

Denosumab

HCPCS: J0897 Injection, denosumab, 1 mg (Prolia, Xgeva), Q5136 Injection, denosumab-bbdz, biosimilar 1 mg (Jubbonti, Wyost), Q5157 Injection, denosumab-bmwo, biosimilar, 1 mg (Stoboclo/Osenvelt), Q5158 Injection, denosumab-bnht, biosimilar, 1 mg (Bomyntra/Conexxence), Q5161 Injection, denosumab-kyqq biosimilar, 1 mg (Aukelso/Bosaya), Q5162 Injection, denosumab-nxxp biosimilar, 1 mg (Bildyos/Bilprevda), Q5171 Injection, denosumab-mobz, biosimilar, 1 mg (Boncresa), Q5167 Injection, denosumab-qbde, biosimilar, 1 mg (Enoby/Xtrenbo), Q5166 Injection, denosumab-desu, biosimilar, 1 mg (Osvyrti/Jubereq), Q5165 Injection, denosumab-mobz, biosimilar, 1 mg (Oziltus)

LOB:	MCAL
Duration of Approval:	One year
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	Yes (Prolia, Xgeva)
DHCS Drug Policy:	No

Requires Prior Authorization (PA)
▪ Aukelso (denosumab-kyqq) injection ▪ Bildyos (denosumab-nxxp) injection ▪ Bilprevda (denosumab-nxxp) injection ▪ Bomvntra (denosumab-bnht) injection ▪ Boncresa (denosumab-mobz) injection ▪ Bosaya (denosumab-kyqq) injection ▪ Conexxence (denosumab-bnht) injection ▪ Enoby (denosumab-qbde) injection ▪ Jubereq (denosumab-desu) injection ▪ Jubbonti (denosumab-bbdz) injection ▪ Osenvelt (denosumab-bmwo) injection ▪ Osvyrti (denosumab-desu) injection ▪ Oziltus (denosumab-mobz) injection ▪ Prolia (denosumab) injection ▪ Stoboclo (denosumab-bmwo) injection ▪ Wyost (denosumab-bbdz) injection ▪ Xgeva (denosumab) injection ▪ Xtrenbo (denosumab-qbde) injection

PA CRITERIA FOR APPROVAL:**Aukelso, Bilprevda, Bomvntra, Jubereq, Osenvelt, Oziltus, Xgeva, Xtrenbo, Wyost****New Therapy**

1. The member has a diagnosis for a Food and Drug (FDA)-approved indication (refer to package insert under References), a National Comprehensive Cancer Network (NCCN)-supported indication **OR** a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication **AND**
2. The medication was prescribed by an oncologist or hematologist/oncologist **AND**
3. Hypocalcemia is absent or the member is being treated with calcium and vitamin D as necessary **AND**
4. **For diagnosis of hypercalcemia of malignancy: ALL** of the following are met (**a–b**):
 - a. The member has an albumin-corrected calcium of >12.5 mg/dL (3.1 mmol/L)
 - b. The member has a history of failure, contraindication or reasons for intolerance to IV bisphosphonate therapy (e.g., pamidronate or zoledronic acid)

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References), an NCCN-supported indication **OR** a compendia-supported (Drugdex or AHFS) indication **AND**

Denosumab

HCPCS: J0897 Injection, denosumab, 1 mg (Prolia, Xgeva), Q5136 Injection, denosumab-bbdz, biosimilar 1 mg (Jubbonti, Wyost), Q5157 Injection, denosumab-bmwo, biosimilar, 1 mg (Stoboclo/Osenvelt), Q5158 Injection, denosumab-bnht, biosimilar, 1 mg (Bomynta/Conexence), Q5161 Injection, denosumab-kyqq biosimilar, 1 mg (Aukelso/Bosaya), Q5162 Injection, denosumab-nxxp biosimilar, 1 mg (Bildyos/Bilprevda), Q5171 Injection, denosumab-mobz, biosimilar, 1 mg (Boncresa), Q5167 Injection, denosumab-qbde, biosimilar, 1 mg (Enoby/Xtrenbo), Q5166 Injection, denosumab-desu, biosimilar, 1 mg (Osvyrti/Jubereq), Q5165 Injection, denosumab-mobz, biosimilar, 1 mg (Oziltus)

