Memorial Healthcare System

TEPLIZUMAB (TZIELD)

PATIENT INFORMATION / REFERRAL STATUS

Referral Status: □ New Referral □ Updated Order □ Order Renewal **Date:** _____

Patient Name: _____ DOB: _____

ICD-10 Code: _____ ICD-10 Description/Diagnosis: _____

Allergies: □ NKDA Allergies: _____ Weight: _____ □ lbs/□ kg Height: _____

Patient Status: □ New to Therapy □ Continuing Therapy Last Treatment Date: _____ Next Due Date: _____

PROVIDER / PRACTICE INFORMATION

Ordering Provider: _____ Provider NPI: _____

Referring Practice Name: _____ Phone: _____ Fax: _____

Practice Address: _____ City: _____ State: _____ Zip: _____

Referral Coordinator Name: _____ Email: _____ Alternative Phone Number: _____

REFERRING PROVIDER COMMUNICATIONS

□ I have reviewed the prescribing information and medication guide for Tzield (Teplizumab).

- Consider screening patients for active serious infection or chronic active infection other than localized skin infections and CRITERIA FOR USE:
  - Confirmed Stage 2 Type 1 Diabetes (presence of > = 2 pancreatic islet autoantibodies + dysglycemia without overt hyperglycemia)
  - No active infections (e.g., EBV, CMV)
  - No live or live-attenuated vaccines within 8 weeks prior to treatment
  - No inactivated or mRNA vaccines within 2 weeks prior to treatment
  - Normal CBC and liver function tests
  - No prior treatment with Teplizumab
  - Not on concurrent immunosuppressive therapies

NURSING PROTOCOL COMMUNICATIONS

☒ Provide nursing care, vital signs, monitoring according to Memorial Outpatient Procedures. Establish/maintain IV access and administer medication as ordered. Remove peripheral IV access after infusion completion if applicable. Follow infusion-related/hypersensitivity reactions management according to MHS Outpatient Adverse Reaction Protocol available for review on at mhs.net/services/pharmacy/infusion-services/outpatient-infusion.

☒ Discharge/Follow-up instructions according to Memorial Outpatient Procedures.

LABORATORY ORDERS

☒ ***Pregnancy, Urine for females of childbearing potential who have not undergone a hysterectomy:*** Once

☒ ***POCT Glucose:*** Every visit

Day 1, Day 3, Day 5, Day 8, Day 11, Day 14:

☒ ***CBC with Diff:*** Once

☒ ***Comprehensive Metabolic Panel:*** Once

Memorial Healthcare System

TEPLIZUMAB (TZIELD)

PRE-MEDICATION ORDERS DAYS 1-5 (30 Minutes Prior to Therapy)

☒ Acetaminophen (Tylenol) 650 mg PO
☒ Ondansetron (Zofran-ODT) 4 mg PO
☒ Diphenhydramine (Benadryl) ☐ 25 mg ☐ 50 mg PO
☐ Loratadine (Claritin) 10 mg PO
☐ Ibuprofen (Advil) 400 mg PO

PRE-MEDICATION ORDERS DAYS 6-14 (30 Minutes Prior to Therapy)

☒ Acetaminophen (Tylenol) 650 mg PO
☒ Ondansetron (Zofran-ODT) 4 mg PO
☐ Diphenhydramine (Benadryl) ☐ 25 mg ☐ 50 mg PO
☐ Loratadine (Claritin) 10 mg PO
☐ Ibuprofen (Advil) 400 mg PO

THERAPY PLAN

Medication Name: Teplizumab-mzwv (TZIELD)

Loading Dose:

- Day 1: 65 mcg/m² at 50 mL/hr
- Day 2: 125 mcg/m² at 50 mL/hr
- Day 3: 250 mcg/m² at 50 mL/hr
- Day 4: 500 mcg/m² at 50 mL/hr

Maintenance Dose: 1,030 mcg/m² at 50 mL/hr daily on Days 5-14 (10 treatments)

Route: ☒ IV ☐ SQ ☐ IM

Infuse over: ☒ 30 minutes ☐ 1 Hour ☐ 2 Hours ☐ Other:_____

Diluent/Volume/Concentration/Special tubing/Filters will be in accordance with the product package insert.

☒ Flush with 0.9% sodium chloride at completion per protocol or medication-specific instructions

Additional Administration Instructions:

Do not shake. Administration of teplizumab must begin within 2 hours after start of preparation through a dedicated IV line. Infuse over at least 30 minutes and no more than 240 minutes. Monitor for signs/symptoms of cytokine-release syndrome, infection, or hypersensitivity reactions.

Note to Pharmacy/Comments:

_____

_____

Refills: ☐ Zero ☐ for 12 months ☐ Other:_____

(if not indicated, order will expire one year from date signed)

_____	_____	_____
Provider Name (Print)	***Provider Signature***	***Date***

Memorial Healthcare System

Adverse Reaction Management Protocol (Adult)

Observe patient for infusion related and hypersensitivity reactions such as fever, chills, rigors, pruritus, rash, cough, sneezing, throat irritation, nausea, vomiting.

If reaction occurs:

- Stop infusion and assess patient.
- Maintain or establish vascular access if needed
- **Administer emergency medication(s) according to symptoms:**

☒ Acetaminophen 650 mg PO once PRN headache, pain, fever >100.4F, chills or rigors.

☒ Diphenhydramine 50 mg IV once PRN itching, allergies, infusion reaction, hives, pruritic and other nonspecific symptoms of allergic reaction **OR**

☒ Diphenhydramine 50 mg IM once PRN itching, allergies, infusion reaction, hives, pruritic and other nonspecific symptoms of allergic reaction (if no IV access)

☒ Dexamethasone 10 mg IV once PRN shortness of breath or wheezing **OR**

☒ Dexamethasone 10 mg IM once PRN shortness of breath or wheezing (if no IV access)

☒ Ondansetron 4 mg IV once PRN nausea, vomiting **OR**

☒ Ondansetron 4 mg IM once PRN nausea, vomiting (if no IV access)

- May re-start therapy if appropriate when symptoms resolve. Resume infusion at 50% of the previous rate and increase per manufacturer's guidelines.

If a severe allergic/anaphylactic reaction occurs

- Symptoms are rapidly progressing or continuing after administration of PRN medications and/or signs and symptoms of severe allergic/anaphylactic reaction (angioedema, swelling of the mouth, tongue, lips, or airway, dyspnea, bronchospasm with or without hypotension or hypertension)

☒ Notify the Rapid Response / Rescue Alert Team / Blue Alert / 911.

☒ Initiate BLS/ Cardiopulmonary resuscitation if necessary.

☒ Administer Epinephrine 0.3 mg intramuscularly, every 5 MIN PRN rapidly progressing or continuing after administration of PRN medication or signs and symptoms of severe allergic/anaphylactic reaction. Administer every 5-15 minutes as needed preferably in the outer thigh.

☒ Place the patient in a recumbent position, elevate lower extremities.

☒ Continuously monitor vital signs (blood pressure, pulse oximetry, and heart rate).

☒ Contact and notify the referring provider on the day of occurrence once patient is stabilized.

☒ Document reaction in the medical record and complete an incident report once patient is stabilized.