BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**4/1/2019**
LAST REVIEW DATE:	**5/20/2021**
LAST CRITERIA REVISION DATE:	**5/20/2021**
ARCHIVE DATE:	

FORTEO (teriparatide) subcutaneous injection
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
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Forteo (teriparatide)
Teriparatide

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

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist, Rheumatologist, Gynecologist, Geriatrician, Physiatrist, or Orthopedic Specialist

2. Individual is 18 years of age or older

3. Individual with **ONE** of the following:
    a. Established osteoporosis [T-score of -2.5 or worse (e.g., -3.0, -3.5, etc.)]

    b. Osteopenia [T-score of -1.0 or worse] with a history of prior fragility fracture

    c. A low trauma fragility bone fracture

    d. Individual with a FRAX 10-year probability risk of 3% or more for a hip fracture **OR** 20% or more for other bone fracture, as assessed by the World Health Organization Fracture Risk Assessment Tool (FRAX tool) that can be obtained at https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9

    e. Glucocorticoid-induced osteoporosis and is 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. Documented failure, contraindication per FDA label, intolerance to at least **ONE** of the following agents:
    a. Alendronate
    b. Ibandronate
    c. Risedronate
    d. Zoledronic acid

5. Documented failure, contraindication per FDA label, intolerance to Prolia (denosumab)

6. **For brand Forteo (teriparatide):** documented failure, contraindication per FDA label, intolerance to generic teriparatide

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

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

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

Initial approval duration:
Duration will be determined by combining the number of months of use of any parathyroid hormone analog to allow for an initial duration of 12 months
Total life-time use of more than 24-months of any parathyroid hormone analog will not be approved

- **Criteria for continuation of coverage (renewal request):** Forteo (teriparatide) and generic 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 the patient's diagnosis or is in consultation with an Endocrinologist, Rheumatologist, Gynecologist, Geriatrician, Physiatrist, or Orthopedic Specialist

2. Individual's condition responded while on
    a. Response is defined as **BOTH** of the following:
        i. Achieved and maintains increased bone mineral density (e.g., lumbar spine, femoral neck, or total hip) and **ONE** of the following:
            1. Reduced incidence of new vertebral fractures in previously non-deformed vertebrae
            2. Reduced incidence of non-vertebral fractures (e.g., ankle/foot, hip, humerus, pelvis, wrists, ribs, or other sites)

        ii. 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 adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. Osteosarcoma
        ii. Severe or sustained hypercalcemia
        iii. Calciphylaxis or worsening of previously stable cutaneous calcification

Renewal duration:
Duration will be determined by combining the number of months of use of any parathyroid hormone analog to allow for an additional duration of 12 months
Total lifetime use of more than 24-months of any parathyroid hormone analog will not be approved

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- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of a Non-cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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 the patient's diagnosis or is in consultation with an Endocrinologist, Rheumatologist, Gynecologist, Geriatrician, Physiatrist, or Orthopedic Specialist

  2. Individual is 18 years of age or older

  3. Individual with **ONE** of the following:
     a. Established osteoporosis [T-score of -2.5 or worse (e.g., -3.0, -3.5, etc.)]

     b. Osteopenia [T-score of -1.0 or worse] with a history of prior fragility fracture

     c. A low trauma fragility bone fracture

     d. Individual with a FRAX 10-year probability risk of 3% or more for a hip fracture **OR** 20% or more for other bone fracture, as assessed by the World Health Organization Fracture Risk Assessment Tool (FRAX tool) that can be obtained at https://www.sheffield.ac.uk/FRAX/tool.aspx?country=9

  4. Documented failure, contraindication per FDA label, intolerance to at least **ONE** of the following agents:
     a. Alendronate
     b. Ibandronate
     c. Risedronate
     d. Zoledronic acid

  5. Documented failure, contraindication per FDA label, intolerance to Prolia (denosumab)

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

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

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

Initial approval duration:
Duration will be determined by combining the number of months of use of any parathyroid hormone analog to allow for an initial duration of 12 months
Total lifetime use of more than 24-months of any parathyroid hormone analog will not be approved

- **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 the patient's diagnosis or is in consultation with an Endocrinologist, Rheumatologist, Gynecologist, Geriatrician, Physiatrist, or Orthopedic Specialist

2. Individual's condition responded while on
    a. Response is defined as **BOTH** of the following:
        i. Achieved and maintains increased bone mineral density (e.g., lumbar spine, femoral neck, or total hip) and **ONE** of the following:
            1. Reduced incidence of new vertebral fractures in previously non-deformed vertebrae
            2. Reduced incidence of non-vertebral fractures (e.g., ankle/foot, hip, humerus, pelvis, wrists, or other sites)

        ii. 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 adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. Osteosarcoma
        ii. Severe or sustained hypercalcemia

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Renewal duration:
Duration will be determined by combining the number of months of use of any parathyroid hormone analog to allow for an additional duration of 12 months
Total lifetime use of more than 24-months of any parathyroid hormone analog will not be approved

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of a Non-Cancer Medications**
2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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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Guideline for Pharmacologic Intervention in Postmenopausal Woman and Male 50 years of age or older:

History of hip or vertebral fracture
T-score ≤ -2.5 (DKA) at the femoral neck or spine, after exclusion of secondary causes
T-score between -1 and -2.5 at the femoral neck or spine and a 10-year probability of hip fracture ≥ 3% or a 10-year probability of any major osteoporosis-related fracture ≥ 20% based on the WHO algorithm

Available FDA-approved medications for the prevention of osteoporosis in postmenopausal women:

Drug Class	Medication	Dose
Estrogens	Many	Variable
Biphosphonates	Alendronate	35 mg/week or 5 mg/day
	Risedronate	35 mg/week or 5 mg/day
	Ibandronate	150 mg/month
	Zoledronic acid	5 mg IV once every 2-years
Selective estrogen receptor modulator	Raloxifene	60 mg/day
	Bazedoxifene + conjugated equine estrogen	20 mg + 0.45 mg daily
There is no FDA-approved medications for prevention of osteoporosis in men		

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

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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, revised by Eli Lilly and Company 11-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on April 16, 2021.

Teriparatide product information, revised by Alvogen, Inc. 11-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on April 16, 2021.

Tymlos (abaloparatide) product information, revised by Radius Health, Inc. 10-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on April 16, 2021.

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Finkelstein JS, Yu EW. Treatment of osteoporosis in men. In: UpToDate, Rosen CJ, Mulder JE (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on April 16, 2021.

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