CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

GUIDELINES FOR OUTPATIENT TEPEZZA (Teprotumumab) THERAPY

Section: Nursing
Compliance: ACHC Infusion Pharmacy
ACHC Standards: N/A
URAC Standards: N/A
Policy ID: NUR229
Effective: 3/1/20
Reviewed: 6/1/20, 5/1/22
Revised: 7/1/21, 2/1/22
Approved by: Kathleen Patrick, President, 3/1/20, 7/1/21, 2/1/22

I. POLICY

Teprotumumab is a full human monoclonal antibody used for the treatment of Thyroid Eye Disease (TED). TED is associated with a hyperactive thyroid gland, but it can also be the result of autoimmune disease. Patients with TED can suffer from inflammation, redness, pain, excessive dryness, proptosis, diplopia, vision impairment, corneal ulceration, optic nerve dysfunction, and insecurities with the appearance of bulging eyes. Teprotumumab is currently the only therapy with an FDA indication for the treatment of TED and is formulated for IV administration. Teprotumumab targets and inhibits Insulin-like growth factor I receptor. In turn, the inhibition of insulin-like growth factor receptor prevents downregulation of cytokine and hyaluronan production and cellular differentiation.

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 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. History of diabetes
   4. Other relevant social and/or medical history
   5. Caution is taken in females of child-bearing age

C. CarePathRx treatment protocol for anaphylaxis will be instituted unless a more comprehensive patient-specific orders are provided by physician. See policy NUR012 (Appendix A).

D. All patients referred for teprotumumab therapy shall meet the clinical admission criteria

E. Onboarding information will include:
   1. Horizon Patient Services™ Patient Enrollment Form
   2. Past Medical History

3. For female patients of child-bearing age, confirmation of negative pregnancy test, date of last menstrual cycle, and documentation of contraceptive use
4. Glucometer availability
5. Fax/email information for prescribing office

F. Physician orders for Teprotumumab must include:
1. Patient weight (actual)
2. Drug and weight-based dosage
3. Route of administration
4. Frequency of administration
5. Ana-kit per protocol (required for first doses)

III. ADMINISTRATIVE GUIDELINES

A. Usual dose and administration:
1. Teprotumumab can be given via peripheral or central intravenous access
2. Week 0 dosed at 10mg/kg; week 3 and subsequent infusions dosed at 20mg/kg
3. Frequency is every 3 weeks for a total of 8 infusions
4. The first two infusions must be administered over 90 minutes after which the infusion time may be reduced to 60 minutes if well tolerated. Do not administer as IV push or bolus. **Use in-line 0.2-micron low protein-binding filter.**

B. A subsequent cycle of treatment may be trialed for patients who do not respond to Teprotumumab or have relapsing symptoms after the first cycle of 8 infusions. Dosing and duration are at the discretion of the treating physician or may be indicated by the patient's insurance.

C. CarePathRx treatment protocol for anaphylaxis will be instituted unless otherwise ordered by physician. See policy NUR012. (Appendix A)

IV. NURSING PROCEDURE:

A. Supplies:
1. Syringes of normal saline
2. Alcohol swabs
3. Vials of Teprotumumab 500mg
4. Vials of SWFI for reconstitution
5. Syringes for reconstitution (10 mL) and for removing excess saline (35-50mL) and needles (20 Gx 1")
6. Bag of sodium chloride 0.9%
7. IV pole
8. IV administration set with 0.2-micron filter
9. IV start kit
10. Anaphylaxis Kit (required for first doses)

11. Epinephrine Kit (for patients coming on service for infusions 2-8)

B. Photographing

NOTE: For treatment purposes, nurses may request to take photographs of a patient's face to monitor proptosis, eye redness, and related clinical markers. Permission and actions must comply with institutional policy. *UPMC Policy HS-FM0214 provides permission to photograph for treatment purposes. Verify that ***Authorization for Video, Audio, Recording, and Photographic Participation*** (Attachment A) is signed and on file in patient chart.

