Denosumab

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

This policy informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

This program applies to the denosumab products specified in this policy. Coverage for a non-preferred product is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. For this program, Jubbonti, Wyost, Stoboclo, and Osenvelt are the preferred products. Coverage for non-preferred products, Aukelso, Bilprevda, Bildyos, Bomyntra, Bosaya, Conexxence, Enoby, Jubereq, Ospomyv, Osvyrti, Prolia, Xbryk, Xgeva, and Xtrenbo is provided based on clinical circumstances that would exclude the use of the preferred product(s) and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with the non-preferred product.

Note:
The preferred products Jubbonti, Wyost, Stoboclo, and Osenvelt do not require prior approval

Table 1. Denosumab Products (Prolia)

Medication	Generic Name
Preferred Products:	
Jubbonti	denosumab-bbdz
Stoboclo	denosumab-bmwo
Targeted/Non-Preferred Products:	

Prolia	denosumab
Conexxence	denosumab-bnht
Bildyos	denosumab-nxxp
Ospomyv	denosumab-dssb
Enoby	denosumab-qbde
Bosaya	denosumab-kyqq
Osvyrti	denosumab-desu

Table 2. Denosumab Products (Xgeva)

Medication	Generic Name
Preferred Products:	
Wyost	denosumab-bbdz
Osenvelt	denosumab-bmwo
Targeted/Non-Preferred Products:	
Xgeva	denosumab
Bomyntra	denosumab-bnht
Bilprevda	denosumab-nxxp
Xbryk	denosumab-dssb
Aukelso	denosumab-kyqq
Jubereq	denosumab-desu
Xtrenbo	denosumab-qbde

Policy

*The preferred products Jubbonti, Wyost, Stoboclo, and Osenvelt are considered medically necessary and **do not require prior authorization.**

EXCEPTION CRITERIA

Coverage for a non-preferred product is provided when the following criteria is met:

- The member has had a documented intolerable adverse event to the corresponding preferred biosimilar products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0897 – Inj. denosumab, 1 mg
- Q5136 - Inj. denosumab-bbdz (Jubbonti, Wyost), 1 mg
- Q5157 – Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg
- Q5158 – Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg
- Q5161 – Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg (effective 4/1/26)
- Q5162 – Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg (effective 4/1/26)
- Q5165 – Injection, denosumab-mobz (ozlitus), biosimilar, 1 mg (effective 7/1/2026)
- Q5166 – Injection, desoumab-desu (osvyrti/jubereq), biosimilar, 1 mg (effective 7/1/2026)
- Q5167 – Injection, denosumab-qdbe (enoby/xtrenbo), biosimilar, 1 mg (effective 7/1/2026)
- Q5171 – Injection, denosumab-mobz (boncresa), biosimilar, 1 mg (effective 7/1/2026)
- J3490 Unclassified drugs
- J3590 Unclassified biologics
- C9399 Unclassified drugs or biologicals

REFERENCES

- Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2025
- Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2025
- Jubbonti [package insert]. Princeton, NJ: Sandoz Inc.; October 2024
- Wyost [package insert]. Princeton, NJ: Sandoz Inc.; April 2024
- Stoboclo [package insert]. Jersey City, NJ: Celltrion USA Inc.; February 2025
- Osenvelt [package insert]. Jersey City, NJ: Celltrion USA Inc.; February 2025
- Conexxence [package insert]. Lake Zurich, IL: Fresenius Kabi USA LLC.; March 2025
- Bomyntra [package insert]. Lake Zurich, IL: Fresenius Kabi USA LLC.; March 2025
- Bildyos [package insert]. Jersey City, NJ: Organon & Co.; August 2025
- Bilprevda [package insert]. Jersey City, NJ: Organon & Co.; August 2025
- Aukelso [package insert]. Cambridge, MA: Biocon Biologics Inc.; September 2025
- Bosaya [package insert]. Cambridge, MA: Biocon Biologics Inc.; September 2025
- Enoby [package insert]. Cherry Hill, NJ: Hikma Pharmaceuticals USA Inc.; September 2025
- Xtrenbo [package insert]. Cherry Hill, NJ: Hikma Pharmaceuticals USA Inc.; September 2025

- Osvyrti [package insert]. Raleigh, NC: Accord BioPharma Inc.; October 2025
- Jubereq [package insert]. Raleigh, NC: Accord BioPharma Inc.; October 2025
- Ospomyv [package insert]. Incheon, ROK: Samsung Bioepis Co., Ltd.; October 2025
- Xbryk [package insert]. Incheon, ROK: Samsung Bioepis Co., Ltd.; October 2025

POLICY HISTORY

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