denosumab (Prolia®)

Policy # 00265
Original Effective Date: 07/21/2011
Current Effective Date: 08/12/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Women

Based on review of available data, the Company may consider the use of denosumab (Prolia®)‡ for the treatment of postmenopausal women with osteoporosis at high risk for fracture OR to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor (AI) therapy for breast cancer to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of denosumab (Prolia) for the treatment of women will be considered when the following criteria are met:

- Patient is a woman with high risk for fracture (i.e., has a history of osteoporotic or fragility fracture, has a pre-treatment T-score of -1 or lower, has multiple risk factors for fracture, or has failed or is intolerant to other available osteoporosis therapy) and is receiving adjuvant AI therapy for breast cancer; OR
- Patient is a postmenopausal woman who meets ONE of the following diagnostic criteria for osteoporosis:
    - Presence of a central dual x-ray absorptiometry (DXA) bone mineral density (BMD) T-score less than or equal to -2.5, confirming osteoporosis; OR
    - Patient has experienced a fragility fracture [defined as a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures]; OR

  - Patient has a BMD T-score between -1.0 and -2.5 with an increased fracture risk (Defined as fracture risk assessment tool [FRAX®]‡ 10-year probability of major osteoporotic fracture ≥20% or 10-year probability of hip fracture ≥3%); AND
- Patient has or has had 1 of the following:
  - An inability to take bisphosphonates; OR
  - A 12-month trial of oral bisphosphonates with documentation of new fractures or significant loss of bone mineral density; OR
  - Patient has experienced a fracture within the past 12 months; OR
  - Patient has a history of multiple fractures; OR
  - Patient has a T score less than -3.0; OR
  - Patient is at high risk of falls or has a history of falls; OR
  - Patient has a FRAX 10-year probability of major osteoporotic fracture >30%; OR
  - Patient has a FRAX 10-year probability of hip fracture >4.5%.
    *(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*

Men

Based on review of available data, the Company may consider the use of denosumab (Prolia) for the treatment of men with osteoporosis at high risk for fracture **or** to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of denosumab (Prolia) for the treatment of men will be considered when the following criteria are met:

- Patient is a man at high risk for fracture (i.e., has a history of osteoporotic or fragility fracture, has pre-treatment T-score of -1 or lower, has multiple risk factors for fracture, or has failed or is intolerant to other available osteoporosis therapy) and is receiving androgen deprivation therapy for nonmetastatic prostate cancer; OR
- Patient is a man who meets ONE of the following diagnostic criteria for osteoporosis:
  - Presence of a central dual x-ray absorptiometry (DXA) bone mineral density (BMD) T-score less than or equal to -2.5, confirming osteoporosis; OR

- Patient has experienced a fragility fracture [defined as a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures]; OR
- Patient has a BMD T-score between -1.0 and -2.5 with an increased fracture risk (Defined as a FRAX 10-year probability of major osteoporotic fracture ≥20% or 10-year probability of hip fracture ≥3%); AND

- Patient has or has had 1 of the following:
  - An inability to take bisphosphonates; OR
  - A 12-month trial of oral bisphosphonates with documentation of new fractures or significant loss of bone mineral density; OR
  - Patient has experienced a fracture within the past 12 months; OR
  - Patient has a history of multiple fractures; OR
  - Patient has a T score less than -3.0; OR
  - Patient is at high risk of falls or has a history of falls; OR
  - Patient has a FRAX 10-year probability of major osteoporotic fracture >30%; OR
  - Patient has a FRAX 10-year probability of hip fracture >4.5%.
    *(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*

Glucocorticoid Induced Osteoporosis

Based on review of available data, the Company may consider the use of denosumab (Prolia) for the treatment of men and women with glucocorticoid induced osteoporosis to be **eligible for coverage.****

Patient Selection Criteria:

Coverage eligibility will be considered for the treatment of patients with glucocorticoid induced osteoporosis with denosumab (Prolia) when the following criteria are met:

- Patient is 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; AND
- Patient meets ONE of the following:
  - Presence of a central DXA BMD T-score less than or equal to -2.5, confirming osteoporosis; OR

