

# Xgeva®, Prolia® (Denosumab)

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[↪ Terms and Conditions](#)

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<p><b>Related Medicare Advantage Policy Guideline</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Coverage of Drugs and Biologicals for Label and Off-Label Uses</a></li> </ul>
<p><b>Related Medicare Advantage Reimbursement Policy</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Discarded Drugs and Biologicals Policy, Professional</a></li> </ul>
<p><b>Related Medicare Advantage Coverage Summaries</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Chemotherapy, and Associated Drugs and Treatments</a></li> <li>• <a href="#">Medications/Drugs (Outpatient/Part B)</a></li> </ul>

## Policy Summary

[↪ See Purpose](#)

### Overview

Denosumab is a monoclonal antibody used for the treatment of osteoporosis in postmenopausal women with a high risk of bone fractures that were not successful with other osteoporosis therapies. Denosumab reduces the possibility of fractures of the hip and vertebral and non-vertebral fractures because it is a RANK Ligand inhibitor. It works by binding to the Rank Ligand inhibiting osteoclast formation, function, and survival, therefore preventing the osteoclasts from resorbing bone.

The FDA has approved the use of denosumab (Prolia). Medicare has determined under Section [1861\(t\)](#) that this drug may be paid when it is administered incident to a physician's service and is determined to be reasonable and necessary.

### Guidelines

Note: This policy does not describe drug and biological coverage under the Medicare Part D benefit.

### Indications

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fractures.
- For the treatment of postmenopausal women with osteoporosis who have failed or are intolerant to other available osteoporosis therapy.
- For patients with significant renal failure where treatment with bisphosphonate is not indicated, CrCl less than 35 ml/min.
- The FDA approved a second indication for denosumab (Xgeva). Xgeva is approved for the treatment of patients with bone metastases from solid tumors.
- The FDA approved denosumab (Prolia) as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures.
- Prolia is also indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

- The FDA approved denosumab (Prolia) as a 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.
- The FDA approved denosumab (XGEVA) for the 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.
- Effective for dates of service on or after 01/04/2018, the FDA has approved denosumab (Xgeva®) for the treatment of skeletal-related events in patients with multiple myeloma.

Supplemental calcium and vitamin D are required. Hypocalcemia must be corrected prior to initiation of denosumab therapy.

### **Limitations**

Prolia is contraindicated for the following condition:

- Hypocalcemia
- Patients receiving Xgeva

Xgeva is contraindicated for the following conditions:

- Hypocalcemia
- Hypersensitivity to Xgeva
- Patients receiving Prolia

As published in [CMS IOM 100-08, Section 13.5.1](#), in order to be covered under Medicare, a service shall be reasonable and necessary.

[Medicare Benefit Policy Manual- Pub. 100-02, Chapter 15, Section 50](#), describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.

Coverage for medication is based on the patient's condition, the appropriateness of the dose and route of administration, based on the clinical condition and the standard of medical practice regarding the effectiveness of the drug for the diagnosis and condition. The drug must be used according to the indication and protocol listed in the accepted compendia ratings listed below.

- National Comprehensive Cancer Network (NCCN) Drugs and Biologies Compendium
- Thomson Micromedex DrugDex
- American Hospital Formulary Service-Drug Information (AHFS-DI)
- Clinical Pharmacology

The compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium. In general, a use is identified by a compendium as medically accepted if the:

- Indication is a Category 1 or 2A in NCCN
- Class I, Class IIa, or Class IIb in DrugDex; or,
- Narrative text in AHFS or Clinical Pharmacology is supportive.

## **Applicable Codes**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J0897	Injection, denosumab, 1 mg

Modifier	Description
50	Bilateral procedure
EJ	Subsequent doses in a series
JW	Drug amount discarded/not administered to any patient
LT	Left side (used to identify procedures performed on the left side of the body)
RT	Right side (used to identify procedures performed on the right side of the body)
50	Bilateral procedure
EJ	Subsequent doses in a series

#### Diagnosis Code

[Xgeva®, Prolia® \(Denosumab\): Diagnosis Code List](#)

