CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

GUIDELINES FOR OUTPATIENT INTRAVENOUS RISANKIZUMAB (SKYRIZI)

Section: Nursing
Compliance: ACHC Infusion Pharmacy
ACHC Standards: N/A
URAC Standards: N/A
TJC Standards: N/A
Policy ID: NUR239
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Reviewed:
Revised:
Approved by: Kathleen Patrick, President, 6/29/22

I. POLICY

Risankizumab is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Risankizumab acts as an interleukin-23 (IL-23) antagonist and inhibits the downstream release of pro-inflammatory cytokines and chemokines. The following outlines the procedures and protocol for coordination of servicing patients in need of outpatient intravenous risankizumab.

II. PATIENT ACCEPTANCE CRITERIA

A. All candidates for home care service must be evaluated by the clinician(s) and deemed appropriate to receive home care based upon dispensing pharmcy admission criteria.

B. The decision to administer a first dose in the home by a field nurse will be determined on a case-by-case basis and reviewed by nursing and pharmacy management. The following criteria will be evaluated:
    1. Prescriber preference
    2. Allergy profile
    3. Age ≥18 years
    4. Ability to secure contracted nursing for subsequent infusions
    5. Other relevant social and/or medical history
    6. Indication is appropriate for intravenous route of administration

C. Patients must have TB screening and be free from infection

D. Patients receiving this medication for Crohn's Disease must have baseline liver enzymes and bilirubin prior to initiating treatment with Risankizumab

E. Dispensing the pharmacy treatment protocol for anaphylaxis will be instituted unless a more comprehensive, patient-specific order is provided by physician. Refer to policy NUR012 or Appendix A.

III. PHARMACOLOGIC OVERVIEW

A. Indications
    1. Plaque psoriasis, moderate to severe (Ps) - will not be discussed in this policy as administration is only approved for subcutaneous (SC) injection
    2. Psoriatic arthritis (PsA) – will not be discussed in this policy as administration is only approved for subcutaneous (SC) injection
    3. Crohn's disease, moderate to severe

B. Dosage
    1. Crohn's Disease
        a. Induction
            i. 600 mg IV at 0,4, and 8 weeks
        b. Maintenance
            i. 360 mg SC at week 12 and then every 8 weeks thereafter

C. Contraindications
    1. Patients with a history of hypersensitivity to risankizumab or any component of the formulation.

D. Precautions
    1. Antibody formation:
        a. Formation of neutralizing anti-drug antibodies may occur with risankizumab and may be associated with loss of efficacy
    2. Hypersensitivity reactions:
        a. Serious hypersensitivity, including anaphylaxis, has been reported
        b. Discontinue immediately with signs/symptoms of a serious hypersensitivity reaction and treat appropriately, as indicated
    3. Infections:
        a. Risankizumab may increase the risk of infections
        b. Treatment should not be initiated in patients with active infections until it is resolved or treated
        c. If a serious infection develops discontinue risankizumab until the infection resolves
    4. Tuberculosis:
        a. Patients should be evaluated for tuberculosis (TB) infection prior to initiating therapy
        b. Treatment for latent TB should be administered prior to administering risankizumab
    5. Immunizations:
        a. Patients should be brought up to date with all immunizations before initiating therapy
        b. Live vaccines should not be given concurrently
    6. Hepatotoxicity
        a. In psoriatic arthritis trials, the incidence of hepatic events was higher
        b. Drug-induced liver injury was reported in a patient with Crohn's disease
        c. Consider an alternative treatment for patients with evidence of liver cirrhosis

E. Adverse Reactions
    1. >10%:
        a. Antibody development
        b. Infection
            i. Upper respiratory tract infection
    2. 1% to 10%:
        a. Elevated liver enzymes (serum aspartate aminotransferase, ALT, and SGPT)
        b. Hypersensitivity reaction
        c. Local Injection site reaction

d. Fatigue
e. Headache
f. Abdominal pain
g. Anemia
h. Pyrexia
i. Arthralgia and back pain

