Department:	Pharmacy Management	**Original Approval:**	01/20/2016
Policy No:	PM134	**Last Approval:**	02/06/2026
Policy Title:	Denosumab (Prolia®) Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☒ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☒ **Apple Health Expansion** ☒ **Medicare Advantage/Special Needs Plan** ☒ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

Documentation required to determine medical necessity for Denosumab (Prolia):

- History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service
- Diagnosis
- Labs/Diagnostics
- Dosing and duration requested
- Initial/Extended approval
- Medical records from the last 6 months showing the patient's problems, history, prior treatments, response to treatment, imaging and laboratory studies, details of the skilled needs, details of any specific needs related to risk/trauma/cultural etc., assessment and plan
- Prescribed by or in consultation with a specialist, when indicated

Background

Denosumab products (Prolia, biosimilars) are indicated for the following uses:[1-5]

- **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

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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.

Bildyos, Conexxence, Jubbonti, and Stoboclo were approved as biosimilars to Prolia, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Prolia. However, minor differences in clinically inactive components are allowed.

Policy Statement

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.

Definitions

None.

Indications/Criteria

Medicaid Members	***Continue to criteria for approval below*** ***This policy is in alignment with HCA medical policy no. 30.04.45 Bone Density Regulators – Rank Ligand (RANKL) Inhibitors.*** ***Preferred Product: Jubbonti*** ***Non-Preferred Products: Bildyos, Conexxence, Enoby, Ospomyv, Prolia, Stoboclo***
Individual & Family (Cascade Select) Members	***Continue to criteria for approval below*** ***Preferred Products: Jubbonti, Prolia, Stoboclo*** ***Non-Preferred Products: Bildyos, Conexxence, Enovy, Ospomyv***
Medicare Members	***Continue to criteria for approval below*** ***Preferred Products: Jubbonti, Prolia, Stoboclo***

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	Non-Preferred Products: Bildyos, Conexxence, Enovy, Ospomyv

Medicaid Criteria (HCA medical policy no. 30.04.45 Bone Density Regulators – *Rank Ligand (RANKL) Inhibitors*)

1. **Postmenopausal Osteoporosis**. Approve for 1 year if the patient meets ALL of the following:
   - **A)** Patient is 18 years of age or older; AND
   - **B)** Diagnosis of osteoporosis; AND
   - **C)** Patient is postmenopausal female; AND
   - **D)** At least **ONE** of the following fracture risk categories is met:
     - **i.** Presence of fragility fractures of the hip or spine regardless of bone mineral density; OR
     - **ii.** T-score ≤ -2.5 in the lumbar spine, femoral neck, total hip; OR
     - **iii.** T-score between -1 and -2.5 with a history of recent fragility fracture of proximal humerus, pelvis, or distal forearm; OR
     - **iv.** T-score score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; AND
   - **E)** Medication will not be used in combination with other bone density regulators (e.g., bisphosphonates, raloxifene, Xgeva); AND
   - **F)** History of at least ONE of the following:
     - **i.** Treatment with at least one Preferred Apple Health Preferred Drug List (PDL) oral or intravenous bisphosphonate medication (e.g., alendronate, ibandronate, zoledronic acid) has been ineffective unless all are contraindicated or not tolerated [minimum trial of 12 months]; OR
     - **ii.** Treatment with at least one Preferred Apple Health Preferred Drug List (PDL) selective estrogen receptor modulator (SERM) medication (e.g., raloxifene) has been ineffective unless all are contraindicated, or not tolerated [minimum trial of 24 months]; AND
   - **G)** If the patient is requesting a non-preferred denosumab biosimilar, documentation has been provided to confirm that the patient has tried and failed at least one preferred denosumab products; AND
     Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
   - **H)** If the patient is requesting brand denosumab (Prolia), patient meets all of the following:
     - **i.** Trial of one preferred denosumab product; AND
       Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
     - **ii.** Trial of at least 5 denosumab (Prolia) biosimilars.

Reauthorization: Approve for 1 year if the patient meets all of the following:

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A) Medication will not be used in combination with other bone density regulators (e.g., bisphosphonates, raloxifene, Xgeva); AND

B) Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., patient has not suffered a fragility fracture, bone mineral density continues to improve/remain stable); AND

C) If the patient is requesting a non-preferred denosumab biosimilar, documentation has been provided to confirm that the patient has tried and failed at least one preferred denosumab products; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.

D) If the patient is requesting brand denosumab (Prolia), patient meets all of the following:

i. Trial of one preferred denosumab product; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.

ii. Trial of at least 5 denosumab (Prolia) biosimilars.

