CareSource Rxinnovations

# PHARMACY POLICY STATEMENT
## Georgia Medicaid

| DRUG NAME | Forteo (teriparatide) |
|---|---|
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Forteo (teriparatide) was initially approved by the FDA in 2002 and is a parathyroid hormone analog. It is indicated for the treatment of postemenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with primary or hypogonadal osteoporosis at high risk of fracture, and for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

Forteo (teriparatide) will be considered for coverage when the following criteria are met:

## Osteoporosis in Postmenopausal Women

For **initial** authorization:

1. Member is a postmenopausal woman; AND
2. Member has a diagnosis of osteoporosis, as evidenced by one of the following:
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, total proximal femur, or 1/3 radius;
   b) Low-trauma spine or hip fracture (regardless of BMD);
   c) Osteopenia (T-score between –1 and –2.5) with a fragility fracture of proximal humerus, pelvis, or distal forearm;
   d) Osteopenia (T-score between –1 and –2.5) with FRAX fracture probability of ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture; AND
3. Member meets one of the following:
   a) Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate) OR
   b) Member has very high risk for fracture (e.g., having multiple fractures, very low T score (-3.0 or below), T-score -2.5 or below plus fractures, fractures while taking osteoporosis drug, FRAX > 30% for major osteoporosis fracture or 4.5% for hip fracture); AND
4. For Forteo requests, trial and failure of teriparatide.
5. **Dosage allowed/Quantity limit:** 20 mcg subcutaneously once daily (1 pen per 28 days)

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

1. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression; AND
2. Duration of treatment does NOT exceed 24 months OR member remains at high risk for fracture.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## Osteoporosis in Men

For **initial** authorization:

1. Member is a male 18 years of age or older; AND
2. Medication is being used to treat osteoporosis; AND
3. Member is at high-risk for fracture as evidenced by one of the following:
   a) Hip or vertebral fracture without major trauma
   b) BMD of the spine, femoral neck, and/or total hip is 2.5 SD or more below the mean of normal young white males (T-score -2.5 or less)
   c) T-score between −1.0 and −2.5 in the spine, femoral neck, or total hip plus a 10-yr risk of experiencing any fracture ≥ 20% or 10-yr risk of hip fracture ≥ 3% using FRAX; AND
4. Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast)), unless not tolerated or contraindicated; AND
5. For Forteo requests, trial and failure of teriparatide.
6. **Dosage allowed/Quantity limit:** 20 mcg subcutaneously once daily (1 pen per 28 days)

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

1. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression; AND
2. Duration of treatment does NOT exceed 24 months OR member remains at high risk for fracture.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## Glucocorticoid-Induced Osteoporosis

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication is being used for glucocorticoid-induced osteoporosis; AND
3. Member is initiating or continuing systemic glucocorticoids (GC) equivalent to 2.5 mg/day or greater of prednisone and will remain on therapy for more than 3 months; AND
4. Member meets one of the following (a, b, or c):
   a) Moderate fracture risk:
      i) Age 40 years or greater and both of the following:
         (1) FRAX 10-year risk of major osteoporotic fracture of 10 to 19%, hip >1 to <3%, or BMD t- score between -1 and -2.4; AND
         (2) Inadequate response to at least 12 months of a bisphosphonate; OR
      ii) Age <40 years and both of the following:
         (1) GC 7.5 mg/day or greater for 6 months or longer AND BMD z-score less than -3 OR significant BMD loss (more than the least significant change of DXA); AND
         (2) Inadequate response to at least 12 months of a bisphosphonate
   b) High fracture risk: Age 40 years or greater and BMD t-score ≤−2.5 but >−3.5 or FRAX 10-year risk of major osteoporotic fracture of 20 to 29% or hip 3 to 4.4%

c) Very high fracture risk: Prior osteoporotic fracture, BMD t-score -3.5 or less, FRAX 10-year risk of major osteoporotic fracture of 30% or greater or hip 4.5% or greater, or GC 30 mg/day or greater for more than 30 days or cumulative 5 g/year or more; AND
5. For Forteo requests, trial and failure of teriparatide.
6. **Dosage allowed/Quantity limit:** 20 mcg subcutaneously once daily (1 pen per 28 days)

***If all the above requirements are met, the medication will be approved for up to 12 months.***

For **reauthorization**:
1. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression; AND
2. Duration of treatment does NOT exceed 24 months OR member remains at high risk for fracture***.***

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## CareSource considers Forteo (teriparatide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|---|---|
| **08/01/2019** | New policy for Forteo created. |
| **07/31/2020** | Removed uncorrected hypocalcemia and dental disease. Removed list of reasons oral bisphosphonates cannot be used. Removed risk factor appendix. Removed calcium and vitamin D requirements. Modified osteoporosis definitions to include GC-induced high-risk groups. Specified length of oral bisphosphonate trial for 12 months. Added age requirement. Specified 2nd line trials to be any IV bisphosphonate or Prolia. Added no more than 2 years of treatment to initial and reauth. Changed length of initial approval to 12 months. Changed reauth language to say stable or increase BMD with no evidence of new fractures. |
| **04/26/2022** | Transferred to new template. Added references. Split each indication into separate sections. Removed “stable” from renewal; BMD should increase.<br>Postmenopausal women: Added criterion for those at very high risk of fracture.<br>Men: Clarified definition of high risk.<br>GIO: Revised who is eligible for treatment to match guidelines. |
| **02/01/2023** | Adding trial and failure of teriparatide. |
| **02/17/2023** | All indications: Removed renewal criteria and changed initial authorization period to total of 24 months.<br>Removed zoledronic acid trial for very high risk postmenopausal women. |
| **05/21/2024** | Updated references. Changed initial auth duration from 24 mo to 12 mo and added renewal criteria; added that they can continue beyond 24 mo if remain at high fracture risk.<br>GIO: Changed prednisone 7.5 mg and 6 months to 2.5 mg and 3 months, added moderate and very high risk criteria instead of just high risk, updated criteria for high risk, added continuation of GC or remain at high to very high risk for renewal (Humphrey et al.; ACR). |

References:

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