group health Cooperative of eau claire **KMTSJ, Inc.**	DEPARTMENT:	Utilization Management
	SUBJECT:	Osteoporosis Treatments
	PRODUCT LINE:	All
	POLICY NUMBER:	UM121
	ORIGINAL POLICY EFFECTIVE DATE:	12/11/2017
	LAST REVISED DATE:	07/08/2020
	LAST REVIEWED DATE:	07/12/2023

SCOPE: To ensure Group Health Cooperative of Eau Claire (the Cooperative) consistently and correctly administers benefits to all members according policy benefits and medical necessity criteria.

POLICY: It is the policy of the Cooperative to review prior authorization requests for IV bisphosphonates.

PROCEDURE: Prior Authorization Required: YES

Medication Indications:

Medications Used for Treatment of Osteoporosis include:

- Bisphosphonates
  Oral Meds (Fosamax, Actonel, Boniva)
  IV Meds (Reclast)
- Monoclonal antibodies
  SQ Meds (Prolia)
- Recombinant parathyroid hormone (PTH)
  SQ Meds (Forteo)

Reclast (Zoledronic acid) is indicated for the treatment of:

- Paget's disease when the serum alkaline phosphatase is at least two times higher than the upper limit of normal, or the patient is symptomatic, or the patient is at risk for complications from the disease
- Post-Menopausal osteoporosis
- Osteoporosis in men
- Glucocorticoid - induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months
- Osteogenesis imperfecta in persons who have failed or are intolerant of pamidronate

Prolia (denosumab)

- Osteoporosis
- Cancer (refer to NCCN guidelines for coverage criteria)

Forteo (teriparatide)

- Osteoporosis

The following drugs are not used for treatment of post-menopausal osteoporosis. If used for a cancer related diagnoses, then refer to the NCCN guidelines for coverage criteria.

Zometa (zoledronic acid) is indicated for the treatment of:

- Acute hypercalcemia of malignancy

- Multiple myeloma
- Bone metastases
- Osteogenesis imperfecta in persons who have failed or are intolerant of pamidronate
- Drug-induced osteopenia, secondary to androgen-deprivation therapy in prostate cancer patients
- Cancer treatment-induced bone loss in breast cancer

Xgeva (denosumab)

- Multiple myeloma
- Bone metastases from a solid tumor
- Giant cell tumor of bone
- Hypercalcemia of malignancy - for the treatment of hypercalcemia of malignancy that is refractory to intravenous (IV) bisphosphonate therapy

Coverage Criteria for Initial Requests:

If the request is for a cancer related condition, please refer to the NCCN guidelines for coverage criteria.

Zoledronic acid and denosumab are considered medically necessary to treat osteoporosis when the following criteria have been met:

1. Must have a diagnosis of osteoporosis as defined by a BMD T score of 2.5 or more standard deviations below the mean value (T score less than -2.5), **AND**
2. Failed an adequate trial of two oral bisphosphonates (An adequate trial is considered one year of therapy including adequate calcium and vit D supplementation.)
   a. Alendronate (Fosamax) PO QD or Q WK $70/month
   b. Ibandronate (Boniva) PO QD or Q MON $153/month
   c. Risedronate (Actonel) PO QD, Q WK, or Q MON $199/month

Cost comparisons for other osteoporosis treatments:

Zoledronic acid (Reclast) 5mg IV Q YR		CAH: $2,500/dose EAPG $850/dose NonCAH: $850/dose EAPG $150/dose
Teriparatide (Forteo)	SQ QD (can be self-administered)	$1,545/month
Prolia (denosumab)	SQ Q 6 MON (cannot be self-administered)	CAH: $2,300-4,455/dose EAPG $1,700/dose NonCAH: $2,500/dose

EAPG $280/dose
Home Infusion: $1,574/dose

Cost comparisons for cancer treatments

Xgeva (denosumab) 120mg SQ Q 12 weeks (see above)

Coverage Criteria for Continuation of Therapy
Continuation of denosumab or zoledronic acid is considered medically necessary in members who meet all initial criteria and experience clinical benefit after a year of therapy.

Experimental/Investigational
Prolia and Xgeva are considered 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
- Hyperparathyroidism
- Immobilization hypercalcemia
- Osteogenesis imperfecta
- Osteopenia (other than due to systemic mastocytosis)
- Paget's disease of bone
- Primary bone sarcomas
- Rheumatoid arthritis.

APPROVED: _____ DATE: 07/12/2023

Formal policies and procedures require department manager review, approval and signature. Executive and/or administrative policies and procedures require CEO/General Manager review, approval and signature.

REVISION HISTORY:

Rev. Date	Revised By/Title	Summary of Revision
02/20/2019	Michele Bauer, MD, CMO	Reviewed, no changes
09/24/2019	Michele Bauer, MD, CMO	Updated required T score value
07/08/2020	Michele Bauer, MD, CMO	Updated coverage criteria
07/15/2021	Michele Bauer, MD, CMO	Updated Xgeva dosing
07/15/2022	Michele Bauer, MD, CMO	Reviewed. No updates.

07/12/2023	Michele Bauer, MD, CMO	Reviewed. No updates.