JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS107
		Effective Date	10/18/2017
		Review Date	10/21/2020
	Subject **Tymlos, Forteo, Teriparatide injection**	*Revision Date*	12/08/2021
		Page	1 of 5

This document applies to the following Participating Organizations:

Priority Partners

Keywords: forteo, tymlos

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
	A. Tymlos	**1**
	B. Forteo	**2**
	C. Teriparatide injection	**3**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**4**
IV.	**EXCLUSIONS**	**4**
V.	**RECOMMENDED DOSE**	**5**
VI.	**REFERENCES**	**5**
VII.	**APPROVALS**	**5**

I. POLICY

Tymlos (abaloparatide), Forteo (teriparatide), and brand Teriparatide injection will require prior authorization to ensure appropriate use. It will require prior authorization for outpatient prescription drug benefit coverage to ensure this medication is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare PolicyManual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Tymlos** may be approved for patients who have the following condition and meet the following:
   I. **Postmenopausal osteoporosis**
      a. Patient is female and 18 years of age or older
      b. Documentation has been provided showing a diagnosis of postmenopausal osteoporosis
         1. AND **ONE** of the following:
            i. Bone Mineral Density (BMD) T-score of -2.5 or below in the lumbar spine, femoral neck, hip, and/or 33% (one-third) radius OR
            ii. Patient is at high risk of fracture defined as:
               A. A history of previous osteoporotic (fragility) fracture (fracture of the spine, hip, proximal humerus, pelvis, or distal forearm) regardless of T-score OR
               B. Having a T-score between -1.0 and -2.5 in the spine, femoral neck, hip, or 33% radius AND ONE of the following:
                  I. Fracture Risk Assessment (FRAX) 10-year probability for major osteoporotic fracture is 20% or greater, or the 10-year probability of hip fracture is 3% or greater OR

II. Documented history of repeat falls

c. Documentation of treatment failure or contraindication to conventional osteoporosis therapy (two independent bisphosphonate regimens)

d. Documentation of treatment failure or contraindication to Teriparatide injection

B. **Forteo** may also be approved for patients who meet the following criteria:

I. **Postmenopausal osteoporosis**

a. Patient is female and 18 years of age or older

b. Documentation has been provided showing a diagnosis of postmenopausal osteoporosis

1. AND **ONE** of the following:

i. BMD T-score of -2.5 or below in the lumbar spine, femoral neck, hip, and/or 33% (one-third) radius OR

ii. Patient is at high risk of fracture defined as:

A. A history of previous osteoporotic (fragility) fracture (fracture of the spine, hip, proximal humerus, pelvis, or distal forearm) regardless of T-score OR

B. Having a T-score between -1.0 and -2.5 in the spine, femoral neck, hip, or 33% radius AND **ONE** of the following:

I. Fracture Risk Assessment (FRAX) 10-year probability for major osteoporotic fracture is 20% or greater, or the 10-year probability of hip fracture is 3% or greater OR

II. Documented history of repeat falls

c. Documentation of treatment failure or contraindication to conventional osteoporosis therapy (two independent bisphosphonate regimens)

d. Documentation of treatment failure or contraindication to Teriparatide injection

II. **Primary or hypogonadal osteoporosis**

a. Patient is male and 18 years of age or older

b. Documentation has been provided showing a diagnosis of primary or hypogonadal osteoporosis

1. AND **ONE** of the following:

i. BMD T-score of -2.5 or below in the lumbar spine, femoral neck, hip, and/or 33% (one-third) radius OR

ii. Patient is at high risk of fracture defined as:

A. A history of previous osteoporotic (fragility) fracture (fracture of the spine, hip, proximal humerus, pelvis, or distal forearm) regardless of T-score OR

B. Having a T-score between -1.0 and -2.5 in the spine, femoral neck, hip, or 33% radius AND **ONE** of the following:

I. Fracture Risk Assessment (FRAX) 10-year probability for major osteoporotic fracture is 20% or greater, or the 10-year probability of hip fracture is 3% or greater OR

II. Documented history of repeat falls

c. Documentation of treatment failure or contraindication to conventional osteoporosis therapy (two independent bisphosphonate regimens)

d. Documentation of treatment failure or contraindication to Teriparatide injection

III. **Glucocorticoid-induced Osteoporosis**

a. Patient is 18 years of age or older

b. Documentation has been provided showing a diagnosis of glucocorticoid-induced osteoporosis

1. Patient is using an equivalent of prednisone 5 mg daily or more for 3 consecutive months or longer

A. AND **ONE** of the following:

i. BMD T-score of -2.5 or below in the lumbar spine, femoral neck, hip, and/or 33% (one-third) radius OR
ii. Patient is at high risk of fracture defined as:
a. A history of previous osteoporotic (fragility) fracture (fracture of the spine, hip, proximal humerus, pelvis, or distal forearm) regardless of T-score OR
b. Having a T-score between -1.0 and -2.5 in the spine, femoral neck, hip, or 33% radius AND **ONE** of the following:
I. Fracture Risk Assessment (FRAX) 10-year probability for major osteoporotic fracture is 20% or greater, or the 10-year probability of hip fracture is 3% or greater OR
II. Documented history of repeat falls

c. Patient has a documented history of treatment failure or contraindication to conventional osteoporosis therapy (two independent bisphosphonate regimens)
d. Documentation of treatment failure or contraindication to Teriparatide injection

