EXPRESS SCRIPTS®

PRIOR AUTHORIZATION POLICY

POLICY: Bone Modifiers – Bisphosphonates (intravenous)
- Reclast (zoledronic acid injection – Novartis, generics)
- Boniva® (ibandronate injection – Genentech/Roche, generics)

TAC APPROVAL DATE: 02/14/2018

OVERVIEW

Zoldedronic acid (Reclast) and ibandronate injection (Boniva IV) are both bisphosphonates given intravenously.[1-2] Zoledronic acid injection (Reclast) is indicated for the treatment of osteoporosis in postmenopausal women; for the prevention of postmenopausal osteoporosis (PMO) in women; the treatment of Paget's disease of bone in men and women; for the treatment to increase bone mass in men with osteoporosis; and for the treatment and prevention of glucocorticoid-induced osteoporosis (GIO) in patients expected to be on systemic glucocorticoids (daily dosage equivalent to ≥ 7.5 mg of prednisone) for at least 12 months.[1] In PMO, zoledronic acid injection (Reclast) reduces the incidence of fractures (hip, vertebral and non-vertebral osteoporosis-related fractures). Also, for patients at high risk of fracture, defined as a recent low-trauma hip fracture, zoledronic acid injection (Reclast) reduces the incidence of new clinical fractures.[1] For the treatment of PMO; the treatment and prevention of GIO; and for the treatment to increase bone mass in men with osteoporosis, Zoledronic acid injection (Reclast) is given as a single 5 mg intravenous (IV) infusion over no less than 15 minutes once a year. For the prevention of PMO, the recommended dose is a single 5 mg IV infusion given once every 2 years. For the treatment of Paget's disease of the bone, a single 5 mg IV infusion is given over 15 minutes and retreatment is considered based on increases in serum alkaline phosphatase or the patient's clinical status.[1] Ibandronate injection (Boniva IV) is indicated for the treatment of PMO in women. The dosing regimen for this indication is 3 mg IV over 15 to 30 seconds every 3 months.[2] Both agents have a limitation of use stating that the optimal duration of use has not been determined. For patients at low-risk for fracture, consider drug discontinuation after 3 to 5 years of use.[1-2]

Another zoledronic acid injection product, Zometa®, is indicated for hypercalcemia of malignancy; and for multiple myeloma and bone metastases from solid tumors.[3] The recommended dosing interval for Zometa differs from Reclast. For hypercalcemia of malignancy, the maximum recommended Zometa dose is 4 mg as a single dose IV infusion over no less than 15 minutes. The recommended Zometa dose in multiple myeloma and metastatic bone lesions from solid tumors is a 4 mg IV infusion given over 15 minutes every 3 to 4 weeks.[3]

Bisphosphonates are also available orally and have several indications. Alendronate, risedronate, and oral ibandronate are all indicated for the treatment and prevention of PMO.[4-6] Atelvia® (risedronate delayed-release tablets) is indicated for the treatment of PMO.[7] Fosamax® Plus D tablets (alendronate/cholecalciferol tablets) are indicated for treatment of PMO.[8] Alendronate[4] and risedronate[5] are indicated for the treatment of GIO and the treatment of Paget's disease in men and women. Alendronate, Fosamax Plus D, and risedronate also have an indication for treatment to increase bone mass in men with osteoporosis.[4-5,8] Risedronate is also approved for the prevention of GIO in men and women.[5] Binosto® (effervescent tablet for oral solution) is indicated for the treatment

of osteoporosis in postmenopausal women and to increase bone mass for the treatment of osteoporosis in men.[24]

