

PRIOR AUTHORIZATION POLICY

POLICY: Bone Modifiers – Forteo® (teriparatide injection for subcutaneous use – Eli Lilly)

TAC APPROVAL DATE: 06/20/2018

OVERVIEW

Forteo is recombinant human parathyroid hormone (PTH) [1-34] that is indicated for: 1) the treatment of postmenopausal women with osteoporosis at high risk for fracture; 2) to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; and 3) the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoids therapy (daily dose equivalent to 5 mg or greater of prednisone) at high risk for fracture. For all indications, patients at high risk for fracture are defined as those with a history of osteoporotic fractures, have multiple risk factors for fracture, or have failed or are intolerant to other osteoporosis therapy. The recommended dose of Forteo is 20 mcg subcutaneously (SC) once daily (QD).¹

Clinical Efficacy

Osteoporosis in Postmenopausal Women

In a pivotal, double-blind, multicenter trial^{1,2} 1,637 postmenopausal women with osteoporosis received Forteo 20 mcg SC QD, Forteo 40 mcg SC QD, or placebo for a median of 19 months. Results are reported with the FDA-approved dose of Forteo only. At endpoint the rate of new vertebral fractures, the primary efficacy variable, was 14% for placebo and 5% for Forteo 20 mcg SC QD. As compared with placebo, administration of Forteo 20 mcg QD led to a 65% reduction in new vertebral fractures; and a 53% reduction in any nonvertebral fractures. Lumbar spine bone mineral density (BMD) increased from baseline to last visit by 9.7% for Forteo 20 mcg QD compared with 1.1% for placebo; increases in BMD at other sites were also noted.^{1,2}

Increased Bone Mass in Men

A double-blind, multicenter, placebo-controlled clinical study^{1,3} randomized 437 men with either primary (idiopathic) or hypogonadal osteoporosis to receive placebo, Forteo 20 mcg SC QD or Forteo 40 mcg SC QD, in addition to 1,000 mg of oral calcium and at least 400 IU of oral vitamin D. The study was stopped after a median duration of 11 months. Results are reported for the FDA-approved dose of Forteo only. At endpoint, lumbar spine BMD increased by 5.9% with Forteo 20 mcg QD compared with 0.5% for placebo. The increases commenced at 3 months. Compared with placebo, femoral neck BMD increased statistically significantly with Forteo 20 mcg QD (1.5%).

Glucocorticoid-Induced Osteoporosis (GIO)

In an 18-month, randomized, double-blind study^{1,4} 428 women and men with osteoporosis (aged 22 to 89 years) who had previously received glucocorticoids for at least 3 months (prednisone equivalent of ≥ 5 mg) were randomized to Forteo 20 mcg SC QD or alendronate 10 mg QD. Most patients were female (80%) and T-scores in the lumbar spine were -2.5 and -2.6 in the Forteo and alendronate groups, respectively. The mean change in BMD of the lumbar spine, the primary efficacy endpoint, had increased by a greater extent in the Forteo group compared with the alendronate group (7.2% vs. 3.4%; $P < 0.001$). At 18 months the change in BMD at the total hip was also superior for patients given Forteo compared with alendronate ($P = 0.005$). Fewer new vertebral fractures were noted in the Forteo group (0.6%) vs. the alendronate group (6.1%) [$P = 0.004$].^{1,4}

Guidelines

Osteoporosis in Postmenopausal Women

In 2016 the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) updated clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis (PMO).⁷ 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 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 of 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/ACE guidelines state approved agents with efficacy to reduce hip, non-vertebral and spine fractures include alendronate, risedronate, Reclast (zoledronic acid injection, generics), and Prolia[®] (denosumab injection for SC use) which are appropriate as initial therapy for most patients at high-risk of fracture. Forteo, Prolia or 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. Raloxifene or ibandronate may be appropriate initial therapies in some scenarios in which patients require medications with spine-specific efficacy. Concomitant use of agents for the prevention or treatment of postmenopausal osteoporosis is not recommended.

