Parathyroid Hormones: teriparatide (Forteo®), abaloparatide (Tymlos®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO146

Description

Teriparatide, teriparatide (Forteo), and abaloparatide (Tymlos) are human parathyroid hormone related peptide [PTHrP (1-34)] analogs.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Indication	Dosage Form	Quantity Limit
teriparatide (Forteo)	Primary Osteoporosis/Hypogonadal-related Osteoporosis in Men Post-Menopausal Osteoporosis in Women Glucocorticoid-induced Osteoporosis	600 mcg/2.4 mL pen-injector	1 pen (2.4 mL)/28 days
generic teriparatide			
teriparatide (biosimilar formulation)		620 mcg/2.48 mL pen-injector	1 pen (2.4 mL)/28 days
abaloparatide (Tymlos)	Primary Osteoporosis/Hypogonadal-related Osteoporosis in Men Post-Menopausal Osteoporosis in Women	3120 mcg/1.56 mL (2000 mcg/mL)	1 pen (1.56 mL)/30 days

Initial Evaluation

I. **Abaloparatide (Tymlos), teriparatide (biosimilar formulation), generic teriparatide, and teriparatide (Forteo)** may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Member will not have received treatment with a parathyroid hormone for more than two years during their lifetime; **OR**
      1. Member will have received treatment with a parathyroid hormone for more than two years during their lifetime; **AND**
         i. Provider attestation that patient remains, or has returned to, having high or very high fracture risk (e.g., a fracture in the past 12 months, a fracture while on osteoporosis therapy, a history of multiple fractures, fractures while on long-term glucocorticoids, T-score ≤ -3.0, high risk for falls or a

history of injurious falls, a FRAX 10-year probably for major fracture >30% or hip fracture >4.5%, etc.); **AND**

C. Medication will not be used in combination with other osteoporotic agents [e.g., denosumab (Prolia), bisphosphonates (alendronate, risedronate, ibandronate, zoledronic acid injection), calcitonin nasal spray, or raloxifene]; **AND**

D. One of the following fracture risk categories is met:
   1. Member has a fracture of the hip or spine regardless of BMD; **OR**
   2. Member has a T-score ≤ -2.5 in spine, femoral neck, total hip or 1/3 radius; **OR**
   3. Member has a T-score ≤ -1 and a history of recent fracture of proximal humerus, pelvis, or distal forearm; **OR**
   4. Member has a T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; **AND**

E. Provider attestation of treatment failure or ineffective response to <u>one</u> of the following, unless all are contraindicated (*Please note: These agents may be subject to prior authorization or step therapy and may require an additional review):
   1. Oral bisphosphonate (e.g., alendronate, ibandronate), **OR**
   2. Intravenous bisphosphonate (e.g., zoledronic acid injection*); **OR**
   3. Denosumab (Prolia)*; **AND**

F. For abaloparatide (Tymlos), a diagnosis of one of the following:
   1. **Post-Menopausal Osteoporosis in Women; OR**
   2. **Primary Osteoporosis/Hypogonadal-related Osteoporosis in Men; OR**

G. For teriparatide (biosimilar formulation), a diagnosis of one of the following:
   1. **Post-Menopausal Osteoporosis in Women; AND**
      i. Treatment with abaloparatide (Tymlos) has been ineffective, not tolerated, or contraindicated; **OR**
   2. **Primary Osteoporosis/Hypogonadal-related Osteoporosis in Men; AND**
      i. Treatment with abaloparatide (Tymlos) has been ineffective, not tolerated, or contraindicated; **OR**
   3. **Glucocorticoid-induced Osteoporosis; AND**
      i. Member is taking ≥ 5 mg prednisone or its equivalent daily with an anticipated duration of ≥ 3 months; **OR**