2. The medication was prescribed by an oncologist or hematologist/oncologist

Bildyos, Boncresa, Bosaya, Conexence, Enoby, Jubbonti, Osvyrti, Prolia, Stoboclo

New Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References), a compendia-supported (Drugdex or AHFS) indication **OR ONE** of the following off-label diagnoses (**a–b**):
 - a. Postmenopausal osteoporosis prevention (bone mineral density [BMD] T-score of -1 to -2.4)
 - b. Osteoporosis prevention in men aged 50 years and older**AND**
2. The member meets ALL of the following (**a–b**):
 - a. Hypocalcemia is absent **OR** the member is being treated with calcium and vitamin D as necessary
 - b. Member is not pregnant**AND**
3. **For treatment/prevention of bone mass loss in postmenopausal women and men and glucocorticoid-induced osteoporosis: ALL** of the following are met (**a–c**):
 - a. The member has a history of failure to **ONE** bisphosphonate (such as alendronate, risedronate, ibandronate, zoledronic acid). If no trial of oral bisphosphonate due to contraindication/anticipated intolerance, medical justification is required explaining why zoledronic acid cannot be used**AND**
 - b. The member is at high risk of fracture, defined as **ONE** of the following (**1, 2 or 3**):
 - 1) A history of osteoporotic fractures
 - 2) T-score at the lumbar spine, total hip or femoral neck of ≤ -2.5 as evidenced via bone density scan
 - 3) T-score at the lumbar spine, total hip or femoral neck between -1 and -2.4 as evidenced via bone density scan **AND** one of the following (**Note:** Use the [FRAX calculation tool](#) to calculate FRAX 10-year probability if score is not provided):
 - a) FRAX 10-year fracture probabilities: major osteoporotic fracture at $\geq 20\%$
 - b) FRAX 10-year fracture probabilities: hip fracture at $\geq 3\%$**AND**
 - c. **For glucocorticoid-induced osteoporosis:** The member is on prednisone ≥ 7.5 mg/day (or equivalent) and plans to continue therapy for at least six months**OR**
4. **For diagnosis of prevention of bone mass loss in female with breast cancer or male with prostate cancer:**
 - a. The medication is prescribed or recommended by an oncologist or hematologist/oncologist **AND**
 - b. For prostate cancer, member is receiving androgen deprivation therapy (such as leuprolide, bicalutamide, etc.)**OR**
 - c. For breast cancer, member is receiving adjuvant aromatase inhibitor therapy (such as anastrozole, exemestane)

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or AHFS) indication **AND**
2. The member meets **ALL** of the following (**a–b**):
 - a. Hypocalcemia is absent **OR** the member is being treated with calcium and vitamin D as necessary
 - b. Member is not pregnant

Denosumab

HCPCS: J0897 Injection, denosumab, 1 mg (Prolia, Xgeva), Q5136 Injection, denosumab-bbdz, biosimilar 1 mg (Jubbonti, Wyost), Q5157 Injection, denosumab-bmwo, biosimilar, 1 mg (Stoboclo/Osenvelt), Q5158 Injection, denosumab-bnht, biosimilar, 1 mg (Bomyntra/Conexxence), Q5161 Injection, denosumab-kyqq biosimilar, 1 mg (Aukelso/Bosaya), Q5162 Injection, denosumab-nxxp biosimilar, 1 mg (Bildyos/Bilprevda), Q5171 Injection, denosumab-mobz, biosimilar, 1 mg (Boncresa), Q5167 Injection, denosumab-qbde, biosimilar, 1 mg (Enoby/Xtrenbo), Q5166 Injection, denosumab-desu, biosimilar, 1 mg (Osvyrti/Jubereq), Q5165 Injection, denosumab-mobz, biosimilar, 1 mg (Oziltus)

OTHER INFORMATION

HCPCS	Description	Brand name
J0897	Injection, denosumab, 1 mg	Xgeva, Prolia
Q5136	Injection, denosumab-bbdz, biosimilar 1mg	Jubbonti, Wyost
Q5157	Injection, denosumab-bmwo (Stoboclo/Osenvelt), biosimilar, 1 mg	Stoboclo, Osenvelt
Q5158	Injection, denosumab-bnht (Bomyntra/Conexxence), biosimilar, 1 mg	Bomyntra, Conexxence
Q5161	Injection, denosumab-kyqq (Aukelso/Bosaya), biosimilar, 1 mg	Aukelso, Bosaya
Q5162	Injection, denosumab-nxxp (Bildyos/Bilprevda), biosimilar, 1 mg	Bildyos, Bilprevda
Q5159	Injection, denosumab-dssb (ospomyv/xbryk), biosimilar, 1 mg	Ospomyv
Q5165	Injection, denosumab-mobz (oziltus), biosimilar, 1 mg	Oziltus
Q5166	Injection, denosumab-desu (osvyrti/jubereq), biosimilar, 1 mg	Osvyrti, Jubereq
Q5167	Injection, denosumab-qbde (enoby/xtrenbo), biosimilar, 1 mg	Enoby, Xtrenbo
Q5171	Injection, denosumab-mobz (boncresa), biosimilar, 1 mg	Boncresa

