Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCEND087.1025	**ENDOCRINE AND METABOLIC DRUGS** **Denosumab**
Effective Date: 1/1/2026	**Review/Revised Date**:
Original Effective Date: 01/26	**P&T Committee Meeting Date**: 10/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Medically-Accepted Indications

REQUIRED MEDICAL INFORMATION:
Non-preferred products require documented trial and failure, intolerance or contraindication to all preferred biosimilar products (see Table 1)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

QUANTITY LIMIT: Dosing and frequency must be in accordance with FDA-approved labeling or supported drug compendia

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Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive

Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION: Denosumab is a monoclonal antibody that is a Receptor Activator of Nuclear factor Kappa-B Ligand (RANKL) inhibitor. RANKL plays a key role in the development of osteoclasts, which are responsible for bone resorption. Denosumab limits the activity of RANKL, thereby reducing the activity of osteoclasts and decreasing bone resorption.[1-2]

FDA APPROVED INDICATIONS:[1]

Bildyos®, Conexxence®, Jubbonti®, Stoboclo®, Ospomyv®, Prolia®

- Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
    - In postmenopausal women with osteoporosis, denosumab reduces the incidence of vertebral, nonvertebral, and hip fractures
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months.
    - High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer.
    - In these patients denosumab also reduced the incidence of vertebral fractures
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Bilprevda®, Bomyntra®, Osenvelt®, Wyost®, Xbryk®, Xgeva®

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors
- 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

POSITION STATEMENT:
Several biosimilar products for denosumab were approved by the FDA.[3] Interchangeable biosimilars have met more stringent requirements by the Food & Drug Administration (FDA) to show their similarity to the reference product in terms of safety and effectiveness. These products may be substituted by a pharmacy (dependent on state laws) without the approval of the prescriber, similar to traditional generic drugs.[4]

Table 1. Denosumab products applicable to this policy

Generic Name	Brand Name
No Prior Authorization Required (Preferred Products)	
denosumab-bmwo	Stoboclo®/ Osenvelt®
denosumab-nxxp	Bildyos®/ Bilprevda®
Prior Authorization Required	
denosumab	Prolia®/Xgeva® (innovator/reference products)
denosumab-bnht	Bomyntra®/ Conexxence®
denosumab-dssb	Ospomyv®/ Xbryk®
denosumab-bbdz	Jubbonti®/Wyost®

Table 2. Billing and Coding Information

DRUG CODES*		
HCPCS Code	**Coding Description**	**Brand Name**
Q5136	Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg	Jubbonti®/ Wyost®
J0897	Injection, denosumab, 1 mg	Prolia®/ Xgeva®
Q5158	Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg	Bomyntra®/ Conexxence®
Q5157	Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg	Stoboclo®/ Osenvelt®
Q5159	Injection, denosumab-dssb (ospomyv/xbryk), biosimilar, 1 mg	Ospomyv®/ Xbryk®
J3590/C9399	Unclassified drugs or biologics	Bildyos®/ Bilprevda®
ADMINISTRATION CODES		
96372	Ther/proph/diag inj sc/im	
96401	Chemo anti-neopl sq/im	
MODIFIER CODES†		
-JA	Administered Intravenously	

-JB	Administered Subcutaneously	
-JW	Drug Amount Discarded/Not Administered to Any Patient	
-JZ	Zero drug amount discarded/Not administered to Any Patient	

*Coding Notes:
• The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
• HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

†Must be billed with the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for the subcutaneous injection form of administration Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy FAQ

REFERENCE/RESOURCES:

1. Relevant package labeling
2. Denosumab. In: DRUGDEX® System [Internet database]. Ann Arbor, MI: Merative Micromedex. Updated periodically.
3. US Food & Drug Administration (FDA). Purple Book Database of Licensed Biological Products. Available at https://purplebooksearch.fda.gov/ (Accessed September 8, 2025)
4. FDA. Biosimilars: Overview for Health Care Professionals. Available https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals (Accessed September 9, 2025)