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

2. **Glucocorticoid-induced osteoporosis**. Approve for 1 year if the patient meets ALL of the following:

A) Patient is 18 years of age or older; AND

B) Diagnosis of osteoporosis; AND

C) Patient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to ≥ 7.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least 6 months; AND

D) At least **ONE** of the following fracture risk categories is met:

i. Presence of fragility fractures of the hip or spine regardless of bone mineral density; OR

ii. T-score ≤ -2.5 in the lumbar spine, femoral neck, total hip; OR

iii. T-score between -1 and -2.5 with a history of recent fragility fracture of proximal humerus, pelvis, or distal forearm; OR

iv. T-score score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; AND

E) Medication will not be used in combination with other bone density regulators (e.g., bisphosphonates, raloxifene, Xgeva); AND

F) Treatment with at least one Preferred Apple Health Preferred Drug List (PDL) oral or intravenous bisphosphonate medication (e.g., alendronate, ibandronate, zoledronic

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acid) indicated for glucocorticoid induced osteoporosis has been ineffective unless all are contraindicated or not tolerated [minimum trial of 12 months]; AND

G) If the patient is requesting a non-preferred denosumab biosimilar, documentation has been provided to confirm that the patient has tried and failed at least one preferred denosumab products; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.

H) If the patient is requesting brand denosumab (Prolia), patient meets all of the following:
- **i.** Trial of one preferred denosumab product; AND
  Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
- **ii.** Trial of at least 5 denosumab (Prolia) biosimilars.

Reauthorization: Approve for 1 year if the patient meets all of the following:

A) Patient has not suffered a fragility fracture while on treatment; AND

B) Medication will not be used in combination with other bone density regulators (e.g., bisphosphonates, raloxifene, Xgeva); AND

C) Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., patient has not suffered a fragility fracture, bone mineral density continues to improve/remain stable); AND

D) If the patient is requesting a non-preferred denosumab biosimilar, documentation has been provided to confirm that the patient has tried and failed at least one preferred denosumab products; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.

E) If the patient is requesting brand denosumab (Prolia), patient meets all of the following:
- **i.** Trial of one preferred denosumab product; AND
  Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
- **ii.** Trial of at least 5 denosumab (Prolia) biosimilars.

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

3. **Treatment of bone loss in men with prostate cancer.** Approve for 1 year if the patient meets ALL of the following:

A) Patient is 18 years of age or older; AND

B) Patient has a diagnosis of bone loss or osteoporosis indicated by one or more of the following:

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i. Presence of fragility fractures of the hip or spine regardless of bone mineral density; OR
ii. T-score ≤ -2.5 in the lumbar spine, femoral neck, total hip; OR
iii. T-score between -1 and -2.5 with a history of recent fragility fracture of proximal humerus, pelvis, or distal forearm; OR
iv. T-score score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; AND

C) Patient is currently receiving androgen deprivation therapy (ADT) (e.g., leuprolide, degarelix, relugolix) for non-metastatic prostate cancer unless all are contraindicated or not tolerated; AND
D) Medication will not be used in combination with denosumab (Xgeva); AND
E) Treatment with at least one Preferred Apple Health Preferred Drug List (PDL) oral or intravenous bisphosphonate medication (e.g., alendronate, ibandronate, zoledronic acid) has been ineffective unless all are contraindicated or not tolerated [minimum trial of 12 months]; AND
F) If the patient is requesting a non-preferred denosumab biosimilar, documentation has been provided to confirm that the patient has tried and failed at least one preferred denosumab products; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
G) If the patient is requesting brand denosumab (Prolia), patient meets all of the following:
i. Trial of one preferred denosumab product; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
ii. Trial of at least 5 denosumab (Prolia) biosimilars.

Reauthorization: Approve for 1 year if the patient meets all of the following:

A) Patient is currently receiving androgen deprivation therapy (ADT) (e.g., leuprolide, degarelix, relugolix) for non-metastatic prostate cancer unless all are contraindicated or not tolerated; AND
B) Medication will not be used in combination with denosumab (Xgeva); AND
C) Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., patient has not suffered a fragility fracture, bone mineral density continues to improve/remain stable); AND
D) If the patient is requesting a non-preferred denosumab biosimilar, documentation has been provided to confirm that the patient has tried and failed at least one preferred denosumab products; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
E) If the patient is requesting brand denosumab (Prolia), patient meets all of the following:

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i. Trial of one preferred denosumab product; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
ii. Trial of at least 5 denosumab (Prolia) biosimilars.

