



## Prior Authorization Approval Criteria

### *Krystexxa (pegloticase)*

<b>Generic name:</b>	pegloticase
<b>Brand name:</b>	Krystexxa
<b>Medication class:</b>	Agents for Gout
<b>FDA-approved uses:</b>	indicated for the treatment of chronic gout in adults who are refractory to conventional therapy
<b>Available dosage forms:</b>	solution for injection 8mg/ml
<b>Usual dose:</b>	8mg every 2 weeks given as an IV infusion over at least 2 hours.
<b>Approximate monthly cost:</b> (based on AWP 2011)	\$4600.00/month
<b>Duration of therapy:</b>	Has not been established.

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must have documented evidence of gout with hyperuricemia
- Must be highly symptomatic.
- Must have tried and failed or intolerant to allopurinol.
- Must have tried and failed or intolerant to Uloric\*
- Must be refractory to conventional therapy
  - Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid or whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.
  - Strategies that should be considered prior to deciding if the patient is refractory to the current therapy include determining if the current drugs have had their doses optimized and assessment of patient adherence to the drug regimen.

*\*Uloric requires a prior authorization and the criteria that must be met for approval is available at [www.fchp.org](http://www.fchp.org).*

**Caution:**

- Development of anti-pegloticase antibodies which can interfere with continued treatment and lead to serious adverse effects.
- 92% of patients treated with Krystexxa developed anti-bodies.
- Risk of anaphylaxis and infusion reactions is increased in patients whose uric acid levels have risen higher than 6mg/dl prior to subsequent infusions, especially when 2 consecutive levels are >6mg/dl.
- Krystexxa should be discontinued in patients who are presumed to have high anti-pegloticase antibody titers as demonstrated by serum uric acid levels >6mg/dl prior to 2 consecutive subsequent infusions.  
It is advised that patients receive pre-infusion prophylaxis for infusion reactions.

**Monitoring:**

- Patients should be monitored for evidence of hypersensitivity reactions or infusion reactions for approximately 1 hour postinfusion. Serum uric acid concentrations should be monitored prior to each infusion, with discontinuation of therapy if levels increase to greater than 6 mg/dL prior to 2 consecutive infusions

**Contraindication:**

- Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Patients with G6PD deficiency were excluded from pegloticase studies. Patients of African and Mediterranean ancestry should be screened for deficiency because of the risk of hemolysis and methemoglobinemia

**Not approved if:**

- Pegloticase is not recommended for the treatment of asymptomatic hyperuricemia.
- Does not meet the above stated criteria.
- Have any contraindications to the use of Krystexxa.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 06/08/11  
Revised 12/14/11