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Next Review Due By: 07/2024
Policy Number: C17354-A

Tymlos (abaloparatide)

PRODUCTS AFFECTED

Tymlos (abaloparatide)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Osteoporosis in postmenopausal women, men with osteoporosis at high risk for fracture

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. OSTEOPOROSIS:
   1. Documented diagnosis of postmenopausal osteoporosis in women who are at a high risk of fracture OR osteoporosis in men
      AND

2. (a) The member 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
   (b) The member has had an osteoporotic fracture or a fragility fracture of the spine, hip, proximal humerus, pelvis, or distal forearm
   OR
   (c) The member has low bone mass (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]) and the prescriber determines the member is at high risk for fracture
   AND
3. Prescriber attests that member has been counseled to concurrently take calcium (1000 mg) and vitamin D (400-1200 international units) supplements in conjunction with Tymlos (abaloparatide)
   AND
4. Documentation of failure (12-month trial), contraindication, or serious side effects to oral AND IV bisphosphonate therapy (Document drug, date, and duration of trial)
   NOTE: Treatment failure is defined by progression of bone loss as documented by bone density measurements (BMD) after at least 12 months of therapy OR Occurrence of an osteoporotic fracture after having been compliant on at least 12 months of therapy on an oral bisphosphonate
   AND
5. Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Forteo, Tymlos) during the member's lifetime
   AND
6. Prescriber attests that Tymlos will not be used concurrently with bisphosphonates, RANKL inhibitor (e.g., denosumab), parathyroid hormone analog (e.g., Forteo), or other anabolic agent (e.g., Evenity)
   AND
7. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Tymlos (abaloparatide) include: Hypersensitivity to Tymlos, patients with increased risk of osteosarcoma including patients with open epiphyses, metabolic bone diseases including Paget's disease, bone metastases or history of skeletal malignancies, prior external beam or implant radiation therapy involving the skeleton, and hereditary disorders predisposing to osteosarcoma, patients with pre-existing hypercalcemia and those known to have an underlying hypercalcemic disorder such as primary hyperparathyroidism]

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Authorization will be issued for up to 24 months. (Duration of coverage will be limited to 24 months of cumulative parathyroid hormone analog therapy (e.g., Forteo, Tymlos) in the member's lifetime.)

PRESCRIBER REQUIREMENTS:
No requirement

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
1 pen (3120mcg/1.56mL) per 30 days
Maximum Quantity Limits – 1 pen (3120mcg/1.56mL) per 30 days

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Parathyroid Hormone And Derivatives

FDA-APPROVED USES:
Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, treatment to increase bone density in men with osteoporosis at high risk for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
Limitations of Use: The safety and efficacy of Tymlos have not been evaluated beyond 2 years of treatment. Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Tymlos is a human parathyroid hormone related peptide analog indicated for the treatment of postmenopausal members with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or members who have failed or are intolerant to other available osteoporosis therapy1. The participants of the leading study of Tymlos for the treatment of osteoporosis had baseline mean T-scores of -2.9 at the lumbar spine, -2.1 at the femoral neck, and -1.9 at the total hip. At baseline, 24% of members had at least one prevalent vertebral fracture and 48% had at least one prior nonvertebral fracture. Current guidelines define osteoporosis as a bone mineral density (BMD) T-score of -2.5 or below, and osteopenia as a T- score between -1 and -2.5. Additionally, guidelines state that osteoporosis can also be diagnosed by the history of a low- trauma spine or hip fracture regardless of BMD, a history of a fragility fracture in osteopenic members, or in osteopenic members with an elevated fracture risk as defined by the FRAX® fracture assessment tool. 2 Available literature defines high risk for fracture as bone mineral density (BMD) T- scores of -3.5 or less, while it defines severe osteoporosis as T-scores of -2.5 or less with at least one fragility fracture.2-7 The FRAX tool is designed to assist clinicians in predicting the ten- year probability of fracture with or without the addition of femoral neck bone mineral density (BMD).8 Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a member's lifetime is not recommended.

Tymlos (abaloparatide) received approval for treatment to increase bone density in men with osteoporosis at high risk of fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture). This was based on the Phase 3 ATOM study (NCT 03512262), a double-blind, placebo-controlled trial that evaluated percent change from baseline in lumbar spine BMD at 12 months in patient treated with Tymlos compared to placebo. At baseline, the mean T-scores were -2.1 at the lumbar spine,

-2.1 at the femoral neck, and -1.7 at the total hip. Patients took daily supplemental calcium and vitamin D. The percent change from baseline in bone mineral density (BMD) at the lumbar spine at 12 months was 8.5% in the Tymlos 80 mcg group and 1.2% in the placebo group. The treatment difference between Tymlos and placebo was 7.3% (99% CI: 5.1%, 9.6%; p<0.0001). Treatment with Tymlos also resulted in increases in BMD compared to placebo at the total hip and femoral neck (p<0.0001).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Tymlos (abaloparatide) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Tymlos (abaloparatide) include: Hypersensitivity to Tymlos, patients with increased risk of osteosarcoma including patients with open epiphyses, metabolic bone diseases including Paget's disease, bone metastases or history of skeletal malignancies, prior external beam or implant radiation therapy involving the skeleton, and hereditary disorders predisposing to osteosarcoma, patients with pre-existing hypercalcemia and those known to have an underlying hypercalcemic disorder such as primary hyperparathyroidism.

OTHER SPECIAL CONSIDERATIONS:

Administer the first several doses where the member can sit or lie down if necessary in case symptoms of orthostatic hypotension occur.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:

Tymlos SOPN 3120MCG/1.56ML

REFERENCES

1. Tymlos (abaloparatide) [prescribing information]. Waltham, MA: Radius Health; December 2022.
2. Eastell R, Rosen CJ, Black DM, Cheung AM, Murad MH, Shoback D. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2019;104(5):1595-1622. [PubMed 30907953]10.1210/jc.2019-00221
3. Camacho, P., Petak, S., Binkley, N., Diab, D., Eldeiry, L., Farooki, A., Harris, S., Hurley, D., Kelly, J., Lewiecki, E., Pessah-Pollack, R., McClung, M., Wimalawansa, S. and Watts, N., 2020. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis— 2020 Update. Endocrine Practice, 26, pp.1-46.
4. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014. Osteoporos Int.2014 Oct;25(10):2359-81. Epub 2014 Aug. 15.
5. Forteo (teriparatide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2021.
6. American Association of Clinical Endocrinologists Medical Guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis. Endocrine Practice. September 2016;22(4):1-42.
7. Qaseem, A., Hicks, L. A., Etxeandia-Ikobaltzeta, I., Shamliyan, T., & Cooney, T. G. (2023). Pharmacologic treatment of primary osteoporosis or low bone mass to prevent fractures in adults: A living clinical guideline from the American College of Physicians. Annals of Internal Medicine, 176(2),

224–238. doi:10.7326/m22-1034

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Drug Class Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Diagnosis Required Medical Information FDA-Approved Uses Background	Q1 2023
REVISION- Notable revisions: Required Medical Information Contraindications/Exclusions/Discontinuation References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file