## References

### CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
<a href="#">L33270 Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications</a>	<a href="#">A57603 Billing and Coding: Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications</a>	First Coast	FL, PR, VI	FL, PR, VI
N/A	<a href="#">A52953 Billing and Coding: Chemotherapy Administration</a>	Noridian	AS, CA (Northern and Southern), GU, HI, MP, NV	AS, CA (Entire State), GU, HI, MP, NV
N/A	<a href="#">A52991 Billing and Coding: Chemotherapy Administration</a>	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
<a href="#">L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses</a>	<a href="#">A52399 Billing and Coding: Denosumab (Prolia™, Xgeva™)</a>	NGS	CT, IL, MA, ME, MN, NH, NY (Entire State), RI, VT, WI	CT, IL, MA, ME, MN, NH, NY (Upstate, Downstate, Queens), RI, VT, WI
N/A	<a href="#">A54176 Billing and Coding: Drug Administration</a>	WPS	AK, AL, AR, AZ, CA (Entire State), CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO (Entire State), MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, KS, MO, NE, IN, MI

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	<a href="#">A55297 Billing and Coding: Drug and Biological Infusions</a>	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

## CMS Benefit Policy Manual

[Chapter 15: § 50 Drugs and Biologicals](#)

## CMS Claims Processing Manual

[Chapter 17: § 40 Discarded Drugs and Biologicals](#)

[Chapter 32 Billing Requirements for Special Services](#)

## Other(s)

[Chemo and Biological Drug Chart](#)

[Medicare Program Integrity Manual, Chapter 13 Local Coverage Determinations; § 13.5.1 Reasonable and Necessary Provisions in LCDs](#)

[NCCN Drugs & Biologics Compendium, National Comprehensive Cancer Network Website](#)

Social Security Act (Title XVIII) Standard References, Sections:

- [1862\(a\)\(1\)\(A\) Medically Reasonable & Necessary](#)
- [1862\(a\)\(1\)\(D\) Investigational or Experimental](#)
- [1833\(e\) Incomplete Claim](#)
- [1861\(t\) \(1\) Drugs and Biologicals](#)

## Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>• Reformatted policy; transferred content to new template</li> </ul>
09/09/2020	<p><b>Related Policies</b></p> <ul style="list-style-type: none"> <li>• Added reference link to: <ul style="list-style-type: none"> <li>○ The Medicare Advantage Policy Guideline titled <i>Coverage of Drugs and Biologicals for Label and Off-Label Uses</i></li> <li>○ The Medicare Advantage Reimbursement policy titled <i>Discarded Drugs and Biologicals Policy, Professional</i></li> </ul> </li> <li>• Removed reference link to the Medicare Advantage Policy Guideline titled <i>Self-Administered Drug(s) (SAD)</i></li> </ul> <p><b>Policy Summary</b></p> <p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>• Removed language pertaining to self-administered drugs</li> </ul> <p><b>Applicable Codes</b></p> <p><b>Modifiers</b></p> <ul style="list-style-type: none"> <li>• Added Modifier codes 50, EJ, JW, LT, and RT</li> </ul> <p><b>ICD-10 Diagnosis Codes</b></p> <ul style="list-style-type: none"> <li>• Added ICD-10 diagnosis codes C94.30, C94.31, and C94.32</li> <li>• Added notation to indicate ICD-10 diagnosis codes C41.0, C41.1, C41.2, C41.3, C41.4, C7B.03, C7B.09, C7B.8, M48.51XA, M48.52XA, M48.53XA, M48.54XA, M48.55XA, M48.56XA, M48.57XA, M48.58XA, M84.411A, M84.412A, M84.421A, M84.422A, M84.431A, M84.433A, M84.434A, M84.441A, M84.442A, M84.444A, M84.445A, M84.451A, M84.452A, M84.459A, M84.461A, M84.462A, M84.463A, M84.464A, M84.471A, M84.472A, M84.474A, M84.475A, M84.477A, M84.478A, M84.48XA, M84.611A, M84.612A, M84.621A, M84.631A, M84.632A, M84.633A,</li> </ul>

Date	Summary of Changes
	<p>M84.634A, M84.641A, M84.642A, M84.650A, M84.651A, M84.652A, M84.659A, M84.661A, M84.662A, M84.663A, M84.664A, M84.671A, M84.672A, M84.674A, M84.675A, M84.68XA, M84.432A, M84.454A, M84.622A, M94.9, Z79.3, Z79.818, Z79.891, and Z85.528 were “deleted June 7, 2020”</p> <p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Removed definition of “Off-Label Drug Use”</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>References</i> section to reflect the most current information</li> <li>Archived previous policy version MPG355.06</li> </ul>

## Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

## Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document\* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and

Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

\*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).