



Gout Drugs
Krystexxa (Pegloticase) J2507
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

Form section with checkboxes for NEW START - Start Date and Continuation (within 365 days), and fields for Date Requested, Requestor, Clinic name, Phone, and Fax.

MEMBER INFORMATION

*Name: *ID#: *DOB:

PRESCRIBER INFORMATION

*Name: MD FNP DO NP PA *Phone:

*Address: *Fax:

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: Phone:

*Address: Fax:

PROCEDURE / PRODUCT INFORMATION

Table with 5 columns: HCPC Code, Name of Drug (with Self-administered checkbox), Dose (Wt: kg Ht:), Frequency, End Date if known.

Chart notes attached. Other important information:

Diagnosis: ICD10: Description:

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)
Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.
If not, please provide clinical rationale for formulary exception:

Continuation Requests: (Clinical documentation required for all requests)
Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.
Patient had an adequate response or significant improvement while on this medication.
If not, please provide clinical rationale for continuing this medication:

ACKNOWLEDGEMENT

Request By (Signature Required): Date: / /

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Gout Drugs PA

Drug Name(s):

**KRYSTEXXA
PEGLOTICASE**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approvals will be for 6 months

FDA Indications:

Krystexxa

- Gout, Refractory to conventional therapy

Off-Label Uses:

N/A

Age Restrictions:

Safety and effectiveness have not been established in pediatric patients

Other Clinical Considerations:

Anaphylaxis and Infusion Reactions; G6PD Deficiency Associated Hemolysis and Methemoglobinemia

Anaphylaxis and infusion reactions have been reported to occur during and after administration of pegloticase.

Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. However, delayed-type hypersensitivity reactions have also been reported.

Pegloticase should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.

Patients should be premedicated with antihistamines and corticosteroids.

Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of pegloticase. Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.

Screen patients at risk for G6PD deficiency prior to starting pegloticase. Hemolysis and methemoglobinemia have been reported with pegloticase in patients with G6PD deficiency. Do not administer pegloticase to patients with G6PD deficiency

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/4B9996/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8CE4E7/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Pegloticase&UserSearchTerm=Pegloticase&SearchFilter=filterNone&navitem=searchGlobal#

https://careweb.careguidelines.com/ed24/ac/ac04_112.htm

CLINICAL / CMS
ONLY