CVS/caremark

PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**PROLIA**
(generic)	**(denosumab)**
Status: CVS/caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 642-A***

FDA-APPROVED INDICATIONS[1]

- Prolia is indicated for the 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 therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures.

- Prolia is indicated as a treatment to increase bone mass in men 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 therapy

- Prolia is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients, Prolia also reduced the incidence of vertebral fractures.

- Prolia is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

COMPENDIAL USES[2]

- Prevention or treatment of osteoporosis during androgen deprivation therapy for patients with high fracture risk.

CRITERIA FOR APPROVAL

1	Is Prolia requested to increase bone mass in a patient with prostate cancer? [If no, skip to question 3.]	Yes	No
2	Is the patient receiving androgen deprivation therapy? [No further questions.]	Yes	No
3	Is Prolia requested to increase bone mass in a patient with breast cancer? [If no, skip to question 5.]	Yes	No
4	Is the patient receiving adjuvant aromatase inhibitor therapy? [No further questions.]	Yes	No
5	Is Prolia requested for a man with osteoporosis? [If no, skip to question 7.]	Yes	No
6	Does the patient meet ANY of the following criteria? A) The patient has a history of an osteoporotic vertebral or hip fracture, OR B) The patient has a pre-treatment T-score of -2.5 or less, OR C) The patient has a pre-treatment T-score of greater than -2.5 to -1 AND a pre-treatment FRAX score of 20 percent or greater for any major osteoporotic fracture, OR D) The patient has a pre-treatment T-score of greater than -2.5 to -1 AND a pre-treatment FRAX score of 3 percent or greater for hip fracture. [No further questions.]	Yes	No

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7 Is Prolia requested for postmenopausal osteoporosis?
[If no, no further questions.]

8 Does the patient have a history of fragility fractures?
[If yes, no further questions.]

9 Does the patient have pre-treatment T-score of less than or equal to -2.5?
[If yes, skip to question 11.]

10 Does the patient have ANY of the following? A) The patient has a pre-treatment T-score of greater than -2.5 to -1 AND a pre-treatment FRAX score of 20 percent or greater for any major osteoporotic fracture, OR B) The patient has a pre-treatment T-score of greater than -2.5 to -1 AND a pre-treatment FRAX score of 3 percent or greater for hip fracture
[If no, no further questions.]

11 Does the patient have ANY of the following? A) Indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR B) Patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo]), OR C) Patient 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.

Guidelines for Approval					
Duration of Approval			**12 months**		
Set 1: Increase bone mass in prostate cancer		**Set 2:** Increase bone mass in breast cancer		**Set 3:** Male osteoporosis	
Yes to Question(s)	**No to Question(s)**	**Yes to Question(s)**	**No to Question(s)**	**Yes to Question(s)**	**No to Question(s)**
1	None	3	1	5	1
2		4		6	3
Set 4: Postmenopausal OP, hx of fragility fractures		**Set 5:** Postmenopausal OP, T-score< -2.5		**Set 5:** Postmenopausal OP, osteopenia with high FRAX	
Yes to Question(s)	**No to Question(s)**	**Yes to Question(s)**	**No to Question(s)**	**Yes to Question(s)**	**No to Question(s)**
7	1	7	1	7	1
8	3	9	3	10	3
	5	11	5	11	5
			8		8
					9

Internal Use Only – Mapping Instructions		
	Yes	**No**
1.	Go to 2	Go to 3
2.	Approve, 12 months	Deny
3.	Go to 4	Go to 5
4.	Approve, 12 months	Deny
5.	Go to 6	Go to 7
6.	Approve, 12 months	Deny
7.	Go to 8	Deny
8.	Approve, 12 months	Go to 9

9.	Go to 11	Go to 10
10.	Go to 11	Deny
11.	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare-approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 23, 2016.
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 September 20, 2016. Available at: http://pathways.nice.org.uk/pathways/osteoporosis. Accessed October 17, 2016.
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.
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 7, 2015.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (KR) 06/2010
Revised:	09/2010 (P&T); GY 09/2011 (added cancer-related indications), 11/2011; GY 11/2011; HY 09/2012 (CMS), 10/2012 (new indication), 04/2013; ST 11/2014, 08/2015 (CMS); JP 10/2015, 06/2016 (CMS), PK 07/2017
Reviewed:	CDPR/WLF 06/2010; KP 09/2011; MG 11/2011; DNC 10/2012, LMS 04/2013, SES 12/2014, DNC 10/2015, ADA 11/2016
External Review:	06/2010; 12/2011; 12/2012, 05/2013, 01/2015, 01/2016, 02/2017