Pharmacy Benefit Coverage Criteria

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Parathyroid Hormone Analogs (Osteoporosis)

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Medical Necessity Criteria

Teriparatide (Forteo) is considered medically necessary when ALL of the following criteria are met:

- For the treatment of osteoporosis in a postmenopausal woman at high risk for fractures defined as ANY of the following:
  - History of fragility (non-traumatic) or osteoporotic fracture
  - Bone mineral density (BMD) T-score less than or equal to -2.5 or lower in the lumbar spine, femoral neck, total hip, and/or 33% (one third) radius [wrist]
  - T-score between -1.0 and -2.5 if the FRAX® 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%

- Treatment of primary or hypogonadal osteoporosis in men defined as ANY of the following
  - History of fragility (non-traumatic) or osteoporotic fracture
  - Bone mineral density (BMD) T-score less than or equal to -2.5 or lower in the lumbar spine, femoral neck, total hip, and/or 33% (one third) radius [wrist]
  - T-score between -1.0 and -2.5 if the FRAX® 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%

- Treatment of Glucocorticoid-Induced Osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) for at least 3 months

- Individual will not exceed lifetime maximum of 24 monthly doses of treatment [(including previous use of Tymlos (abaloparatide)]

- No concomitant use with other osteoporosis therapy (for example, bisphosphonates, Prolia, Tymlos, Evenity)
Abaloparatide (Tymlos) is considered medically necessary when ALL of the following criteria are met:

- Treatment of osteoporosis in a postmenopausal woman at high risk for fractures defined as ANY of the following:
  - History of fragility (non-traumatic) or osteoporotic fracture
  - Bone mineral density (BMD) T-score less than or equal to -2.5 or lower in the lumbar spine, femoral neck, total hip, and/or 33% (one third) radius [wrist]
  - T-score between −1.0 and −2.5 if the FRAX® 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%

- Individual will not exceed lifetime maximum of 24 monthly doses of treatment [including previous use of Forteo (teriparatide)]

- No concomitant use with other osteoporosis therapy (for example, bisphosphonates, Prolia, Forteo, Evenity)

Authorization is up to 24 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Forteo (teriparatide) and Tymlos (abaloparatide) considered experimental, investigational or unproven for ANY other use.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage

*If you’re a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.

### FDA Approved Indications

#### FDA Approved Indication

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Approved Indication</th>
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<tbody>
<tr>
<td>Forteo (teriparatide)</td>
<td>Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture</td>
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<tr>
<td></td>
<td>- Forteo is 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 patients who have failed or are intolerant to other available osteoporosis therapy</td>
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<tr>
<td></td>
<td>- In postmenopausal women with osteoporosis, Forteo reduces the risk of vertebral and nonvertebral fractures</td>
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<tr>
<td></td>
<td>Increase of Bone Mass in Men with Primary or Hypogonadal Osteoporosis at High Risk for Fracture</td>
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<tr>
<td></td>
<td>- Forteo is indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy</td>
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<tr>
<td></td>
<td>Treatment of Men and Women with Glucocorticoid-Induced Osteoporosis at High Risk for Fracture</td>
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<tr>
<td></td>
<td>- Forteo is indicated for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy</td>
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<tr>
<td>Tymlos (abaloparatide)</td>
<td>Tymlos is 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</td>
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fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures.

Limitations of Use:
Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient’s lifetime is not recommended.

Recommended Dosing

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Recommended Dosing</th>
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| **Forteo** (teriparatide) | Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture  
- The recommended dose is 20 mcg subcutaneously once a day  
Increase of Bone Mass in Men with Primary or Hypogonadal Osteoporosis at High Risk for Fracture  
- The recommended dose is 20 mcg subcutaneously once a day  
Treatment of Men and Women with Glucocorticoid-Induced Osteoporosis at High Risk for Fracture  
- The recommended dose is 20 mcg subcutaneously once a day  
The safety and efficacy of Forteo have not been evaluated beyond 2 years of treatment. Consequently, use of the drug for more than 2 years during a patient’s lifetime is not recommended. |
| **Tymlos** (abaloparatide) | The recommended dosage of Tymlos is 80 mcg subcutaneously once daily.  
Cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient’s lifetime is not recommended. |

Drug Availability

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Drug Availability</th>
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<tbody>
<tr>
<td><strong>Forteo</strong> (teriparatide)</td>
<td>Subcutaneous injection: single-patient-use multi-dose prefilled pen delivers 28 daily doses, each containing 20 mcg of teriparatide.</td>
</tr>
<tr>
<td><strong>Tymlos</strong> (abaloparatide)</td>
<td>Subcutaneous injection: single-patient-use multi-dose prefilled pen delivers 30 daily doses, each containing 80 mcg of abaloparatide.</td>
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Background

Therapeutic Alternatives
The parathyroid hormone analogs, abaloparatide and teriparatide, are therapeutic alternatives to one another.