In 2014 the National Osteoporosis Foundation (NOF) updated recommendations for the prevention and treatment of osteoporosis.⁵ The guidelines state to initiate pharmacologic treatment in the following circumstances: 1) in those with hip or vertebral (clinical or asymptomatic) fractures; 2) in those with T-scores ≤ -2.5 at the femoral neck total hip, or lumbar spine by dual-energy X-ray absorptiometry (DXA); 3) in postmenopausal women and men ≥ 50 years of age with low bone mass (T-score between -1.0 and -2.5 , osteopenia) at the femoral neck, total hip, or lumbar spine by DXA and a 10-year hip fracture probability $\geq 3\%$ or a 10-year major osteoporosis-related fracture probability $\geq 20\%$ based on the USA-adapted WHO absolute fracture risk model (Fracture Risk Algorithm [FRAX]).

The guideline by the NOF discusses the medications used in osteoporosis.⁵ However, a preferred agent is not specified. The guidelines state that alendronate reduces spine and hip fractures by about 50% over 3 years in those with a prior vertebral fracture. It also decreases the incidence of vertebral fractures by about 48% over 3 years in those without a prior vertebral fracture. Ibandronate reduces the incidence of vertebral fractures by about 50% over 3 years. Risedronate reduces vertebral fractures by about 41% to 49% and non-vertebral fractures by about 36% over 3 years, with significant risk reduction happening after 1 year of treatment in those with a prior vertebral fracture. Reclast reduces vertebral fractures by about 70% (with significant reduction at 1 year), hip fractures by about 41%, and non-vertebral fractures by about 25% over 3 years. Raloxifene reduces the risk of vertebral fractures by approximately 30% in those with a prior vertebral fracture and by about 55% in patients without a prior vertebral fracture over 3 years. After 18 months of therapy, Forteo has been shown to decrease the risk of vertebral fractures by 65% and non-vertebral fractures by 53% in patients with osteoporosis.

The North American Menopause Society (NAMS) updated a position statement in 2010 regarding the management of osteoporosis in postmenopausal women.⁶ Some recommendations from NAMS regarding pharmacologic therapy are that bisphosphonates are first-line drugs for treating postmenopausal osteoporosis. These agents have reduced the risk of vertebral fractures by 40% to 70% and reduced the incidence of nonvertebral fracture, including hip fracture, by approximately one-half that amount. Evista can be considered for postmenopausal women with low bone mass or younger postmenopausal women with osteoporosis. It prevents bone loss and reduces the risk of vertebral fractures; however, its

effectiveness in reducing other fractures is not known. Forteo is generally offered to women with postmenopausal osteoporosis at high risk for fracture. Use has stimulated bone formation and improved bone density. However, therapy should be less than 24 months. Hormone therapy can be considered for the bone effects, but its benefits and risks should be considered; it may be an option for a few years post menopause. The treatment of postmenopausal osteoporosis should be long-term. If drug-related adverse effects (AEs) occur, appropriate management strategies can be employed. If AEs continue, consider switching to another agent.

Osteoporosis in Men

In 2012, the Endocrine Society published a clinical practice guideline for osteoporosis in men.⁸ Pharmacologic therapy for men at high risk for fracture includes the following: 1) men who have a hip or vertebral fracture without major trauma; 2) men who have not experienced a spine or hip fracture but whose BMD of the spine, femoral neck, and/or total hip to 2.5 standard deviations or more below the mean of normal young white males; 3) in the US, men who have a T-score between -1.0 and -2.5 in the spine, femoral neck, or total hip plus a 10-year risk of experiencing any fracture $\geq 20\%$ or 10-year risk of hip fracture $\geq 3\%$ using FRAX; further studies will be needed to determine appropriate intervention levels using other fracture risk assessment algorithms; and 4) men who are receiving long-term glucocorticoid therapy in pharmacological doses (e.g., prednisone or equivalent > 7.5 mg/day). Patients at high risk of fracture are recommended to receive therapy with one of the following agents: alendronate, Actonel, Reclast, or Forteo. In men with a recent hip fracture, Reclast is recommended. When Forteo is given, it should not be given with concomitant antiresorptive therapy. For the management of hypogonadal men at high risk of fracture who are receiving testosterone therapy it is recommended to add an agent with proven antifracture efficacy (e.g., a bisphosphonate or Forteo).

