Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

☒ **Commercial (Small & Large Group)** ☒ **ASO** ☒ **Exchange/ACA**
☐ **Medicare Advantage (MAPD)**

PROLIA,(denosumab) MB9409

Covered Service: Yes

Prior Authorization Required: Yes for Prolia

Additional Information: Must be prescribed by (or prescribed in consultation with) Oncology, Rheumatology, Internal Medicine, Family Medicine, Orthopedic Surgery, or Endocrinology specialists.

Medicare Policy: Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and the plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

Wisconsin Medicaid Policy Coverage of prescription drug benefits is administered by the Wisconsin Medicaid program. Coverage of medical drug benefits is administered by the Wisconsin Medicaid fee-for-service program. Medical drugs not paid on a fee-for-service basis by the Wisconsin Medicaid program are covered by the plan with no PA required.

Plan Approved Criteria:

1.0 Injections of drugs that are administered at an excessive frequency or dose are not medically necessary. Frequency or dosing are considered excessive when services are performed more frequently or at a higher dose than listed in the FDA-approved package insert, listed in this document or generally accepted by peers and the reason for additional services is not justified by submitted documentation of clinical evidence. Route of administration of injectable drugs should follow the FDA-approved package insert.

2.0 If approved, may be authorized in quantities:

2.1 PROLIA:

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2.1.1 Two 60 mg injections per year

Initial criteria (approved for up to one year, subject to formulary changes):

1.0 PROLIA (denosumab) requires prior authorization and is considered medically appropriate for those meeting the following criteria:

1.1 Members are at high risk for fracture defined by meeting at least ONE of the following:

1.1.1 Have a bone mineral density that is 2.5 or more standard deviations below that of a “young normal” adult (T-score at or below -2.5)

1.1.2 Have osteopenia (T-score between -1 and -2.5) with either Fracture Risk Assessment Tool (FRAX) osteoporotic fracture score $\geq$ 20% of FRAX hip fracture score $\geq$ 3%

1.1.3 Receiving systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone

1.1.4 History of osteoporotic fracture

1.1.5 Men receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer

1.1.6 Women receiving adjuvant aromatase inhibitor therapy for breast cancer;

1.1.7 Taking a daily dose of prednisone $\geq$ 2.5 mg daily AND

1.2 Supplementation (via diet or pills) of calcium 1000 mg and at least 400 IU of vitamin D daily while on denosumab to prevent hypocalcemia

1.3 Step therapy of at least one of the following:

1.3.1 At least one bisphosphonate

1.3.2 bisphosphonates (both oral and IV) are not tolerated due to documented clinical side effects

1.3.3 bisphosphonates (both oral and IV) are contraindicated based on current medical literature and objective documentation describing the contraindication is provided (including, but not limited to, creatinine clearance of less than 35 mL/min) **(Documentation required)**

Renewal criteria (approved for up to one year, subject to formulary changes):

1.0 Member must still present with appropriate diagnosis for continued therapy with a a high risk of of fracture ; AND
2.0 No concomitant use with other bone density products (abaloparatide, teriparatide, romosozumab); AND
3.0 Confirm that member is still receiving calcium and vitamin D supplementation

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Comments:

1.0 Quantity limits are to maximum daily doses based on the package insert or NCCN recommendations

2.0 Documentation is expected to be maintained in the member's medical record and to be available to the plan. Every page of the record is expected to be legible and include both the appropriate member identification information (e.g., complete name dates of service(s)), and information identifying the physician or non-physician practitioner responsible for and providing the care of the member. The member's medical record must contain documentation that fully supports the medical necessity for services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

2.1 The medical record must include the following information:

2.1.1 A physician's order

2.1.2 The name of the drug or biological administered

2.1.3 The route of administration

2.1.4 The dosage (e.g., mgs, mcgs, cc's or IU's)

2.1.5 When a portion of the drug or biological is discarded, the medical record must clearly document the amount administered and the amount wasted or discarded.

3.0 The following are key points to remember when billing for denosumab (J0897):

3.1 J0897 is defined in the HCPCS manual as: injection, denosumab 1mg

3.2 Coverage only when an FDA approved indication or an approved off-labeled indication accompanies J0897

4.0 Coding specifications*

*Codes and descriptors listed in this document are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with the plan. Inclusion of a code in the table does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

4.1 NDC and HCPCS codes

Medication Name		How Supplied	National Drug Code (NDC)	HCPCS code
Brand	Generic			
PROLIA	denosumab	60 mg/1 mL single-use prefilled syringe	55513-710-01	J0897

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5.0 **NOTE: The use of physician samples or manufacturer discounts does not guarantee later coverage under the provisions of the medical certificate and/or pharmacy benefit. All criteria must be met in order to obtain coverage of the listed drug product.**

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