  - Patient has experienced a fragility fracture [defined as a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures]; OR
  - Patient has a BMD T-score between -1.0 and -2.5 with an increased fracture risk (Defined as a FRAX 10-year probability of major osteoporotic fracture ≥20% or 10-year probability of hip fracture ≥3%); AND
- Patient has or has had 1 of the following:
  - An inability to take bisphosphonates; OR
  - A 12-month trial of oral bisphosphonates with documentation of new fractures or significant loss of bone mineral density; OR
  - Patient has experienced a fracture within the past 12 months; OR
  - Patient has a history of multiple fractures; OR
  - Patient has a T score less than -3.0; OR
  - Patient is at high risk of falls or has a history of falls; OR
  - Patient has a FRAX 10-year probability of major osteoporotic fracture >30%; OR
  - Patient has a FRAX 10-year probability of hip fracture >4.5%.
    *(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of denosumab (Prolia) when the following criteria are NOT met to be **not medically necessary.****

- Patient has an inability to take bisphosphonates; OR
- Patient has a 12-month trial of oral bisphosphonates with documentation of new fractures or significant loss of bone mineral density; OR
- Patient has experienced a fracture within the past 12 months; OR
- Patient has a history of multiple fractures; OR
- Patient has a T-score less than -3.0; OR
- Patient is at high risk of falls or has a history of falls; OR
- Patient has a FRAX 10-year probability of major osteoporotic fracture >30%; OR
- Patient has a FRAX 10-year probability of hip fracture >4.5%.

denosumab (Prolia®)

Policy # 00265
Original Effective Date: 07/21/2011
Current Effective Date: 08/12/2024

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of denosumab (Prolia) when patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) OR for use in any other indication than those listed above to be **investigational.***

Background/Overview

Osteoporosis is a major metabolic bone disease that causes fractures in 40% of aging women and 15% of aging men over their lifetimes. Osteoporosis can be diagnosed based on DXA scans revealing a T-score less than or equal to -2.5, or presence of a fragility fracture (regardless of T-score), or a T-score between -1.0 and -2.5 with an increased fracture risk using FRAX score. A fragility fracture is a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures. The fracture risk assessment tool (FRAX) estimates the 10-year probability of hip fracture and major osteoporotic fracture (hip, clinical spine, proximal humerus, or forearm) in untreated patients aged 40 to 90 years using easily obtainable clinical risk factors for fracture and femoral neck BMD when available. The data used by the FRAX was collected in large, prospective, observational studies across world regions. The tool has been validated in approximately 26 independent cohorts, and its country-specific prediction algorithms are available for many countries online. The United States FRAX can be accessed at https://frax.shef.ac.uk/FRAX/tool.aspx?country=9.

Recent studies have shown that estrogen deficiency is the cause of both the early and the late forms of osteoporosis in postmenopausal women and contributes to the development of osteoporosis in aging men. Estrogen deficiency is associated with an increase in bone resorption over bone formation, leading to excessive and sustained bone loss. The increase in bone resorption is due both to increased osteoclastogenesis and to decreased osteoclast apoptosis. Receptor activator of nuclear factor-kappaB (RANK ligand or RANKL) is a key mediator of bone resorption in normal and pathological states. In normal bone turnover and in bone metastasis, RANKL stimulates the formation and activity of bone-removing cells, osteoclasts.

denosumab (Prolia®)

Policy # 00265
Original Effective Date: 07/21/2011
Current Effective Date: 08/12/2024

Prolia is known as a RANK Ligand inhibitor; it works by decreasing the breakdown of bone by osteoclasts. It is a highly specific monoclonal antibody produced in genetically engineered mammalian (Chinese hamster ovary) cells. Prolia binds to RANKL, a transmembrane or soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption. Prolia prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts and their precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone. Prolia is dosed 60 mg every 6 months as a subcutaneous injection in the upper arm, upper thigh, or abdomen.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Prolia was approved in 2010 for the treatment of postmenopausal women with osteoporosis at high risk for fracture. In 2011, Prolia received indications for the treatment of men or women with a high risk of fracture that are undergoing hormone ablation therapy in either prostate or breast cancer. In 2012, Prolia was approved for the treatment of osteoporosis in men. In 2018, Prolia received the additional indication for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Postmenopausal Women with Osteoporosis

