This policy applies to the following:

| Standard Control (SF) | Managed Medicaid Template (MMT) | ACSF Chart (ACSFC) | Medical Benefit | ✓ | Medicare Part B |
|---|------------------------------------|------------------------|--|----------|---|
| Standard Control – Choice (SCCF) | Marketplace (MF) | SF Chart (SFC) | Medical: Advanced Biosimilars First | ~ | Medicare Part B: Advanced Biosimilars First |
| Preferred Drug Plan Design (PDPD) | Aetna Health Exchange (AHE) | VF Chart (VFC) | Medical Benefit: Managed Medicaid | | |
| Advanced Control Specialty (ACSF) | IVL | New to Market (NTM) | Medical Benefit: Add-on | | |
| Advanced Control Specialty – Choice (ACSCF) | Value (VF) | | | | |

| Reference # |
|-------------|
| 5826-D |
| |

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 the targeted 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 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.

Osteoporosis

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This policy applies to the following:

| is policy applies to the | Tollowing. | | | | |
|---|------------------------------------|-----------------------|--|----------|---|
| Standard Control (SF) | Managed Medicaid Template (MMT) | ACSF Chart (ACSFC) | Medical Benefit | > | Medicare Part B |
| Standard Control – Choice (SCCF) | Marketplace (MF) | SF Chart (SFC) | Medical: Advanced Biosimilars First | ✓ | Medicare Part B: Advanced Biosimilars First |
| Preferred Drug Plan Design (PDPD) | Aetna Health Exchange (AHE) | VF Chart (VFC) | Medical Benefit: Managed Medicaid | | |
| Advanced Control Specialty (ACSF) | IVL | New to Market (NTM) | Medical Benefit: Add-on | | |
| Advanced Control Specialty – Choice (ACSCF) | Value (VF) | | | | |

| Reference # |
|-------------|
| 5826-D |
| |

- 2. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2024.
- 3. Zoledronic acid [package insert]. Princeton, NJ: Fosun Pharma USA, Inc.; June 2023.

Osteoporosis

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