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 the health plan's preferred product, Teriparatide, 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 product, Teriparatide, is the follow-on biologic product 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

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

POLICY

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.

Criteria for Initial Approval

A. Postmenopausal osteoporosis

Authorization for Tymlos (abaloparatide) 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 the preferred product Teriparatide
   b. Member has experienced a documented intolerable adverse event with the preferred product Teriparatide
   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

   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:
   i). 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)
   ii). Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], denosumab [Prolia])
   iii). 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 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 as evidenced by no adverse events during therapy (i.e., no clinically significant adverse reaction to Tymlos, no new fracture seen on radiography).

Other

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

Appendix

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 ≥ 20% or hip fracture risk ≥ 3%.
- 10-year probability; calculation tool available at: https://www.sheffield.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

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POLICY HISTORY

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