curative

Parathyroid Hormone Analog Prior Authorization

Drug(s) Applied:	**teriparatide, Tymlos** (abaloparatide)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. Osteoporosis** as indicated by chart notes within past 12 months
  1. ONE of the following:
     a) Patient's sex is male and is over 50 years of age
     b) Patient's sex is female and is postmenopausal
     c) Prescriber has provided information that the requested agent is medically appropriate for the patient's sex, age, or menopause status **and**
  2. Diagnosis confirmed by ONE of the following:
     a) Fragility fracture in the hip or spine without other metabolic bone disorders (e.g., Paget's disease)
     b) T-score of -2.5 or lower in the lumbar spine, total hip, femoral neck, or distal (one-third) radius, even without a prevalent fracture
     c) T-score of -1.0 to -2.5 and ONE of the following:
        (1) Fragility fracture of a proximal humerus, pelvis, or distal forearm
        (2) Major osteoporotic fracture risk (10 year Fracture Risk Assessment Tool (FRAX)) of 20% or more
        (3) Hip fracture risk (10 year FRAX) of 3% or more **and**
  3. ONE of the following:
     a) Patient has tried and had an inadequate response (e.g., bone mineral density loss or lack of bone mineral density improvement) to an oral bisphosphonate after a minimum 12 month trial
     b) Patient has an intolerance to an oral bisphosphonate
     c) Patient has an FDA labeled contraindication to ALL bisphosphonates (e.g., hypocalcemia, abnormalities of the esophagus which delay esophageal emptying, inability to stand or sit upright for at least 30 minutes, increased risk of aspiration (oral solution))
     d) Patient is at a very high fracture risk as defined by ONE of the following:
        (1) Fractures while using prescription osteoporosis therapy (e.g., bisphosphonates)

(2) History of multiple fragility fractures
(3) T-score less than -3.0
(4) A high risk for falls or has a history of injurious falls
(5) Very high fracture probability by FRAX (e.g. major osteoporosis fracture >30%, hip fracture >4.5%) **and**

4. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with a bisphosphonate, selective estrogen receptor modulator (SERM), denosumab, Evenity, or another parathyroid hormone analog **and**
5. ONE of the following:
    a) Total duration of treatment with all parathyroid hormone analogs has NOT exceeded 24 months in lifetime
    b) If for teriparatide, total duration of treatment with all parathyroid hormone analogs has exceeded 24 months in lifetime and there is a documented high risk for fracture as defined by ONE of the following:
        (a) Fractures while using prescription osteoporosis therapy (e.g., bisphosphonates)
        (b) History of multiple fragility fractures
        (c) T-score less than -3.0
        (d) A high risk for falls or has a history of injurious falls
        (e) Very high fracture probability by FRAX (e.g. major osteoporosis fracture >30%, hip fracture >4.5%)

Approval Duration: up to 24 months of lifetime treatment; If lifetime treatment is 24 months or more for teriparatide, further approval is 12 months

B. Glucocorticoid-induced osteoporosis as indicated by chart notes within past 120 days

1. Patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 5mg or higher of prednisone and expected current course of therapy is for a period of at least 3 months **and**
2. Diagnosis confirmed by ONE of the following:
    a) Fragility fracture in the hip or spine without other metabolic bone disorders (e.g., Paget's disease)
    b) T-score of -2.5 or lower in the lumbar spine, total hip, femoral neck, or distal (one-third) radius, even without a prevalent fracture
    c) T-score of -1.0 to -2.5 and ONE of the following:
        (1) Fragility fracture of a proximal humerus, pelvis, or distal forearm
        (2) Major osteoporotic fracture risk (10 year FRAX) of 20% or more
        (3) Hip fracture risk (10 year FRAX) of 3% or more **and**

3. ONE of the following:
    a) Patient has tried and had an inadequate response (e.g., bone mineral density loss or lack of bone mineral density improvement) to an oral bisphosphonate after a minimum 12 month trial
    b) Patient has an intolerance to an oral bisphosphonate
    c) Patient has an FDA labeled contraindication (e.g., hypocalcemia, abnormalities of the esophagus which delay esophageal emptying, inability to stand or sit upright for at least 30 minutes, increased risk of aspiration (oral solution)) to ALL bisphosphonates
    d) Patient is at a very high fracture risk as defined by ONE of the following:
        (1) Fractures while using prescription osteoporosis therapy or while on drugs causing skeletal harm (e.g. long-term glucocorticoids)
        (2) History of multiple fragility fractures
        (3) T-score less than -3.0
        (4) A high risk for falls or has a history of injurious falls
        (5) Very high fracture probability by FRAX (e.g. major osteoporosis fracture >30%, hip fracture >4.5%) **and**
4. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with a bisphosphonate, SERM, denosumab, Evenity, or another parathyroid hormone analog **and**
5. ONE of the following:
    a) Total duration of treatment with all parathyroid hormone analogs has NOT exceeded 24 months in lifetime
    b) If for teriparatide, total duration of treatment with all parathyroid hormone analogs has exceeded 24 months in lifetime and there is a documented high risk for fracture as defined by ONE of the following:
        (1) Fractures while using prescription osteoporosis therapy (e.g., bisphosphonates)
        (2) History of multiple fragility fractures
        (3) T-score less than -3.0
        (4) A high risk for falls or has a history of injurious falls
        (5) Very high fracture probability by FRAX (e.g. major osteoporosis fracture >30%, hip fracture >4.5%)

Approval Duration: Up to 24 months of lifetime treatment;
If for teriparatide lifetime treatment is 24 months or more, further approval is 12 months

II. Continued Therapy Criteria

A. All indications as indicated by chart notes within past 12 months

1. Patient has been previously approved for the requested agent through the plan's

Prior Authorization process or meets the initial therapy criteria above **and**

2. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with a bisphosphonate, SERM, denosumab, Evenity, or another parathyroid hormone analog **and**
3. ONE of the following:
    a) Total duration of treatment with all parathyroid hormone analogs has NOT exceeded 24 months in lifetime
    b) If for teriparatide, total duration of treatment with all parathyroid hormone analogs has exceeded 24 months in lifetime and there is a documented high risk for fracture as defined by ONE of the following:
        (1) Fractures while using prescription osteoporosis therapy (e.g., bisphosphonates)
        (2) History of multiple fragility fractures
        (3) T-score less than -3.0
        (4) A high risk for falls or has a history of injurious falls
        (5) Very high fracture probability by FRAX (e.g. major osteoporosis fracture >30%, hip fracture >4.5%)

Approval Duration: Up to 24 months of lifetime treatment;
If for teriparatide lifetime treatment is 24 months or more, further approval is 12 months

Policy Owned by: Curative PBM team