Glucocorticoid-Induced Osteoporosis (GIO)

In 2017, the American College of Rheumatology (ACR) updated guidelines for the prevention and treatment of GIO.⁹ In various clinical scenarios, Forteo is recommended after trial of other agents (e.g., oral bisphosphonates, IV bisphosphonates).

Safety

The prescribing information for Forteo includes a Boxed Warning regarding an increased incidence of osteosarcoma in rats at doses 3 to 60 times the exposure in humans administered as a 20 mcg dose.¹ Due to these risks, the agent should not be given to those who have an increased baseline risk for osteosarcoma. The prescribing information does not recommend use of Forteo for more than 2 years because its safety and efficacy beyond this timeframe have not been evaluated.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Forteo. Coverage cumulative with Forteo and Tymlos™ (abaloparatide injection for SC use) is recommended for up to 2 years of a patient's lifetime. All approval(s) are provided for up to 2 years in duration unless otherwise noted below. In the approval indication, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Forteo is recommended in those who meet the following criteria:

FDA-Approved Indications

- 1. Osteoporosis Treatment for a Postmenopausal Patient.** Approve Forteo for up to 2 years if the patient meets the following criteria (A and B):
 - A)** The patient meets ONE of the following conditions (i, ii, or iii):
 - i.** The patient has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist); OR
 - ii.** The patient has had an osteoporotic fracture or a fragility fracture; OR
 - iii.** The patient has low bone mass (T-score [current or at any time in the past] between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% [one-third] radius [wrist]) and the physician determines the patient is at high risk for fracture; AND
 - B)** The patient meets ONE of the following (i, ii, iii, or iv):
 - i.** The patient has tried one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):
 - a)** The patient has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of BMD, lack of BMD increase); OR
 - b)** The patient has had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy; OR
 - c)** The patient has experienced intolerability to an oral bisphosphonate (e.g., severe gastrointestinal [GI]-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture); OR
 - ii.** The patient cannot take an oral bisphosphonate due to one of the following circumstances (a, b, or c):
 - a)** The patient cannot swallow or has difficulty swallowing; OR
 - b)** The patient cannot remain in an upright position post oral bisphosphonate administration; OR
 - c)** The patient has a pre-existing gastrointestinal (GI) medical condition (e.g., patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]); OR
 - iii.** The patient has tried ibandronate injection (Boniva) or zoledronic acid injection (Reclast); OR
 - iv.** The patient meets one of the following conditions (a, b, or c):
 - a)** Severe renal impairment (creatinine clearance < 35 mL/min); OR
 - b)** Chronic kidney disease (CKD); OR
 - c)** The patient has had an osteoporotic fracture or a fragility fracture.

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.¹ Various guidelines support use of bisphosphonate therapy as first-line in many clinical scenarios.⁵⁻⁷ In the AACE guidelines for PMO, osteoporosis is defined as a T-score of -2.5 or below in the lumbar spine, femoral neck or total hip and/or 33% (one-third) radius.⁶ Other scenarios also are indicators for a diagnosis of osteoporosis (e.g., low trauma spine or hip fracture [regardless of BMD]). Bisphosphonates should not be used in patients with renal impairment. Oral bisphosphonates have caused severe gastrointestinal (GI) AEs and severe musculoskeletal pain has been reported. Albeit rare, bisphosphonates have been associated with femoral fractures. Oral bisphosphonates are contraindicated if patients have

abnormalities of the esophagus which delay emptying (stricture or achalasia). Patients must also not lie down for at least 30 minutes post oral bisphosphonate administration.