H. For generic teriparatide, a diagnosis of one of the following:
   1. **Post-Menopausal Osteoporosis in Women; AND**
      i. Treatment with abaloparatide (Tymlos) AND teriparatide (biosimilar formulation) have been ineffective, not tolerated, or contraindicated; **OR**
   2. **Primary Osteoporosis/Hypogonadal-related Osteoporosis in Men; AND**
      i. Treatment with abaloparatide (Tymlos) AND teriparatide (biosimilar formulation) have been ineffective, not tolerated, or contraindicated; **OR**
   3. **Glucocorticoid-induced Osteoporosis; AND**

i. Member is taking ≥ 5 mg prednisone or its equivalent daily with an anticipated duration of ≥ 3 months; **AND**
ii. Treatment with teriparatide (biosimilar formulation) has been ineffective, not tolerated or contraindicated; **OR**

I. For BRAND teriparatide (Forteo), a diagnosis of one of the following:
1. **Post-Menopausal Osteoporosis in Women; AND**
i. Treatment with abaloparatide (Tymlos), teriparatide (biosimilar formulation) AND generic teriparatide have been ineffective, not tolerated, or contraindicated; **OR**
2. **Primary Osteoporosis/Hypogonadal-related Osteoporosis in Men; AND**
i. Treatment with abaloparatide (Tymlos), teriparatide (biosimilar formulation) AND generic teriparatide have been ineffective, not tolerated, or contraindicated; **OR**
3. **Glucocorticoid-induced Osteoporosis; AND**
i. Member is taking ≥ 5 mg prednisone or its equivalent daily with an anticipated duration of ≥ 3 months; **AND**
ii. Treatment with teriparatide (biosimilar formulation) AND generic teriparatide has been ineffective, not tolerated or contraindicated

II. Parathyroid hormones are considered investigational when used for all other conditions, including but not limited to:
A. Osteoporosis prophylaxis
B. Promote fracture healing
C. Promote post-fusion healing
D. The use of abaloparatide (Tymlos) for glucocorticoid-induced osteoporosis.

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Medication will not be used in combination with other osteoporotic agents [e.g., denosumab (Prolia), bisphosphonates (alendronate, risedronate, ibandronate, zoledronic acid injection), calcitonin nasal spray, or raloxifene]; **AND**
IV. If the request is for BRAND teriparatide (Forteo), treatment with teriparatide (biosimilar formulation) AND generic teriparatide has been ineffective, not tolerated or contraindicated; **AND**

V. If the request is for generic teriparatide, treatment with teriparatide (biosimilar formulation) has been ineffective, not tolerated or contraindicated; **AND**

VI. Member has not received treatment with parathyroid hormone for more than a total of two years during their lifetime; **AND**

   A. Provider attestation that member has demonstrated clinical improvement or stability of osteoporosis (e.g., stable, or improved bone mineral density (BMD), reduction in or no new fracture(s), reduction in fracture risk) with parathyroid hormone therapy; **OR**

VII. Member will have received treatment with a parathyroid hormone for more than two years during their lifetime; **AND**

   A. Provider attestation that patient remains or has returned to having high or very high fracture risk (e.g., a fracture while on osteoporosis therapy, a history of multiple fractures, fractures while on long-term glucocorticoids, T-score ≤ -3.0, high risk for falls or a history of injurious falls, a FRAX 10-year probably for major fracture >30% or hip fracture >4.5%, etc.)

Supporting Evidence

I. Osteoporosis is characterized by decreased bone mass and increased fracture risk, most commonly at the spine, hip, and wrist. The definition of osteoporosis with high risk of fracture is defined for men and women as BMD T-score of spine, femoral neck, and/or total hip <-2.5 without fracture, having history of hip or vertebral fracture regardless of BMD, T-score ≤ -1 and a history of recent fracture of proximal humerus, pelvis, or distal forearm, T-score between -1.0 and -2.5 in the spine, femoral neck, or total hip with a -20% 10-year FRAX risk of any fracture or -3% risk of hip fracture, and receiving long-term glucocorticoid doses greater than or equal to prednisone 7.5mg per day. Although BMD is a surrogate marker, meta-analyses have found that treatment-related changes in BMD after 24 months were significantly associated with hip, vertebral, and nonvertebral fracture risk reduction in men and women with osteoporosis. Bone turnover markers (BTM) also reflect the pharmacological response to osteoporosis therapies and decline in BTM largely contributes to antifracture effect. It is suggested that BTM is used in clinical studies to compliment BMD in assessing pharmacological response to treatment.

