Subject: **Denosumab (Prolia® and Xgeva®)**

Effective Date: **June 20, 2017**

Department(s): **Utilization Management**

Policy: Denosumab (Prolia and Xgeva) (**HCPCS J0897**), a monoclonal antibody that blocks nuclear factor-kappa ligand (RANKL) and inhibits osteoclast formation, is reimbursable under Plans administered by QualCare, Inc. under the circumstances enumerated in this Policy.

Objective: To assure proper and consistent reimbursement and to delineate criteria for coverage of a specific therapeutic agent.

Procedure:

A. Denosumab(Prolia) is reimbursable for any of the following circumstances:
   1. Osteoporosis(ICD-10- M80-M80.88XS,M81.0,M81.8, Z87.310) in a man or woman meeting ANY of the following:
      - Bone mineral density(BMD) score ≤ -2.5
      - History of fragility fracture(non-traumatic, occurring from a fall from standing height or less, without major trauma)
      - T-score between -1.0 and -2.5 if the FRAX® 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%

      AND documentation of ONE of the following:
      - Failure of bisphosphonate therapy

- Not a candidate for oral or intravenous bisphosphonate therapy(e.g. contradindication, including creatinine clearance < 35 ml/min)
- Intolerance to oral AND intravenous bisphosphonate therapy

2. Bone loss in non-metastatic prostate cancer when ALL of the following are met:
    - Receiving androgen deprivation therapy(surgical orchiectomy or medical with GnRH agonist or antagonist therapy)
    - High risk for fracture indicated by BMD $\leq$ -2.5, or history of non-fragility fracture, or T score between -1.0 and -2.4 with FRAX® calculated probability of osteoporotic or hip fracture of 20% and 3% respectively.

3. Bone loss in a woman receiving aromatase inhibitor therapy(exemestane, letrazole, or anastrazole) with high risk for fracture indicated by a BMD $\leq$ -1.0

Denosumab (Prolia) is not reimbursable for any other use because it it is considered experimental, investigational or unproven.

B. Denosumab (Xgeva) is reimbursable for any of the following circumstances:
    1. Prevention of skeletal-related events in an individual with bone metastases from solid tumors AND the following criteria(when applicable)-
        - If breast cancer, individual has an expected survival of 3 months or greater
        - If prostate cancer, individual has castration recurrent disease(e.g. no longer responsive to androgen deprivation therapy)
    2. Treatment of giant cell tumor of bone in adults and skeletally mature adolescents and denosumab is used
        - As a single agent use for localized or metastatic disease;

          OR
        - combination use with interferon alfa or radiation therapy for localized disease

3. Treatment of hypercalcemia of malignancy when there is failure of intravenous bisphosphonate therapy.

Denosumab (Xgeva) is not reimbursable for any other use including multiple myeloma because it is considered experimental, investigational or unproven.

Note- The FRAX® tool is utilized to evaluate fracture risk and is available at: https://www.shef.ac.uk/FRAX/

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*Consistent with Summary Plan Description (SPD). If there is discordance with the SPD, provisions of the SPD take precedence.