



## MED RX POLICY

- POLICY:** Bone Modifiers – Denosumab Products (Prolia) Med Rx Policy
- Bildyos® (denosumab-nxxp subcutaneous injection – Organon)
  - Conexence® (denosumab-bnht subcutaneous injection – Fresenius Kabi)
  - Enoby™ (denosumab-qbde subcutaneous injection – Hikma)
  - Jubbonti® (denosumab-bbdz subcutaneous injection – Sandoz)
  - Prolia® (denosumab subcutaneous injection – Amgen)
  - Stoboclo® (denosumab-bmwo subcutaneous injection – Celltrion)

**REVIEW DATE:** 09/03/2025; selected revision 10/15/2025, 01/21/2026 and 02/11/2026

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### OVERVIEW

Denosumab products (Prolia, biosimilars) are indicated for the following uses:<sup>1-6</sup>

- **Bone loss (treatment to increase bone mass), in men with nonmetastatic prostate cancer** at high risk for fracture receiving androgen deprivation therapy.
- **Bone loss (treatment to increase bone mass), in women with breast cancer** at high risk for fracture receiving adjuvant aromatase inhibitor therapy.
- **Glucocorticoid-induced osteoporosis (treatment)**, 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.
- **Osteoporosis, treatment of postmenopausal women** at high risk of fracture.
- **Osteoporosis, treatment to increase bone mass in men** at high risk for fracture.

Bildyos, Conexence, Enoby, Jubbonti, and Stoboclo were approved as biosimilars to Prolia, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Prolia. However, minor differences in clinically inactive components are allowed.

### POLICY STATEMENT

This Med Rx program has been developed to encourage the use of Preferred Products. For all Non-Preferred Products, the patient is required to meet the standard *Bone Modifiers – Denosumab Products (Prolia) Utilization Management Medical Policy* criteria. The program also directs the patient to try at least two Preferred Products prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted in the standard *Bone Modifiers – Denosumab Products (Prolia) Utilization Management Medical Policy*.

**Automation:** None

**Preferred Products:** Jubbonti, Prolia, Stoboclo  
**Non-Preferred Products:** Bildyos, Conexence, Enoby

**RECOMMENDED EXCEPTION CRITERIA**

Non-Preferred Products	Exception Criteria
Bildyos, Conexence, Enoby,	<p><b>1.</b> Approve if the patient meets ALL of the following (A, B <u>and</u> C):</p> <p><b>A)</b> Patient meets the standard <i>Bone Modifiers – Denosumab Products (Prolia) Utilization Management Medical Policy</i> criteria; AND</p> <p><b>B)</b> Patient has tried at least TWO of the following: Jubbonti, Prolia, Stoboclo; AND</p> <p><b>C)</b> Patient cannot continue to use the Preferred products due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction.</p>

**REFERENCES**

1. Prolia® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; May 2025.
2. Conexence® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; March 2025.
3. Jubbonti® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; October 2024.
4. Stoboclo® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; February 2025.
5. Bildyos® subcutaneous injection [prescribing information]. Jersey City, NJ: Organon; September 2025.
6. Enoby™ subcutaneous injection [prescribing information]. Cherry Hill, NJ: Hikma, September 2025.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 01/01/2026.	09/03/2025
Selected Revision	<p><b>Effective 01/01/2026.</b></p> <p>Bildyos was added to the policy as a Non-Preferred product. The same exception criteria apply as the other Non-Preferred products.</p>	10/15/2025
Selected Revision	<p>Enoby was added to the policy as a Non-Preferred product. The same exception criteria apply as the other Non-Preferred products.</p> <p><b>Effective 07/01/2026.</b></p> <p>Bildyos and Conexence were moved to Preferred. Prolia and Stoboclo were moved to Non-Preferred. The exception criteria were updated to reflect the new Preferreds.</p>	01/21/2026
Selected Revision	<p>Prolia and Stoboclo were moved to Preferred. Bildyos and Conexence were moved to Non-Preferred. The exception criteria were updated to reflect the new Preferreds.</p>	02/11/2026