

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Xgeva (denosumab)

CG-DRUG-73

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Xgeva (denosumab) subcutaneous solution 120 mg/1.7mL (70 mg/mL) vial	1 vial per 28 days*

*Initiation of therapy for giant cell tumor of bone or for hypercalcemia of malignancy:
May allow up to two additional vials (120 mg/1.7 mL) in the first 28 days of treatment.

APPROVAL CRITERIA

Requests for Xgeva (denosumab) may be approved if the following criteria are met:

- I. Xgeva (denosumab) is being used for the prevention of skeletal-related events in adults* when used for one of the following conditions:
 - A. Multiple myeloma; **OR**
 - B. Solid tumor bone metastases (excluding prostate cancer unless castration resistant/recurrent);

OR

- II. Individual is using for the treatment of hypercalcemia of malignancy, defined as an albumin-corrected serum calcium level great than 12.5 mg/dL (3.1 mmol/L), when both of the following criteria are met:
 - A. Adults*; **AND**
 - B. Refractory to recent (within last 30 days) treatment with intravenous bisphosphonate therapy (for example, pamidronate, zoledronic acid);

OR

- III. Individual is using for the treatment of localized or metastatic giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity when either or the following criteria below are met:
 - A. Adults*; **OR**
 - B. Skeletally mature adolescents (defined by at least 1 mature long bone [for example; closed epiphyseal growth plate of the humerus]).

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0195-18

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***Note:** Adult is defined as an individual greater than or equal to 18 years of age.

Xgeva (denosumab) may not be approved for the following:

- I. When all of the criteria specified above are not met, for presence of uncorrected pre-existing hypocalcemia or for the treatment of all other indications.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Amgen. Safety Study of Denosumab in subjects with recurrent or unresectable giant cell tumor of bone. NLM Identifier: NCT00680992. Last updated on December 14, 2017. Available at: <https://clinicaltrials.gov/ct2/show/NCT00680992>. Accessed on April 04, 2018.
2. Amgen. Study of denosumab in the treatment of hypercalcemia of malignancy in subjects with elevated serum calcium. NLM Identifier: NCT00896454. Last updated on March 15, 2016. Available at: <https://clinicaltrials.gov/ct2/show/NCT00896454>. Accessed on April 04, 2018.
3. Denosumab Monograph. Lexicomp® Online, American Hospital Formulary Services® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised January 2, 2014. Accessed on April 04, 2018.
4. Denosumab (systemic). In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated February 5, 2018. Available at: <http://www.micromedexsolutions.com>. Accessed on April 04, 2018.
5. NCCN Clinical Practice Guidelines in Oncology™ (NCCN). © 2018 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website at: <http://www.nccn.org/index.asp>. Accessed on April 04, 2018.
 - Bone Cancer (V.2.2018). Revised March 28, 2018.
 - Breast Cancer (V.1.2018) Revised March 20, 2018.
 - Kidney Cancer (V.3.2018). Revised February 06, 2018.
 - Multiple Myeloma (V.4.2018). Revised February 12, 2018.
 - Non-Small Cell Lung Cancer (V.3.2018). Revised February 21, 2018.
 - Prostate Cancer (V.2.2018). Revised March 08, 2018.
 - Thyroid Carcinoma (V.2.2017). Revised May 17, 2017.
6. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (electronic version). For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on April 04, 2018.
7. Van Poznak CH, Von Roenn JH, Temin S, et al. American Society of Clinical Oncology Clinical Practice Guideline Update on the Role of Bone-modifying agents in metastatic breast cancer. J Oncol Pract. 2011; 7(2):117-121.
8. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists (AACE). American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract. 2010; 16 Suppl 3:1-37.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

9. Xgeva [Product Information]. Thousand Oaks, CA. Amgen Inc.; January 5, 2018. Available at: http://pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/xgeva/xgeva_pi.pdf. Accessed on April 04, 2018.

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