II. The maximum duration of use for parathyroid hormone agents (e.g., abaloparatide, teriparatide) is two years. As of November 2021, the safety and efficacy of these therapies remains undetermined. Treatment guidelines [e.g., Endocrine Society, American Association of Clinical Endocrinologists (AACE), American College of Endocrinology (ACE), American College of Rheumatology (ACR)] continue to recommend that use of parathyroid analogs be limited to 2 years. If further therapy is warranted, transition to bisphosphonates, denosumab, or raloxifene should be considered to maintain bone density gains experienced from PTH agents.

   A. In November 2020, teriparatide (Forteo) prescribing information was revised to indicate that use beyond two years may be considered if the patient remains, or has returned to, having high fracture risk. The black box warning for high risk of osteosarcoma was

removed based on the results of three retrospective claims studies that did not indicate an increased risk of osteosarcoma associated with the use of teriparatide (Forteo). At this time, it is recognized that there is conflicting evidence for increased osteosarcoma risk with PTH therapies; however, there remains lack of evidence for safety and efficacy beyond two years of therapy. Further research is needed to determine the risk/benefit profile and medical necessity of extended therapy.

B. It is reasonable to consider extending duration of therapy beyond two years in patients who remain, or have returned to, having high or very high fracture risk when benefits of extended therapy outweigh the risks. Examples of this patient population may include, but are not limited to, a fracture while on osteoporosis therapy, a history of multiple fractures, fractures while on long-term glucocorticoids, T-score ≤ -3.0, high risk for falls or a history of injurious falls, a FRAX 10-year probably for major fracture >30% or hip fracture >4.5%, etc.

III. There is lack of head-to-head trials evaluating comparative efficacy and safety of PTH analogs, teriparatide (Forteo), teriparatide biosimilar, and abaloparatide (Tymlos). Therefore, clinical superiority of one agent over the other is not established at this time. All PTH analogs have been evaluated against placebo and were found to increase BMD and/or reduce fracture risk, depending on the indication. Given the known safety, efficacy, and cost-effectiveness, trial of abaloparatide (Tymlos) is required prior to use of teriparatide biosimilar and teriparatide (Forteo) in the indicated populations.

IV. **Post-Menopausal Osteoporosis in Women:**

A. The safety and efficacy of once-daily teriparatide (Forteo) and teriparatide, with a median exposure to treatment of 19 months, was examined in a double-blind, multicenter, placebo-controlled clinical study of 1637 postmenopausal women with osteoporosis (FORTEO 20 mcg, n=541). The absolute risk reduction for new fracture in favor of teriparatide (Forteo) was a 9.3% reduction in vertebral fracture: 95% CI (5.5 – 13.1).

B. The safety and efficacy of abaloparatide (Tymlos) was evaluated in an 18-month, randomized, multicenter, double-blind, placebo-controlled clinical trial in postmenopausal women aged 49 to 86 years (mean age of 69) who were randomized to receive abaloparatide (Tymlos) 80 mcg (N = 824) or placebo (N = 821). The absolute risk reduction for fractures in favor of abaloparatide (Tymlos) was 3.6% reduction in vertebral fractures: 95% CI (2.1 – 5.4).