1. Explain the reason why we are photographing
2. Advise the patient that the photograph will be used for treatment purposes only
3. Assure the patient that the photograph will be scanned and filed in their confidential EMR

C. Administration

1. Wash hands

2. Obtain baseline vital signs and blood glucose level

    a. There is currently no recommendation to hold the infusion based on hyperglycemia. If blood glucose level prior to infusion is > 250mg/dL:
        - Determine patient's baseline levels (if routinely monitored)
        - Assess recent oral intake and/or medication use for other causes of hyperglycemia
        - Proceed with infusion based on clinical judgement and patient's status

3. Don gloves

4. Establish venous access prior to preparation of drug

5. Counsel the patient on warnings, precautions, and potential side effects including but not limited to:
    a. infusion reactions, nausea, diarrhea, hyperglycemia, headache, alopecia, dry skin, hearing impairments

6. Counsel females of reproductive potential on risk of fetal harm and need to use effective contraception.

7. Counsel patients benefit of smoking cessation, if applicable

8. Prepare product:

    a. Each Teprotumumab vial contains 500 mg of Teprotumumab. Store vials at 2°-8°C (36°-46°F) and protect from light.
    b. Reconstitute each vial with 10mL of SWFI. Ensure stream of diluent is not directed onto the lyophilized powder. Swirl gently to dissolve powder; **do not shake**.
    c. The reconstituted solution has a volume of 10.5mL. Visually inspect solution for any

particulate matter or discoloration.

d. Total dose of reconstituted product should be further diluted in 0.9% sodium chloride to a final max concentration of 18mg/mL. Withdraw volume of sodium chloride from the bag equivalent to amount of reconstituted teprotumumab prior to adding drug.
   - If dose is 1800 mg or less, total volume will be 100mL
   - If dose is greater than 1800 mg, total volume will be 250mL

e. Reconstituted product must be infused within 1 hour of compounding

9. Begin infusion at prescribed rate using. **Use in-line 0.2-micron low protein-binding filter.**

10. Obtain TPR and BP:
    a. 15 minutes after infusion has been started
    b. Every 30 minutes thereafter during infusion based on RN evaluation of the patient's response
    c. 15 minutes following completion of infusion
    d. Caregiver may be taught vital sign monitoring

11. In case of mild adverse reaction:
    a. Stop infusion until symptoms subside
    b. Resume infusion at slower rate

12. If reaction continues or increases:
    a. Stop infusion
    b. Administer emergency meds
    c. Notify physician immediately. Patient may be transferred to Emergency room or appropriate medical setting if necessary.

13. Discontinue infusion or heparinize line when complete.

14. Document administration on Teprotumumab Nursing Assessment form and forward with pictures to prescriber.

V. MONITORING:

A. Follow-up pharmacy assessment will include:
   1. Assessment of signs and symptoms of disease progression and therapy response
   2. Evaluation of comorbidities that may be impacted by teprotumumab (i.e. Inflammatory bowel disease)
   3. Assessment of signs and symptoms of adverse effects
   4. Confirmation of contraceptive use in female patients of reproductive potential

VI. REFERENCES:

Tepezza [package insert]. Lake Forest, IL. Horizon Therapeutics. 2020.

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

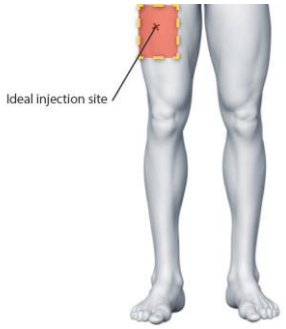
1. **Remove 1 of each item:**
   a. 1 -syringe
   b. 1 – brown labeled filter needle (BD Filter Needle)- **for ampul use only**
   c. 1 – black labeled safety needle (Magellan Hypodermic Safety Needle 22G x 1”)
   d. 1 ampul of epinephrine

Prepare IM (intramuscular) injection of Epinephrine:

1. **Attach the brown filtered needle to syringe.** 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 ampule. **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 **hold 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.