

# EXCEPTIONS CRITERIA

## BONE METASTASES

### PREFERRED PRODUCTS: PAMIDRONATE AND ZOLEDRONIC ACID

#### POLICY

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

#### I. PLAN DESIGN SUMMARY

This program applies to the bone metastases products specified in this policy. Coverage for targeted products 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 members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Bone Metastases Products

	Product(s)
Preferred*	<ul style="list-style-type: none"><li>• pamidronate</li><li>• zoledronic acid</li></ul>
Targeted	<ul style="list-style-type: none"><li>• Xgeva (denosumab)</li></ul>

\*Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

#### II. EXCEPTION CRITERIA

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

Coverage for a targeted product is provided when any of the following criteria are met:

- A. Member has received treatment with the targeted product in the past 365 days.
- B. Member has a documented inadequate response with either of the preferred products.
- C. Member has a documented intolerable adverse event or documented contraindication to therapy with both the preferred products (i.e., severe renal impairment [creatinine clearance less than 35 mL/min])

#### REFERENCES

1. Pamidronate [package insert]. Lake Forest, IL: Akorn-Strides, LLC.; November 2008.
2. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
3. Zoledronic acid [package insert]. Memphis, TN: Northstar Rx LLC; April 2019.

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