C. The 2020 AACE/ACE guidelines treatment recommendations are as follows:

i. Initial treatment for high fracture risk: alendronate, denosumab, risedronate, or zoledronate (strong recommendation, high quality evidence)

ii. Treatment for very-high fracture risk or patients, who cannot tolerate or adhere to oral bisphosphonates: zoledronate, abaloparatide, denosumab,

romosozumab, teriparatide, and (strong recommendation, high quality evidence).

iii. Follow-up treatment after parathyroid hormone: bisphosphonate or denosumab

D. Additionally, the 2020 Endocrine Society guidelines recommend bisphosphonates as initial treatment for high-risk patients, while denosumab may be considered as an alternative initial treatment (strong recommendation, high quality evidence). For patients with a very high risk of fracture, teriparatide and abaloparatide are recommended (strong recommendation, moderate quality evidence). It is recommended that antiresorptive therapies follow treatment with parathyroid hormones.

E. The majority of efficacy and safety data for the recommended pharmacologic treatments of postmenopausal osteoporosis are rooted in trials of bisphosphonates, which have reported robust long-term efficacy and relative safety. Similarly, denosumab (Prolia) has well established long-term safety and efficacy as an initial treatment option. Alternatively, recommendations for use of parathyroid hormone therapy in the first-line setting for patients with severe osteoporosis or very high fracture risk are primarily supported only by Phase 3 studies that compared teriparatide to bisphosphonates: NCT00051558, NCT00343252 and the VERO study. While these studies showed statistically significant improvements with teriparatide in surrogate markers related to osteoporosis (e.g., BMD changes, reduction in pain severity, and incidence of vertebral fracture) when compared to a bisphosphonate, they are confounded due to factors such as small sample sizes, high dropout rates, and high previous exposure to bisphosphonates. Additionally, clinical meaningfulness remains uncertain due to lack of longer-term applicability to broader osteoporosis population, and lack of outcomes related to long-term morbidity; thus, the overall quality of evidence is considered low to moderate and may not be sufficient to drive clinical decisions. As such, weighing the safety, efficacy, cost, and clinical experience, oral and intravenous bisphosphonates and denosumab (Prolia) are considered standard and appropriate high-value treatment options in this setting.

V. **Primary Osteoporosis/Hypogonadal-related Osteoporosis in Men**

A. The safety and efficacy of once-daily teriparatide (Forteo) and teriparatide injection was examined in a double-blind, multicenter, placebo-controlled clinical study of 437 men with either primary (idiopathic) or hypogonadal osteoporosis (n=151) for a median exposure of 10 months. Patients were included if they were 30-85 years old, ambulatory, free of chronic conditions and lumbar or proximal spine BMD of at least 2 standard deviations below the average. Baseline characteristics were similar in all groups: mostly 99% white, average age 59 years, BM 25kg/m2, and average lumbar BMD T-score -2.2. The primary endpoint, change in lumbar spine bone mass density (BMD) from baseline, was met in 94% of men treated. Fifty-three percent of patients treated with teriparatide

(Forteo) achieved at least a 5% increase in spine BMD, and fourteen percent of patients gained ≥10% in spine BMD.

B. The safety and efficacy of once-daily abaloparatide (Tymlos) was examined in a 12-month double-blind, multicenter, placebo-controlled clinical study with 228 men with primary or hypogonadal osteoporosis with high risk of fracture. The primary endpoint was percent change in lumbar spine BMD from baseline at 12 months. Men 40-85 years old were included if they had a diagnosis of osteoporosis (T-scores ≤ -2.5 and > -3.5 at the lumbar spine, total hip, or femoral neck, >65 years of age with BMD T-scores ≤ −2.0 (based upon the male reference database) and stable hydroxyvitamin D levels. Baseline characteristics were similar across both groups: mean age 68.3 years, mean lumbar spine BMD T-score -2.1, mean BMI 26.5 kg/m2, 56.6% of patients had prior fractures. The mean change in BMD at lumbar spine at 12 months for the abaloparatide (Tymlos) group was 8.48% compared to placebo, 1.17% ($p<0.001$). No new safety concerns with abaloparatide (Tymlos) were observed and several of the most frequently reported AEs in men were also among the most frequent previously reported in the ACTIVE study in women (dizziness, arthralgia, upper respiratory tract infection, headache, hypertension, and nasopharyngitis).

