Drug Coverage Policy

Effective Date.....8/1/2026
Coverage Policy Number.....IP0329
Policy Title.....Tymlos

Bone Modifiers – Tymlos

- Tymlos® (abaloparatide subcutaneous injection – Radius)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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

Tymlos, a human parathyroid hormone related peptide (PTHrP 1-340) 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.

In general, for all indications, 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) as well as from the American Association of Clinical Endocrinologists and the American College of Endocrinology (2020) discuss Tymlos.[2-3] 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 guidelines for the diagnosis and treatment of postmenopausal osteoporosis list Tymlos as an option for patients unable to use oral therapy and as initial therapy option for patients at very high fracture risk.[3] Guidelines describe patients at very high risk for fracture as those with a recent fracture, fractures while on therapy, multiple fractures, fractures on medications that cause skeletal harm (e.g., long-term glucocorticoids), a very low T-score (e.g., < -3.0), or high risk/history of injurious falls. The Bone Health and Osteoporosis clinician guide for the prevention and treatment of osteoporosis (2022) cites robust reductions in vertebral and non-vertebral fractures with Tymlos therapy in postmenopausal women with osteoporosis.[4]

Safety
The safety and efficacy of Tymlos have not been evaluated beyond 2 years of therapy.[1] Use of the medication for more than 2 years 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 with a baseline risk of osteosarcoma.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Tymlos. All approvals are provided for the duration noted below. In the approval indication, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Tymlos is considered medically necessary when the following are met:

FDA-Approved Indications

1. **Osteoporosis Treatment for a Postmenopausal Patient.** Approve for up to 2 years (total) during a patient's lifetime if the patient meets BOTH of the following (A, B and C):
   Note: For example, a patient who has already received 3 months of treatment with Tymlos should be approved for a duration of 21 months. This allows for completion of a maximum of 2 years of therapy during the patient's lifetime.
   A) Patient meets ONE of the following (i, ii, or iii):
      i. Patient has had a 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); OR
      ii. Patient has had an osteoporotic fracture or a fragility fracture; OR
      iii. The patient meets BOTH of the following (a and b):
         a) Patient has low bone mass; AND

Note: An example of low bone mass includes 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) According to the prescriber, patient is at high risk for fracture; AND

B) Patient meets ONE of the following (i, ii, iii, or iv):

i. Patient has tried ibandronate intravenous or zoledronic acid intravenous infusion (Reclast); OR

ii. Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets ONE of the following (a or b):
Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), Binosto (alendronate effervescent tablets for oral solution), and Boniva (ibandronate tablets).

a) According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack or a BMD increase, and/or an osteoporotic fracture or a fragility fracture.

b) Patient has experienced significant intolerance to an oral bisphosphonate; OR
Note: Examples of significant intolerance include severe gastrointestinal related adverse events and/or severe musculoskeletal related adverse events.

iii. Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):

a) Patient cannot swallow or has difficulty swallowing; OR

b) Patient cannot remain in an upright position post oral bisphosphonate administration; OR

c) Patient has a pre-existing gastrointestinal medical condition; OR
Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).

iv. Patient meets ONE of the following (a, b, or c):

a) According to the prescriber, the patient has severe renal impairment or chronic kidney disease; OR
Note: An example of severe renal impairment is a creatinine clearance < 35 mL/minute.

b) Patient has had an osteoporotic fracture or a fragility fracture; OR

c) Patient has a very low T-score < -3.0.

C) Preferred product criteria is met for the product(s) as listed in the below table(s).

2. Osteoporosis Treatment for Men*. Approve for up to 2 years (total) during a patient's lifetime if the patient meets BOTH of the following (A, B, and C):
Note: For example, a patient who has already received 3 months of treatment with Tymlos should be approved for a duration of 21 months. This allows for completion of a maximum of 2 years of therapy during the patient's lifetime.

