Drug Coverage Policy

Effective Date……10/01/2025
Coverage Policy Number……IP0331
Policy Title……Denosumab Products (Prolia)

Bone Modifiers – Denosumab Products (Prolia)

- Jubbonti® (denosumab-bbdz subcutaneous injection – Sandoz)
- Prolia® (denosumab subcutaneous injection – Amgen)
- Stoboclo® (denosumab-bmwo subcutaneous injection – Celltrion)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used

as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview
Denosumab products (Prolia, biosimilars) are receptor activator of nuclear factor kappa-B ligand inhibitors indicated for the following uses:[1-3]

- **Bone loss (treatment to increase bone mass), in men with nonmetastatic prostate cancer** at high risk for fracture receiving androgen deprivation therapy.
- **Bone loss (treatment to increase bone mass), in women with breast cancer** at high risk for fracture receiving adjuvant aromatase inhibitor therapy.
- **Glucocorticoid-induced osteoporosis** (treatment), in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months.
- **Osteoporosis**, treatment of **postmenopausal women** at high risk of fracture.
- **Osteoporosis**, treatment to **increase bone mass in men** at high risk for fracture.

In general, high risk of fractures is 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.[1-3] Of note, denosumab subcutaneous injection is also available under the brand name Xgeva® (and biosimilars) and is indicated for the prevention of skeletal-related events in patients with multiple myeloma, as well as in patients with bone metastases from solid tumors, giant cell tumor of bone, and hypercalcemia of malignancy.[4]

Dosing Information
For all indications, the dose is 60 mg once every 6 months as a subcutaneous injection.[1-3]

Guidelines
Several guidelines address denosumab products (Prolia, biosimilars).

- **Breast Cancer/Prostate Cancer:** The National Comprehensive Cancer Network guidelines for breast cancer (version 4.2024 – July 3, 2024)[5] and prostate cancer (version 4.2024 – May 17, 2024)[6] note that if patients are receiving agents that impact bone mineral density (BMD), bisphosphonates (oral/intravenous), as well as denosumab (Prolia, biosimilars), should be considered to maintain or improve BMD and/or reduce the risk of fractures.
- **Glucocorticoid-Induced Osteoporosis (GIO):** In 2022, the American College of Rheumatology published guidelines for the prevention and treatment of GIO.[7] In various clinical scenarios, oral bisphosphonates are preferred, followed by intravenous bisphosphonates (e.g., zoledronic acid intravenous infusion [Reclast]). Denosumab products (Prolia, biosimilars) have a role in higher-risk patients.
- **Postmenopausal Osteoporosis:** Denosumab products (Prolia, biosimilars) are prominently featured in guidelines for postmenopausal osteoporosis by the Endocrine Society (2019)[8] and the American Association of Clinical Endocrinologists and the American College of Endocrinology (2020).[9] Denosumab products (Prolia, biosimilars) are one of several agents cited as an alternative for patients at high risk for fractures. The Bone Health and Osteoporosis Foundation clinician's guide for prevention and treatment of

osteoporosis (2022) cites denosumab products (Prolia, biosimilars) as robustly reducing vertebral and non-vertebral fractures in studies involving women with postmenopausal osteoporosis.[10]

Safety
There is a Boxed Warning for denosumab products (Prolia, biosimilars) regarding hypocalcemia in patients with advanced kidney disease.[1-3] Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following denosumab (Prolia, biosimilar) administration. Severe hypocalcemia resulting in hospitalization, life-threatening events, and fatal cases have been reported. The presence of chronic kidney disease mineral and bone disorder (CKD-MBD) greatly increases the risk of hypocalcemia. Before starting denosumab products (Prolia, biosimilars) in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with denosumab products (Prolia, biosimilars) in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Coverage Policy

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of denosumab products (Prolia, biosimilars). Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for 1 year in duration. 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.

FDA-Approved Indications

Denosumab products (Prolia, biosimilars) are considered medically necessary when ONE the following is met (1, 2, 3, 4, 5, 6, or 7):

1. **Bone Loss (Treatment to Increase Bone Mass) in Patients with Breast Cancer at High Risk for Fracture Receiving Adjuvant Aromatase Inhibitor Therapy.** Approve for 1 year if the patient meets BOTH the following (A and B):
   - **A.** Patient has breast cancer that is not metastatic to bone; AND
   - **B.** Patient is receiving aromatase inhibitor therapy
     Note: Examples of aromatase inhibitor therapy are anastrozole, letrozole, or exemestane.

     Dosing. Approve 60 mg subcutaneously once every 6 months.