C. According to the 2020 AACE/ACE guidelines, first-line treatment for men with osteoporosis are bisphosphonates and denosumab may be considered as an alternative initial treatment (strong recommendation, high quality evidence). Selection of therapy is based on individualized factors such as gastrointestinal problems and concomitant androgen deprivation therapy. The National Osteoporosis Foundation (NOF), Endocrine Society, and AACE/ACE guidelines recommend that alendronate, risedronate, zoledronate and denosumab have evidence for “broad-spectrum” antifracture efficacy and should be, in the absence of contraindications, be considered as first line therapy in treatment of osteoporosis. According to the 2012 Endocrine Society guidelines, it is recommended that initial treatment of osteoporosis in men with recent hip fracture should receive zoledronic acid (strong recommendation, low quality evidence), while men with high fracture risk on testosterone should receive an effective anti-fracture agent such as a bisphosphonate or teriparatide (conditional recommendation, low quality evidence). Teriparatide (Forteo) is recommended in treatment of men and women with osteoporosis with upper or lower gastrointestinal problems, when nonoral therapy is preferred, or when patients cannot tolerate or do not respond adequately to bisphosphonates. Guidelines have not been updated to include abaloparatide (Tymlos) in therapy recommendations in men with osteoporosis.

D. The guidelines note that there is increasing evidence to support that BMD gains may be greater when an anabolic drug is administered before the antiresorptive drug compared with the opposite sequence in patients with high-risk fracture. The 2022 NOF guidelines states that when sequential treatment is considered in patients with recent fractures

and/or very low BMD (e.g., T-score < − 3.0), starting with anabolic therapy following an antiresorptive agent is preferred. The 2020 AACE/ACE guidelines also note that it probably is not advisable to use teriparatide (or abaloparatide) if denosumab is stopped. It is hypothesized that bone resorption is required, in part, for PTH analogs to stimulate new bone formation. If antiresorptive agents are suppressing bone resorption, the anabolic action of PTH analogs may be impaired. Although the 2022 NOF and 2020 AACE/ACE guidelines note that sequential therapy (anabolic preceding antiresorptive) may be considered in patients with recent fractures and/or very low BMD, the quality of evidence supporting this statement is low. There are three low quality studies which explored the question of sequential therapy. The studies should not be used for medical decision making due to small study populations, lack of blinding, lack of adherence assessment, and inconsistent BMD outcomes. More research is necessary to determine efficacy and appropriateness of sequential therapy at this time.

i. The DATA-switch study (Leder et al) was a randomized cross over study investigating the effect of sequential osteoporosis therapy in BMD in 77 postmenopausal women, 45 years or older, with osteoporosis. Participants were randomized 1:1:1 to receive teriparatide 20 mcg daily for 24 months then switched to denosumab 60mg every 6 months, denosumab every 6 months for 24 months then switched to teriparatide daily, or denosumab and teriparatide for 24 months, then switched to denosumab every 6 months. BMD at the spine, hip, and wrist were measured at 6, 12, 18, and 24 months after switching therapy. The primary endpoint, percent change in spine BMD over 4 years, was not statistically significant between all three groups (18.3%, 14.0% and 16.0%, p=0.13). The secondary outcome, hip BMD increase, was greater in the teriparatide to denosumab group (6.6%, 95% CI 5.3-7.9) compared to denosumab to teriparatide (2.8%, 95% CI 1.3-4.2), p=0.0002. After 48 months, radius bone mineral density was unchanged in the teriparatide to denosumab group (0.0% [95% CI -1.3 to 1.4]), whereas it decreased by -1.8% (-5.0 to 0.3), p=0.0075, in the denosumab to teriparatide group, and increased by 2.8% (1.2-4.4), p=0.0099, in the combination to denosumab group.
    a. The study is of low quality with concerns regarding validity of results due to open label study design, and a small size of the population studied. The primary endpoint did not meet statistical significance and the results of the secondary endpoints were inconsistent. Therefore, specific clinical impact of the transient bone loss that occurs in women switching from denosumab to teriparatide cannot be precisely estimated.