The efficacy and safety of Prolia in the treatment of postmenopausal osteoporosis was demonstrated in a 3-year, randomized, double-blind, placebo-controlled trial. Enrolled women had a baseline BMD T-score between -2.5 and -4.0 at either the lumbar spine or total hip. Women with other diseases (such as rheumatoid arthritis, osteogenesis imperfecta, and Paget's disease) or on therapies that affect bone were excluded from this study. The 7808 enrolled women were aged 60 to 91 years with a mean age of 72 years. Overall, the mean baseline lumbar spine BMD T-score was -2.8 and

23% of women had a vertebral fracture at baseline. Women were randomized to receive subcutaneous injections of either placebo. (N = 3906) or Prolia 60 mg (N = 3902) once every 6 months. All women received at least 1000 mg calcium and 400 IU vitamin D supplementation daily.

The primary efficacy variable was the incidence of new morphometric (radiologically-diagnosed) vertebral fractures at three years. Vertebral fractures were diagnosed based on lateral spine radiographs (T4-L4) using a semiquantitative scoring method. Secondary efficacy variables included the incidence of hip fracture and nonvertebral fracture, assessed at three years.

Prolia significantly reduced the incidence of new morphometric vertebral fractures at 1, 2 and 3 years ($p < 0.0001$). The incidence of new vertebral fractures at year 3 was 7.2% in the placebo-treated women compared to 2.3% for the Prolia-treated women. The absolute risk reduction was 4.8% and relative risk reduction was 68% for new morphometric vertebral fractures at year 3. The incidence of hip fracture was 1.2% for placebo-treated women compared to 0.7% for Prolia-treated women at year 3. The age-adjusted absolute risk reduction of hip fractures was 0.3% with a relative risk reduction of 40% at 3 years ($p = 0.04$). Treatment with Prolia resulted in a significant reduction in the incidence of nonvertebral fractures at year 3. Treatment with Prolia significantly increased BMD at all anatomic sites measured at three years. The treatment differences in BMD at 3 years were 8.8% at the lumbar spine, 6.4% at the total hip, and 5.2% at the femoral neck. Consistent effects on BMD were observed at the lumbar spine, regardless of baseline age, race, weight/body mass index (BMI), baseline BMD, and level of bone turnover.

Treatment to Increase Bone Mass in Men with Osteoporosis

The efficacy and safety of Prolia in the treatment to increase bone mass in men with osteoporosis was demonstrated in a 1-year, randomized, double-blind, placebo-controlled trial. Enrolled men had a baseline BMD T-score between -2.0 and -3.5 at the lumbar spine or femoral neck. Men with a BMD T-score between -1.0 and -3.5 at the lumbar spine or femoral neck were also enrolled if there was a history of prior fragility fracture. Men with other diseases (such as rheumatoid arthritis, osteogenesis imperfecta, and Paget's disease) or on therapies that may affect bone were excluded from this study. The 242 men enrolled in the study ranged in age from 31 to 84 years with a mean age of 65 years. Men were randomized to receive SC injections of either placebo (n = 121) or Prolia 60 mg (n = 121) once every 6 months. All men received at least 1000 mg calcium and at least 800 IU vitamin D supplementation daily. The primary efficacy variable was percent change in lumbar spine BMD from baseline to 1 year. Secondary efficacy variables included percent change in total

hip, and femoral neck BMD from baseline to 1 year. Treatment with Prolia significantly increased BMD at 1 year. The treatment differences in BMD at 1 year were 4.8% (+0.9% placebo, +5.7% Prolia; (95% confidence interval [CI]: 4.0, 5.6); $p < 0.0001$) at the lumbar spine, 2.0% (+0.3% placebo, +2.4% Prolia) at the total hip, and 2.2% (0.0% placebo, +2.1% Prolia) at femoral neck. Consistent effects on BMD were observed at the lumbar spine regardless of baseline age, race, BMD, testosterone concentrations and level of bone turnover.

