Subject: **Pegloticase (Krystexxa®)**

Effective Date: **June 20, 2017**

Department(s): **Utilization Management**

Policy: Pegloticase (Krystexxa®) (**HCPCS J2507**), a pegylated recombinant form of urate-oxidase enzyme, 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:

Pegloticase is reimbursable for use in treating adults with chronic gout (**ICD-10 M10.0-M10.071**), when the criteria in 1 **and** 2 below are met:

1. At least **one** of the following is documented in the clinical history:
   a. At least three gout flares in the previous 18 months
   b. At least one gouty tophus
   c. Chronic gouty arthritis

AND

2. **Either** of the following:
   a. Failure to normalize serum uric acid level to < 6 mg/dl after use of the maximum medically appropriate dose of ONE xanthine oxidase inhibitor[maximum recommended dosage-allopurinol(Zyloprim) is 800 mg/day; febuxostat(Uporic) is 80 mg/day] followed by combination with ONE uricosuric agent(e.g.probenecid).
   b. Contraindication to xanthine oxidase inhibitors and/or probenecid).

NOTE- Pegloticase is not reimbursable for any other indication, including chronic kidney disease as it is considered experimental, investigational or unproven.

NOTE- FDA recommended dosing of Krystexxa ® in adults is 8mg (uricase protein) by intravenous infusion every two weeks.The optimal treatment duration with Krystexxa® has not been determined.

References

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