abaloparatide (Tymlos™)

Policy # 00573
Original Effective Date: 07/19/2017
Current Effective Date: 07/11/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider abaloparatide (Tymlos™)‡ for the treatment of postmenopausal women with osteoporosis at high risk for fracture to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility for abaloparatide (Tymlos) will be considered when ALL of the following criteria are met:

- Patient is a postmenopausal woman who has central dual x-ray absorptiometry (DXA) bone mineral density (BMD) T-score less than or equal to -2.5, confirming osteoporosis, OR a fragility fracture [defined as a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures]; AND
- Patient has not been on Tymlos (or another parathyroid hormone product, e.g., teriparatide [Forteo®]‡) for more than 2 years of cumulative therapy; AND
- Patient has or has had one of the following:
    - Inability to take oral bisphosphonates; or
    - A 12-month trial of oral bisphosphonates without documented improvement
      *(Note: This criterion is an additional requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of abaloparatide (Tymlos) in the absence of a 12-month trial of oral bisphosphonates (or in the absence of an inability to take oral bisphosphonates) in postmenopausal women with osteoporosis at high risk for fracture to be **not medically necessary.****

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of abaloparatide (Tymlos) when patient selection criteria are not met to be **investigational* [except** in the absence of a 12-month trial of bisphosphonates (or in the absence of an inability to take oral bisphosphonates), which will be denied as **not medically necessary**].**

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Based on review of available data, the Company considers the use of abaloparatide (Tymlos) when used for indications other than those approved by the U.S. Food and Drug Administration (FDA) to be **investigational.***

Background/Overview

Tymlos is a human parathyroid hormone related peptide analog indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The recommended dose of Tymlos is 80 mcg subcutaneously once daily into the periumbilical region of the abdomen. Tymlos is supplied as a 3120 mcg/1.56 mL single patient use prefilled pen, which delivers 30 daily doses of 80 mcg Tymlos. Parathyroid hormone regulates bone metabolism, renal tubular reabsorption of calcium and phosphate, and intestinal calcium absorption. These actions stimulate new bone formation on travecular and cortical bone surfaces by preferential stimulation of osteoblastic activity over osteoclastic activity. A boxed warning indicates that Tymlos (or any other parathyroid hormone product, such as Forteo) should not be given for more than 2 cumulative years of therapy.

Osteoporosis

Osteoporosis is characterized by decreased bone mass and increased fracture risk, most commonly at the spine, hip and wrist. DXA scans of patients with osteoporosis reveal a T-score less than or equal to -2.5. In addition to those patients with a DXA score representing osteoporosis, treatment should be considered in those patients with a fragility fracture. A fragility fracture is a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g. a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures. While osteoporosis occurs in both men and women, it is most common among women following menopause. In healthy humans, bone formation and resorption are closely linked; old bone is resorbed and replaced by newly formed bone. In postmenopausal osteoporosis, bone resorption exceeds bone formation, leading to bone loss and increased risk of fracture. After menopause, the risk of fractures of the spine and hip increases; approximately 40% of 50-year old women will experience an osteoporosis-related fracture during their remaining lifetimes.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Tymlos is a human parathyroid hormone related peptide analog indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The efficacy of Tymlos for the treatment of postmenopausal osteoporosis was evaluated in an 18 month randomized, placebo-controlled trial in postmenopausal women aged 49 to 86 years. The subjects either received Tymlos 80 mcg or placebo given subcutaneously daily. Subjects also received supplemental calcium and vitamin D. The efficacy study was extended as an open label study in which subjects no longer received Tymlos or placebo, but were maintained in their original treatment group and received 70 mg of alendronate weekly (with calcium and vitamin D) for 6 months. In totality, the trial was over a period of 25 months (18 months of either Tymlos or placebo, 1 month of no treatment, and then 6 months of alendronate therapy). The primary endpoint in the study was the incidence of new vertebral fractures in patients treated with Tymlos compared to placebo. At 18 months, subjects receiving Tymlos had a significant reduction in the incidence of new vertebral fractures as compared to those receiving placebo (0.6% vs. 4.2%, $p<0.0001$). This equates to an 86% relative risk reduction in vertebral fracture with Tymlos versus placebo at 18 months. At 25 months, the incidence of new vertebral fractures was 0.6% in subjects treated with Tymlos then alendronate versus 4.4% in subjects treated with placebo then alendronate ($p<0.0001$). There are also secondary endpoints which exhibit a significant reduction in nonvertebral fractures and increases in BMD.

References

1. Tymlos [package insert]. Radius Health, Incorporated. Waltham, Massachusetts. Updated April 2017.
2. Clinician's Guide to Prevention and Treatment of Osteoporosis. Natoinal Osteoporosis Foundation. 2015,

Policy History

Original Effective Date: 07/19/2017
Current Effective Date: 07/11/2018
07/06/2017 Medical Policy Committee review
07/19/2017 Medical Policy Implementation Committee approval. New policy.
07/05/2018 Medical Policy Committee review
07/11/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 07/2019

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.