2. Osteoporosis in Men* to Increase Bone Mass in Patients with Primary or Hypogonadal Osteoporosis. Approve Forteo for up to 2 years if the patient meets the following criteria (A and B):

- A) The patient meets ONE of the following conditions (i, ii, or iii):
- i. The patient has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist); OR
 - ii. The patient has had an osteoporotic fracture or a fragility fracture; OR
 - iii. The patient has low bone mass (T-score [current or at any time in the past] between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% [one-third] radius [wrist]) and the physician determines the patient is at high risk for fracture; AND
- B) The patient meets one of the following (i, ii, iii, or iv):
- i. The patient has tried one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):
 - a) The patient has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase); OR
 - b) The patient has had an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy; OR
 - c) The patient has experienced intolerability to an oral bisphosphonate (e.g., severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture); OR
 - ii. The patient cannot take an oral bisphosphonate due to one of the following circumstances (a, b, or c):
 - a) The patient cannot swallow or has difficulty swallowing; OR
 - b) The patient cannot remain in an upright position post oral bisphosphonate administration; OR
 - c) The patient has a pre-existing GI medical condition (e.g., patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]); OR
 - iii. The patient has tried zoledronic acid injection (Reclast); OR
 - iv. The patient meets one of the following conditions (a, b, or c):
 - a) Severe renal impairment (creatinine clearance < 35 mL/min); OR
 - b) Chronic kidney disease (CKD); OR
 - c) The patient has had an osteoporotic fracture or a fragility fracture.

* Refer to the Policy Statement.

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.¹ Several bisphosphonates are indicated for osteoporosis in males (e.g., alendronate, Actonel and Reclast).⁸ Clinical practice guidelines from the Endocrine Society for osteoporosis in men⁸ recommend that in the management of hypogonadal men at high risk for fracture who are receiving a testosterone therapy, an agent with proven antifracture efficacy should be used (e.g., a bisphosphonate or Forteo). Therapy is recommended in men who have had a hip or vertebral fracture and in men whose BMD of the spine is -2.5 or below in the spine, femoral neck or total hip. Bisphosphonates should not be used in patients with renal impairment. Oral bisphosphonates have caused severe GI adverse effects and severe musculoskeletal pain has been reported. Oral bisphosphonates are contraindicated if patients

have abnormalities of the esophagus which delay emptying (stricture or achalasia). Patients must also not lie down for at least 30 minutes post oral bisphosphonate administration. In the professional opinion of specialized physicians reviewing the data, we have adopted these criteria.

- 3. Glucocorticoid-Induced Osteoporosis (GIO) Treatment.** Approve Forteo for up to 2 years for the treatment of GIO if the patient meets the following criteria (A and B):
- A)** The patient is either initiating or continuing systemic glucocorticoids (e.g., prednisone); **AND**
- B)** The patient meets **ONE** of the following (i, ii, iii, or iv):
- i.** The patient has tried one oral bisphosphonate or oral bisphosphonate-containing product and meets one of the following (a, b, or c):
 - a)** The patient has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of BMD, lack of BMD increase); **OR**
 - b)** The patient has had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy; **OR**
 - c)** The patient has experienced intolerability to an oral bisphosphonate (e.g., severe gastrointestinal [GI]-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture); **OR**
 - ii.** The patient cannot take an oral bisphosphonate due to one of the following circumstances (a, b, or c):
 - a)** The patient cannot swallow or has difficulty swallowing; **OR**
 - b)** The patient cannot remain in an upright position post oral bisphosphonate administration; **OR**
 - c)** The patient has a pre-existing gastrointestinal (GI) medical condition (e.g., patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]); **OR**
 - iii.** The patient has tried zoledronic acid injection (Reclast); **OR**
 - iv.** The patient meets one of the following conditions (a, b, or c):
 - a)** Severe renal impairment (creatinine clearance < 35 mL/min); **OR**
 - b)** Chronic kidney disease (CKD); **OR**
 - c)** The patient has had an osteoporotic fracture or a fragility fracture.