3. <1%:
    a. Folliculitis, urticarial
    b. Anaphylaxis (psoriatic arthritis)
    c. Eczema
    d. Facial Swelling

F. Drug Interactions
    1. Live vaccines
        a. Concurrent use of Risankizumab and live vaccines may result in reduced effectiveness of immunization and increased risk of infection
    2. Biologics and Immunosuppressants
        a. May enhance immunosuppressive effect when combined

G. Pharmacokinetics
    1. Half-life elimination: ~28 days
    2. Onset of action (Psoriasis) - response best determined after 12 weeks

III. ADMINISTRATIVE GUIDELINES

A. Administrative guidelines
    1. IV infusions should be given immediately after dilution; diluted solution must be used within one hour of preparation per current USP Immediate-Use Guidelines
    2. Do not co-administer other products in the same infusion line.

B. Duration
    1. Duration of therapy is dependent on patient response and adverse reactions.

C. Dose Adjustment
    1. There are no dosage adjustments provided in the manufacturer's labeling.

IV. NURSING PROCEDURE

A. Supplies
    1. Alcohol Swabs
    2. Gloves
    3. Risankizumab Drug vials
    4. Bag of D5W for dilution (100ml, 250ml, or 500 ml).
    5. Dressing change kit
    6. IV Pole
    7. IV Start Kit
    8. Peripheral IV catheter (ex. 22 Gauge x1” and 24 Gauge x ¾” for patients needing peripheral access)
    9. Port access needle (ex. 22 Gauge x ¾ to 1” safe step for patients with a port)

10. Tape
11. Extension set 8”
12. IV injection cap
13. IV administration set (dial-a-flow or gravity)
14. Syringes (10mL) with needles (20 G x 1”)
15. Normal saline flushes
16. Sharps container

B. How Supplied
    1. Intravenous Infusion
        a. Risankizumab Vial
            i. Injection: 600 mg/10 mL (60 mg/mL) as a colorless to slightly yellow, and clear to slightly opalescent solution in each single-dose vial.

C. Storage and Handling
    1. Store in a refrigerator at 36°F to 46° F (2°C to 8°C)
    2. Do not freeze
    3. Do not shake
    4. Keep in the original cartons to protect from light
    5. Not made with natural rubber latex

D. Compatibility
    1. Intravenous infusion has only been studied in D5W. Use of normal saline to flush the IV line is at the discretion of the healthcare provider, per manufacturer guidance.

E. Procedures: Preparation of product, Infusion rates, post infusion monitoring time.
    1. Explain the reasoning for visit and use of Risankizumab
    2. Don gloves.
    3. Establish venous access prior to preparation of drug.
    4. Counsel patient on warnings, precautions, and potential side effects including but not limited to:
    5. Prior to Treatment Initiation
        a. Evaluate patients for tuberculosis (TB)
        b. Complete all age-appropriate vaccinations as recommended by current immunization guidelines
        c. Additionally for patients treating Crohn’s disease, obtain liver enzymes and bilirubin levels prior to initiation

    6. Preparation for Crohn’s Disease for Induction
        a. Intravenous Induction
            i. Remove vial of risankizumab from refrigerator 30-60 minutes prior to preparation to warm to room temperature
            ii. Withdraw 10 mL of risankizumab solution from the vial and inject into an intravenous infusion bag or glass bottle containing 5% Dextrose Injection (600 mg/10 mL in 100 mL, or 250 mL, or 500 mL) for a final concentration of approximately 1.2 mg/mL to 6 mg/mL and discard any remaining solution in the vial
            iii. Do not shake the vial or diluted solution in the infusion bag or glass bottle
            iv. Infuse the diluted solution intravenously over a period of at least one hour.
            v. Monitor vitals periodically throughout the infusion and for at least 30 minutes after end of infusion per INS guidelines.

