a bone mineral density (BMD) T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist)
        ii. Has had an osteoporotic fracture or a fragility fracture

iii. **BOTH** of the following:
    a. Has low bone mass (for example, a T-score [current or at any time in the past] between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% [one third] radius [wrist])
    b. Prescriber determines that the individual is at high risk for fracture (for example, the FRAX® [fracture risk assessment tool] 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%)

B. Documentation of **ONE** of the following:
    i. Failure or inadequate response to at least **ONE** of the following oral or intravenous bisphosphonate products (examples of failure/inadequate response include, osteoporotic or fragility fracture while receiving bisphosphonate therapy, ongoing and significant loss of BMD, or lack of a BMD increase):
        a. alendronate tablets or oral solution (Fosamax)
        b. ibandronate intravenous injection or tablets (Boniva)
        c. risedronate tablets/delayed release tablets (Actonel/Atelvia)
        d. zoledronic acid intravenous infusion (Reclast)
    ii. Has a contraindication or intolerance to **BOTH** oral and intravenous bisphosphonate therapy
    iii. Is at very high risk for fracture (examples include, recent fracture within past 12 months, fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm [e.g., long-term glucocorticoids], very low T-score [e.g., less than − 3.0], high risk for falls or history of injurious falls, and very high fracture probability by FRAX® [fracture risk assessment tool] [e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%])
C. Will not exceed a total of 24 months of therapy [including previous use of teriparatide (Forteo®)] An exception can be made for those individuals who remain at or have returned to having a high risk of fracture. Examples of high risk for fracture include, a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, or a very low bone mineral density.
D. Preferred product criteria is met for the products listed in the below table(s)

2. **Osteoporosis Treatment for Men.** Individual meets **ALL** of the following criteria:
A. Meets **ONE** of the following conditions:
    i. Has had a bone mineral density (BMD) T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist)
    ii. Has had an osteoporotic fracture or a fragility fracture
    iii. **BOTH** of the following:
        a. Has low bone mass (for example, a T-score [current or at any time in the past] between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% [one third] radius [wrist])
        b. Prescriber determines that the individual is at high risk for fracture (for example, the FRAX® [fracture risk assessment tool] 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%)
B. Documentation of **ONE** of the following:
    i. Failure or inadequate response to at least **ONE** of the following oral or intravenous bisphosphonate products (examples of failure/inadequate response include, osteoporotic or fragility fracture while receiving bisphosphonate therapy, ongoing and significant loss of BMD, or lack of a BMD increase):
        a. alendronate tablets or oral solution (Fosamax)
        b. ibandronate intravenous injection or tablets (Boniva)
        c. risedronate tablets/delayed release tablets (Actonel/Atelvia)
        d. zoledronic acid intravenous infusion (Reclast)

ii. Has a contraindication or intolerance to **BOTH** oral and intravenous bisphosphonate therapy
iii. Is at very high risk for fracture (examples include, recent fracture within past 12 months, fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm [e.g., long-term glucocorticoids], very low T-score [e.g., less than − 3.0], high risk for falls or history of injurious falls, and very high fracture probability by FRAX® [fracture risk assessment tool] [e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%])

C. Will not exceed a total of 24 months of therapy (including previous use of teriparatide [Forteo®]) An exception can be made for those individuals who remain at or have returned to having a high risk of fracture. Examples of high risk for fracture include, a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, or a very low bone mineral density.
D. Preferred product criteria is met for the products listed in the below table(s)

Employer Plans:

Product	Criteria
Tymlos (abaloparatide subcutaneous injection)	**EFFECTIVE 7/1/2024** Documentation of failure, contraindication, or intolerance to teriparatide subcutaneous injection

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of abaloparatide (Tymlos) beyond 24 months is considered medically necessary for **ALL** covered diagnoses when the above medical necessity criteria are met AND there is documentation that the individual remains at or has returned to a high risk for fracture and the prescriber has determined the potential benefit of continued therapy outweighs the risk.

Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, or a very low bone mineral density.

Authorization Duration

Initial approval duration: up to 24 months

The initial approval duration should not exceed the necessary duration to complete a total of 24 months of therapy with parathyroid hormone analogs (abaloparatide [Tymlos] or teriparatide [Forteo]).

Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use with Other Medications for Osteoporosis.** Examples of medications for osteoporosis that Tymlos should not be given with include Prolia (denosumab subcutaneous injection), oral bisphosphonates (alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid

intravenous infusion [Reclast], ibandronate intravenous injection), calcitonin nasal spray (Miacalcin/Fortical), teriparatide subcutaneous injection (Forteo), and Evenity (romosozumab-aqqg subcutaneous injection). However, this does NOT exclude use of calcium and/or vitamin D supplements in combination with Tymlos.

2. **Osteoporosis Prevention.** Tymlos has not been studied in this patient population. The benefits and risks of building bone with Tymlos in a condition in which substantial bone loss has not occurred have not been investigated.[1]

Background

OVERVIEW
Tymlos, a human parathyroid hormone related peptide analog, is indicated for the following uses:[1]

- **Osteoporosis, treatment of postmenopausal women**, at high risk for fracture.
- **Osteoporosis, treatment to increase bone density in men**, at high risk for fracture.

Patients at high risk for fracture are defined as those with a history of osteoporotic fracture, have multiple risk factors for fracture, or have failed or are intolerant to other osteoporosis therapy.

Guidelines
Guidelines for osteoporosis in postmenopausal women from the Endocrine Society (2019)[2] as well as from the American Association of Clinical Endocrinologists and the American College of Endocrinology (2020)[3] discuss Tymlos. In general, Tymlos is one of several alternatives recommended in patients who are at high risk of fracture or in those unable to utilize oral bisphosphonate therapy. The Bone Health and Osteoporosis clinician guide to prevent and treat osteoporosis (2022) cites robust reductions in vertebral and non-vertebral fractures with Tymlos therapy in postmenopausal women with osteoporosis.[4]

Safety
The prescribing information for Tymlos states that the safety and efficacy of Tymlos have not been evaluated beyond 2 years of therapy. Use of the medication for more than 2 year during a patient's lifetime is not recommended. There are limited data evaluating the risk of osteosarcoma beyond 2 years of Tymlos and/or use of a parathyroid hormone analog. Avoid use of Tymlos in patients who are at increased baseline risk of osteosarcoma (e.g., open epiphyses [pediatric and young adult patients], those with metabolic bone disease, patients with bone metastases or a history of skeletal malignancies).

References

1. Tymlos® subcutaneous injection [prescribing information]. Boston, MA: Radius; June 2023.
2. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2019;104(5):1595-1622.
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. *Endocrin Pract*. 2020;26(Suppl 1):1-46.
4. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporosis Int*. 2022;33(10):2049-2102.