Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 1, 2026

Bildyos® (denosumab-nxxp)/Conexxence® (denosumab-bnht)/Jubbonti® (denosumab-bbdz)/Prolia® (denosumab)/Stoboclo (denosumab-bmwo) Injections

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:
INITIATION OF THERAPY:

- Product must be considered in accordance with the FDA approved recommendations for patient age.

For the treatment of men and postmenopausal women with osteoporosis at high risk for fracture:

- Prescribed by or in consultation with a specialist (endocrinologist, rheumatologist, or obstetrician/gynecologist) **-AND-**
- The patient is taking calcium and vitamin D (Must be confirmed in medical records or pharmacy claims) **-AND-**
- Documented diagnosis of osteoporosis with a DXA hip (femoral neck), spine T-score, ≤ -2.5 (dated within the past 2 years). ***(Must be confirmed in medical records.)***
    - **No Reclast trial required**

    -OR-
- Documented diagnosis of osteoporosis of the 1/3 radius (distal radius) if the patient has primary hyperparathyroidism, or if the femoral neck or spine are not evaluable. ***(Must be confirmed in medical records.)***
    - **No Reclast trial required**

    -OR-
- History of a fracture of the spine or hip. ***(Must be confirmed in medical records.)***
    - **No Reclast trial required**

    -OR-
- Trial (minimum of one year) and failure of the bisphosphonate zoledronate (documentation required).
    - **NOTE: If the patient is unable to swallow oral bisphosphonates or unable to maintain an upright position after taking an oral bisphosphonate a trial of IV Reclast is still required.**
    - Failure may be defined as intolerance (adverse reaction, contraindication . . .) to other bisphosphonates or no increase from baseline bone mineral density (BMD) (as indicated by the T-score history) or recurring fractures (in the absence of major trauma) following at least one year of therapy.
    - If patient has adverse reaction to other bisphosphonates, a one-year trial is not required.

    -AND-
- History of T-score between -1.0 and -2.5 if FRAX (WHO fracture Risk Assessment Tool) major osteoporotic fracture probability is ≥ 20% or hip fracture probability is 3%. ***(Must be confirmed in medical records.)***

For the treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer; treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture:

- Verify diagnosis through progress notes

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CONTINUATION OF THERAPY:

- The patient is taking calcium and vitamin D (Must be confirmed in medical records or pharmacy claims)
  -AND-
- Medical records must demonstrate a stable BMD (within interventional goals) or an increasing BMD after a minimum trial of one year of therapy.
  - T-score test results may date back as far as five years.
  - Depending on level of BMD progression retesting may be done from every one to five years.
  - Medical records should demonstrate improvement by providing reference to the sequential progression or stability of the BMD.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/

Note: Bildyos®, Conexxence®, Jubbonti®, and Stoboclo® are biosimilars for Prolia.