BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 4/1/19
LAST REVIEW DATE: 2/21/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

FORTEO (teriparatide) subcutaneous injection
TYMLOS (abaloparatide) subcutaneous injection

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy 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 BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

FORTEO (teriparatide) subcutaneous injection
TYMLOS (abaloparatide) subcutaneous injection (cont.)

Criteria: Forteo (teriparatide)

- **Criteria for initial therapy:** Forteo (teriparatide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in or is in consultation with an Endocrinologist, Rheumatologist, or Orthopedics

2. Individual is 18 years of age or older

3. Individual with **ONE** of the following:
   - Established osteoporosis [T-score of -2.5 or worse (e.g., -3.0, -3.5, etc.)]
   - Osteopenia [T-score of -1.0 or worse] with a history of prior fragility fracture
   - A low trauma fragility bone fracture
   - At high risk for fracture as evidenced by multiple factors such as significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, (e.g., seizure medicines, blood thinners, high doses of vitamins A or D)
   - Glucocorticoid-induced osteoporosis at high risk for fracture associated with current and sustained use of Prednisone (or equivalent glucocorticoid) at a daily dose of 5 mg or more and expected to remain on glucocorticoids for 3 months or more

4. Individual has failed, or is intolerant to, or has a contraindication to at least **ONE** of the following agents:
   - Alendronate
   - Ibandronate
   - Risedronate
   - Zoledronic acid

5. Individual is receiving supplemental calcium **AND** vitamin D with doses adjusted per usual laboratory monitoring

6. No dual therapy with another parathyroid hormone related product such as: Tymlos (abaloparatide) or Natpara (parathyroid hormone)

7. No previous use of another parathyroid hormone related product of 2 years duration

8. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
   - Alkaline phosphatsase
   - Parathyroid hormone
   - Serum calcium
   - Serum phosphorus

- Serum uric acid

Initial approval duration: 12 months if previous use of any drug in this drug category is less than 12 months

- **Criteria for continuation of coverage (renewal request):** Forteo (teriparatide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in or is in consultation with an Endocrinologist, Rheumatologist, or Orthopedics

2. **ONE** of the following:
   - Established osteoporosis [T-score of -2.5 or worse (e.g., -3.0, -3.5, etc.)]
   - Osteopenia [T-score of -1.0 or worse] with a history of prior fragility fracture
   - A low trauma fragility bone fracture
   - At high risk for fracture as evidenced by multiple factors such as significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, (e.g., seizure medicines, blood thinners, high doses of vitamins A or D)
   - Glucocorticoid-induced osteoporosis at high risk for fracture associated with current and sustained use of Prednisone (or equivalent glucocorticoid) at a daily dose of 5 mg or more and expected to remain on glucocorticoids for 3 months or more
   - No evidence of disease progression
3. Individual has been adherent with the medication
4. Individual is receiving supplemental calcium **AND** vitamin D with doses adjusted per usual laboratory monitoring
5. No dual therapy with another parathyroid hormone related product such as: Tymlos (abaloparatide) or Natpara (parathyroid hormone)
6. No previous use of another parathyroid hormone related product of 2 years duration
7. Individual has not developed any significant unacceptable level 4 adverse drug effects that may exclude continued use
   - Significant adverse effect such as:
     - Hypersensitivity to teriparatide or any of its excipients
     - Osteosarcoma
     - Severe or sustained hypercalcemia
     - Hypercalciuria (urine calcium > 300mg/24 hours or > 7.5 mmol/24 hours)

FORTEO (teriparatide) subcutaneous injection
TYMLOS (abaloparatide) subcutaneous injection (cont.)

