RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	teriparatide
Policy Number:	RxA.138
Drug(s) Applied:	Forteo®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All Line of Business

Background

Forteo® is parathyroid hormone analog, (PTH 1-34), indicated for:

- 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 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
teriparatide (Forteo®)	Osteoporosis	20 mcg SC once daily	20 mcg/day for up to 2 years cumulative

Dosage Forms

- Injection: 620 mcg/2.48 mL (250 mcg/mL) in a single-patient-use prefilled delivery device (pen) containing 28 daily doses of 20 mcg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

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

1. Diagnosis of osteoporosis;
2. Age ≥ 18 years or documentation of closed epiphyses (e.g., x-ray);
3. Member meets one of the following (a or b):
   a. Prescribed by or in consultation with one of the following specialists: a gynecologist, endocrinologist, rheumatologist, geriatrician, orthopaedist, or physiatrist;

b. 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;

4. Member has not received cumulative therapy on PTH analogs (e.g., Tymlos®, Forteo®) that exceeds 2 years;
5. Dose does not exceed 20 mcg per day (1 pen every 28 days).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Member has not received cumulative therapy on PTH analogs (e.g., Tymlos, Forteo) that exceeds 2 years;
4. If request is for a dose increase, new dose does not exceed 20 mcg per day (1 pen every 28 days).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PTH: parathyroid hormone

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax®)	Osteoporosis 10 mg PO once daily or 70 mg PO q week Glucocorticoid-induced osteoporosis 5 mg PO once daily or 10 mg PO once daily (in postmenopausal women not receiving estrogen) Osteoporosis prophylaxis 5 mg PO once daily or 35 mg PO q week	Osteoporosis 10 mg/day or 70 mg/week Glucocorticoid-induced osteoporosis 5 mg/day or 10 mg/day (in postmenopausal women not receivi estrogen) Osteoporosis prophylaxis 5 mg/day or 35 mg/week

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Fosamax® Plus D (alendronate/ cholecalciferol)	Osteoporosis 70 mg alendronate/2,800 units cholecalciferol or 70 mg alendronate/5,600 units cholecalciferol PO q week	Osteoporosis 70 mg alendronate/5,600 units cholecalciferol/week
risedronate (Actonel®, Atelvia®)	Osteoporosis (including prophylaxis) 5 mg PO once daily or 35 mg PO q week or 75 mg PO once daily for 2 consecutive days for 2 doses/month or 150 mg PO q month Glucocorticoid-induced osteoporosis 5 mg PO once daily	Osteoporosis (including prophylaxis) 5 mg/day or 35 mg/week or 75 mg/day for 2 days per month or 150 mg/month Glucocorticoid-induced osteoporosis 5 mg/day
zoledronic acid (Reclast®)	Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid- induced osteoporosis 5 mg IV q year Postmenopausal osteoporosis prophylaxis 5 mg IV q 2 years	Postmenopausal osteoporosis, men with osteoporosis, glucocorticoid-induced osteoporosis 5 mg/year Postmenopausal osteoporosis prophylaxis 5 mg/2 years
ibandronate (Boniva®)	Postmenopausal osteoporosis 150 mg PO q month or 3 mg IV every 3 months Postmenopausal osteoporosis prophylaxis 150 mg PO q month	150 mg/month or 3 mg/3 months

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to teriparatide or to any of its excipients.

- Boxed warning(s):
  - N/A

APPENDIX D: General Information

- The World Health Organization uses the following classifications for osteoporosis and osteopenia:

Category	T-score
Normal	-1.0 or above
Low bone mass (osteopenia)	Between -1.0 and -2.5
Osteoporosis	-2.5 or below

- Men with hypogonadal osteoporosis are defined as those who are receiving testosterone therapy but remain at high risk for fracture, or those who have a contraindication to testosterone therapy.

References

1. Forteo Prescribing Information. Indianapolis, IN: Eli Lilly and Company; November 2020. Available at http://www.forteo.com. Accessed January 25, 2020.
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3. 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. Accessed January 25, 2020.
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5. 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.
6. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guidelines. J Clin Endocrinol Metab 2012;97(6):1802-1822.
7. 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.
8. Camacho PM, Petak SM, Brinkley N et al. AACE/ACE Guidelines- American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocrine Practice Vol 22 (suppl 4) September 2016.
9. Richard Eastell, Clifford J Rosen, Dennis M Black, Angela M Cheung, M Hassan Murad, Dolores Shoback, Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical

Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221

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. Appendix B: "Therapeutic alternatives verbiage was updated to below are suggested therapeutic alternatives based on clinical guidance...." 7. References were reviewed and updated. 8. Dosage Form updated to: Injection: 620 mcg/2.48 mL (250 mcg/mL) in a single-patient-use prefilled delivery device (pen)	01/25/2021	03/09/2021

containing 28 daily doses of 20 mcg 9. Removed osteosarcoma boxed warning 10. Background updated to: Forteo® is parathyroid hormone analog, (PTH 1-34), indicated for: 11. 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 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. 12. Contraindications updated to: Hypersensitivity to teriparatide or to any of its excipients		