

Policy Name:	Tymlos (abaloparatide)	Policy #:	2611P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Tymlos.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Tymlos under the Specialty Pharmacy benefit when the following criteria have been met.

Definitions

Bisphosphonate or denosumab failure	Continued bone loss after 5 consecutive years of continuous treatment. Note: bone mineral density that is stable or improving is evidence for a treatment response
High risk for fractures	Current cigarette smoking, body weight less than 58 kg, alcohol use of greater than 3 beverages per day, family history of hip fracture, previous fragility fracture, advanced age, rheumatoid arthritis
IV bisphosphonate contraindication	Hypersensitivity to another bisphosphonate, CrCl < 35 mL/minute
Long-term glucocorticoid therapy	Mean daily dose of at least 5 mg of prednisone, or an equivalent dose of a different glucocorticoid, taken for 3 or more consecutive months
Oral bisphosphonate contraindication	Severe allergic reaction to another bisphosphonate, inability to stand or sit upright for at least 30 minutes, inability to swallow, achalasia, scleroderma esophagus, esophageal strictures, CrCl < 35 mL/minute, increased risk of aspiration (effervescent tablets; oral solution)
Osteopenia	T score between -1 to 2.5
Osteoporosis	T score -2.5
Severe osteoporosis	T score -3.5 without previous fracture or -2.5 with previous fragility fracture

Criteria

1. Treatment of osteoporosis in adults

- 1.1 Diagnosis of osteoporosis
- 1.2 High-risk for fractures
- 1.3 Postmenopausal female or male
- 1.4 Documented failure, intolerance, or contraindication to any of the following; OR:
 - two oral bisphosphonates, such as alendronate or ibandronate

- one oral bisphosphonate and IV zoledronic acid (Reclast)
 - one oral bisphosphonate and denosumab (Prolia)
- 1.5 Documented severe osteoporosis with continued fracture after one year of continuous bisphosphonate use
 - 1.6 Patients with severe osteoporosis (T-score \leq -3 or several vertebral fractures) can bypass trial with bisphosphonates/Prolia based on evidence supporting maximized bone density when receiving Tymlos prior to bisphosphonates/Prolia

2. Approval Times

- 2.1 Up to 24 months (lifetime)
 - Approved members are eligible for a maximum of 24 months total of Parathyroid Hormone Analog treatment, including both Forteo (teriparatide) and Tymlos (abaloparatide) therapies

3. Exclusions

- 3.1 Combination therapy involving the use of Tymlos with another bone mineral density- modifying drug
- 3.2 Treatment with Tymlos following long-term bisphosphonate use in patients seeking a drug holiday, and the continued use of bisphosphonates is not contraindicated
- 3.3 Treatment of osteopenia
- 3.4 Tymlos will not be covered if the member has previously been treated with Forteo for 24 months or Evenity for 12 months

CPT Codes

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HCPCS Codes

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References

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2. Tymlos (abaloparatide) [prescribing information]. Boston, MA: Radius Health Inc; December 2022.
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. *Endocr Pract.* 2020;26(suppl 1):1-46.
4. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. *J Clin Endocrinol Metab.* 2020 Mar 1;105(3):dgaa048.
5. Kittleson MM, Maurer MS, Ambardekar AV, et al. Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. *Menopause.* 2021 Sep 1;28(9):973-997.
6. Cosman F. Anabolic Therapy and Optimal Treatment Sequences for Patients With Osteoporosis at High Risk for Fracture. *Endocr Pract* 2020; 26:777.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical 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. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.