| Reference number(s) |
|---|
| 6928-D |

**This document applies to the following:**

| Product | Applies |
|---|---|
| Medicare Part B | ☐ |
| Medicare Part B: Advanced Biosimilars First | ☑ |

# Medicare Part B Step Therapy Osteoporosis-Bone Density

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

These criteria were developed to align with the following: Medicare Part B: Advanced Biosimilars First.

## Plan Design Summary

This program applies to the osteoporosis products specified in this document. Coverage for the non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred products 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 products.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

### Table. Osteoporosis Products

Medications considered preferred on your plan may still require a clinical prior authorization review.

| | **Product(s)** |
|---|---|
| Preferred | • Jubbonti (denosumab-bbdz)<br>• zoledronic acid |
| Non-preferred | • Evenity (romosozumab-aqqg)<br>• Prolia (denosumab) |

| Reference number(s) |
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| 6928-D |

# Step Therapy Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

## Evenity

Coverage for Evenity is provided when any of the following criteria are met:

- Member has received treatment with the non-preferred product in the past 365 days.
- Member meets both of the following criteria:
    - Member has had a documented inadequate response, intolerable adverse event, contraindication, or clinical reason to avoid Jubbonti.
    - Member has had a documented inadequate response, intolerable adverse event, or contraindication to zoledronic acid (e.g., creatinine clearance less than 35 mL/min).

## Prolia

Coverage for Prolia is provided when any of the following criteria are met:

- Member has received treatment with the non-preferred product in the past 365 days.
- Member has both of the following:
    - Member has had a documented intolerable adverse event to the preferred 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 product).
    - Member has had a documented inadequate response, intolerable adverse event, or a contraindication to zoledronic acid (e.g., creatinine clearance less than 35 mL/min).

# References


1. Evenity [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. Jubbonti [package insert]. Princeton, NJ: Sandoz Inc.; October 2024.
3. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2024.
4. Zoledronic acid [package insert]. Princeton, NJ: Fosun Pharma USA Inc.; February 2023.