Infusion Checklist

PATIENT NAME: _____ (First) _____ (Last)

DATE OF ADMINISTRATION: _____

Step 1 Check and confirm

Prior to the first infusion

- ◯ **Confirm the patient has normal G6PD* activity from lab tests and has discontinued taking urate-lowering therapies (eg, allopurinol, febuxostat)**
  - **Do not administer** KRYSTEXXA to patients with G6PD deficiency
- ◯ **Remind the patient why they are not taking oral urate-lowering therapies and ensure they are taking gout flare prophylaxis (NSAID or colchicine)**
- ◯ **Initiate oral methotrexate (15 mg once weekly) and oral folic acid (1 mg daily) at least 4 weeks prior to the start of KRYSTEXXA and for the duration of treatment, if applicable**

Prior to each subsequent infusion

- ◯ **Confirm sUA level was tested, preferably in the last 48 hours, beginning after the first infusion**
  - Notify prescribing healthcare provider if sUA level has not been tested or if the preinfusion sUA level is >6 mg/dL. Discontinue treatment if sUA level increases to above 6 mg/dL, particularly after 2 consecutive levels above 6 mg/dL are observed

Step 2 Counsel your patients

- ◯ **Answer any questions regarding treatment; address limitations of diet changes**
- ◯ **Describe how KRYSTEXXA works and educate on the risk of infusion reactions, including anaphylaxis**
- ◯ **Amgen By Your Side is a patient support program with a dedicated team that provides non-medical, logistical support throughout treatment**

Step 3 Prepare and infuse

- ◯ **Administer pretreatment medications per prescribing orders of healthcare provider**

  IV corticosteroid _____ Antihistamine _____ Oral analgesic _____
- ◯ **Remind the patient that they may experience gout flares after starting KRYSTEXXA and that this can actually be a sign that it is working**
- ◯ **Visually inspect vial for particulate matter and ensure solution is clear and colorless**
- ◯ **Using aseptic technique, withdraw 1 mL into a sterile syringe. Inject into a 250 mL bag of normal or half-normal saline. Gently mix the bag by inverting several times. Discard any unused portion of the remaining product. Do not shake**
  - No loading dose recommended or required
  - KRYSTEXXA is a single-dose vial
- ◯ **The diluted solution should be used within 4 hours**
- ◯ **Before administration, allow the diluted solution of KRYSTEXXA to reach room temperature**
  - Artificial heating should not be used
  - If not administered immediately, it is recommended that the diluted solution should be stored in the refrigerator and away from light
- ◯ **Initiate infusion at a rate of 125 mL/h or slower via infusion pump or gravity feed**
  - Infuse over no less than 2 hours

Do not administer as intravenous push or bolus

- ◯ **The sticker on the KRYSTEXXA box is available for use on your patient's chart, if desired**
- ◯ **Use your normal protocol to monitor for infusion reactions**
  - In the event of an infusion reaction, as clinically indicated, the infusion can be slowed or stopped and restarted at a slower rate

Step 4 Postinfusion reminders

- ◯ **Observation of patients for approximately an hour post-infusion should be considered**
- ◯ **Remind the patient of their next sUA test, upcoming KRYSTEXXA infusion appointments, and the importance of continuing to take all premedications, including methotrexate and folic acid, if applicable**
  - KRYSTEXXA should be given every 2 weeks
  - It is recommended to provide a standing order to the lab to check the patient's sUA level prior to each infusion

*G6PD deficiency is an abnormally low level of glucose-6-phosphate dehydrogenase. Patients of African, Mediterranean, and Southern Asian ancestry have a higher risk of G6PD deficiency.
NSAID, non-steroidal anti-inflammatory drug; sUA, serum uric acid.

Please see Full Important Safety Information on page 2 and click for Full Prescribing Information, including Boxed Warning.

KRYSTEXXA® pegloticase

INDICATION

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.

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

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS AND INFUSION REACTIONS, G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA

- **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. Delayed hypersensitivity reactions have also been reported.**
- **KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.**
- **Premedicate with antihistamines and corticosteroids and closely monitor for anaphylaxis for an appropriate period after administration of KRYSTEXXA.**
- **Monitor serum uric acid levels prior to each infusion and discontinue 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 glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. KRYSTEXXA is contraindicated in patients with G6PD deficiency.**

CONTRAINDICATIONS:

- In patients with G6PD deficiency.
- In patients with history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components.

WARNINGS AND PRECAUTIONS

Gout Flares: An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including KRYSTEXXA. 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 formally studied in patients with congestive heart failure, but some patients in the pre-marketing placebo-controlled clinical trials experienced exacerbation. Exercise caution in patients who have congestive heart failure and monitor patients closely following infusion.

ADVERSE REACTIONS

The most commonly reported adverse reactions (≥5%) are:

KRYSTEXXA co-administration with methotrexate trial:
KRYSTEXXA with methotrexate: gout flares, arthralgia, COVID-19, nausea, and fatigue; KRYSTEXXA alone: gout flares, arthralgia, COVID-19, nausea, fatigue, infusion reaction, pain in extremity, hypertension, and vomiting.

KRYSTEXXA pre-marketing placebo-controlled trials:
gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, and vomiting.

Please click for Full Prescribing Information, including Boxed Warning.

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