AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Parathyroid Hormone Analogs

Drug Requested: Select one drug below

❑ Forteo® **(teriparatide)** injection	❑ **generic teriparatide** (Forteo®)	❑ **Tymlos®** (abaloparatide) injection

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Quantity Limit: Maximum 2.24 mL/28 days for teriparatide (Forteo®). Maximum 1.56 mL/28 days for Tymlos. Maximum 24-month approval (total cumulative lifetime therapy) for **ALL** parathyroid analog products

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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SECTION A: Diagnosis Criteria (All applicable criteria MUST be met for approval)

- ❑ Member must have **ONE** of the following diagnoses:
  - ❑ Female with post-menopausal osteoporosis
  - ❑ Male with primary or hypogonadal osteoporosis
  - ❑ Systematic glucocorticoid-induced osteoporosis
- ❑ Diagnosis of osteoporosis was confirmed by **ONE** of the following **(chart notes, radiographs, BMD assessment or FRAX assessment must be submitted for documentation):**
  - ❑ Member has a history of vertebral fracture(s), low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] within the past 5 years
  - ❑ Member has a T-score that is ≤ -2.5 in spine, femoral neck, total hip or 1/3 radius OR T-score is -1 to >-2.5 with high pre-treatment FRAX fracture probability (10-year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%)
  - ❑ Member has a very high risk for fracture* defined as a T-score ≤-3.0, a T-score ≤-2.5 with a history of fragility fractures [e.g., prior fracture from minor trauma such as falling from standing height or less] or severe or multiple vertebral fractures

    ***Provider Please Note:** Members with very high risk for fracture as documented above are **NOT** subject to prior trial and failure requirements with bisphosphonates.

SECTION B: Prerequisite Therapy Criteria (All applicable criteria MUST be met for approval)

- ❑ Member must meet **ONE** of the following prior trial and failure requirements:
  - ❑ Member has had a 12-month minimum trial of **ONE (1)** of the following bisphosphonates with evidence of no bone mineral density (BMD) improvement at end of trials, decline in BMD, or fracture while on bisphosphonate therapy **(submit BMD assessments, radiographs and/or chart note documentation of failures)**:

❑ **alendronate** (Fosamax®)	❑ **ibandronate** (Boniva®)
❑ **risedronate** (Actonel®)	❑ **zoledronic acid** (Reclast®)

  - ❑ Member has a documented intolerance, FDA-labeled contraindication, or hypersensitivity to both an oral and IV bisphosphonate defined by two of the following (documentation of contraindication or hypersensitivity must be submitted):

❑ Hypersensitivity to **TWO** bisphosphonates (one of which must be alendronate)
❑ Inability to stand or sit upright for at least 30 minutes
❑ Pre-existing gastrointestinal disorders (e.g., Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis)
❑ Uncorrected hypocalcemia
❑ Severe renal insufficiency as defined by CrCL < 35 mL/min for alendronate agents and zoledronic acid or CrCL < 30 mL/min for risedronate and ibandronate

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- ❑ For approval of Brand Forteo® or Tymlos®, member must have had trial and failure of generic teriparatide injection **(chart notes documenting therapy failure must be submitted for documentation)**

SECTION C: Contraindications (All criteria MUST be met for approval)

- ❑ Member is **NOT** currently using and will **NOT** initiate therapy with a bisphosphonate, SERM, calcitonin (Miacalcin or Fortical), denosumab (Prolia or Xgeva), or Evenity (romosozumab) while using the requested medication
- ❑ Member does **NOT** have any contraindication to therapy with the requested agent, including history of skeletal irradiation, history of osteosarcoma, open epiphyses, Paget's disease, hypercalcemia or hyperparathyroidism

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

Previous therapies will be verified through p harmacy paid claims or submitted chart notes.*