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.¹ Several bisphosphonates are indicated for the treatment of GIO (e.g., alendronate, risedronate and Reclast) and are recommended in ACR 2017 guidelines for the prevention and treatment of GIO.⁹ Bisphosphonates should not be used in patients with renal impairment. Oral bisphosphonates have caused severe GI adverse effects and severe musculoskeletal pain has been reported. Oral bisphosphonates are contraindicated if patients have abnormalities of the esophagus which delay emptying (stricture or achalasia). Patients must also not lie down for at least 30 minutes post oral bisphosphonate administration. In the professional opinion of specialized physicians reviewing the data, we have adopted these criteria.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Forteo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Hypoparathyroidism.** Only limited data support the use of Forteo for this condition.¹⁰⁻¹⁵
2. **Osteoporosis Prevention.** Forteo has not been studied in this patient population. The benefits and risks of building bone with Forteo in a condition in which substantial bone loss has not occurred have not been investigated.¹
3. **Previous Use of Forteo and/or Tymlos For a Combined Total No Greater than 2 Years Duration During a Patient’s Lifetime.** Cumulative use of Forteo and/or Tymlos for > 2 years during a patient’s lifetime is not recommended. This is related to the risk of osteosarcoma.^{1,6,16}
4. **Concurrent Use of Forteo with Other Medications for Osteoporosis** (e.g., Prolia [denosumab for SC injection], bisphosphonates [alendronate, risedronate, ibandronate, zoledronic acid injection {Reclast}], calcitonin nasal spray, Tymlos™ [abaloparatide injection for SC use]), except calcium and Vitamin D.
5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision.	No criteria changes.	01/06/2016
Selected revision	For the diagnosis of osteoporosis for postmenopausal women, changed “women” to “patient”; for the diagnosis of glucocorticoid-induced osteoporosis in men and women and osteoporosis prevention (women and men), deleted “men and women” from the respective indications.	08/10/2016
Selected revision	In the Policy Statement, added legal language to define men. This is noted with “*” next to “men” in the Osteoporosis indication. A note was added below the approval criteria to refer to Policy Statement.	10/05/2016
Annual revision	No criteria changes.	01/25/2017
Early annual revision	For the osteoporosis treatment for a postmenopausal patient and for osteoporosis in men, regarding the T-score it was added to include 33% (one-third) radius (wrist) as a site. Also, a fragility fracture was also accepted as a manner to diagnose osteoporosis, in addition to an osteoporotic fracture. Also, regarding previous criteria that addressed patients with T-score at or below -2.0, the criteria were revised to state low bone mass or osteopenia (T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist) and the physician determines the patient is at high risk for fracture. Also, patients with a fragility fracture while receiving oral bisphosphonate therapy are permitted to use Forteo (in addition to meeting other criteria). The criteria that allows exceptions to use of an oral bisphosphonate if the patient had experienced multiple osteoporotic fractures was changed to that the patient has had an osteoporotic fracture or a fragility fracture. For patients using Forteo for treatment of GIO, patients with a fragility fracture while receiving oral bisphosphonate therapy are permitted to use Forteo (in addition to meeting other criteria). Also, regarding GIO, the criteria that allows exceptions to use of an oral bisphosphonate if the patient had experienced multiple osteoporotic fractures was changed to that the patient has had an osteoporotic fracture or a fragility fracture. Evista was deleted from the list of osteoporosis medications in which Forteo should not be used with concurrently; Tymlos was added to this list. For the conditions not recommended for approval, it was added that previous use of Forteo and/or Tymlos for > 2 years duration during a patient’s lifetime is not recommended.	06/07/2017
Selected revision	For the criteria regarding osteoporosis treatment in a postmenopausal patient and osteoporosis in men, removed the word “osteopenia” when referencing low bone mass.	10/18/2017
Annual revision	No criteria changes.	06/20/2018

* For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>; TAC – Therapeutic Assessment Committee; GIO – Glucocorticoid-induced osteoporosis.