vi. Do not administer risankizumab diluted solution concomitantly in the same intravenous line with other medicinal products

V. CLINICAL MONITORING

A. Prior to therapy
1. TB screening
2. Hepatitis B virus (HBV)/hepatitis C virus screening
3. Liver enzymes and bilirubin (Crohn's patients)

B. During therapy
1. Signs/symptoms of infection
2. Signs of hypersensitivity reactions
3. Liver enzymes and bilirubin during induction and routinely thereafter
4. CBC and BMP routinely

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APPENDICES

Appendix A: Anaphylaxis Kit Instructions

APPENDIX A: ANAPHYLAXIS KIT INTRUCTIONS
Emergency Medication After Your Infusion

Please call your pharmacy if you have any questions or concerns. In the event of an emergency, always call 911.

Your nurse will tell you when you need to use Emergency Medications.
The epinephrine dose will be noted on the Anaphylaxis Protocol included with your kit.

Start with a clean work surface and clean hands.

Open the supply bag labeled Anaphylaxis Kit Contents.

You will need:

1. **Bag containing Pills** (2 Acetaminophen and 2 Diphenhydramine)
2. **Bag containing Alcohol Prep Pads**
3. **Bag labeled IM Epinephrine**

All other contents will not be needed.

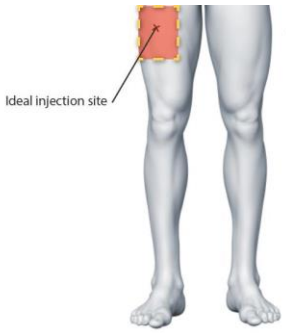
Open the IM Epinephrine Bag

1. **Remove 1 of each item**
    a. 1 -syringe
    b. 1 – brown labeled filter needle (BD Filter Needle)- **for ampul use only**
    c. 1 – black labeled safety needle (Magellan Hypodermic Safety Needle 22G x 1")
    d. 1 ampul of epinephrine

Prepare IM (intramuscular) injection of Epinephrine:

1. **Attach the brown filtered needle to syringe**
    a. Be careful to not touch the tip of the syringe or the needle.
2. Using an **alcohol swab, wipe the neck of the epinephrine ampul.**
3. Holding the ampul upright, **swirl and flick the ampul until all fluid flows to the bottom chamber** (the top chamber should be empty).
4. Using a new alcohol wipe, grasp the neck of the ampul and with your other hand grasp the bottom chamber of the ampul. **Quickly snap the top of the ampul off, directing the snap way from you.**
5. **Place the tip of the brown filter needle inside the ampul**. Tilting the ampul, **withdraw dose of medication into the syringe** by gently pulling back on the plunger. Be careful to not pull the plunger out of the syringe.
6. Remove the needle from the ampul and h**old the syringe upright** with the needle pointing upward. **Gently tap the side of the syringe to bring any air to the top of the syringe.**
7. **Push the air out of the syringe by gently pushing on the plunger**.
8. Replace the cap on the brown filter needle. Discard remainder in ampul.
9. **Remove the brown filter needle and place the black safety needle onto the syringe.**

Give your IM Epinephrine injection



1. **Grasp your leg muscle at the outer mid-thigh** and **cleanse the area** with a new alcohol wipe.
2. **Push the needle into your leg muscle straight** in at a 90-degree angle.
3. **Inject the medication** by depressing the plunger in a slow and steady motion.
4. **Remove the needle** and wipe the site with the alcohol wipe.
5. May repeat dose every 5 minutes (**maximum 3 doses**) if ordered per protocol.

Take the pills by mouth.

a. 2 – Acetaminophen
b. 2 – Diphenhydramine

Place all trash in the bag the pills came in and take with you when you seek medical care. **Give the bag to the nurse or EMT**, so your doctor will know what medication you already took. They will properly dispose of the syringe and needles.
Call 911 or have someone drive you to the emergency department.