II. The DATA-Switch HR-pQCT study (Tsai et al) assessed the effects of sequential therapy on bone microarchitecture and strength at the distal tibia and radius in the DATA-Switch population. Study results found that women switching from

teriparatide to denosumab had an increase in tibial BMD (net 48-month change -0.8% ± 2.4%) and combination-to-denosumab groups (net 48-month changes +2.4% ± 4.1%) and decreased in the denosumab to teriparatide group (net 48-month change -3.4% ± 3.2%, p<0.001). Changes in total volumetric BMD followed similar patterns. Tibial cortical porosity increased in the denosumab-to-teriparatide group (+16.2% ± 11.5%, p <0.05 versus other groups).

a. The study is of low quality with concerns regarding validity of results due to open label study design and a small size of the population studied. Guidelines recommend that when spine and hip BMD are not evaluable, distal radius may be evaluated for initiation of therapy or therapy monitoring. Spine fractures are more common than hip and radius fractures. Hip fractures typically result in more severe outcomes such as increase in one-year mortality rate and loss of independence. Tibial BMD change and porosity trends may demonstrate changes in microarchitecture that influence bone strength at the tibia. However, tibia BMD values are not typically measured at baseline and there is uncertain applicability and value of these study results.

III. A European open-label, prospective, randomized trial (Obermayer-Pietsch, et al) evaluated the efficacy of osteoporosis sequential treatment regimens in 503 postmenopausal women with osteoporosis who received 24 months of teriparatide. The participants were divided into three groups based on prior antiresorptive treatment (treatment naïve, N=84, pretreated with no evidence of inadequate response to antiresorptive treatment, N=134, and pretreated with inadequate response, N=285). The majority of patients previously treated with antiresorptive treatment were treated with bisphosphonates, most commonly alendronate (86.6% and 93.0%). The primary endpoint was change in BMD at lumbar spine and secondary endpoints were changes in total hip BMD and femoral neck BMD. The mean gain in lumbar BMD was greater in the treatment naïve group (13.1%) compared to the pretreated without response (10.2%, p<0.005) and pretreated with inadequate response (9.8%, p<0.001). The mean gain in total hip BMD were 3.8%, 2.3%, and 2.3%, respectively. The difference in femoral neck BMD between the treatment-naïve and the inadequate responder subgroups was significant after 12 months, however, the mean changes were not significantly different across the three groups at 24 months (4.8%, 3.4%, 3.9%). The study concluded that the prior antiresorptive treatment blunted the BMD response to teriparatide.

a. There is low confidence in the study as it was open label, adherence was not addressed, and clinically meaningful differences in change of BMD is currently unknown, therefore it is difficult to draw conclusions. Additionally, confidence in study results is uncertain as the results in change in BMD

across lumbar spine, total hip and femoral neck are inconsistent. The study showed increase in BMD at lumbar spine and hip, but no statistical difference at the femoral neck. Limitations in the study precludes drawing conclusions regarding sequential therapy.

VI. **Glucocorticoid-induced osteoporosis:**

A. The efficacy of teriparatide (Forteo) and teriparatide injection was assessed in a randomized, double blind, active-controlled trial of 428 patients (19% men, 81% women) aged 22 to 89 years (mean 57 years) treated with ≥ 5 mg/day prednisone or equivalent for a minimum of 3 months. The duration of the trial was 18 months with 214 patients exposed to teriparatide (Forteo). In patients treated with teriparatide (Forteo), the mean percent change in BMD from baseline to endpoint was 7.2% at the lumbar spine, 3.6% at the total hip, and 3.7% at the femoral neck ($p<0.001$ all sites).

