



Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

DRUG POLICY

Tymlos (abaloparatide)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Tymlos (abaloparatide) policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. The criteria will require the use of one of the health plan's preferred products, Teriparatide or Bonsity, before the use of Tymlos, unless there are clinical circumstances that exclude the use of the preferred product and may be based on previous use of a product. The preferred products, Teriparatide and Bonsity, are follow-on biologic products to Forteo. Forteo is not a preferred product.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Tymlos (abaloparatide) is indicated for the treatment postmenopausal women with osteoporosis at high risk for fracture (defined as history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.
2. Tymlos (abaloparatide) is indicated for the treatment to increase bone density in men with osteoporosis at high risk for fracture (defined as history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review: Supporting chart notes or medical record indicating a history of fractures, T-score, and FRAX fracture probability as applicable to Criteria for Initial Approval below.

Preferred Drug Plan Design

Criteria for initial approval for Tymlos for postmenopausal osteoporosis or osteoporosis in men will only apply when one of the following criteria are met:

1. The patient has had an inadequate response to treatment, intolerable adverse event, or has a contraindication to therapy with one of the preferred products, Teriparatide (Recombinant, Alvogen) or Bonsity.

Criteria for Initial Approval

A. Postmenopausal osteoporosis

Authorization for Tymlos (abaloparatide) of an initial total of up to 12 months may be granted to postmenopausal members with osteoporosis when the following criteria are met:

1. Member meets any of the following exception criteria for non-preferred product
 - a. Member has had a documented inadequate response to one of the preferred products, Teriparatide or Bonsity
 - b. Member has experienced a documented intolerable adverse event with one of the preferred products, Teriparatide or Bonsity
 - c. Member is currently receiving treatment with a targeted product, excluding when the targeted product is obtained as samples or via manufacturer's patient assistance programs.
 2. Member has a history of fragility fractures
- OR**
3. Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria:
 - a. Member has indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3], or increased fall risk)
 - b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], denosumab [Prolia])
 - c. Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)

B. Osteoporosis in men

Authorization for Tymlos (abaloparatide) of an initial total of up to 12 months may be granted to male members with osteoporosis when the following criteria are met:

1. Member meets any of the following exception criteria for non-preferred product:
 - a. Member has had a documented inadequate response to one of the preferred products, Teriparatide or Bonsity
 - b. Member has experienced a documented intolerable adverse event with one of the preferred products, Teriparatide or Bonsity

- c. Member is currently receiving treatment with a targeted product, excluding when the targeted product is obtained as samples or via manufacturer's patient assistance programs
2. Member has a history of osteoporotic vertebral or hip fracture
OR
3. Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B) and meets ANY of the following criteria:
 - a. Member has indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3], or increased fall risk)
 - b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], denosumab [Prolia])
 - c. Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (see Appendix A)

Continuation of Therapy

Authorization of up to 12 months may be granted for all members (including new members) who are currently receiving the requested medication through a previously authorized pharmacy or medical benefit, who meet one of the following:

- A. Member has experienced clinical benefit as evidenced by a bone mass measurement showing an improvement or stabilization in T-score compared with the previous bone mass measurement and member has not experienced any adverse effects.
- B. Member has experienced clinical benefit (e.g., no new fracture seen on radiography) and has not experienced clinically significant adverse events during therapy.

Other

The cumulative duration of parathyroid hormone analogs (teriparatide and abaloparatide) will not exceed a total of 24 months in the member's lifetime.

Non-Formulary Exception Criteria

Non-Formulary Exception Criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Appendices

Appendix A. Clinical reasons to avoid oral bisphosphonate therapy

- Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g., achalasia, stricture, or dysmotility)
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Presence of documented or potential gastrointestinal malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance < 35 mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B. WHO Fracture Risk Assessment Tool

- High FRAX fracture probability: 10-year major osteoporotic fracture risk \geq 20% or hip fracture risk \geq 3%
- 10-year probability; calculation tool available at: <https://www.shef.ac.uk/FRAX/>
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

- Tymlos [package insert]. Boston, MA: Radius Health, Inc. February 2024.
- Bisphosphonates. *Drug Facts and Comparisons*. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; March 21, 2019. Accessed October 7, 2020.
- Miller PD, Hattersley G, Riis BJ, et al. Effect of Abaloparatide Vs Placebo on New Vertebral Fractures in Postmenopausal Women with Osteoporosis: A Randomized Clinical Trial. *JAMA*. 2016; 316 (7): 722:733.
- 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. *Endocr Pract*. 2016;22 (Suppl 1):1-46.
- FRAX® fracture risk assessment tool. © Centre for Metabolic Bone Diseases: University of Sheffield, UK. Available at: <https://www.shef.ac.uk/FRAX/>. Accessed October 12, 2024.
- Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Bone Disorders Clinical Programs. April 2019.
- Ensrud KE, Crandall CJ. Osteoporosis. *Ann Intern Med* 2017;167(03):ITC17–ITC32.
- 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;104:1595-1622.
- Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Bone Disorders Clinical Programs. December 2019.
- Carey, John. What is failure of bisphosphonate therapy for osteoporosis. *Cleve Clin J Med*. 2005; 72:1033-1039.

- Fink HA, Gordon G, Buckley L, et al. 2017 American College of Rheumatology Guidelines for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Care Res.* 2017;69:1521-1537.
- Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2020;105(3):587-594.
- Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocr Metab.* 2012;97(6):1802-1822.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.20.62

Original Effective Date: January 1, 2019

Reviewed: January 2026

Revised: January 2026

Current Effective Date: March 10, 2026