

Reference number(s)
5826-D

This document applies to the following:

Product	Applies
Medicare Part B	<input checked="" type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input type="checkbox"/>

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.

Plan Design Summary

This program applies to the osteoporosis products specified in this document. Coverage for the 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. 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.

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	<ul style="list-style-type: none"> Jubbonti (denosumab-bbdz) Prolia (denosumab) zoledronic acid
Non-preferred	<ul style="list-style-type: none"> Evenity (romosozumab-aqqg)

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Step Therapy Criteria

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

Coverage for the non-preferred product is provided when the member meets one of the following criteria:

- 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 or Prolia.
 - Member has had a documented inadequate response, intolerable adverse event, or 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.