Clinical Policy Title:	Parathyroid Hormone Analogs
Policy Number:	RxA.138
Drug(s) Applied:	Teriperatide (620 mcg/2.48 mL), Tymlos
Original Policy Date:	02/07/2020
Last Review Date:	7/3/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Osteoporosis (must meet all)**:**

1. Diagnosis of one the following (a or b):
   a. Post menopausal osteoporosis (PMO) or osteopenia;
   b. Primary or hypogonadal osteoporosis in men;
2. Member meets one of the following (a or b):
   a. Bone mineral density (BMD) T-score of less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site);
   b. History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm;
3. Trial and failure, contraindication, or intolerance to at least one bisphosphonate;
4. For teriparatide or Tymlos only
   a. One of the following (a or b):
      i. Treatment duration of PTH analogs has not exceeded a total of 24 months during the member's lifetime;
      ii. Member remains at or has returned to having a high risk for fracture despite a total of 24 months of use of PTH analogs

Approval Duration
All Lines of Business (except Medicare): 24 months

B. Glucocorticoid-induced osteoporosis (GIO):

1. History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months;
2. One of the following:
   a. BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius;
   b. History of one of the following fractures resulting from minimal trauma from vertebral compression, hip, distal radius, pelvis, or proximal humerus;
3. Trial and failure, contraindication, or intolerance to at least one bisphosphonate
4. One of the following (a or b):
   a. Treatment duration of PTH analogs has not exceeded a total of 24 months during the member's lifetime;
   b. Member remains at or has returned to having a high risk for fracture despite a total of 24 months of use of PTH analogs;

Approval Duration
All Lines of Business (except Medicare): 24 months

Continued Therapy Approval

A. All indications (must meet all)**:**
1. Therapy is limited to 24 months, additional therapy is subject to initial approval criteria.

References

1. National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International 2014. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4176573/. Accessed October 17, 2022.
2. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract 2010;16(Suppl 3):1-37. Available at: https://pubmed.ncbi.nlm.nih.gov/21224201/. Accessed October 17, 2022.
3. Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis Rheumatol. 2017; 69(8): 1521-1537. Available at: https://pubmed.ncbi.nlm.nih.gov/28585373/. Accessed October 17, 2022.
4. American College of Physicians. Treatment of low bone density or osteoporosis to prevent fractures in men and women: a clinical practice guideline update from the American College of Physicians. Ann intern Med. 2017; 166: 818-839. Available at: https://pubmed.ncbi.nlm.nih.gov/28492856/. Accessed October 17, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy was reviewed: rephrased Continued Therapy criteria A.1. to "currently receiving medication that has been authorized by RxAdvance benefit". References were reviewed and updated	05/2020	05/21/2020
Policy was reviewed: 1. Clinical policy title table was updated. 2. Drug(s) applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Initial approval and continued therapy approval criteria updated for 6 and 12 months and removed limited to 2 years cumulative use of PTH analogs per lifetime. 6. References were reviewed and updated. 7. For the treatment of postmenopausal women with osteoporosis at high risk for fracture (defined herein as having a history of osteoporotic fracture or multiple risk factors	01/25/2021	03/09/2021

for fracture) or who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, FORTEO reduces the risk of vertebral and nonvertebral fractures. To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy. For the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.		
Policy was reviewed: 1. Initial Approval Criteria: Updated a. I.A.3.a Updated prescriber criteria from Prescribed by or in consultation with one of the following specialists: a gynecologist, endocrinologist, rheumatologist, geriatrician, orthopaedist, or physiatrist to Prescribed by or in consultation with one of the following specialists: a gynecologist, endocrinologist, rheumatologist, geriatrician, orthopaedic surgeon, or physiatrist. b. I.A.4: Updated diagnostic criteria from member has not received cumulative therapy on PTH analogs (e.g., Tymlos®, Forteo®) that exceeds 2 years to Member meets any of the following (a or b), a. Member has not received cumulative therapy on PTH analogs (e.g., Tymlos®, Forteo®) that exceeds 2 years; b. Use of more than.. has high risk of fracture. 2. Continued Therapy Approval Crtieria, II.A.3: Updated diagnostic criteria from Member has not received cumulative therapy on PTH analogs (e.g., Tymlos®, Forteo®) that exceeds	11/29/2021	01/17/2022

2 years to Member meets any of the following (a or b), a. Member has not received cumulative therapy on PTH analogs (e.g., Tymlos®, Forteo®) that exceeds 2 years; b. Use of more than 2 years…risk of fracture. 3. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: "Diagnosis of osteoporosis" was replaced with Diagnosis of PMO, GIO, or male osteoporosis and one of the following (a or b): a. Member is at very high risk for fracture as evidenced by one of the following (i, ii, or iii): i. Recent osteoporotic fracture (within the past 12 months); ii. Bone mineral density (BMD) T-score at hip or spine ≤ -3.0; iii. BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus); b. Member has completed a 3-year trial of bisphosphonate therapy at up to maximally indicated doses, unless one of the following (i-v): i. All bisphosphonates are contraindicated; ii. Clinically significant adverse effects are experienced to both intravenous and oral formulations; iii. Member has experienced a loss of BMD while receiving bisphosphonate therapy; iv. Member has experienced a lack of BMD increase after ≥ 12 months of bisphosphonate therapy; v. Member experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy; *Prior authorization may be required for	10/17/2022	01/17/2023

bisphosphonates. 2. Initial Approval Criteria, I.A.3.b: Updated to remove prior trial and failure criteria "Failure of a 12-month trial of a bisphosphonate (alendronate is preferred) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced". 3. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy reviewed: 1. Policy fully reviewed to simplify the following: a. Diagnosis and diagnostic requirements b. Removed embedded step edit treatment duration requirement. c. Changed approval duration to 24 months and no reauthorization for continuation.	3/15/2024	3/15/2024
Added Forteo Changed policy title to “Parathyroid Hormone Analogs”	7/3/2024	7/3/2024
Removed Forteo	9/1/2024	9/1/2024