2. **Bone Loss (Treatment to Increase Bone Mass) in Patients with Nonmetastatic Prostate Cancer at High Risk for Fracture Receiving Androgen Deprivation Therapy.** Approve for 1 year if the patient meets BOTH the following (A and B):
   - **A.** Patient has prostate cancer that is not metastatic to bone; AND
   - **B.** Patient meets ONE of the following (i or ii):
     - **i.** Patient is receiving androgen deprivation therapy; OR
       Note: Examples of androgen deprivation therapy are Lupron Depot (leuprolide depot suspension injection), Eligard (leuprolide acetate suspension injectable),

Trelstar (triptorelin pamoate suspension injection), and Zoladex (goserelin implant).

ii. Patient has undergone bilateral orchiectomy

Dosing. Approve 60 mg subcutaneously once every 6 months.

3. **Glucocorticoid-Induced Osteoporosis – Treatment.** Approve for 1 year if the patient meets BOTH the following (A and B):
   - **A.** Patient is either initiating or continuing chronic systemic glucocorticoids; AND
     Note: An example of a systemic glucocorticoid is prednisone.
   - **B.** Patient meets of ONE of the following (i, ii, iii, or iv):
     - **i.** Patient has tried zoledronic acid intravenous infusion (Reclast); OR
     - **ii.** Patient has tried at least ONE of oral bisphosphonate product or oral bisphosphonate-containing product and meets ONE of the following (a or b):
       Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
       - **a.** According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
         Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
       - **b.** Patient has experienced significant intolerance to an oral bisphosphonate; OR
         Note: Examples of significant intolerance include severe gastrointestinal related adverse events and/or severe musculoskeletal related adverse events.
     - **iii.** Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):
       - **a.** Patient cannot swallow or has difficulty swallowing; OR
       - **b.** Patient cannot remain in an upright position post oral bisphosphonate administration; OR
       - **c.** Patient has a pre-existing gastrointestinal medical condition; OR
         Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).
     - **iv.** Patient meets ONE of the following (a or b):
       - **a.** Patient meets BOTH of the following [(1) and (2)]:
         - **1)** According to the prescriber, the patient has severe renal impairment or chronic kidney disease; AND
           Note: An example of severe renal impairment is a creatinine clearance < 35 mL/minute.
         - **2)** Patient has been evaluated for the presence of chronic kidney disease mineral and bone disorder to reduce the risk of denosumab (Prolia, biosimilar)-induced hypocalcemia; OR
       - **b.** Patient has had an osteoporotic fracture or a fragility fracture.

   Dosing. Approve 60 mg subcutaneously once every 6 months.

4. **Osteoporosis Treatment for a Postmenopausal Patient.** Approve for 1 year if the patient meets BOTH the following (A and B):

A. Patient meets ONE of the following (i, ii, or iii):
- **i.** 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.** Patient has had an osteoporotic fracture or a fragility fracture; OR
- **iii.** Patient meets BOTH of the following (a and b):
  - **a.** Patient has low bone mass; AND
    Note: An example of low bone mass includes 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)
  - **b.** According to the prescriber the patient is at high risk for fracture; AND

B. Patient meets ONE of the following (i, ii, iii, or iv):
- **i.** Patient has tried ibandronate intravenous injection (Boniva) or zoledronic acid intravenous infusion (Reclast); OR
- **ii.** Patient has tried at least ONE oral bisphosphonate product or oral bisphosphonate-containing product and meets ONE of the following (a or b):
  Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
  - **a.** According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
    Note: Examples of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
  - **b.** Patient has experienced significant intolerance to an oral bisphosphonate; OR
    Note: Examples of significant intolerance include severe gastrointestinal related adverse events and/or severe musculoskeletal related adverse events.
- **iii.** Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):
  - **a.** Patient cannot swallow or has difficulty swallowing; OR
  - **b.** Patient cannot remain in an upright position post oral bisphosphonate administration; OR
  - **c.** Patient has a pre-existing gastrointestinal medical condition; OR
    Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).
- **iv.** Patient meets ONE of the following (a or b):
  - **a.** Patient meets BOTH of the following [(1) and (2)]:
    - **1)** According to the prescriber, the patient has severe renal impairment or chronic kidney disease; AND
      Note: An example of severe renal impairment is a creatinine clearance < 35 mL/minute.
    - **2)** Patient has been evaluated for the presence of chronic kidney disease mineral and bone disorder to reduce the risk of denosumab (Prolia, biosimilar)-induced hypocalcemia; OR
  - **b.** Patient has had an osteoporotic fracture or a fragility fracture.

Dosing. Approve 60 mg subcutaneously once every 6 months.

