BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

BONSITY (teriparatide) subcutaneous injection
FORTEO (teriparatide) subcutaneous injection
Teriparatide subcutaneous injection
TYMLOS (abaloparatide) subcutaneous injection
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for BONSITY (teriparatide), FORTEO (teriparatide), Teriparatide generic, TYMLOS (abaloparatide)

Criteria for Initial Therapy:

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Prescriber Qualifications

- Prescribed by or in consultation with Endocrinologist, Rheumatologist, Gynecologist, Geriatrician, Physiatrist, Orthopedic Specialist

Indication

- **ONE** of the following:
  - Osteoporosis (T-score of -2.5 or worse) at high risk for fracture OR failed or intolerant to other osteoporosis therapy
  - Osteopenia (T-score of -1.0 or worse) with prior fragility fracture OR failed or intolerant to other osteoporosis therapy
  - History of low trauma fragility fracture OR failed or intolerant to other osteoporosis therapy
  - FRAX 10-year risk 3% or greater for hip fracture greater OR 20% or greater for other fracture, as assessed by 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
  - **For teriparatide products:** Glucocorticoid-induced osteoporosis with sustained prednisone (or equivalent) at 5 mg or more daily for 3 months or longer

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- DEXA Scan
- Receiving supplemental calcium and vitamin D with doses adjusted per usual laboratory monitoring

Alternative Therapies

- Failure contraindication, or intolerance to **ONE** of the following:
  - Alendronate
  - Risedronate
  - Zoledronic acid
- Failure, contraindication, or intolerance to a denosumab product
- **For Forteo:** Failure, contraindication, or intolerance to Bonsity (teriparatide)

Brand Specific Criteria

- **For Tymlos:** Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (FDA) (see Definitions section)

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Safety

- No concomitant use with Evenity (romosozumab) or another parathyroid hormone related product
- No prior use of another parathyroid hormone related product for 2 years or Evenity for 1 year
- No underlying hypercalcemic disorder such as primary hyperparathyroidism

Documentation Requirements

- A completed request form must be submitted, including:
  - Chart notes
  - Lab results (T-score, FRAX, calcium levels)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- Duration will be determined by combining the number of months of use of any parathyroid hormone analog or Evenity (romosozumab) to allow for an initial duration of 12 months or end of plan year

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Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification

- Continues to be seen by a physician specializing in or in consultation with Endocrinologist, Rheumatologist, Gynecologist, Geriatrician, Physiatrist, Orthopedic Specialist

Clinical Response

- **BOTH** of the following:
  - 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)
  - No evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Alternative Therapies

- **For Forteo:** Failure, contraindication, or intolerance, to Bonsity (teriparatide)

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Brand Specific Criteria

- **For Tymlos:** Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No concomitant use with Evenity (romosozumab) or another parathyroid hormone related product
- No prior cumulative use greater than 24 months of any parathyroid hormone analog
- No significant adverse effects such as:
  - osteosarcoma,
  - severe or sustained hypercalcemia,
  - calciphylaxis or worsening cutaneous calcification

Additional Requirements

- Receiving supplemental calcium and vitamin D with doses adjusted per usual laboratory monitoring

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe use

Continuation Approval Duration

- Duration will be determined by combining the number of months of use of any parathyroid hormone analog or Evenity (romosozumab) to allow for an additional duration of 12 months or end of plan year
- Total lifetime use of more than 24-months of any parathyroid hormone analog will not be approved

Criteria for Off-Label Use Requests:

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 Non-Cancer Medications
2. Off-Label Use of Cancer Medications

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Description:

Teriparatide (brand Forteo and generic) is a recombinant form of human parathyroid hormone [rhPTH] which is the primary regulator of bone and mineral metabolism. Teriparatide 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.

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 teriparatide or abaloparatide 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.

Generally, teriparatide and abaloparatide are given as a 2-year course of treatment. Cumulative use of teriparatide and abaloparatide and parathyroid hormone for more than 2 years during a patient's lifetime is not recommended. There are limited data assessing the risk of osteosarcoma beyond 2 years of use. Use for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Parathyroid Hormone Analogs for Osteoporosis:

Drug	Available Products	Pen-Injector Strength	Manufacturer	NDC
Teriparatide	Forteo	560mcg/2.24ml	Lilly	00002-8400-01
	Teriparatide (generic for Forteo)	560mcg/2.24ml	Apotex Prasco Laboratories Teva	60505-6188-00 66993-0495-28 00093-1106-16
	Teriparatide (authorized brand alternative for Forteo)	560mcg/2.24ml	Alvogen	47781-0652-89
	Bonsity (teriparatide)	560mcg/2.24ml	Alvogen	47781-0852-89
Abaloparatide	Tymlos	3120mcg/1.56ml	Radius Health	70539-0001-02 70539-0001-01

Adult: Age 18 years and older

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

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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

Fragility fracture:
- A fracture at the spine, hip, wrist, humerus, rib, or pelvis occurring from a fall from standing height or less, without a major trauma such as motor vehicle accident. Fracture at the skull, cervical spine, hands, or feet are not considered fragility fractures. Stress fractures from repetitive injury are also not considered 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

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

Increased risk of osteosarcoma patients with:
- Open epiphyses
- Metabolic bone diseases including Paget's disease
- Bone metastases or history of skeletal malignancies
- Prior external beam or implant radiation therapy involving the skeleton
- Hereditary disorders predisposing to osteosarcoma.

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

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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		

***Oral* bisphosphonates should not be used as initial therapy in the following:**

- Patients with esophageal disorders (e.g., achalasia, esophageal strictures, esophageal varices, Barrett's esophagus)
- Inability to follow the dosing requirements (e.g., stay upright for at least 30 to 60 minutes)
- Chronic kidney disease (CKD; estimated glomerular filtration [eGFR] rate <30 mL/min)
- After certain types of bariatric surgery in which surgical anastomoses are present in the gastrointestinal tract (e.g., Roux-en-Y gastric bypass)

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) 600 mcg/2.4 mL subcutaneous injection product information, revised by Eli Lilly and Company 07-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 18, 2025.

Teriparatide 600 mcg/2.4 mL subcutaneous injection product information, revised by Prasco Laboratories. 09-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 18, 2025.

Teriparatide 620 mcg/2.48 mL subcutaneous injection product information, revised by Alvogen, Inc. 11-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 26, 2025.

Bonsity (teriparatide) subcutaneous injection product information, revised by Alvogen Inc. 06-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed June 25, 2025.

Tymlos (abaloparatide) 3120 mcg/1.56 mL subcutaneous injection product information, revised by Radius Health, Inc. 12-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 18, 2025.

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