Guidelines

Osteoporosis in Postmenopausal Women

In 2014, the National Osteoporosis Foundation (NOF) updated guidelines regarding the prevention and treatment of osteoporosis.[9] It is estimated that almost 10 million Americans have osteoporosis and an additional 43 million have low bone density. Approximately one out of every two Caucasian women will experience an osteoporosis-related fracture during their lifetime. Annually, two million fractures yearly are believed to be due to osteoporosis. Pharmacologic treatment should be initiated in the following patients: 1) 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 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 ≥ 3% or a 10-year major osteoporosis-related fracture probability ≥ 20% based on the US-adapted WHO absolute fracture risk model. Regarding bisphosphonates, alendronate reduces the incidence of spine, hip and wrist fractures by about 50% over 3 years in patients with a prior spine fracture. It also reduces the incidence of spine fractures by 48% over 3 years in patients without a prior spine fracture. Risedronate reduces the incidence of spine fractures by 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. Ibandronate has been shown to reduce the incidence of spine fractures by about 50% over 3 years but reduction in the risk of nonvertebral fractures has not been demonstrated. Zoledronic acid injection (Reclast) reduces the risk of spine fractures by 70%, hip fractures by 41%, and non-vertebral fractures by 25% over 3 years. A preferred bisphosphonate product is not mentioned.

The North American Menopause Society (NAMS) updated a position statement in 2010 regarding the management of osteoporosis in postmenopausal women.[10] NAMS recommends bisphosphonates as first-line drugs for treating PMO. 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.

In 2016 the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology updated clinical practice guidelines for the diagnosis and treatment of PMO.[11] Approved agents with efficacy to reduce hip, non-vertebral and spine fractures include alendronate, risedronate, zoledronic acid injection (Reclast), and Prolia® (denosumab injection for subcutaneous use) which are appropriate as initial therapy for most patients at high-risk of fracture. Forteo® (teriparatide injection for subcutaneous use), 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. 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 2017, the American College of Physicians ACP updated the 2008 ACP recommendations regarding the treatment of low bone density and osteoporosis to prevent fractures in men and women.[27] Many recommendations are cited which involve bisphosphonates. One main recommendation is that clinicians should offer pharmacologic treatment with alendronate, risedronate, zoledronic acid injection (Reclast) or denosumab to reduce the risk for hip and vertebral fractures in women who have known osteoporosis (Grade: strong recommendation; high-quality evidence).

Osteoporosis in Men
The Endocrine Society published medical guidelines for osteoporosis in men in 2012.[12] It is recommended that men at high risk of fracture receive medications that are indicated for osteoporosis in men (e.g., alendronate, risedronate, zoledronic acid injection [Reclast], Forteo® [teriparatide injection]). For men receiving testosterone therapy, an agent with proven antifracture efficacy should be utilized (e.g., a bisphosphonate or Forteo).

GIO Guidelines
Guidelines from the American College of Rheumatology (ACR) for the prevention and treatment of GIO, updated in 2017, recommended use of oral and intravenous bisphosphonates in various clinical scenarios.[13] Oral bisphosphonates are preferred in most situations. Generally, IV bisphosphonates can be considered in high-risk patients.

Safety
Perforations, ulcerations, and bleeding episodes have been noted with all bisphosphonates except for IV bisphosphonates.[14] Esophageal ulcerations were reported in all the bisphosphonate trials except zoledronic acid injection (Reclast).[14] Zoledronic acid injection (Reclast) and ibandronate injection (Boniva IV) are not associated with GI events because they are given IV and do not accumulate in the GI tract.[15]

Most oral bisphosphonates should be taken at least 30 to 60 minutes before the first food, beverages, medications or supplements (e.g., calcium) of the day. To facilitate delivery to the stomach, the oral bisphosphonates should be swallowed while the patient is in an upright position and with a full glass of plain water (6 to 8 oz). Atelvia should be taken in the morning immediately after breakfast with at least 4 ounces of plain water. With all oral bisphosphonates, patients must remain upright for ≥ 30 minutes.[5-8] IV bisphosphonates do not have these restrictions.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of zoledronic acid injection (Reclast) and ibandronate injection (Boniva IV). All approvals are provided for 3 years in duration unless otherwise noted below. In the approval indication for zoledronic acid injection (Reclast), 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
I. Coverage of ibandronate injection (Boniva IV) is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Osteoporosis Treatment for a Postmenopausal Patient.** Approve ibandronate injection (Boniva IV) for 3 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 that the patient it 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 gastrointestinal [GI]-related adverse effects); 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 in which IV bisphosphonate therapy may be warranted (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 IV) or zoledronic acid injection (Reclast); OR
iv. The patient has had an osteoporotic fracture or a fragility fracture.