5. **Osteoporosis Treatment (to Increase Bone Mass) for Men.** Approve for 1 year if t**he** patient meets BOTH of the following (A and B):
   - **A.** Patient meets ONE of the following (i, ii, or iii):
     - **i.** 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.** Patient has had an osteoporotic fracture or a fragility fracture; OR
     - **iii.** Patient meets BOTH of the following (a and b):
       - **a.** Patient has low bone mass; AND
         Note: An example of low bone mass includes 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)
       - **b.** According to the prescriber the patient is at high risk for fracture ; AND
   - **B.** Patient meets of ONE of the following (i, ii, iii, or iv):
     - **i.** Patient has tried zoledronic acid intravenous infusion (Reclast); OR
     - **ii.** Patient has tried at least ONE oral bisphosphonate product or oral bisphosphonate-containing product and has had ONE of the following (a or b):
       Note: Examples of oral bisphosphonate products include Fosamax (alendronate tablets and oral solution), Fosamax Plus D (alendronate/cholecalciferol tablets), Actonel (risedronate tablets), Atelvia (risedronate delayed-release tablets), and Boniva (ibandronate tablets).
       - **a.** According to the prescriber, patient has experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months; OR
         Note: Example of inadequate efficacy are ongoing and significant loss of bone mineral density (BMD), lack of a BMD increase, and/or an osteoporotic fracture or a fragility fracture.
       - **b.** Patient has experienced significant intolerance to an oral bisphosphonate; OR
         Note: Examples of significant intolerance include severe gastrointestinal related adverse events and/or severe musculoskeletal related adverse events.
     - **iii.** Patient cannot take an oral bisphosphonate due to ONE of the following (a, b, or c):
       - **a.** Patient cannot swallow or has difficulty swallowing; OR
       - **b.** Patient cannot remain in an upright position post oral bisphosphonate administration; OR
       - **c.** Patient has a pre-existing gastrointestinal medical condition; OR
         Note: Examples of pre-existing gastrointestinal medical conditions include esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying (stricture, achalasia).
     - **iv.** Patient meets ONE of the following (a or b):
       - **a.** Patient meets BOTH of the following [(1) and (2)]:
         - **1)** According to the prescriber, the patient has severe renal impairment or chronic kidney disease; AND
           Note: An example of severe renal impairment is a creatinine clearance < 35 mL/minute.

2) Patient has been evaluated for the presence of chronic kidney disease mineral and bone disorder to reduce the risk of denosumab (Prolia, biosimilar)-induced hypocalcemia; OR

b. Patient has had an osteoporotic fracture or a fragility fracture.

Dosing. Approve 60 mg subcutaneously once every 6 months.

6. **Treatment of Bone Loss in Patients with Prostate Cancer Receiving Androgen Deprivation Therapy.** Approve for 1 year if the patient is receiving androgen deprivation therapy.
   Note: Examples of androgen deprivation therapy are Lupron Depot (leuprolide depot suspension injection), Eligard (leuprolide acetate suspension injectable), Trelstar (triptorelin pamoate suspension injection), Zoladex (goserelin implant), and Orgovyx (relugolix tablets).

   Dosing. Approve 60 mg subcutaneously once every 6 months.

7. **Increase Bone Mineral Density in Patients with Breast Cancer.** Approve for 1 year if the patient meets **ONE** of the following (i or ii):
   - **i.** Patient meets BOTH of the following (a and b):
     - **a)** Patient is postmenopausal; AND
     - **b)** Patient is receiving aromatase inhibitor therapy; OR
       Note: Examples of aromatase inhibitor therapy are anastrozole, letrozole, or exemestane.
   - **ii.** Patient meets BOTH of the following (a and b):
     - **a)** Patient is premenopausal; AND
     - **b)** Patient is receiving estrogen deprivation therapy
       Note: Examples of estrogen deprivation therapy are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection), anastrozole, letrozole, and exemestane.

Dosing. Approve 60 mg subcutaneously once every 6 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.

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

Conditions Not Covered

Denosumab products (Prolia, biosimilars) for any other use is considered not medically necessary including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent Use with Other Medications for Osteoporosis.**
   Note: Examples of medications for osteoporosis that denosumab products (Prolia, biosimilars) should not be given with include teriparatide subcutaneous injection (Forteo), Tymlos (abaloparatide subcutaneous injection), oral bisphosphonates (e.g., alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid intravenous infusion [Reclast], ibandronate intravenous infusion), calcitonin nasal spray (Miacalcin/Fortical), and Evenity (romosozumab-aqqg subcutaneous injection).

Denosumab products (Prolia, biosimilars) are not indicated for use as combination therapy.[1] However, this does NOT exclude use of calcium and/or vitamin D supplements in combination with denosumab products (Prolia, biosimilars).

