EXCEPTIONS CRITERIA OSTEOPOROSIS

PREFERRED PRODUCTS: PROLIA 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 osteoporosis products specified in this policy. Coverage for targeted 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 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. Osteoporosis Products

	Products
Preferred*	Prolia (denosumab)
	zoledronic acid
Targeted	Evenity (romosozumab-aqqg)

^{*}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.

Postmenopausal Osteoporosis

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 to both of the preferred products.
- C. Member has a documented intolerable adverse event or contraindication to both of the preferred products. (e.g., creatinine clearance less than 35 mL/min for zoledronic acid).

REFERENCES

- 1. Evenity [package insert]. Thousand Oaks, CA: Amgen, Inc.; April 2020.
- 2. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2023.
- Zoledronic acid [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; February 2017.

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