Treatment of Bone Loss in Men with Prostate Cancer

The efficacy and safety of Prolia in the treatment of bone loss in men with nonmetastatic prostate cancer receiving ADT were demonstrated in a 3-year, randomized (1:1), double blind, placebo-controlled, multinational study. Men less than 70 years of age had either a BMD T-score at the lumbar spine, total hip, or femoral neck between -1.0 and -4.0, or a history of an osteoporotic fracture. The mean baseline lumbar spine BMD T-score was -0.4, and 22% of men had a vertebral fracture at baseline. The 1468 men enrolled ranged in age from 48 to 97 years (median 76 years). Men were randomized to receive subcutaneous injections of either placebo (n = 734) or Prolia 60 mg (n = 734) once every 6 months for a total of 6 doses. Randomization was stratified by age (< 70 years vs. ≥ 70 years) and duration of ADT at trial entry (≤ 6 months vs. > 6 months). Seventy-nine percent of patients received ADT for more than 6 months at study entry. All men received at least 1000 mg calcium and 400 IU vitamin D supplementation daily. The primary efficacy variable was percent change in lumbar spine BMD from baseline to month 24. An additional key secondary efficacy variable was the incidence of new vertebral fracture through month 36 diagnosed based on x-ray evaluation by two independent radiologists. Lumbar spine BMD was higher at 2 years in Prolia-treated patients as compared to placebo-treated patients [-1.0% placebo, +5.6% Prolia; treatment difference 6.7% (95% CI: 6.2, 7.1); $p < 0.0001$]. With approximately 62% of patients followed for 3 years, treatment differences in BMD at 3 years were 7.9% (-1.2% placebo, +6.8% Prolia) at the lumbar spine, 5.7% (-2.6% placebo, +3.2% Prolia) at the total hip, and 4.9% (-1.8% placebo, +3.0% Prolia) at the femoral neck. Consistent effects on BMD were observed at the lumbar spine in relevant subgroups defined by baseline age, BMD, and baseline history of vertebral fracture. Prolia significantly reduced the incidence of new vertebral fractures at 3 years ($p = 0.0125$).

Treatment of Bone Loss in Women with Breast Cancer

The efficacy and safety of Prolia in the treatment of bone loss in women receiving adjuvant AI therapy for breast cancer was assessed in a 2-year, randomized (1:1), double-blind, placebo controlled, multinational study. Women had baseline BMD T-scores between -1.0 to -2.5 at the

lumbar spine, total hip, or femoral neck, and had not experienced fracture after age 25. The mean baseline lumbar spine BMD T-score was -1.1, and 2.0% of women had a vertebral fracture at baseline. The 252 women enrolled ranged in age from 35 to 84 years (median 59 years). Women were randomized to receive subcutaneous injections of either placebo (n = 125) or Prolia 60 mg (n = 127) once every 6 months for a total of 4 doses. Randomization was stratified by duration of adjuvant AI therapy at trial entry (≤ 6 months vs. > 6 months). Sixty-two percent of patients received adjuvant AI therapy for more than 6 months at study entry. All women received at least 1000 mg calcium and 400 IU vitamin D supplementation daily. The primary efficacy variable was percent change in lumbar spine BMD from baseline to month 12. Lumbar spine BMD was higher at 12 months in Prolia-treated patients as compared to placebo-treated patients [-0.7% placebo, +4.8% Prolia; treatment difference 5.5% (95% CI: 4.8, 6.3); p < 0.0001]. With approximately 81% of patients followed for 2 years, treatment differences in BMD at 2 years were 7.6% (-1.4% placebo, +6.2% Prolia) at the lumbar spine, 4.7 % (-1.0% placebo, +3.8% Prolia) at the total hip, and 3.6% (-0.8% placebo, +2.8% Prolia) at the femoral neck.

