

Parathyroid Hormone Analogs
Forteo (teriparatide)
Teriparatide
Tymlos (abaloparatide)
Effective 09/01/2022

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Parathyroid hormone-related protein analogs are medications used to treat osteoporosis

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Forteo, Teriparatide or Tymlos **and** have received less than a total of 24 months of treatment, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Forteo and Teriparatide

Postmenopausal osteoporosis

Authorization may be granted to postmenopausal members with osteoporosis when ANY of the following criteria are met and documentation is provided:

1. Member has a history of fragility fractures
2. 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:
 - a. 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)

- b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], denosumab [Prolia], abaloparatide [Tymlos])
- c. 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)

Primary or hypogonadal osteoporosis in men

Authorization may be granted to male members with primary or hypogonadal osteoporosis when ANY of the following criteria are met:

- 1. Member has a history of an osteoporotic vertebral or hip fracture
- 2. Member meets criteria BOTH of the following criteria:
 - a. 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)
 - b. Member has had an oral OR injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (See Appendix A)

Glucocorticoid-induced Osteoporosis

Authorization may be granted for members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:

- 1. Member has had an oral OR injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (See Appendix A)
- 2. Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥ 2.5 mg/day for ≥ 3 months.
- 3. Member meets ANY of the following criteria:
 - a. Member has a history of a fragility fracture
 - b. Member has a pre-treatment T-score less than or equal to -2.5
 - c. 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)

Tymlos

Authorization may be granted to postmenopausal members with osteoporosis when ANY of the following criteria are met:

- 1. Member has a history of fragility fractures
- 2. Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pretreatment 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:
 - a. 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)
 - b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], denosumab [Prolia])
 - c. 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

Resubmission by prescriber when ONE of the following is met:

- 1. Member has experienced clinical benefit (e.g., no new fracture seen on radiography) and has not experienced clinically significant adverse events during therapy.



2. 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.

Limitations

1. Approvals will be limited to a total of 24 months.

Appendices

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 $\geq 20\%$ or hip fracture risk $\geq 3\%$.
- 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.

References

1. Forteo (teriparatide) [prescribing information]. Indianapolis, IN: Lilly USA LLC; September 2021
2. Tymlos (abaloparatide) [prescribing information]. Boston, MA: Radius Health Inc; December 2021.
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2020 update. *Endocr Pract.* 2020;26(suppl 1):1-46. doi:10.4158/GL-2020-0524SUPPL
4. Rosen HN, Drezner MK. Overview of the management of osteoporosis in postmenopausal women. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com>. Accessed November 4, 2021
5. 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

Review History

06/22/2022: Created and Reviewed June P&T, combined Forteo, Teriparatide & Tymlos into one custom document, renaming document to Parathyroid hormone analogs, updated approval durations to a total of 24 months; started and stabilized statement now includes "members who have received less than 24 months of treatment"; removed reauthorization approvals, removed Bonsity from document (obsolete). Effective 9/01/2022.