A) Patient meets ONE of the following (i, ii, or iii):

i. Patient has had a 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); OR

ii. Patient has had an osteoporotic fracture or a fragility fracture; OR

iii. The patient meets BOTH of the following (a and b):

a) Patient has low bone mass; AND
Note: An example of low bone mass includes 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) According to the prescriber, patient is at high risk for fracture; AND

B) Patient meets ONE of the following (i, ii, iii, or iv):
- **i.** Patient has tried zoledronic acid intravenous infusion (Reclast); OR
- **ii.** Patient has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and meets ONE of the following (a or b):
  Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), Binosto (alendronate effervescent tablets for oral solution), and Boniva (ibandronate tablets).
  - **a)** According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
    Note: Examples of an inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack or a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
  - **b)** Patient has experienced significant intolerance to an oral bisphosphonate; OR
    Note: Examples of significant intolerance include severe gastrointestinal related adverse events and/or severe musculoskeletal related adverse events.
- **iii.** Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):
  - **a)** Patient cannot swallow or has difficulty swallowing; OR
  - **b)** Patient cannot remain in an upright position post oral bisphosphonate administration; OR
  - **c)** Patient has a pre-existing gastrointestinal medical condition; OR
    Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).
- **iv.** Patient meets ONE of the following (a or b):
  - **a)** According to the prescriber, the patient has severe renal impairment or chronic kidney disease; OR
    Note: An example of severe renal impairment is a creatinine clearance < 35 mL/minute.
  - **b)** Patient has had an osteoporotic fracture or a fragility fracture.

C) Preferred product criteria is met for the product(s) as listed in the below table(s).

***** Refer to the Policy Statement.

Employer Plans:

Product	Criteria
Tymlos (abaloparatide subcutaneous injection)	**1.** Approve for up to 2 years if the patient meets the following (A): **A)** Patient has tried one of teriparatide pen (Forteo, generic), brand teriparatide, or Bonsity NOTE: Approval should only be granted if the patient has NOT received more than 2 years of cumulative therapy with Tymlos.

Conditions Not Covered

Tymlos for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **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]

2. **Concurrent Use with Other Medications for Osteoporosis.**
   Note: Examples of medications for osteoporosis that Tymlos should not be given with include oral bisphosphonates (alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid intravenous infusion [Reclast], ibandronate intravenous injection), denosumab products (Prolia, biosimilars), calcitonin nasal spray (Miacalcin/Fortical), teriparatide subcutaneous injection (Forteo), and Evenity (romosozumab-aqqg subcutaneous injection). However, calcium and/or vitamin D supplements may be used in combination with this medication.

References

1. Tymlos® subcutaneous injection [prescribing information]. Boston, MA: Radius; March 2025.
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, GreenspanSL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporosis Int*. 2022;33(10):2049-2102.

Revision Details

Summary of Changes	Review Date	Effective Date
No criteria changes.	11/14/2024	1/15/2025
Osteoporosis Treatment for a Postmenopausal Patient: • Binosto (alendronate effervescent tablets for oral solution) added as an example of a bisphosphonate. • Added examples for inadequate efficacy and intolerance. • Added criterion for approval of teriparatide where patients cannot take oral bisphosphonates. • Added criterion for approval of Tymlos where patient has severe renal impairment for. **Osteoporosis Treatment for Men:** • Binosto (alendronate effervescent tablets for oral solution) added as an example of a bisphosphonate. • Added examples for inadequate efficacy and intolerance. • Added criterion for approval of teriparatide where patients cannot take oral bisphosphonates. • Added criterion for approval of Tymlos where patient has severe renal impairment for. **Conditions Not Recommended for Approval:** For Concurrent Use with Other Medications for Osteoporosis, the Note was modified from "this does NOT exclude use of calcium and/or vitamin D supplements in combination with Tymlos" to "calcium and/or vitamin D supplements may be used in combination with this medication." **Updated Coverage Policy Title:**	12/4/2025	2/1/2026

Changed from "*Abaloparatide*" to "*Bone Modifiers – Tymlos.*" **Other Updates:** • Updated policy template and criteria format. • Added Bonsity to Preferred Product Criteria for Tymlos.		
Osteoporosis – Treatment of a Postmenopausal Patient: Added an exception allowing bypass of bisphosphonate trial for a patient with a very low T-score < -3.0.	5/21/2026	8/1/2026

The policy effective date is in force until updated or retired.

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