- Hypophosphatemia (< 0.74 mmil/L or 2.4 mg/dL)

Renewal duration: 12 months if previous use of any drug in this drug category is less than 24 months

Criteria: Tymlos (abaloparatide)

- **Criteria for initial therapy:** Tymlos (abaloparatide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in or is in consultation with an Endocrinologist, Rheumatologist, or Orthopedics
2. Individual is 18 years of age or older
3. Individual with **ONE** of the following:
   - Established osteoporosis [T-score of -2.5 or worse (e.g., -3.0, -3.5, etc.)]
   - Osteopenia [T-score of -1.0 or worse] with a history of prior fragility fracture
   - A low trauma fragility bone fracture
   - At high risk for fracture as evidenced by multiple factors such as significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, (e.g., seizure medicines, blood thinners, corticosteroids, high doses of vitamins A or D)
4. Individual has failed, or is intolerant to, or has a contraindication to at least **ONE** of the following agents:
   - Alendronate
   - Ibandronate
   - Risedronate
   - Zoledronic acid
5. Individual is receiving supplemental calcium **and** vitamin D with doses adjusted per usual laboratory monitoring
6. No dual therapy with another parathyroid hormone related product such as: Forteo (teriparatide) or Natpara (parathyroid hormone)
7. No previous use of another parathyroid hormone related product of 2 years duration
8. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
   - Alkaline phosphatsase

FORTEO (teriparatide) subcutaneous injection
TYMLOS (abaloparatide) subcutaneous injection (cont.)

- Parathyroid hormone
- Serum calcium
- Serum phosphorus
- Serum uric acid

Initial approval duration: 12 months if previous use of any drug in this drug category is less than 12 months

- **Criteria for continuation of coverage (renewal request):** Tymlos (abaloparatide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in or is in consultation with an Endocrinologist, Rheumatologist, or Orthopedics

2. **ONE** of the following:
   - Established osteoporosis [T-score of -2.5 or worse (e.g., -3.0, -3.5, etc.)]
   - Osteopenia [T-score of -1.0 or worse] with a history of prior fragility fracture
   - A low trauma fragility bone fracture
   - At high risk for fracture as evidenced by multiple factors such as significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, (e.g., seizure medicines, blood thinners, high doses of vitamins A or D)
   - Glucocorticoid-induced osteoporosis at high risk for fracture associated with current and sustained use of Prednisone (or equivalent glucocorticoid) at a daily dose of 5 mg or more and expected to remain on glucocorticoids for 3 months or more
   - No evidence of disease progression

3. Individual has been adherent with the medication

4. Individual is receiving supplemental calcium **and** vitamin D with doses adjusted per usual laboratory monitoring

5. No dual therapy with another parathyroid hormone related product such as: Forteo (teriparatide) or Natpara (parathyroid hormone)

6. No previous use of another parathyroid hormone related product of 2 years duration

7. Individual has not developed any significant unacceptable level 4 adverse drug effects that may exclude continued use
   - Significant adverse effect such as:
     - Osteosarcoma
     - Severe or sustained hypercalcemia

FORTEO (teriparatide) subcutaneous injection
TYMLOS (abaloparatide) subcutaneous injection (cont.)

- Hypercalciuria (urine calcium > 300mg/24 hours or > 7.5 mmol/24 hours)

Renewal duration: 12 months if previous use of any drug in this drug category is less than 24 months

- Forteo (teriparatide) and Tymlos (abaloparatide) for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
3. Insufficient evidence to support improvement of the net health outcome, and
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to:*
- Treatment with dosing or frequency outside the FDA-approved dosing and frequency

Description:

Forteo (teriparatide) is a recombinant form of human parathyroid hormone [rhPTH] that is the primary regulator of bone and mineral metabolism. Forteo may be used for treatment of osteoporosis in postmenopausal women, to increase bone mass in men with osteoporosis and for treatment of women and men with osteoporosis associated with sustained systemic glucocorticoid therapy. Generally, Forteo is given as a 2 year course of treatment.

Tymlos (abaloparatide) is an analog of human parathyroid hormone related peptide [PTHrP(1-34)] indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture or individuals who have failed or are intolerant to other available osteoporosis therapy.

The use of Forteo or Tymlos is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.