REFERENCES:

1. Prolia Prescribing Information. www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Prolia/prolia_pi.pdf. 05/2025.
2. Xgeva Prescribing Information. www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Xgeva/xgeva_pi.pdf. 05/2025.
3. Jubbonti Prescribing Information. www.accessdata.fda.gov/drugsatfda_docs/label/2024/761362s000lbl.pdf. 03/2024.
4. Wyost Prescribing Information. pro-wyost-com.cms.sandoz.com/sites/default/files/2024-03/Wyost%20PI%203.2024.pdf. 03/2024.
5. Bomyntra Prescribing Information. biosimilars.fresenius-kabi.com/portfolio/products/bomyntra/full-prescribing-information. 10/2025.
6. Conexxence Prescribing Information. biosimilars.fresenius-kabi.com/portfolio/products/conexxence/full-prescribing-information. 10/2025.
7. Osenvelt Prescribing Information. www.accessdata.fda.gov/drugsatfda_docs/label/2025/761404s000Orig2lbl.pdf. 02/2025.
8. Stoboclo Prescribing Information. www.stoboclo.com/wp-content/uploads/2025/05/stoboclo-prescribing-information.pdf. 10/2025.
9. Aukelso Prescribing Information. www.dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=547cb095-f7f5-f933-75ce-5e6abf2ad5bc&type=display. 09/2025.
10. Bildyos Prescribing Information. www.organon.com/product/usa/pi_circulars/b/bildyos/bildyos_pi.pdf. 08/2025.
11. Bilprevda Prescribing Information. www.organon.com/product/usa/pi_circulars/b/bilprevda/bilprevda_pi.pdf. 08/2025.
12. Bosaya Prescribing Information. www.dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1e5e8c88-3c65-3076-e44b-02d92c2d343d&type=display. 09/2025.
13. Boncresa Prescribing Information. www.accessdata.fda.gov/drugsatfda_docs/label/2025/761456s000lbl.pdf. 12/2025.
14. Oziltus Prescribing Information. www.accessdata.fda.gov/drugsatfda_docs/label/2025/761457s000lbl.pdf. 12/2025.

Denosumab

HCPCS: J0897 Injection, denosumab, 1 mg (Prolia, Xgeva), Q5136 Injection, denosumab-bbdz, biosimilar 1 mg (Jubbonti, Wyost), Q5157 Injection, denosumab-bmwo, biosimilar, 1 mg (Stoboclo/Osenvelt), Q5158 Injection, denosumab-bnht, biosimilar, 1 mg (Bomynta/Conexence), Q5161 Injection, denosumab-kyqq biosimilar, 1 mg (Aukelso/Bosaya), Q5162 Injection, denosumab-nxxp biosimilar, 1 mg (Bildyos/Bilprevda), Q5171 Injection, denosumab-mobz, biosimilar, 1 mg (Boncresa), Q5167 Injection, denosumab-qbde, biosimilar, 1 mg (Enoby/Xtrenbo), Q5166 Injection, denosumab-desu, biosimilar, 1 mg (Osvyrti/Jubereq), Q5165 Injection, denosumab-mobz, biosimilar, 1 mg (Oziltus)

15. Osvyrti Prescribing Information. www.accordbiopharma.com/our-therapies/osvyrti/osvyrti_pi.pdf. 10/2025.
16. Jubereq Prescribing Information. www.accordbiopharma.com/our-therapies/jubereq/jubereq_pi.pdf. 10/2025.
17. Enoby Prescribing Information. enobyinfo.com/wp-content/uploads/2026/01/ENOBYPi.pdf. 09/2025.
18. Xtrenbo Prescribing Information. dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a48a3a33-6b0e-4cf4-8786-8f662d6ee77b. 09/2025.
19. LeBoff MS, Greenspan SL, Insogna KL, et al. The Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis International. 2022; 33: 2049-2102. www.ncbi.nlm.nih.gov/pmc/articles/PMC9546973/
20. American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE): Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis- 2020 Update. [pro.aace.com/sites/default/files/2020-05/Vol%2026%20Supplement%201%20\(May%202020\)%20GL-2019-0524_0.pdf](http://pro.aace.com/sites/default/files/2020-05/Vol%2026%20Supplement%201%20(May%202020)%20GL-2019-0524_0.pdf)
21. Fuleihan GE, Clines GA, Hu, MI, et al. Treatment of Hypercalcemia of Malignancy in Adults: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism, 2023; 108:507-528. academic.oup.com/jcem/article/108/3/507/6916871

P&T APPROVAL HISTORY:

1. February 2011 P&T Review
2. May 2026 P&T Review

UMC REVIEW:

4/2026