curative

TITLE:	OSTEOPOROSIS POLICY
POLICY #:	MM-PNP-027
VERSION #:	01
DEPARTMENT:	UTILIZATION REVIEW
ORIGINAL EFFECTIVE DATE:	12/01/2023
CURRENT REVISION DATE:	N/A

1. PURPOSE

Brand Selection for Medically Necessary Indications

Note: Curative requires a trial/failure of ONE of the following: (oral biophosphonate where indicated. See below in Section 5).

Step therapy failure must be provided along with required clinical documentation.

Health care services are not medically necessary when they are more costly than alternative services that are at least as likely to produce equivalent therapeutic or diagnostic results. Fosamax, Actonel, Boniva, or Reclast are more costly to Curative than other targeted immune modulators for certain indications. There is a lack of reliable evidence that Fosamax, Actonel, Boniva, or Reclast are superior to the lower cost Prolia.

Preferred Drug:

- Prolia

All other drugs are considered non-preferred

2. SCOPE

Medical and UM Departments

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Prior Authorization

Commercial plans: Prior Authorization of Prolia is required of all Curative participating providers and members in applicable plan designs.

Prolia

Criteria for Initial Approval

Osteoporosis: One of the following must be met

- The patient's sex is male and the patient is over 50 years of age
- The patient is postmenopausal

- The prescriber has provided information that the requested agent is medically appropriate for the patient's sex

  AND

- The patient's diagnosis was confirmed by ONE of the following:
  - A fragility fracture in the hip or spine
  - A T-score of -2.5 or lower
  - A T-score of -1.0 to -2.5 and ONE of the following:
- a FRAX 10-year probability for major osteoporotic fracture of ≥20%

  OR

- a FRAX 10-year probability of hip fracture of ≥3%

  AND

  - ONE of the following:
    - The patient is at a very high fracture risk as defined by ONE of the following:
      - Patient had a recent fracture (within the past 12 months)
      - Patient had fractures while on approved osteoporosis therapy
      - Patient has had multiple fractures
      - Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)
      - Patient has a very low T-score (less than -3.0)
      - Patient is at high risk for falls or has a history of injurious falls
      - Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) or by other validated fracture risk algorithm

        OR

  - ONE of the following:
    - The patient has tried and had an inadequate response to a bisphosphonate (medical records required)
    - The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)
    - The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

Osteopenia: ALL of the following:

  - ONE of the following:
    - The patient's sex is male and the patient is over 50 years of age
    - The patient is postmenopausal

- The patient is age 50 years of age or over and the prescriber has provided information that the requested agent is medically appropriate for the patient's sex

AND

- The patient has osteopenia, defined as a T-score between -1.0 to -2.5

AND

- ONE of the following:
  - 10-year probability of a hip fracture ≥ 3% per FRAX
  - 10-year probability of a major osteoporosis-related fracture ≥ 20% per FRAX

AND

- ONE of the following:
  - The patient has tried and had an inadequate response to a bisphosphonate (medical records required)
  - The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)
  - The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

Breast Cancer: BOTH of the following:

The patient is currently receiving aromatase inhibitor therapy

- ONE of the following:
  - The patient has tried and had an inadequate response to a bisphosphonate (medical records required)
  - The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)
  - The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

Nonmetastatic prostate cancer: BOTH of the following:

The patient is currently receiving androgen deprivation therapy (ADT)

AND

- ONE of the following:
  - The patient has tried and had an inadequate response to a bisphosphonate (medical records required)
  - The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)
  - The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

Glucocorticoid-induced osteoporosis: ALL of the following:

- The patient is either initiating or currently taking glucocorticoids in a daily dosage equivalent to 7.5 mg or higher of prednisone
- The patient's expected current course of therapy of glucocorticoids is for a period of at least 6 months
- The patient's diagnosis was confirmed by ONE of the following:
  - A fragility fracture in the hip or spine

OR

  - A T-score of -2.5 or lower

OR

  - A T-score of -1.0 to -2.5 and ONE of the following:
  - a FRAX 10-year probability for major osteoporotic fracture of ≥20%

OR

  - A FRAX 10-year probability of hip fracture of ≥3%

AND

The patient is at a very high fracture risk as defined by ONE of the following:

- Patients had a recent fracture (within the past 12 months)

OR

- Patient had fractures while on approved osteoporosis therapy

OR

- Patient has had multiple fractures

OR

- Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)

OR

- Patient has a very low T-score (less than -3.0)

OR

- Patient is at high risk for falls or has a history of injurious falls

OR

- Patient has a very high fracture probability by FRAX (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) or by other validated fracture risk algorithm

OR

- ONE of the following:
  - The patient has tried and had an inadequate response to a bisphosphonate (medical records required)

OR

- The patient has an intolerance or hypersensitivity to a bisphosphonate (medical records required)

OR

- The patient has an FDA labeled contraindication to ALL bisphosphonates (medical records required)

AND

- The patient will NOT be using the requested agent in combination with a bisphosphonate, SERM, Evenity (romosozumab-aqqg), Xgeva (denosumab), or parathyroid hormone analog (i.e., abaloparatide, teriparatide)

AND

- The patient does not have any FDA labeled contraindications to the requested agent

AND

ONE of the following:

- The requested quantity (dose) is less than or equal to the program quantity limit

Length of approval: 12 months

Curative considers all other indications as experimental and investigational (for additional information, see Experimental and Investigational and Background sections).

Continuation of Therapy

Curative considers continuation of denosumab (Prolia) therapy medically necessary for all members (including new members) who are currently receiving the requested medication through a previously authorized pharmacy or medical benefit, who meet *one* of the following:

- Member has received less than 24 months of therapy and has not experienced clinically significant adverse events during therapy; *or*
- Member has received 24 months of therapy or more and meets *both* of the following:
  - Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement); and
  - Member has not experienced any adverse effects.

Curative considers all other indications as experimental and investigational (for additional information, see Experimental and Investigational and Background sections).

Experimental and Investigational

Curative considers combination therapy of denosumab and intravenous bisphosphonates experimental and investigational because the effectiveness of this approach has not been established.

Curative considers denosumab (Prolia and Xgeva) contraindicated and considered experimental and investigational for members with uncorrected preexisting hypocalcemia, because the safety and effectiveness of denosumab for hypocalcemic persons has not been established.

Curative considers combined denosumab and chemotherapy experimental and investigational for the treatment of non-small-cell lung carcinoma, and osteosarcoma.

Curative considers denosumab (Prolia and Xgeva) experimental and investigational for the following indications (not an all-inclusive list) because of insufficient evidence of its effectiveness:

- Bone loss associated with hormone-ablation therapy (other than aromatase inhibitors) in breast cancer
- Cancer pain
- Central giant cell granuloma
- Hyper-parathyroidism
- Immobilization hypercalcemia
- Osteogenesis imperfecta
- Osteopenia (other than due to systemic mastocytosis)
- Paget's disease of bone
- Primary bone sarcomas (e.g., Ewing's sarcoma and osteosarcoma)
- Rheumatoid arthritis
- Treatment of aneurysmal bone cyst.
    - Treatment of first metatarsophalangeal osteoarthritis (hallux rigidus).

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

- All Curative Medical and Pharmacy UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

- Medical and Pharmacy UM Departments

12. DOCUMENT CONTROL

APPROVED BY:		
(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A: