Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Prolia® (Denosumab)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***July 2010 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *August 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Prolia® (denosumab).

Prolia® (denosumab) is indicated for:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture) or patients who have failed or are intolerant to other available osteoporosis therapies
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture) or patients who have failed or are intolerant to other available osteoporosis therapies
  Treatment of glucocorticoid-induced osteoporosis 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.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Prolia® (denosumab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

- **Postmenopausal Osteoporosis:**
  - Must have ONE of the following:
    - Bone mineral density (BMD) T-score of less than or equal to -2.5 at the conventional skeletal sites including the total hip, femoral neck, lumbar spine (posterior-anterior, not lateral) or radius
    - History of fragility fracture (other than skull, facial bone, finger, and toes) as an adult
    - BMD T-score of -1.0 to -2.5 at the femoral neck or lumbar spine and a 10-year probability of a hip fracture >3% or a 10-year probability of a major osteoporosis-related fracture >20% based on the U.S. adapted World Health Organization (WHO) algorithm
  - Must have tried and failed one oral generic and one intravenous generic bisphosphonate therapy unless contraindicated or intolerant

- **Women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer**
  - Must have tried or be intolerant to one oral generic and one intravenous generic bisphosphonate therapy unless contraindicated

- **Men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer**
  - Must have tried or be intolerant to one oral generic and one intravenous generic bisphosphonate therapy unless contraindicated

- **Men with osteoporosis at high risk for fracture**
  - Must have one of the following:
    - BMD T-score of less than or equal to -2.5 at the conventional skeletal sites including the total hip, femoral neck, lumbar spine (posterior-anterior, not lateral) or radius
    - History of fragility fracture (other than skull, facial bone, finger, and toes) as an adult
  - Must have tried and failed one oral generic and one intravenous generic bisphosphonate therapy unless contraindicated or intolerant

- **Glucocorticoid-induced osteoporosis in patients at high risk for fracture**
  - Must be 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
  - Must have one of the following:
    - BMD T-score of less than or equal to -2.5 at the conventional skeletal sites including the total hip, femoral neck, lumbar spine (posterior-anterior, not lateral) or radius
    - History of fragility fracture (other than skull, facial bone, finger, and toes) as an adult
  - Must have tried and failed one oral generic and one intravenous generic bisphosphonate therapy unless contraindicated or intolerant

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
Vial	1 vial per 180 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Prolia (denosumab) [prescribing information] Thousand Oaks, CA: Amgen Ince.; September 2012.
2. Cummings SR, San Martin J, McClung MR, et al. Denosumab for prevention of fractures in postmenopausal women with osteoporosis. N Engl J Med. 2009;361(8):756-65.
3. Risk Evaluation and Mitigation Strategy: ProliaTM (denosumab). http://wwwext.amgen.com/pdfs/products/ Prolia_REMS_Doc.pdf. Posted June 1, 2010.
4. Lewiecki EM. Denosumab – an emerging treatment for postmenopausal osteoporosis. Expert Opin Biol Ther. 2010;10(3):467-476.
5. Brown JP, Prince RL, Deal C, et al. Comparison of the effect of denosumab and alendronate on BMD and biochemical markers of bone turnover in postmenopausal women with low bone mass: a randomized, blinded, phase 3 trial. J Bone Min Res. 2009;24(1):153-161.
6. Kendler DL, Roux C, Benhamou CL, et al. Effect of denosumab on bone mineral density and bone turnover in postmenopausal women transitioning from alendronate therapy. J Bone Min Res. 2010;25(1):72-81.
7. Clinician's guide to the prevention and treatment of osteoporosis. Developed by the National Osteoporosis Foundation. Revised January 2010. http://nof.org/files/nof/public/content/file/344/upload/159.pdf
8. Management of osteoporosis in postmenopausal women: 2006 position statement of The North American Menopause Society. Menopause: The Journal of The North American Menopause Society. 2006: 13(3): 340-367.
9. Maclean C, Alexander A, Carter J, et al. Comparative effectiveness of treatments to prevent fractures in men and women with low bone density or osteoporosis. Comparative effectiveness Review No. 12. (Prepared by the Southern California/RAND Evidence-based Practice Center under contract 290-02-0003). Rockville, MD. Agency for Healthcare Research and Quality; December2007. http://effectivehealthcare.ahrq.gov/repFiles/LowBoneDensityFinal.pdf
10. Body JJ, Bergmann P, Boonen S, et al. Evidence-based guidelines for the pharmacological treatment of postmenopausal osteoporosis: a consensus document by the Belgian Bone Club. Osteoporosis Int. 2010 May 18 [Epub ahead of print].

11. Qaseem A, Snow V, Shekelle P, et al. Pharmacologic Treatment of Low Bone Density or Osteoporosis to Prevent Fractures: A Clinical Practice Guideline from the American College of Physicians. Annals of Internal Medicine. 2008. 149(6): 404-415.
12. Ellis GK, Bone HG, Chlebowski R, Paul D, Spadafora S, Smith J, Fan M, Jun S. Randomized trial of denosumab in patients receiving adjuvant aromatase inhibitors for nonmetastatic breast cancer. J Clin Oncol. 2008 Oct 20;26(30):4875-82.
13. Smith MR, Egerdie B, Hernández Toriz N, Feldman R, Tammela TL, Saad F, Heracek J, Szwedowski M, Ke C, Kupic A, Leder BZ, Goessl C; Denosumab HALT Prostate Cancer Study Group. Denosumab in men receiving androgen-deprivation therapy for prostate cancer. N Engl J Med. 2009 Aug 20;361(8):745-55.
14. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 4.2011). © 2011 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 27, 2011.
15. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 2.2011). © 2011 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 27, 2011.
16. Orwoll E, Teglbjaer CS, Langdahl BL, et al. A Randomized Placebo-Controlled Study of the Effects of Denosumab for the Treatment of Men with Low Bone Mineral Density. J Clin Endocrinol. 2012. 97: 3161-3169.
17. Bone HG, Bolognese MA, Yuen CK, et al. Effects of denosumab on bone mineral density and bone turnover in postemenopausal women. J Clin Endocrinol. 2008. 93(6):2149-2157.
18. 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. Endrocrine practice. 2010; 16: 1-37.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Indication Update	*8/18*