

Date Effective: 9/2017
Revised: 11/2019, 2/2020
Reviewed: 9/2017, 11/2018, 11/2019, 2/2020, 7/2021, 5/2022
Scope: Medicaid

NON-ONCOLOGY POLICY

PROLIA (denosumab)

For oncology indications, refer to NHPRI Oncology Prolia policy

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Treatment of postmenopausal women with osteoporosis at high risk for fracture
2. Treatment to increase bone mass in men with osteoporosis at high risk for fracture
3. Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Osteoporosis in Postmenopausal Women**

Authorization of 12 months may be granted to postmenopausal female members when ANY of the following criteria are met:

1. Member has a history of fragility fractures
2. Member has a pre-treatment T-score ≤ -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than or equal to -1) with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria:
 - a. Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores, or increased fall risk)
 - b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo])
 - c. Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)

B. **Osteoporosis in Men**

Authorization of 12 months may be granted to male members with osteoporosis when ANY of the following criteria are met:

Date Effective: 9/2017
Revised: 11/2019, 2/2020
Reviewed: 9/2017, 11/2018, 11/2019, 2/2020, 7/2021, 5/2022
Scope: Medicaid

1. Member has a history of an osteoporotic vertebral or hip fracture
2. Member meets both of the following criteria:
 - a. Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (See Appendix B)
 - b. Member has had an oral OR injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (See Appendix A)

C. Glucocorticoid-induced Osteoporosis

Authorization of 12 months may be granted to members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:

1. Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥ 2.5 mg/day for ≥ 3 months
2. Member has had an oral bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)
3. Member meets ANY of the following criteria:
 - a. Member has a history of a fragility fracture
 - b. Member has a pre-treatment T-score ≤ -2.5
 - c. Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than or equal to -1) with a high pre-treatment FRAX fracture probability (See Appendix B)

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who are currently receiving the requested medication and meet one of the following:

1. Member has experienced clinical benefit (e.g., no new fracture seen on radiography) and has not experienced clinically significant adverse events during therapy.
2. Member has experienced clinical benefit as evidenced by a bone mass measurement showing an improvement or stabilization in T-score compared with the previous bone mass measurement and member has not experienced any adverse effects.

IV. QUANTITY LIMIT

1 syringe per 6 months

V. APPENDIX

Appendix A. Clinical reasons to avoid oral bisphosphonate therapy

Date Effective: 9/2017
Revised: 11/2019, 2/2020
Reviewed: 9/2017, 11/2018, 11/2019, 2/2020, 7/2021, 5/2022
Scope: Medicaid

- Esophageal abnormality that delays emptying such as stricture of achalasia
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance <35 mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B. WHO Fracture Risk Assessment Tool

- High FRAX fracture probability: 10 year major osteoporotic fracture risk \geq 20% or hip fracture risk \geq 3%
- 10-year probability; calculation tool available at: <http://www.shef.ac.uk/FRAX/tool.jsp>
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg per day

VI. REFERENCES

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2021.
2. Bisphosphonates. *Drug Facts and Comparisons. Facts & Comparisons® eAnswers* [online]. 2015. Available from Wolters Kluwer Health, Inc. Accessed October 25, 2018.
3. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int.* 2014;25(10): 2359-2381.
4. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. *Am Fam Physician.* 2015;92(4):261-268.
5. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. *Endocr Pract.* 2016;22 (Suppl 4):1-42.
6. ACOG Practice Bulletin Number 129: Osteoporosis. *Obstet Gynecol.* 2012;120(3):718-734.
7. National Institute for Health and Care Excellence. Osteoporosis Overview. Last updated August 2017. Available at: <http://pathways.nice.org.uk/pathways/osteoporosis>. Accessed October 18, 2017.
8. Treatment to prevent osteoporotic fractures: an update. Department of Health and Human Services, Agency for Healthcare Research and Quality. 2012; Publication No. 12-EHC023-EF. Available at www.effectivehealthcare.ahrq.gov/lbd.cfm.
9. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men : an Endocrine Society clinical practice guideline. *J Clin Endocr Metab.* 2012;97(6):1802-1822.
10. Gralow JR, Biermann S, Farooki A, et al. NCCN Task Force Report: Bone Health in Cancer Care. *JNCCN.* 2013; 11(Suppl 3):S1-50.

Date Effective: 9/2017
Revised: 11/2019, 2/2020
Reviewed: 9/2017, 11/2018, 11/2019, 2/2020, 7/2021, 5/2022
Scope: Medicaid

11. FRAX[®] WHO fracture risk assessment tool. © World Health Organization Collaborating Centre for Metabolic Bone Diseases: University of Sheffield, UK. Available at: <http://www.shef.ac.uk/FRAX>. Accessed October 18, 2017.
12. Fink HA, Gordon G, Buckley L, et al. 2017 American College of Rheumatology Guidelines for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Care Res.* 2017;69:1521-1537.