Glucocorticoid Induced Osteoporosis
The efficacy and safety of Prolia in the treatment of patients with glucocorticoid induced osteoporosis was assessed in the 12-month primary analysis of a 2-year, randomized, multicenter, double-blind, parallel-group, active-controlled study of 795 patients. Included patients were aged 20 to 94 years of age and treated with greater than or equal to 7.5 mg/day oral prednisone (or equivalent) for <3 months prior to study enrollment and planning to continue treatment for a total of at least 6 months (glucocorticoid-initiating subpopulation) or ≥3 months prior to study enrollment and planning to continue treatment for a total of at least 6 months (glucocorticoid-continuing subpopulation). Enrolled patients <50 years of age were required to have a history of osteoporotic fracture. Enrolled patients ≥50 years of age who were in the glucocorticoid-continuing subpopulation were required to have a baseline BMD T-score of ≤-2.0 at the lumbar spine, total hip, or femoral neck; or a BMD T-score ≤-1.0 at the lumbar spine, total hip, or femoral neck, and a history of osteoporotic fracture. Patients were randomized 1:1 to receive either an oral daily bisphosphonate or Prolia 60 mg subcutaneously once every 6 months for 1 year. Patients received at least 1000 mg calcium and 800 IU vitamin D supplementation daily.

In the glucocorticoid-initiating subpopulation, Prolia significantly increased lumbar spine BMD compared to the active control at one year (Active control 2.3%, Prolia 4.4%) with a treatment difference of 2.2% (p<0.001). In the glucocorticoid-continuing subpopulation, Prolia significantly

increased lumbar spine BMD compared to active-control at one year (Active control 0.8%, Prolia 3.8%) with a treatment difference of 2.9% ($p<0.001$). Consistent effects on lumbar spine BMD were observed regardless of gender, race, geographic region, menopausal status, baseline age, lumbar spine BMD T-score, and glucocorticoid dose within each subpopulation.

References

1. Prolia (denosumab) [package insert]. Thousand Oaks, CA: Amgen, Inc. March 2020.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/ American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocr Pract 2020;26(1):1-44.
3. Osteoporotic Fracture Risk Assessment. UpToDate. Updated Dec. 2021.

Policy History

Original Effective Date: 07/21/2011
Current Effective Date: 08/12/2024

07/01/2010	Medical Policy Committee review
07/21/2010	Medical Policy Implementation Committee approval.
06/02/2011	Medical Policy Committee review
06/15/2011	Medical Policy Implementation Committee approval. The “and” between the two criteria was changed to “or”.
08/04/2011	Medical Policy Committee review
08/17/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Added that denosumab (Prolia) is eligible for coverage as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. Added that denosumab (Prolia) is eligible for coverage as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Added a *Note* to the criterion regarding the 12-month trial of oral bisphosphonates without documented improvement. Noted that the reason for denial will be not medically necessary if this criterion is not met. The

	not medically necessary denial statement is also incorporated into the Investigational and Not Medically Necessary coverage
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. sections. Added new FDA approved indication for treatment to increase bone mass in men with osteoporosis in high risk for fracture as eligible for coverage with criteria.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. Combined some sections and clarified coverage to match ESI call tree. In the coverage section for men, deleted "with osteoporosis" from the first criteria bullet. Reworded the investigational and not medically necessary sections.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Added language that would allow a patient with a fragility fracture to get the drug as opposed to the DXA requirement.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. No change to coverage.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017	Medical Policy Committee review
04/19/2017	Medical Policy Implementation Committee approval. No change to coverage.
04/05/2018	Medical Policy Committee review
04/18/2018	Medical Policy Implementation Committee approval. Updated definition of fragility fracture.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Added criteria for coverage of new indication of glucocorticoid induced osteoporosis.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2020	Medical Policy Committee review

denosumab (Prolia®)

Policy # 00265
Original Effective Date: 07/21/2011
Current Effective Date: 08/12/2024

05/13/2020	Medical Policy Implementation Committee approval. Updated criteria to clarify the definition of patients at high risk for fracture. Also updated criteria for patients with glucocorticoid-induced osteoporosis to match the FDA indication for daily prednisone equivalent usage. Clarified the definition of failure of bisphosphonates.
05/06/2021	Medical Policy Committee review
05/12/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/05/2022	Medical Policy Committee review
05/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Updated criteria and background information to reflect updated clinical practice guidelines.
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/17/2024	Coding update.

Next Scheduled Review Date: 07/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice

denosumab (Prolia®)

Policy # 00265
Original Effective Date: 07/21/2011
Current Effective Date: 08/12/2024

medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J0897 Add code effective 10/01/2024: Q5136
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

denosumab (Prolia®)

Policy # 00265
Original Effective Date: 07/21/2011
Current Effective Date: 08/12/2024

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.