B. According to the 2017 ACR guidelines, in adults with glucocorticoid-induced osteoporosis regardless of fracture risk, initial treatment should include oral bisphosphonates. In patients who had a fracture in the past 18 months or lost >10% bone density per year, IV bisphosphonates, teriparatide, or denosumab be used in the second-line setting; in patients who remain at moderate-to-high fracture risk, treatment should continue with a bisphosphonate, or may be switched to an alternative class (conditional recommendation, low quality of evidence).

Investigational or Not Medically Necessary Uses

I. Osteoporosis Prophylaxis
   A. There is currently no evidence to support the use of parathyroid hormones for the prevention of postmenopausal osteoporosis.

II. Promote fracture healing and/or post fusion healing
   A. There is limited safety and efficacy evidence to support the use of parathyroid hormones in the setting of fracture healing and/or post fusion healing.

III. Abaloparatide (Tymlos) is only FDA-approved for the treatment of postmenopausal osteoporosis and primary/hypogonadal-related osteoporosis in men; there is currently a lack of sufficient evidence regarding safety and efficacy in other settings.

References

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Related Policies

Policies listed below may be related to the current policy. Related policies are identified based on similar indications, similar mechanisms of action, and/or if a drug in this policy is also referenced in the related policy

Policy Name	Disease state
denosumab (Prolia)	Post-menopausal Osteoporosis in Women
	Osteoporosis in Men
	Increase Bone Mass in Women with Breast Cancer receiving Aromatase Inhibitor Therapy
	Increase Bone Mass in Men with Non-metastatic Prostate Cancer receiving Androgen Deprivation Therapy
	Glucocorticoid-induced Osteoporosis

Policy Implementation/Update:

Action and Summary of Changes	Date
Updated criteria of treatment failure with bisphosphonates or Prolia to allow attestation and removed minimum 12-month trial requirement.	03/2024

Added generic teriparatide to policy	02/2024
Updated dosage forms to be reflective of product availability rather than concentration.	11/2023
Updated criteria to include abaloparatide (Tymlos) in treatment of primary/hypogonadal-related osteoporosis in men. Included criteria regarding fractures despite BMD changes under fracture risk category. Removed primary/hypogonadal-related osteoporosis from investigational section. Added supporting evidence for new indication in osteoporosis in men and sequential therapy. Added related policies section.	12/2022
Added initial and renewal criteria for use beyond two years to demonstrate fracture risk remains high, refined diagnosis criteria to target patients with high fracture risk, and adjusted previous medication trials to require PO, IV bisphosphonate or Prolia while removing raloxifene and calcitonin. Updated and reformatted supporting evidence for limitation on duration of use and requirement of bisphosphonates or Prolia.	12/2021
Added criteria for the biosimilar teriparatide, requiring trial of the biosimilar prior to brand Forteo	11/2020
Added detail around maximum duration of approval [26 (monthly) fills] in order to provide more clarity around fill history. Addition of supporting evidence regarding maximum two year treatment duration	04/2020
Added in fill count to renewal duration, as well as updated to reflect a 28-day supply instead of 30-days in the Forteo QL table	02/2020
Criteria transitioned into policy format with the following additions: supporting evidence, investigational section, and a list of drugs that should not be used in combination with parathyroid hormones. Guidelines reviewed, and the following updates were made: differentiate between T-scores without fragility fracture and with fragility fracture, defined high risk fractures, and provided inclusion criteria for glucocorticoid-induced osteoporosis.	12/2019
Update criteria to include abaloparatide (Tymlos)	08/2017
Reviewed	10/2005, 01/2007, 12/2008, 06/2013, 02/2016, 06/2017, 12/2019
Date effective	03/2016
Policy created	09/2005