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PURPOSE:

- To provide instruction on the safety, preparation, and administration of Rystiggo (rozanolixizumab-noli).

POLICY:

- Rystiggo will be administered by a trained registered nurse in accordance with a physician's order, any available / provided pharmacy or manufacturer instructions, and Agency policy.

GENERAL INFORMATION:

- Rystiggo is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
- The most common adverse reactions are headache, infections, diarrhea, pyrexia, hypersensitivity reactions and nausea.

SPECIAL CONSIDERATIONS:

- Rystiggo is administered **weekly** by a trained registered nurse.
- The recommended dosage of Rystiggo for adult patients with gMG is based on body weight.
 - Less than 50 kg = 420mg = 3ml (2 vials)
 - 50 kg to less than 100 kg = 560mg = 4ml (2 vials)
 - 100 kg and above = 840 mg 6ml = (3 vials)
- Rystiggo vials should be refrigerated at 36°F to 46°F (2°C to 8°C) in their original carton to protect from light. Do not freeze or shake. If needed, vials may be stored at room temperature up to 77°C (25°C) for up to 30 days in the original carton. Once a vial has been stored at room temperature, do not place it back in the refrigerator.

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PROCEDURE

Supplies:

- Required number of vials of Rystiggo
 - Syringe
 - Transfer needles
 - Alcohol wipe
 - Infusion set
 - Tape or transparent dressing
 - Infusion pump
 - Sharps Container
1. Obtain and verify physician's orders including pre-medication orders, concentration, rate of infusion, and emergency protocols (in-date anaphylactic kit on-hand). If you notice any discrepancies in the orders, contact the Agency before proceeding.
 2. Explain procedure and purpose to patient/caregiver.
 3. Perform initial Hand Hygiene and maintain throughout the procedure.
 4. Assemble supplies on a clean, dry surface. Ensure all supplies needed to complete the infusion from beginning to end are available. If any supplies are missing, notify the Agency immediately and prior to starting the infusion process.
 5. Assess and record patient's vital signs to establish a baseline and ensure vital signs are not contraindicative to starting the infusion.
 6. Ensure vials have been allowed to warm to room temperature. Rystiggo vials should be refrigerated at 36°F to 46°F (2°C to 8°C) in their original carton to protect from light. Do not freeze or shake. If needed, vials may be stored at room temperature up to 77°C (25°C) for up to 30 days in the original carton. Once a vial has been stored at room temperature, do not place it back in the refrigerator.
 7. Check each vial prior to using to ensure expiration date has not passed. The solution should be colorless to pale brownish-yellow, clear to slightly opalescent. Do not use the vial if the liquid looks cloudy, contains foreign particles, or has changed color. Do not use vial if the protective cap of the vial is missing or defective.
 8. Transfer Rystiggo from the vial to the syringe. Remove the protective cap off of the vial, clean the vial stopper with an alcohol wipe and allow the stopper to dry.

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9. Attach a sterile transfer needle to the syringe. Extract the entire content of the vial into the syringe. For the second vial, use the other clean transfer needle and repeat the previous step.
10. Remove the needle from the syringe and attach the infusion set to the syringe. NOTE: Rystiggo should be infused within 4 hours of puncturing the vial.
11. Prime the infusion set. Each vial contains excess volume to allow for priming the infusion line. Set the pump to deliver the prescribed volume (for pumps that cannot be set, after priming the infusion line, adjust the volume to be administering by expelling and excess volume).
12. Insert syringe filled with Rystiggo into the infusion pump.
13. Select an area for the infusion on the patient's lower right or left part of the abdomen (below the belly button). NEVER infuse into areas where the skin is tender, bruised, red, or hard. Avoid infusing into tattoos, scars, or stretch marks. Rotate infusion sites from one infusion to the next.
14. Clean the skin at the infusion site using an alcohol wipe. Allow the skin to dry.
15. Using two (2) fingers pinch together the skin around the infusion site. With a quick dart-like motion, insert the infusion set needle into the subcutaneous tissue.
16. Put sterile gauze and tape or transparent dressing over the infusion site to hold the needle in place.
17. Turn on pump and start infusion. Infuse Rystiggo at a constant flow up rate to 20ml/hr.
18. Once infusion is complete, do not flush the infusion line.
19. Continue to monitor the patient for 15 minutes for any signs and symptoms of hypersensitivity reactions.
20. Document the procedure, the patient's response to the procedure, and all lot numbers and expirations dates for vials used.