JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP055
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	Subject **Prolia**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Prolia

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I. POLICY

A. Prolia (denosumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Prolia may be approved for patients who meet the following:
1. Postmenopausal osteoporosis
   a. Documentation has been submitted showing one of the following:
      I. Patient has a history of fragility fractures
      II. Patient has a pre-treatment T-score less than or equal to -2.5, or osteopenia (i.e pretreatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability, and one of the following:
         - Patient has indicators of very high fracture risk , such as: advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3], or increased fall risk
         - Patient has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy
         - Patient has one of the following:
            - Previous oral bisphosphonate trial of at least 1-year duration
            - A clinical reason to avoid treatment with an oral bisphosphonate, evidenced by one of the following:
               - Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g. achalasia, stricture, or dysmotility Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
               - Presence of documented or potential gastrointestinal malabsorption (e.g. gastric bypass procedures, celiac disease, Crohn’s disease, infiltrative disorders, etc.)
               - Inability to stand or sit upright for at least 30 to 60 minutes
               - Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
               - Renal insufficiency (creatinine clearance <35 mL/min)
               - History of intolerance to an oral bisphosphonate

2. Osteoporosis in men
   a. Documentation has been submitted showing one of the following:
      I. Patient has a history of an osteoporotic vertebral or hip fracture
      II. Patient meets both of the following:
         - Patient has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability
         - Patient has one of the following:
            - Previous oral or injectable bisphosphonate trial of at least 1-year duration
            - A clinical reason to avoid treatment with an oral bisphosphonate, evidenced by one of the following:
               - Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g. achalasia, stricture, or dysmotility Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
               - Presence of documented or potential gastrointestinal malabsorption (e.g. gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.)
               - Inability to stand or sit upright for at least 30 to 60 minutes
               - Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
               - Renal insufficiency (creatinine clearance <35 mL/min)
               - History of intolerance to an oral bisphosphonate
3. Glucocorticoid-induced osteoporosis
   a. Documentation has been submitted showing the following:
      I. Patient is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥2.5 mg/day for ≥3 months.
      II. Patient has one of the following:
         - • Previous oral or injectable bisphosphonate trial of at least 1-year duration
            - A clinical reason to avoid treatment with an oral bisphosphonate, evidenced by one of the following:
               - Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g. achalasia, stricture, or dysmotility Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
               - Presence of documented or potential gastrointestinal malabsorption (e.g. gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.)
               - Inability to stand or sit upright for at least 30 to 60 minutes
               - Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
               - Renal insufficiency (creatinine clearance < 35 mL/min)
               - History of intolerance to an oral bisphosphonate
      III. Patient has any of the following:
         - history of a fragility fracture
         - pre-treatment T-score less than or equal to -2.5
         - osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability
4. Breast cancer

a. Documentation has been submitted showing that the patient is receiving adjuvant endocrine therapy for breast cancer.

5. Prostate cancer
   a. Documentation has been submitted showing that the patient is receiving androgen deprivation therapy for prostate cancer.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing at least one of the following:
   1. Patient has not experienced adverse effects and has seen a clinical benefit, evidenced by a bone mass measurement showing an improvement or stabilization in T-score compared with the previous bone mass measurement
   2. Patient has received less than 24 months of therapy and has not experienced adverse effects

IV. EXCLUSIONS

A. Prolia will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	JHCPCS/CPT Code
Injection, denosumab, 1 mg	J0897

VII. REFERENCES

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VIII. APPROVALS

Signature on file at JHHC

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04/20/2022	Policy Creation

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