SECTION 8B: PUMPS & DRUG ADMINISTRATION	POLICY: 8B.24
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PURPOSE:

- To provide instruction on the safe and proper administration of Infliximab and similar biologics to patients in the home setting.

POLICY:

- Remicade (Infliximab) and similar biologics will be administered by a Registered Nurse in accordance with a physician's order, any available / provided pharmacy or manufacturer instructions, and Agency policy.

GENERAL INFORMATION:

- Infliximab is a prescription medication used to treat a variety of gastrointestinal and joint conditions including Crohn's disease, Ulcerative Colitis, Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, and Plaque Psoriasis.
- The most common side effects of Infliximab include respiratory infections such as sinus infections and sore throat, headache, cough, abdominal pain. If a patient reports experiencing these symptoms after an infusion, they should be advised to report the symptoms to their physician for medical advice.
- Renflexis (Infliximab-abda), Inflectra (Infliximab-dyyb), and Avsola (Infliximab-axxq) are approved by the FDA as biosimilar to Infliximab. The FDA requires that a biosimilar be "highly similar" to the exiting biologic product with no clinically meaningful differences in safety, purity, and potency.
- Unlike brand and generic drugs, biosimilars may not be substituted by the Pharmacy without authorization from the prescriber. The prescriber must write a specific prescription for biosimilar products.

SPECIAL CONSIDERATIONS:

- If a patient reports having any symptoms of infection such as fever, chills, muscle aches, cough, blood in phlegm, shortness of breath, runny nose, sore throat, red or painful skin or sores on their body, excessive tiredness, diarrhea, stomach pain, weight loss, or pain during urination, the attending nurse shall notify the Agency so that notification to Pharmacy and MD can be coordinated.

- A registered nurse shall remain with the patient for the entirety of the infusion.

- Infusions are initiated at Week 0, Week 2 (two weeks from Week 0), and Week 6 (four weeks from Week 2). Maintenance dosing continues every 8 weeks thereafter (unless otherwise noted in the order).

- Infliximab is administered per provider order over 2 hours via intravenous infusion (unless otherwise ordered).

- Infliximab is supplied in 100mg vials of lyophilized powder and requires reconstitution with sterile water.

- **DO NOT** administer as an IV push or bolus.

- Infliximab should be allowed to equilibrate to room temperature prior to infusion.
    - Infliximab should be stored at 2° to 8°C (36° to 46°F). If there are any doubts about the storage and viability of the drug, reach out to the Agency immediately so that confirmation may be sought from the Pharmacy.

- RN shall monitor for infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate.

    - If anaphylaxis or other serious infusion-related reactions occurs, discontinue administration of Entyvio immediately and initiate appropriate treatment to include administration of anaphylactic medications as necessary and activating EMS.

    - Notify the Agency as soon as possible so that the Pharmacy & MD may be notified.

PROCEDURE:

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 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. Establish IV access or ensure access is in working condition. **DO NOT** tamper with medication until patent IV access is established and flushed. After 2 unsuccessful IV attempts, notify the Agency immediately for further instruction on how to proceed.

7. Remove the flip off cap from the single dose vial(s) and wipe the top of the vial with alcohol.

8. Reconstitute each 100mg vial of Infliximab with 10ml sterile water to yield a concentration of 10gm/ml. If sterile water is unavailable, please notify the Agency immediately so that Pharmacy approval to use 0.9% Sodium Chloride as an alternative may be obtained.

9. Gently swirl the vial(s) for ~15 seconds to dissolve the powder. **DO NOT** vigorously shake the vial. Allow the reconstituted solution to stand for ~5 minutes to completely dissolve.

10. Once dissolved, visually inspect the solution in each vial for particulate matter and/or discoloration prior to dilution. The solution should be colorless to light yellow and opalescent. The solution may develop a few translucent particles as the medication is a protein. If the solution has not fully dissolved or if there are opaque particles or other foreign particles, **DO NOT** use it. Reach out to the Agency immediately so that the Pharmacy can be notified. The pharmacy will advise as to how to handle the medication (i.e. disposal, return shipping, etc.).

11. Check the expiration date on each vial to ensure it is within date.

12. Immediately withdraw 10ml of solution from each vial. One syringe may be used to draw up the solution from each vial.

13. The reconstituted solution is now ready for dilution. Infliximab is diluted to a total volume of 250ml with 0.9% Sodium Chloride (unless otherwise instructed per the orders/ medication label).

    - Withdraw the volume from the 0.9% Sodium Chloride bag equal to the total volume of reconstituted medication.

    - Add the medication solution to the bag of 0.9% Sodium Chloride creating a total volume of 250ml. Gently mix the solution. **DO NOT** shake the bag

    - ******For volumes greater than 250ml, either use a larger infusion bag (i.e., 500ml) or multiple 250ml infusion bags to ensure that the concentration of the infusion solution does not exceed 4ml/ml.

14. Begin the infusion. Administer Infliximab intravenously over 2 hours (unless otherwise specified in the order). In most cases, Infliximab will be administered via gravity tubing unless the Pharmacy has provided a peristaltic pump.

    - **Note:** Some orders may dictate a specific titration/ramp up for the medication. If not, it should be infused at 125ml/hr to meet the manufacturer's guideline to infuse over 2 hours.

15. Record vitals at baseline, every 15 minutes for the 1st hour, hourly thereafter, and at infusion end.

16. Once infusion is complete, flush the IV with 10ml of 0.9% Normal Saline (unless otherwise specified in the order).

17. Record vitals at infusion end.

18. Disconnect the patient and remove the IV.

19. Place a pressure dressing at the IV site.

20. Clean up your workspace and properly discard all waste, ensuring that all needles have been placed in a sharps container.

21. Document the procedure, the patient's response to the procedure, and all lot numbers and expirations dates for vials used.

22. **Note:** If the infusion is not completed, notify the Agency immediately so the Pharmacy can be notified, and advisement received on how to store or dispose of the medication properly.

    - Examples for incomplete infusions include losing IV access that is unable to be re-established, symptoms of intolerance, medication is unusable or compromised (broken / leaking vial or discolored or altered in normal appearance). **NEVER** discard of the medication without speaking to the Agency first