Bone Resorption Inhibitors

Prolia/Xgeva (denosumab) J0897and Evenity (romosozumab-aqqg) J3111are non-preferred. The preferred products are Oral Bisphophonates and Injectable pamidronate J2430 and zoledronic acid J3489 (no PA required for preferred alts)

Prior Authorization Step Therapy

Medicare Part B Request Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**NEW START - Start Date:**_____	☐	**Continuation** (within 365 days)**:** Date of last treatment _____
☐	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug ☐ Self-administered	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Bone Resorption Inhibitors PA

Drug Name(s):
EVENITY
PROLIA
XGEVA

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE formulary Oral Bisphosphante (alendronate, ibandronate, etc) AND ONE formulary Injectable alternative: **zoledronic acid, pamidronate** OR
   - There is clinical documentation stating Oral AND Injectable formulary alternatives are contraindicated.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
N/A

Coverage Duration:
Approval will be for 12 months

FDA Indications:
Prolia

- Breast cancer - Osteopenia, In women at high risk of fracture receiving adjuvant aromatase inhibitor therapy
- Osteopenia, In men at high risk of fracture receiving androgen deprivation therapy - Prostate cancer, Nonmetastatic
- Postmenopausal osteoporosis, High risk of fracture
- Osteoporosis due to corticosteroid, High fracture risk with 6-month or longer requirement for predniSONE 7.5 mg/day or greater
- Osteoporosis, high risk for fracture, male

Xgeva

- 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
- Hypercalcemia of malignancy refractory to bisphosphonate therapy
- Prophylaxis of skeletal-related events in patients with bone metastases from solid tumors
- Prophylaxis of skeletal-related events in patients with multiple myeloma

Evenity

- Postmenopausal ~~women with~~ osteoporosis at high risk for fracture

Off-Label Uses:

Prolia

- Postmenopausal osteoporosis; Prophylaxis

Step Therapy Drug(s) and FDA Indications:

Zoledronic acid (Reclast):

- Indicated for both prevention and treatment of osteoporosis in postmenopausal women, osteoporosis in men, glucocorticoid induced osteoporosis and Paget's disease of bone. Optimal duration has not been determined (3-5 years). Zoledronic acid (Zometa) is indicated for treatment of hypercalcemia of malignancy (albumin-corrected calcium of greater than 12 mg/dL) and multiple myeloma and bone metastases of solid tumors.
- Off-Label Uses:
  - Breast cancer, Early stage, adjuvant therapy
  - Monoclonal gammopathy of uncertain significance, With osteopenia or osteoporosis
  - Osteopenia, Secondary to androgen-deprivation therapy in prostate cancer patients; Prophylaxis
  - Osteopenia, Secondary to hormone therapy in breast cancer patients; Prophylaxis
  - Osteopenia, Secondary to ovarian dysfunction induced by adjuvant chemotherapy in premenopausal women with early-stage breast cancer; Prophylaxis

Pamidronate (Adrenia):

- Approved by the FDA for use in hypercalcemia of malignancy, Paget's disease of the bone, osteolytic bone metastases from breast cancer and osteolytic lesions of multiple myeloma. The National Comprehensive Cancer Network Drug and Biologics Compendium (NCCN, 2019) recommends pamidronate for the following indications:
  - Breast Cancer – Invasive – Used with calcium and vitamin D supplementation in addition to chemotherapy or endocrine therapy for bone metastasis in patients with expected survival of ≥3 months and adequate renal function
  - Breast cancer – Consider in postmenopausal (natural or induced) patients receiving adjuvant therapy along with calcium and vitamin D supplementation to maintain or improve bone mineral density and reduce risk of fractures
  - Kidney cancer – Used as a component of best supportive care for bony metastases
  - Multiple myeloma – Used in combination with primary myeloma therapy
  - Non-small cell lung cancer – Consider for supportive therapy in patients with bone metastases
  - Systemic mastocytosis – Treatment for osteopenia/osteoporosis
  - Thyroid Carcinoma – Anaplastic Carcinoma, Follicular Carcinoma, Hürthle Cell Carcinoma, Medullary Carcinoma, Papillary Carcinoma – Consider for bone metastases.
- Off-Label Uses:
  - Complex regional pain syndrome type I
  - Drug-induced osteoporosis; Prophylaxis - Gonad regulating hormone adverse reaction
  - Hypercalcemia, Associated with tamoxifen-induced tumor flare
  - Langerhans cell histiocytosis
  - Osteogenesis imperfecta
  - Osteopenia (Acute); Prophylaxis - Total replacement of hip
  - Osteopenia - Tetraplegic cerebral palsy
  - Osteoporosis due to corticosteroid
  - Postmenopausal osteoporosis

Age Restrictions:

Only approved in adults 18 years of age or older

Other Clinical Consideration:

Pre-existing hypocalcemia must be corrected prior to initiating therapy.

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/F0B56E/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/C74685/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=929634&contentSetId=100&title=Denosumab&servicesTitle=Denosumab&brandName=Prolia&UserMdxSearchTerm=prolia&=null#

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