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

4. **Treatment of bone loss in women with breast cancer.** Approve for 1 year if the patient meets ALL of the following:
   A) Patient is 18 years of age or older; AND
   B) Patient has a diagnosis of bone loss or osteoporosis indicated by one or more of the following:
      i. Presence of fragility fractures of the hip or spine regardless of bone mineral density; OR
      ii. T-score ≤ -2.5 in the lumbar spine, femoral neck, total hip; OR
      iii. T-score between -1 and -2.5 with a history of recent fragility fracture of proximal humerus, pelvis, or distal forearm; OR
      iv. T-score score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; AND
   C) Patient is receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, exemestane, letrozole) for breast cancer unless all are contraindicated or not tolerated; AND
   D) Medication will not be used in combination with denosumab (Xgeva); AND
   E) Treatment with at least Preferred Apple Health Preferred Drug List (PDL) oral or intravenous bisphosphonate medication (e.g., alendronate, ibandronate, zoledronic acid) has been ineffective unless all are contraindicated or not tolerated [minimum trial of 12 months]; AND
   F) If the patient is requesting a non-preferred denosumab biosimilar, documentation has been provided to confirm that the patient has tried and failed at least one preferred denosumab products; AND
   Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
   G) If the patient is requesting brand denosumab (Prolia), patient meets all of the following:
      i. Trial of one preferred denosumab product; AND
      Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
      ii. Trial of at least 5 denosumab (Prolia) biosimilars.

Reauthorization: Approve for 1 year if the patient meets all of the following:

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A) Medication will not be used in combination with denosumab (Xgeva); AND
B) Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., patient has not suffered a fragility fracture, bone mineral density continues to improve/remain stable); AND
C) If the patient is requesting a non-preferred denosumab biosimilar, documentation has been provided to confirm that the patient has tried and failed at least one preferred denosumab products; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
D) If the patient is requesting brand denosumab (Prolia), patient meets all of the following:
i. Trial of one preferred denosumab product; AND
Note: Please see Appendix A for the list of preferred denosumab (Prolia) products.
ii. Trial of at least 5 denosumab (Prolia) biosimilars.

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

Cascade Select Medicare Criteria (if requesting Bildyos, Conexxence, *Enovy, or Ospomyv,* please also see Recommended Exception Criteria)

FDA-Approved Indications

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 of 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 of 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

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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 of the patient meets BOTH of the following (A and B):

A) Patient is either initiating or continuing systemic glucocorticoids; AND
Note: An example of a systemic glucocorticoid is prednisone.

B) Patient meets 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 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

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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, biosimilars)-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 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. The 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, 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 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

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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, biosimilars)-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 the 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, or total hip, and/or 33% (one-third) radius (wrist); OR

ii. Patient has had an osteoporotic fracture or a fragility fracture; OR

iii. The 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, patient is at high risk for fracture; AND

B) Patient meets 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 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).

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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, biosimilars)-induced hypocalcemia; OR

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

* Refer to the Policy Statement.

Dosing. Approve 60 mg subcutaneously once every 6 months.

Other Uses with Supportive Evidence

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.

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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.

Recommended Exception Criteria

Non-Preferred Products	Exception Criteria
Cascade Select Criteria Bildyos Conexxence Enovy Ospomyv	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the Denosumab (Prolia) Products criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried TWO of Jubbonti, Prolia, or Stoboclo; AND **ii.** Patient cannot continue to use the Preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.
Medicare Criteria Bildyos Conexxence Enovy Ospomyv	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the Denosumab (Prolia) Products Criteria; AND **B)** The patient meets ONE of the following (i or ii): **i.** Patient meets BOTH of the following (a and b): **a)** Patient has tried TWO of Jubbonti, Prolia, or Stoboclo; AND **b)** Patient cannot continue to use the Preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber,

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	would result in a significant allergy or serious adverse reaction; OR **ii.** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.

Dosage and Quantity Limits for Medicaid

Drug	Indication	FDA Approved Dosing	Dosage Form and Quantity Limit
denosumab (Prolia) and biosimilars	Glucocorticoid-induced osteoporosis Postmenopausal Osteoporosis Treatment of bone loss in women with breast cancer Treatment of bone loss in men with prostate cancer	60 mg every 6 months	• 60 mg/1 mL prefilled syringe 1 mL/168 days

Conditions Not Recommended for Approval

Prolia 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.** Prolia is not indicated for the prevention of osteoporosis.[1]

2. **Concurrent Use of Prolia with Other Medications for Osteoporosis** Note: Examples include teriparatide injection for subcutaneous use (Forteo®/Bonsity®), Tymlos® (abaloparatide injection for subcutaneous use), oral bisphosphonates (e.g., alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid injection [Reclast], intravenous ibandronate), calcitonin nasal spray (Miacalcin®/Fortical®), and Evenity® (romosozumab-aqqg injection for subcutaneous use]). Prolia is not indicated for use as combination therapy.[1]

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3. **Giant Cell Tumor of Bone.** Studies with denosumab in giant cell tumor of the bone used dosing for Xgeva® (denosumab injection for SC use), 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.[2]

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

Special Considerations

None.

Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.
Apple Health Integrated Managed Care	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Cascade Select	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

List of Appendices

None.