Professional Societies/Organizations

**Osteoporosis in Postmenopausal Women**
Endocrine Society (EDS)
In 2019, the EDS updated their clinical practice guidelines for osteoporosis in postmenopausal women. It is recommended to treat postmenopausal women with high risk of fractures as the benefits of pharmacological therapies outweigh the risks. Forteo® (teriparatide) or Tymlos (abaloparatide) are recommended in postmenopausal women with osteoporosis at very high risk of fracture such as patients with severe or multiple vertebral fractures. The treatment duration should be for up to 2 years to reduce vertebral and nonvertebral fractures.
fractures. Comparatively, the evidence base for those two agents and fracture reduction is more limited regarding the numbers of trials and patients involved. The finding of osteosarcoma in rats led to the Boxed Warning with both agents which limits therapy for a maximum of 24 months in a lifetime. (Eastell, 2019)

American Association of Clinical Endocrinologist (AACE) and American College of Endocrinology (ACE)
In 2016, the AACE/ACE updated clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis (PMO). Tymlos is not addressed. Osteoporosis in postmenopausal women can be defined as follows:

1) T-score -2.5 or below in the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius
2) Low trauma spine or hip fracture (regardless of bone mineral density [BMD]), osteopenia or low bone mass (T-score between -1.0 and -2.5) with a fragility fracture of proximal humerus, pelvis or possibly distal forearm
3) Osteopenia or low bone mass (T-score between -1.0 and -2.5) with fragility fracture or proximal humerus, pelvis, or possibly distal forearm
4) Low bone mass or osteopenia and high FRAX® fracture probability based on country-specific thresholds

The AACE and ACE guidelines state Forteo, Prolia or zoledronic acid injection (Reclast) should be considered for patients unable to use oral therapy and as initial therapy for patients who are at especially high-risk of fracture (for example, older women who have had multiple vertebral fractures or hip fractures, or have very low T-scores). Concomitant use of agents for the prevention or treatment of postmenopausal osteoporosis is not recommended. (Camancho, 2016)

Osteoporosis in Males
Endocrine Society (EDS)
In 2012, the EDS published guidelines regarding osteoporosis in men.47 It is recommended that men who are at high risk of fracture be treated with medications that are indicated for use in men such as alendronate, risedronate, zoledronic acid injection (Reclast), and Forteo. The choice of the agent should be individualized based on fracture history, severity of osteoporosis, comorbid conditions, and other factors. In men with a recent hip surgery, treatment with zoledronic acid injection (Reclast) is recommended. For men at high risk of fracture who are receiving testosterone therapy, an agent with proven antifracture efficacy should be added (e.g., a bisphosphonate or Forteo). The effects of bisphosphonates and Forteo on BMD appear similar. (Watts, 2012)

Glucocorticoid-Induced Osteoporosis (GIO)
American College of Rheumatology (ACR)
In 2017, the ACR updated guidelines regarding the prevention and treatment of GIO.48 For adults ≥ 40 years and < 40 years of age at low risk of fracture, optimize calcium and vitamin D intake and lifestyle modifications over treatment with bisphosphonates, Forteo, Prolia, or raloxifene. For adults ≥ 40 years of age at moderate risk of major fracture, treat with an oral bisphosphonate over intravenous (IV) bisphosphonates, Forteo, Prolia, or raloxifene. For adults ≥ 40 years of age at high risk of fracture, treat with an oral bisphosphonate over IV bisphosphonates, Forteo, Prolia or raloxifene. For adults age < 40 years at moderate to high risk of fracture, treat with an oral bisphosphonate over IV bisphosphonates, Forteo or Prolia. (Buckley, 2017)

Off Label Uses
AHFS Drug Information 2019 Edition supports no off-label uses for Forteo (teriparatide) or Tymlos (abaloparatide).

Comparative Studies
There are no head-to-head studies comparing abaloparatide to teriparatide.

References


4. Forteo (teriparatide) [packing insert]; Indianapolis, IN: Lilly USA, LLC. August 2013.
