SAMPLE LETTER OF MEDICAL NECESSITY INSTRUCTIONS

DOWNLOAD THE FOLLOWING RESOURCE TO REQUEST INSURANCE COVERAGE FOR KRYSTEXXA® (PEGLOTICASE) FOR PATIENTS.

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 a patient's circumstances.

Note: This content is a suggestion only.

[MM/DD/YYYY]

[Insurer's company name]
Attn: [Insurer's name]
[Insurer's address:
Street name
City, State, Zip code]
Re: [Patient's name]
Policy No.: [XXXXXXX]
Claim No: [XXXXXX]

Dear [Insurer]:

I am writing to request coverage for KRYSTEXXA® (pegloticase) injection, 8 mg/mL, for intravenous infusion for [Patient's name].

KRYSTEXXA is a PEGylated uric acid-specific enzyme indicated for the treatment of chronic gout in adult patients who have failed to normalize serum uric acid (sUA) level and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors (XOIs) at the maximum medically appropriate dose or for whom these drugs are contraindicated. KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

In my clinical opinion, KRYSTEXXA is medically necessary and appropriate to treat [Patient's name] at this point in [his or her] course of care.

[Patient's name], [age], has had gout for [number of months or years] and has been on the maximum medically appropriate dose of [xanthine oxidase inhibitor drug name] for [number of months or years]. However, [his or her] sUA level is still at [sUA level], and [he or she] is still experiencing [number of flares] flares per year or has visible tophi.

- Lab results: G6PD can be found on page X
- Dates and duration of treatment with XOIs (allopurinol or febuxostat)
- If applicable, dates and duration of treatment with uricosurics (probenecid, lesinurad) can be found on page X
- Lab results: sUA levels throughout previous treatments can be found on page X
- Tender and swollen joint counts can be found on page X
- Number of flares in the last 18 months can be found on page X
- Number of visible tophi, specific location, size, severity, and imaging can be found on page X
- Any additional notes on severity of signs and symptoms, such as hospital admissions or days missed from work, can be found on page X
- Chart notes indicating allergy to urate-lowering therapy can be found on page X
- Primary diagnosis code for renal impairment and secondary diagnosis code for gout due to renal impairment can be found on page X

Based on all these factors, I believe that [Patient's name] is not responding to [his or her] current treatment(s) and that KRYSTEXXA may help relieve [his or her] signs and symptoms of gout.

I am enclosing documentation supporting the medical necessity of KRYSTEXXA for this patient. Please contact me at [office contact information] if you require additional information or would like to discuss the case in greater detail.

Thank you.

[Signature]

[Physician's name]
[Phone No.]
[Street name]
[City, State, Zip code]

Enclosures

P-KRY-00262

SAMPLE LETTER

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

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.

To report SUSPECTED ADVERSE REACTIONS, contact Horizon Pharma Rheumatology LLC at 1-866-479-6742 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Prescribing Information, including Boxed Warning, and Medication Guide.

KRYSTEXXA is a registered trademark of Horizon Pharma Rheumatology LLC.
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