Ibandronate injection (Boniva IV) is indicated for the treatment of osteoporosis in postmenopausal women.[2] Many oral bisphosphonate products are indicated and have proven efficacy. Various guidelines support the use of bisphosphonate therapy first-line in many clinical scenarios.[9-11] In the AACE guidelines for PMO (2016), 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) or as the presence of fragility fractures in the absence of other metabolic bone disorders.[11] IV bisphosphonate therapy may be preferred in some instances over oral therapy (e.g., GI intolerance, a pre-existing GI medical condition). 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 specialist physicians reviewing the data, we have adopted these criteria.

II. Coverage for zoledronic acid injection (Reclast) is recommended for patients who meet the following criteria:

FDA-Approved Indications

1. **Osteoporosis Treatment for a Postmenopausal Patient.** Approve zoledronic acid injection (Reclast) for 3 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 that 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 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); 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 in which IV bisphosphonate therapy may be warranted (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 IV) or zoledronic acid injection (Reclast); OR
iv. The patient has had an osteoporotic fracture or a fragility fracture.

Zoledronic acid injection (Reclast) is indicated for the treatment of PMO.[1] Many oral bisphosphonate products are indicated and have proven efficacy. Various guidelines support use of bisphosphonate therapy as first-line in many clinical scenarios.[9-11] In the AACE guidelines for PMO (2016), 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) or as the presence of fragility fractures in the absence of other metabolic bone disorders.[11] IV bisphosphonate therapy may be preferred in some instances over oral therapy (e.g., GI intolerance, a pre-existing GI medical condition). 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 specialist physicians reviewing the data, we have adopted these criteria.

2. Osteoporosis Treatment for Men*. Approve zoledronic acid injection (Reclast) for 3 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 that 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 gastrointestinal (GI)-related adverse effects); 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 in which IV bisphosphonate therapy may be warranted (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 has had an osteoporotic fracture or a fragility fracture.

***** Refer to the Policy Statement.

Zoledronic acid injection (Reclast) is indicated for this condition and data suggests that an annual infusion led to similar changes in lumbar spine BMD as oral weekly bisphosphonate therapy. Of the oral bisphosphonates, alendronate, Fosamax Plus D, and risedronate are indicated for use in males. A multicenter, double-blind, placebo-controlled trial involving 1,199 men with primary or hypogonadism-associated osteoporosis (aged 50 to 85 years) found that men who received zoledronic acid injection (Reclast) [5 mg IV at baseline and at 12 months] had fewer moderate-to-severe vertebral fractures (P = 0.03) and height loss (P = 0.002) compared with placebo over 24 months.[16] IV bisphosphonate therapy may be preferred in some instances over oral therapy (e.g., GI intolerance, a pre-existing GI medical condition). 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 specialist physicians reviewing the data, we have adopted these criteria.

3. Glucocorticoid-Induced Osteoporosis (GIO) Prevention and Treatment. Approve zoledronic acid injection (Reclast) for 3 years 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 bone mineral density [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 GI-related adverse effects); 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 in which IV bisphosphonate therapy may be warranted (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 has had an osteoporotic fracture or a fragility fracture.

Zoledronic acid injection (Reclast) is indicated for the treatment and prevention of GIO. Guidelines from the ACR for the prevention and treatment of GIO, updated in 2017, recommend use of oral and IV bisphosphonates in various clinical scenarios.[13] IV bisphosphonate therapy may be preferred in some instances over oral therapy (e.g., GI intolerance, a pre-existing GI medical condition). 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 specialist physicians reviewing the data, we have adopted these criteria.

4. **Paget's Disease of the Bone.** Approve zoledronic acid injection (Reclast) for one dose if the patient meets ONE of the following criteria (A, B, or C):
A) The patient has elevations in serum alkaline phosphatase of two times higher than the upper limit of the age-specific normal reference range; OR
B) The patient is symptomatic (e.g., bone pain, hearing loss, osteoarthritis); OR
C) The patient is at risk for complications from their disease (e.g., immobilization, bone deformity, fractures, nerve compression syndrome).