Cumulative use of Forteo and Tymlos and parathyroid hormone for more than 2 years during a patient's lifetime is not recommended.

Definitions:

Adult: Age 18 years and older

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TYMLOS (abaloparatide) subcutaneous injection (cont.)

T-Scores are reported as standard deviations (SD) World Health Organization (WHO) criteria:

Normal:	T-score within 1 SD
Osteopenia:	T-score of -1 to -2.5 SD
Osteoporosis:	T-score of -2.5 or worse SD
Severe Osteoporosis:	T-score of -2.5 or worse SD with fragility fractures

High risk for fracture is defined as *ONE* of the following:

- Osteoporotic fracture
- Multiple risk factors for fracture (significantly low bone mass, frequent falls, limited movement, medical conditions likely to cause bone loss, medicines that may cause bone loss, e.g., seizure medicines, blood thinners, corticosteroids, high doses of vitamins A or D)
- Failed response (as defined by prescribing provider) to previous osteoporosis therapy
- Intolerant to previous osteoporosis therapy

Fragility fracture:

A fracture occurring spontaneously or after a minor trauma.

Fracture Risk Assessment Tool (FRAX tool):

The World Health Organization developed a risk assessment tool to assist providers in evaluating osteopenic individuals. The tool uses clinically proven risk factors to determine a 10 year probability of hip fracture and a 10 year probability for a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fractures). Treatment may be considered if the 10-year risk is 3% or more for hip fracture or if the risk for other bone fracture is 20% or more.

The tool can obtained at https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9

Glucocorticoid Equivalencies:

Betamethasone	0.75 mg
Cortisone	25 mg
Dexamethasone	0.75 mg
Hydrocortisone	20 mg
Methylprednisolone	4 mg
Prednisone	5 mg
Prednisolone	5 mg

Resources:

Forteo (teriparatide) product information accessed 12-17-18 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aae667c5-381f-4f92-93df-2ed6158d07b0

Tymlos (abaloparatide) product information accessed 12-17-18 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=712143d9-e21e-4013-bb3b-3426a21060a8

UpToDate: Overview of the management of osteoporosis in postmenopausal women. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-management-of-osteoporosis-in-postmenopausal-women?search=osteoporosis%20treatment&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

UpToDate: Treatment of osteoporosis in men. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-of-osteoporosis-in-men?search=osteoporosis%20treatment&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3

UpToDate: The use of bisphosphonates in postmenopausal women with osteoporosis. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/the-use-of-bisphosphonates-in-postmenopausal-women-with-osteoporosis?search=osteoporosis%20treatment&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4

UpToDate: Prevention and treatment of glucocorticoid-induced osteoporosis. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/prevention-and-treatment-of-glucocorticoid-induced-osteoporosis?search=osteoporosis%20treatment&source=search_result&selectedTitle=9~150&usage_type=default&display_rank=9

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FORTEO (teriparatide) subcutaneous injection
TYMLOS (abaloparatide) subcutaneous injection (cont.)

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International Society for Clinical Densitometry. 2007 Official Positions.

Khosla, S. Parathyroid Hormone Plus Alendronate A Combination That Does Not Add Up. *The New England Journal of Medicine.* 09/25/2003;349(No. 13):1277-1279.

Liu, H, Paige, N, et, al. Screening for Osteoporosis in Men: A Systematic Review for an American College of Physicians Guideline. *Annals of Internal Medicine.* 05/2008;148(9).

MacLean, C, Newberry, S, et, al. Systematic Review: Comparative Effectiveness of Treatments to Prevent Fractures in Men and Women with Low Bone Density or Osteoporosis. *Annals of Internal Medicine.* 2008.

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National Institutes of Health Osteoporosis and Related Bone Diseases National Resource Center. Osteoporosis in Men. 05/2009.

Saag, K, Shane, E, et, al. Teriparatide or Alendronate in Glucocorticoid-Induced Osteoporosis. *N Engl J Med.* 2007;357:2028-2039.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.