Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 89.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Xgeva (denosumab)

I. Policy:
Xgeva (denosumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Xgeva (denosumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Xgeva (denosumab) binds to RANKL, a transmembrane or soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption. Xgeva prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts and their precursors. Increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Xgeva (denosumab) will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

1. *Bone metastases from solid tumors*
   - Medical record documentation of use for treatment of bone metastases related to disease progression from a solid tumor (e.g. breast, prostate) **AND**
   - Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemented with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L) **AND**
   - Member is not concurrently receiving Prolia (denosumab)

2. *Giant cell tumor of the bone*
   - Medical record documentation of use for treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity **AND**
   - Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemented with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L) **AND**
   - Member is not concurrently receiving Prolia (denosumab)

3. *Hypercalcemia of malignancy*
   - Medical record documentation of use for treatment of hypercalcemia of malignancy that is refractory to intravenous bisphosphonate therapy (defined as an albumin-corrected calcium of > 12.5 mg/dL (3.1 mmol/L) despite treatment with intravenous bisphosphonate therapy in the previous 30 days) **AND**
   - Member is not concurrently receiving Prolia (denosumab)

4. *Prevention of skeletal-related events in Multiple Myeloma*
   - Medical record documentation of use for the prevention of skeletal-related events in patients with multiple myeloma **AND**
   - Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemented with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L) **AND**
   - Member is not concurrently receiving Prolia (denosumab) **AND**
   - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to zoledronic acid (Note: A creatinine clearance less than 35mL/minute is considered a contraindication to the use of zoledronic acid)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Xgeva (denosumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

1. *Bone metastases from solid tumors*
   - Medical record documentation of use for treatment of bone metastases related to disease progression from a solid tumor (e.g. breast, prostate) **AND**
   - Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemented with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L) **AND**
   - Member is not concurrently receiving Prolia (denosumab)

2. *Giant cell tumor of the bone*
- Medical record documentation of use for treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity **AND**
- Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemented with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L) **AND**
- Member is not concurrently receiving Prolia (denosumab)

3. *Hypercalcemia of malignancy*
- Medical record documentation of use for treatment of hypercalcemia of malignancy that is refractory to intravenous bisphosphonate therapy* **AND**
- Member is not concurrently receiving Prolia (denosumab)

4. *Prevention of skeletal-related events in Multiple Myeloma*
- Medical record documentation of use for the prevention of skeletal-related events in patients with multiple myeloma **AND**
- Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemented with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L) **AND**
- Member is not concurrently receiving Prolia (denosumab)

*Note: In clinical trial, refractory hypercalcemia of malignancy was defined as an albumin-corrected calcium of > 12.5 mg/dL (3.1 mmol/L) despite treatment with intravenous bisphosphonate therapy in 7-30 days prior to initiation of Xgeva therapy

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Xgeva [prescribing information]. Thousand Oaks, CA: Amgen Inc; June 2020.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 4/11

Revised: 2/12 (added exclusion); 9/13 (add indication), 08/14, 09/26/14 3/24/15 (formatting, auth duration), 5/19/15 (formatting, new indication), 5/15/18 (multiple myeloma), 1/17/23 (LOB carve out), 12/31/23 (references added), 1/8/24 (Medicaid business segment)

Reviewed: 08/14, 09/26/14, 3/16, 3/30/17, 3/29/18, 4/22/19, 2/1/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23