Reference number(s)
3792-D

This document applies to the following:

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

Medicare Part B Step Therapy Osteoporosis–Hypercalcemia of Malignancy

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 product 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 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–Hypercalcemia of Malignancy

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

	Product(s)
Preferred	• pamidronate • Wyost (denosumab-bbdz) • zoledronic acid
Non-preferred	• Xgeva (denosumab)

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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 either 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 meets either of the following criteria:
        - Member has a documented inadequate response to pamidronate or zoledronic acid.
        - Member has had a documented intolerable adverse event or contraindication to therapy with both pamidronate and zoledronic acid (i.e., severe renal impairment [creatinine clearance less than 35 mL/min]).
    - Member has had a documented intolerable adverse event to Wyost, 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).

References

1. Pamidronate [package insert]. Morgantown, WV: Mylan Institutional LLC; July 2022.
2. Wyost [package insert]. Princeton, NJ: Sandoz Inc.; March 2024.
3. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
4. Zoledronic acid [package insert]. Raleigh, NC: Accord Healthcare, Inc.; September 2023.