C. **Teriparatide injection** may also be approved for patients who meet the following criteria:
I. **Postmenopausal osteoporosis**
a. Patient is female and 18 years of age or older
b. Documentation has been provided showing a diagnosis of postmenopausal osteoporosis
1. AND **ONE** of the following:
i. BMD T-score of -2.5 or below in the lumbar spine, femoral neck, hip, and/or 33% (one-third) radius OR
ii. Patient is at high risk of fracture defined as:
A. A history of previous osteoporotic (fragility) fracture (fracture of the spine, hip, proximal humerus, pelvis, or distal forearm) regardless of T-score OR
B. Having a T-score between -1.0 and -2.5 in the spine, femoral neck, hip, or 33% radius AND **ONE** of the following:
I. Fracture Risk Assessment (FRAX) 10-year probability for major osteoporotic fracture is 20% or greater, or the 10-year probability of hip fracture is 3% or greater OR
II. Documented history of repeat falls

c. Documentation of treatment failure or contraindication to conventional osteoporosis therapy (two independent bisphosphonate regimens)
II. **Primary or hypogonadal osteoporosis**
a. Patient is male and 18 years of age or older
b. Documentation has been provided showing a diagnosis of primary or hypogonadal osteoporosis
1. AND **ONE** of the following:
i. BMD T-score of -2.5 or below in the lumbar spine, femoral neck, hip, and/or 33% (one-third) radius OR
ii. Patient is at high risk of fracture defined as:
A. A history of previous osteoporotic (fragility) fracture (fracture of the spine, hip, proximal humerus, pelvis, or distal forearm) regardless of T-score OR
B. Having a T-score between -1.0 and -2.5 in the spine, femoral neck, hip, or 33% radius AND **ONE** of the following:
I. Fracture Risk Assessment (FRAX) 10-year probability for major osteoporotic fracture is 20% or greater, or the 10-year probability of hip fracture is 3% or greater OR

II. Documented history of repeat falls

c. Documentation of treatment failure or contraindication to conventional osteoporosis therapy (two independent bisphosphonate regimens)

III. **Glucocorticoid-induced Osteoporosis**

a. Patient is 18 years of age or older

b. Documentation has been provided showing a diagnosis of glucocorticoid-induced osteoporosis

1. Patient is using an equivalent of prednisone 5 mg daily or more for 3 consecutive months or longer

A. AND **ONE** of the following:

i. BMD T-score of -2.5 or below in the lumbar spine, femoral neck, hip, and/or 33% (one-third) radius OR

ii. Patient is at high risk of fracture defined as:

a. A history of previous osteoporotic (fragility) fracture (fracture of the spine, hip, proximal humerus, pelvis, or distal forearm) regardless of T-score OR

b. Having a T-score between -1.0 and -2.5 in the spine, femoral neck, hip, or 33% radius AND **ONE** of the following:

I. Fracture Risk Assessment (FRAX) 10-year probability for major osteoporotic fracture is 20% or greater, or the 10-year probability of hip fracture is 3% or greater OR

II. Documented history of repeat falls

c. Patient has a documented history of treatment failure or contraindication to conventional osteoporosis therapy (two independent bisphosphonate regimens)

III. AUTHORIZATION PERIOD/LIMITATIONS

1. Initial authorization period will be limited to 12 months of therapy
2. Continuation of therapy can be approved for a second 12-month period with documentation showing clinical benefit from treatment. Clinical benefit is evidenced by stable or increasing BMD with no display of new fractures or fracture progression

IV. EXCLUSIONS

A. Tymlos, Forteo, and brand Teriparatide will NOT be approved for patients with the following:

a. Risk for osteosarcoma
b. Paget's disease
c. Unexplained elevations of alkaline phosphatase
d. Prior bone radiation
e. Bone metastases or a history of skeletal malignancies
f. Metabolic bone diseases other than osteoporosis
g. High levels of calcium
h. Dual therapy with other human parathyroid hormone related peptide analogs, or monoclonal antibodies

B. Tymlos, Forteo, and brand Teriparatide are not recommended for more than 2 years of cumulative therapy during a patient's lifetime. As a result, neither agent will be approved for an extended duration beyond this timeframe.

C. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

1. Tymlos: 80mcg subcutaneous injection delivered once daily
2. Forteo and brand Teriparatide: 20mcg subcutaneous injection delivered once daily

VI. REFERENCES

1. Tymlos [Prescribing Information] Waltham, MA: Radius Health, Inc. April 2017
2. Forteo [Prescribing Information] Indianapolis, IN: Lilly USA, LLC. March 2012
3. Teriparatide Injection [Prescribing Information] Morristown, NJ: Alvogen, Inc. November 2019
4. WHO Fracture Risk Assessment Tool (FRAX). http://www.shef.ac.uk/FRAX (Accessed July, 2019)
5. Qaseem A, Forciea MA, McLean RM, et al. 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(11):818. 2017 May 9
6. American Association of Clinical Endocrinologists and American College of Endocrinology. Clinical Practice 2016 Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocr. Pract. 2016 Sep;22(9):1111-8. Available at: https://journals.aace.com/doi/pdf/10.4158/EP161435.GL
7. Van Staa TP, Leufkens HG, Cooper C. The epidemiology of corticosteroid-induced osteoporosis: a meta-analysis. Osteoporosis Int. 2002;13(10):777.

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
10/18/2017	Creation of Tymlos PA Criteria
05/11/2018	Addition of criteria for Forteo
07/17/2019	Clarified clinical criteria for both Tymlos and Forteo based on treatment guidelines
10/21/2020	Added criteria for brand Teriparatide injection; Updated criteria for Tymlos and Forteo
12/08/2021	Updated Exclusions section regarding physician samples

Review Date: 10/18/2017, 07/18/2018, 07/17/2019, 10/21/2020

Revision Date: 10/18/2017, 05/11/2018, 07/17/2019, 10/21/2020, 12/08/2021