Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

KRYSTEXXA® (pegloticase)

## GPI CODING:

68000050002020

## DESCRIPTION:

Krystexxa is a pegylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Krystexxa is administered as an intravenous infusion once every two weeks.

## APPROVAL DURATION:

Initial therapy: 6 months
Maintenance therapy: 1 year

## CRITERIA FOR KRYSTEXXA

I. Patient has a diagnosis of symptomatic chronic gout (e.g., tophi, gouty arthropathy, radiographic changes of gout, multiple joint involvement, associated uric acid nephrolithiasis) **AND**
II. Patient has a pre-treatment uric acid level of at least 6 mg/dL **AND**
III. Patient has tried but had a documented inadequate response to at least 3 months of xanthine oxidase (XO) inhibitor therapy (allopurinol or febuxostat) at the maximum medically appropriate dose **OR**
IV. Patient was not able to complete a 3-month trial of XO inhibitor therapy for one of the following documented clinical reasons:
   A. Patient experienced a severe allergic reaction to the XO inhibitor
   B. Patient experienced toxicity with the XO inhibitor
   C. Patient could not tolerate the XO inhibitor
   D. Significant drug interaction with the XO inhibitor
   E. Severe renal dysfunction (for allopurinol only)

**AND**

V. Uric acid levels will be monitored prior to each infusion **AND**
VI. Patients at high risk for glucose 6-phosphate dehydrogenase (G6PD) deficiency (e.g., African or Mediterranean ancestry) must be screened before initiation of therapy <u>and</u> must have negative results **AND**
VII. Krystexxa will be administered in a healthcare setting with access to management of severe anaphylaxis and infusion reactions **AND**
VIII. Patient will be premedicated with antihistamines and corticosteroids prior to each infusion.

*Authorizations for continued* use shall be granted when patients have two consecutive uric acid levels NOT above 6 mg/dL.