Citations & References

CFR	42 CFR § 438.210	
WAC	284-43-2050	
RCW		
LOB & Contract Citation	☒ **WAHIMC** ☐ **BHSO** ☐ **Wraparound** ☐ **SMAC** ☐ **HH**	IMC Section 11.3: Medical Necessity Determination

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	☒ **AHE**	AHE Section 11.3: Medical Necessity Determination
	☒ **MA/DSNP**	P&P supports all LOB requirements
	☒ **CS**	P&P supports all LOB requirements
Other Requirements		
NCQA Elements		
References	1. Prolia® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; May 2025. 2. Conexxence® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; March 2025. 3. Jubbtonti® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; October 2024. 4. Stoboclo® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; February 2025. 5. Bildyos® subcutaneous injection [prescribing information]. Jersey City, NJ: Shanghai Henlius Biotech/Organon; August 2025.	

Revision History

Revision Date	Revision Description	Revision Made By
01/13/2016	New	Kelly Force; Yusuf Rashid, RPh
01/20/2016	Approval	MMLT
01/12/2017	No revisions	Fran McGaugh
01/13/2017	Approval	MMLT
07/24/2017	Criteria completely updated and revised	Michael Sporck, Pharmacy Intern Sophia Yun, PharmD
07/25/2017	Approved	MMLT
03/09/2018	Reassigned from UM146 to PM134	Cindy Bush
05/03/2018	Transferred to new template	Cindy Bush
06/12/2018	No revisions	Jennifer Farley, PharmD
06/14/2018	Approval	UM Committee
08/06/2018	Revised	Jennifer Farley, PharmD

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09/19/2018	Approval	UM Committee
07/08/2019	Annual policy review: If gender is specified as part of the criteria, it refers to the biological traits.	Jennifer Farley, PharmD
07/11/2019	Approval	UM Pharmacy Subcommittee
04/14/2020	Annual review. Added Evenity to the list of medications that should not be used concomitantly with Prolia.	Jennifer Farley, PharmD
04/23/2020	Approval	UM Pharmacy Subcommittee
02/24/2021	Annual review. Added Bonsity to the list of medications that should not be used concomitantly with Prolia.	Jennifer Farley, PharmD
03/08/2021	Approval	UM Pharmacy Subcommittee
01/03/2022	Updating criteria to match with criteria from HCA Policy No. 30.04.00.	Alan Gabot, PharmD
01/06/2022	Approval	UM Pharmacy Subcommittee
07/06/2022	Early update. Updating Medicare LOB criteria to match criteria for Prolia listed under CHPW Medicare Pharmacy Prior Authorization Criteria for pharmacy benefits.	Alan Gabot, PharmD
07/07/2022	Approval	UM Pharmacy Subcommittee
05/03/2023	Annual Update. Formatting changes. No criteria changes.	Alan Gabot, PharmD
05/04/2023	Approval	UM Pharmacy Subcommittee
03/26/2024	Annual Update. No criteria changes.	Alan Gabot, PharmD
03/29/2024	Approval	UM Criteria Subcommittee
12/06/2024	Annual Update. In Medicare criteria for treatment of postmenopausal osteoporosis or osteoporosis in men, osteoporotic fracture or fragility fracture was made into its own sub-criteria independent of other sub-criteria.	Michael Tom, PharmD

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12/11/2024	Approval	UM Criteria Subcommittee
05/13/2025	Early update. Created new criteria for Medicaid and Cascade Select based on HCA Policy No. 30.04.48-2.	Alan Gabot, PharmD
05/14/2025	Approval	UM Criteria Subcommittee
12/11/2025	Early update. Biosimilars for Prolia were added to the policy. Cascade Select and Medicare now share the same clinical criteria and non-preferred product requirements. Separated the non-preferred criteria from the clinical criteria and placed it under the "Recommended Exception Criteria". For Medicaid, criterion was added requiring patients to try and fail two preferred denosumab products. Appendix A was added to show the list of preferred denosumab products. Added Dosage and Quantity Limits table for Medicaid.	Alan Gabot, PharmD
12/12/2025	Approval	UM Criteria Subcommittee
02/05/2026	Early update. Added Enoby and Ospomyv to the policy. For Medicaid, Jubbonti is listed as the only preferred product. All other denosumab biosimilars are listed as non-preferred and are required to try at least one preferred product. For Prolia, the criteria require that the patient try one preferred product and at least 5 denosumab biosimilars. For Cascade Select and Medicare, Enoby and Ospomyv were listed as non-preferred products.	Alan Gabot, PharmD
02/06/2026	Approval	UM Criteria Subcommittee

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Appendix A. Preferred Denosumab (Prolia) Products for Medicaid

Preferred Denosumab (Prolia) Products	Jubbonti

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