

# Xgeva®, Prolia® (Denosumab)

**Guideline Number:** MPG355.10  
**Approval Date:** December 13, 2023

[↪ Terms and Conditions](#)

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Related Medicare Advantage Reimbursement Policy
<ul style="list-style-type: none"> <li><a href="#">Discarded Drugs and Biologicals Policy, Professional</a></li> </ul>
Related Medicare Advantage Coverage Summary
<ul style="list-style-type: none"> <li><a href="#">Medications/Drugs (Outpatient/Part B)</a></li> </ul>

## Policy Summary

[↪ See Purpose](#)

### Overview

Denosumab (Prolia® and Xgeva®) binds to RANKL, a transmembrane of soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption. Denosumab prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts and their precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone.

The FDA has approved the use of denosumab (Prolia® and Xgeva®). 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

Prolia® for all patients is allowed under the following circumstances:

- The oral health of the patient was discussed.
- The patient was instructed to take 1,000 mg of calcium and at least 400 IU of vitamin D per day.

Prolia® for men and postmenopausal women with osteoporosis is allowed under the following circumstances:

- Criteria for the diagnosis of osteoporosis is met; and
- There is a history of treatment as related to progression of disease and ongoing risk factors; and
- The patient meets the definition of osteoporosis with high risk for fracture; or
- The patient has failed or is intolerant of other available osteoporotic therapy.

Prolia® for treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer is allowed under the following circumstance:

- The patient is a woman receiving adjuvant aromatase inhibitor therapy for breast cancer.

Prolia® for treatment of bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer is allowed under the following circumstance:

- The patient is a man receiving androgen deprivation therapy for prostate cancer.

Xgeva® for treatment of all FDA approved indications is allowed under the following circumstance:

- The patient is taking calcium and vitamin D supplements as necessary to treat or prevent hypocalcemia.

### **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.

Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

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 Biologics Compendium.
- Thomson Micromedex DrugDex.
- American Hospital Formulary Service-Drug Information (AHFS-DI).
- Clinical Pharmacology.

The listed 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, or Class I, Class IIa, or Class IIb in DrugDex; or
- Narrative text in AHFS-DI or Clinical Pharmacology is supportive; or
- Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A".

## **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.

<b>HCPCS Code</b>	<b>Description</b>
J0897	Injection, denosumab, 1 mg

## 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
<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="#">A58527 Billing and Coding: Complex Drug Administration Coding</a>	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
N/A	<a href="#">A59074 Billing and Coding: Complex Drug Administration Coding</a>	First Coast	FL, PR, VI	FL, PR, VI
N/A	<a href="#">A59073 Billing and Coding: Complex Drug Administration Coding</a>	Novitas	AR, CO, DC, DE, LA, MD, MS, NM, NJ, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NM, NJ, OK, PA, TX
N/A	<a href="#">A59272 Complex Drug Administration Coding</a>	CGS	KY, OH	KY, OH
N/A	<a href="#">A53049 Billing and Coding: Approved Drugs and Biologicals: Includes Cancer Chemotherapeutic Agents</a>	Novitas	AR, CO, DC, DE, LA, MD, MS, NM, NJ, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NM, NJ, OK, PA, TX
N/A	A58533 Billing and Coding: Complex Drug Administration Coding <b>Retired 04/01/2023</b>	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A58532 Billing and Coding: Complex Drug Administration Coding <b>Retired 04/01/2023</b>	Noridian	AS, CA (Northern and Southern), GU, HI, MP, NV	AS, CA (Entire State), GU, HI, MP, NV
N/A	A58544 - Billing and Coding: Complex Drug Administration Coding <b>Retired 08/12/2022</b>			

### CMS Benefit Policy Manual

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

### CMS Claims Processing Manual

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

## Other(s)

[FDA Package Insert](#)

[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
12/13/2023	<p><b>Policy Summary</b></p> <p><b>Guidelines</b></p> <p>Indications</p> <ul style="list-style-type: none"><li>• Replaced language indicating “Xgeva® for <i>all patients</i> is allowed when the patient is taking calcium and vitamin D supplements as necessary to treat or prevent hypocalcemia” with “Xgeva® for <i>treatment of all FDA approved indications</i> is allowed when the patient is taking calcium and vitamin D supplements as necessary to treat or prevent hypocalcemia”</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 MPG355.09</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 above 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](#).