

| 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)

| Override(s)                           | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization<br>Quantity Limit | 1 year            |

| Medications   | Quantity Limit      |
|---|---------------------|
| Xgeva (denosumab) subcutaneous solution<br>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 when the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
  - II. Individual is using for the prevention of skeletal-related events with one of the following conditions:
    - A. Multiple myeloma; **OR**
    - B. Solid tumor bone metastases (excluding prostate cancer unless castration resistant/recurrent);
- OR**
- III. Individual is 18 years of age or older; **AND**
  - IV. Individual is using for the treatment of hypercalcemia of malignancy [defined as an albumin-corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L)] and is refractory to recent (within last 30 days) treatment with intravenous bisphosphonate therapy (for example, pamidronate or zoledronic acid);
- OR**
- V. 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. Individual is 18 years of age or older; **OR**

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.

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| 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  |

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B. Individual is a skeletally mature adolescents [defined by at least one mature long bone (for example; closed epiphyseal growth plate of the humerus)].

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

**Key References:**

1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2016. *Endocrine Practice*. 2016;22(4):1-42.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 18, 2018.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2018. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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