2. **Giant Cell Tumor of Bone.**
   Studies in giant cell tumor of the bone used dosing for denosumab subcutaneous injection (Xgeva, biosimilars) which is indicated for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.[3,4]

3. **Osteoporosis Prevention.**
   Denosumab products (Prolia, biosimilars) is not indicated for the prevention of osteoporosis.[1-3]

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals (Effective until 09/30/2025)
J0897	Injection, denosumab, 1 mg
J3490	Unclassified drugs (Effective until 09/30/2025)
J3590	Unclassified drugs or biologicals (Effective until 09/30/2025)
Q5136	Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg
Q5157	Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg (Effective Date 10/01/2025)

References

1. Prolia® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2024.
2. Jubbonti® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; October 2024.
3. Stoboclo® subcutaneous injection [prescribing information]. Jersey City, NJ, Celltrion; February 2025.
4. Xgeva® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; June 2020.
5. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – July 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 4, 2024.
6. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 4, 2024.

7. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis Rheumatol*. 2023;75(12):2088-2102.
8. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2019;104(5):1595-1622.
9. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. *Endocrin Pract*. 2020;26(Suppl 1):1-46.
10. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporosis Int*. 2022;33(10):2049-2102.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Treatment of Bone Loss in Patients with Prostate Cancer Receiving Androgen Deprivation Therapy:** This was added as a new condition of approval in the "Other Uses with Supportive Evidence" section. Dosing was added. **Increase Bone Mineral Density in Patients with Breast Cancer:** This was added as a new condition of approval in the "Other Uses with Supportive Evidence" section. Dosing was added.	01/15/2025
Selected Revision	**Updated** policy title form "Denosemab (Prolia)" to "Bone Modifiers – Denosumab Products (Prolia)" **Added** Jubbonti and Stoboclo, Prolia biosimilars, to the policy with the same criteria as Prolia. **Removed** documentation requirements throughout the policy. **Bone Loss (Treatment to Increase Bone Mass) in patients with Breast Cancer at High Risk for Fracture Receiving Adjuvant Aromatase Inhibitor Therapy.** **Added** examples of aromatase inhibitor therapy. **Bone Loss (Treatment to Increase Bone Mass) in Individuals with Nonmetastatic Prostate Cancer at High Risk for Fracture Receiving Androgen Deprivation Therapy.** **Added** examples of androgen deprivation therapy. **Glucocorticoid-Induced Osteoporosis – Treatment.** **Added** an example of a systemic glucocorticoid. **Added** zoledronic acid intravenous infusion as a prerequisite option. **Removed** intravenous bisphosphonate products as a prerequisite option. **Added** oral bisphosphonate-containing products as a prerequisite option.	08/15/2025

	Clarified the oral bisphosphonate or oral bisphosphonate-containing prerequisite trial should be for 12 months. **Added** examples of inadequate efficacy and intolerance to oral bisphosphonate or oral bisphosphonate-containing products. **Updated** the contraindication to bisphosphonate therapy statement. **Osteoporosis Treatment for a Postmenopausal Patient** **Added** zoledronic acid intravenous infusion as a prerequisite option. **Removed** intravenous bisphosphonate products as a prerequisite option. **Added** oral bisphosphonate-containing products as a prerequisite option. **Clarified** the oral bisphosphonate or oral bisphosphonate-containing prerequisite trial should be for 12 months. **Added** examples of inadequate efficacy and intolerance to oral bisphosphonate or oral bisphosphonate-containing products. **Updated** the contraindication to bisphosphonate therapy statement. **Osteoporosis Treatment (to Increase Bone Mass) for Men.** **Added** zoledronic acid intravenous infusion as a prerequisite option. **Removed** intravenous bisphosphonate products as a prerequisite option. **Added** oral bisphosphonate-containing products as a prerequisite option. **Clarified** the oral bisphosphonate or oral bisphosphonate-containing prerequisite trial should be for 12 months. **Added** examples of inadequate efficacy and intolerance to oral bisphosphonate or oral bisphosphonate-containing products. **Updated** the contraindication to bisphosphonate therapy statement. **Conditions Not Covered.** Updated the Concurrent Use with Other Medications for Osteoporosis statement. Updated the Giant Cell Tumor of Bone statement. Updated the Osteoporosis Prevention statement. **Coding Information** **Added Codes:** C9399, J3490, J3590, Q5136	
Selected Revision	**Coding Information:** **Added HCPCS** Q5157 with a code effective date of 10/1/2025	10/01/2025

	Updated the description for C9399, J3490 & J3590 to include the note "Code effective until 09/30/2025"	

The policy effective date is in force until updated or retired.