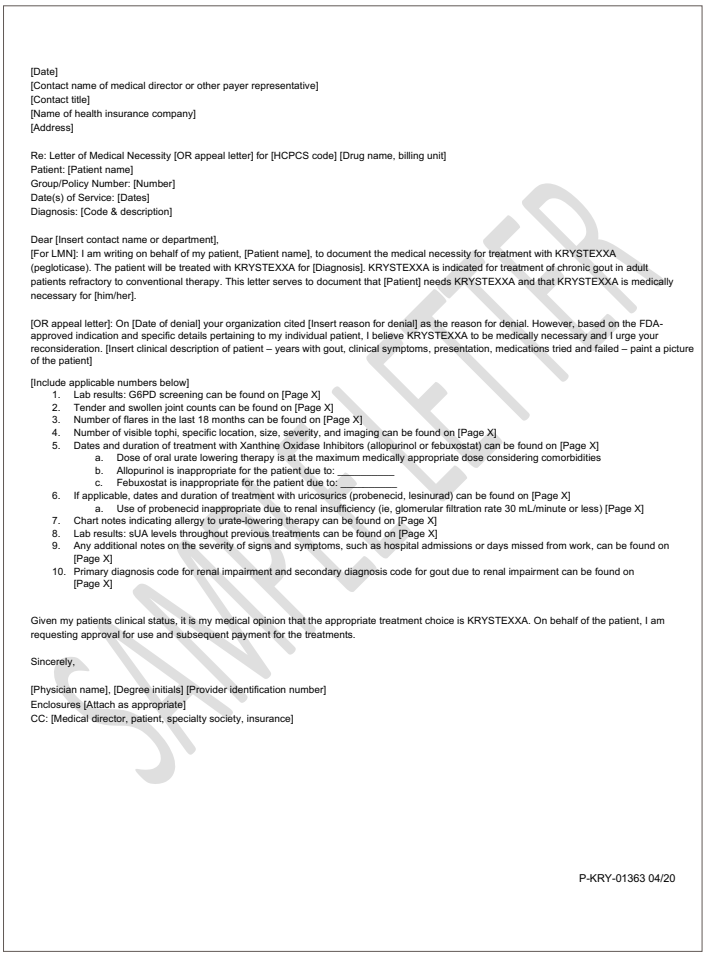
SAMPLE LETTER OF MEDICAL NECESSITY INSTRUCTIONS

DOWNLOAD THE FOLLOWING RESOURCE TO REQUEST INSURANCE COVERAGE FOR PATIENTS ON KRYSTEXXA

This template should be printed on the physician's letterhead. The physician is responsible for completing this letter in a way that completely and accurately represents the patient's circumstances.

Note: This content is a suggestion only.



[Date]
[Contact name of medical director or other payer representative]
[Contact title]
[Name of health insurance company]
[Address]

Re: Letter of Medical Necessity [OR appeal letter] for [HCPCS code] [Drug name, billing unit]
Patient: [Patient name]
Group/Policy Number: [Number]
Date(s) of Service: [Dates]
Diagnosis: [Code & description]

Dear [Insert contact name or department],
[For LMN]: I am writing on behalf of my patient, [Patient name], to document the medical necessity for treatment with KRYSTEXXA (pegloticase). The patient will be treated with KRYSTEXXA for [Diagnosis]. KRYSTEXXA is indicated for treatment of chronic gout in adult patients refractory to conventional therapy. This letter serves to document that [Patient] needs KRYSTEXXA and that KRYSTEXXA is medically necessary for [him/her].

[OR appeal letter]: On [Date of denial] your organization cited [Insert reason for denial] as the reason for denial. However, based on the FDA-approved indication and specific details pertaining to my individual patient, I believe KRYSTEXXA to be medically necessary and I urge your reconsideration. [Insert clinical description of patient – years with gout, clinical symptoms, presentation, medications tried and failed – paint a picture of the patient]

[Include applicable numbers below]
1. Lab results: G6PD screening can be found on [Page X]
2. Tender and swollen joint counts can be found on [Page X]
3. Number of flares in the last 18 months can be found on [Page X]
4. Number of visible tophi, specific location, size, severity, and imaging can be found on [Page X]
5. Dates and duration of treatment with Xanthine Oxidase Inhibitors (allopurinol or febuxostat) can be found on [Page X]
   a. Dose of oral urate lowering therapy is at the maximum medically appropriate dose considering comorbidities
   b. Allopurinol is inappropriate for the patient due to: _____
   c. Febuxostat is inappropriate for the patient due to: _____
6. If applicable, dates and duration of treatment with uricosurics (probenecid, lesinurad) can be found on [Page X]
   a. Use of probenecid inappropriate due to renal insufficiency (ie, glomerular filtration rate 30 mL/minute or less) [Page X]
7. Chart notes indicating allergy to urate-lowering therapy can be found on [Page X]
8. Lab results: sUA levels throughout previous treatments can be found on [Page X]
9. Any additional notes on the severity of signs and symptoms, such as hospital admissions or days missed from work, can be found on [Page X]
10. Primary diagnosis code for renal impairment and secondary diagnosis code for gout due to renal impairment can be found on [Page X]

Given my patients clinical status, it is my medical opinion that the appropriate treatment choice is KRYSTEXXA. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatments.

Sincerely,

[Physician name], [Degree initials] [Provider identification number]
Enclosures [Attach as appropriate]
CC: [Medical director, patient, specialty society, insurance]

SAMPLE LETTER

P-KRY-01363 04/20

Please see Important Safety Information on following page and click for Full Prescribing Information, including Boxed Warning.

KRYSTEXXA® pegloticase

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

KRYSTEXXA® (pegloticase) is indicated for the treatment of chronic gout in adult patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Important Limitations of Use: KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS AND INFUSION REACTIONS

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

The risk of anaphylaxis and infusion reactions is higher in patients who have lost therapeutic response.

Concomitant use of KRYSTEXXA and oral urate-lowering agents may blunt the rise of sUA levels. Patients should discontinue oral urate-lowering agents and not institute therapy with oral urate-lowering agents while taking KRYSTEXXA.

In the event of anaphylaxis or infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate.

Inform patients of the symptoms and signs of anaphylaxis, and instruct them to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting.

CONTRAINDICATIONS: G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA

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

GOUT FLARES

An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including treatment with KRYSTEXXA. If a gout flare occurs during treatment, KRYSTEXXA need not be discontinued. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

CONGESTIVE HEART FAILURE

KRYSTEXXA has not been studied in patients with congestive heart failure, but some patients in the clinical trials experienced exacerbation. Exercise caution when using KRYSTEXXA in patients who have congestive heart failure and monitor patients closely following infusion.

ADVERSE REACTIONS

The most commonly reported adverse reactions in clinical trials with KRYSTEXXA are gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

Please see Full Prescribing Information, including Boxed Warning.

HORIZON

KRYSTEXXA® pegloticase