Zoledronic acid (Reclast) is indicated for this condition. A clinical practice guideline regarding Paget's disease of bone from the Endocrine Society states the zoledronic acid (Reclast), administered as a single 5-mg IV dose, is the treatment of choice.[23] A published, randomized, double-blind study involving patients with Paget's disease documented a more rapid and sustained response with zoledronic acid (Reclast) as compared with risedronate.[1] One dose of zoledronic acid (Reclast) is given, and then patients are evaluated after approximately 6 months of therapy.[1,17] Reasons for treatment, or retreatment, include an elevated serum alkaline phosphatase or the patient has symptoms or is at risk of disease complications.[1,17] In the professional opinion of specialist physicians reviewing the data, we have adopted these criteria.

5. **Osteoporosis Prevention for a Postmenopausal Patient.** Approve zoledronic acid injection (Reclast) for 3 years if the patient meets the following criteria (A and B):
A) The patient meets ONE of the following conditions (i or ii):

i. The patient has had a 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); OR
ii. The patient has had an osteoporotic fracture or a fragility 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); 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 in which IV bisphosphonate therapy may be warranted (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 has had an osteoporotic fracture or a fragility fracture.

Zoledronic acid (Reclast) is indicated for this condition; other oral bisphosphonates are indicated for this condition. IV bisphosphonate therapy may be preferred in some instances over oral therapy (e.g., GI intolerance, a pre-existing GI medical condition). 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 specialist physicians reviewing the data, we have adopted these criteria.

Other Uses with Supportive Evidence

6. Osteogenesis Imperfecta. Approve zoledronic acid injection (Reclast) for 3 years.

Although not indicated, zoledronic acid injection (Reclast) has been used in patients, mainly children, with osteogenesis imperfecta and benefits were noted, such as increases in bone mineral density.[1,18-22,25]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ibandronate injection (Boniva IV) 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. Osteoporosis Prevention. Ibandronate injection (Boniva IV) is not indicated for the prevention of osteoporosis and supporting data are limited.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Zoledronic acid (Reclast) and Boniva injection (Boniva IV) have 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. Concurrent Use with Other Medications for Osteoporosis (e.g., other bisphosphonates [previously listed], Prolia, Forteo, Tymlos® [abaloparatide injection for SC use], calcitonin nasal spray), except calcium and Vitamin D.

2. 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 treatment for a postmenopausal women (Reclast and Boniva) and for osteoporosis prevention for a postmenopausal women (Reclast), changed the word "women" to "patient".	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
Annual revision	Changed the name of the policy to add "Bone Modifiers" – Bisphosphonates (intravenous) PA Policy. For ibandronate injection and zoledronic acid injection regarding osteoporosis treatment for a postmenopausal patient and for zoledronic acid injection for the treatment of 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 added as an accepted manner to diagnose osteoporosis, in addition to an osteoporotic fracture. Also, regarding previous criteria that addressed patients with a T-score at or below -2.0, the criteria were revised to state low bone mass (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" (instead of the word "believes") that the patient is at high risk for fracture. Also, patients who were on oral bisphosphonate therapy and had a fragility fracture (in addition to the previously-cited osteoporotic fracture) are permitted to use either agent (in addition to meeting other criteria). Patients that have had an osteoporotic fracture or a fragility fracture are also granted exceptions as they are at higher risk. For the indication regarding glucocorticoid-induced osteoporosis patients with a fragility fracture (in addition to the previously-listed an osteoporotic fracture) while receiving oral bisphosphonate therapy are permitted to use zoledronic acid injection (in addition to meeting other criteria). Also, patients with an osteoporotic fracture or a fragility fracture can receive zoledronic acid injection if they are on glucocorticosteroids. For osteoporosis prevention for a postmenopausal patient, the 33% (one third) radius (wrist) was added as a site to assess the T-score. Also, a fragility fracture was added as an accepted manner to diagnose this condition, in addition to an osteoporotic fracture. Additionally, patients who were on oral bisphosphonate therapy and had a fragility fracture (in addition to the previously-cited osteoporotic fracture) are permitted to use zoledronic acid-injection (in addition to meeting other criteria). Patients that have had an osteoporotic fracture or a fragility fracture are also granted exceptions as they are at higher risk. Evista (raloxifene) was deleted from the list of osteoporosis medications in which Prolia should not be used with concurrently; Tymlos was added to this list.	02/14/2018

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