

TZIELD MEDICATION ORDER

Patient's Name (Last, First, Middle) _____ DOB _____

Patient's height in feet and inches _____ Patient's weight in pounds _____

■ Diagnosis

E10.8 Type 1 diabetes mellitus with unspecified complications E10.9 Type 1 diabetes mellitus without complications

■ Details Needed for Approval *Please answer all questions and provide supporting documentation.*

- All chart notes which support diagnosis and treatment plan, including labs and other diagnostic results.
- Chart notes should confirm diagnosis of Stage 2 Type 1 Diabetes, and a clinical history that does not suggest Type 2 Diabetes.
- Please include all laboratory results (most carriers require results within the past 45-60 days), including:
 - Pancreatic islet auto-antibodies of at least two of the following varieties: GAD, IAA, IA-2A, ZnT8A and ICA
 - Dysglycemia without overt hyperglycemia using OGTT
 - Depending on the carrier, dysglycemia may be needed via ≥ 1 of the following: fasting glucose ≥ 100 mg/dL and < 126 mg/dL, 2 hour post-prandial glucose level ≥ 140 mg/dL and < 200 mg/dL, 30 or 60 or 90 min post-prandial ≥ 200 mg/dL, or A1C ≥ 5.7 and $< 6.5\%$ or a $\geq 10\%$ increase in A1C.
 - Blood tests including complete blood count and liver enzyme tests.
 - Insurance carriers may have thresholds for levels of lymphocyte count, hemoglobin, platelet count, neutrophil count, and ALT or AST levels.
 - Some carriers require negative results testing for EBV, CMV and active, serious or chronic infection.
- Has the patient previously been treated with Tzield? _____
- Does the patient have symptoms associated with Stage 3 T1D? _____ *If yes, please document in chart notes.*
- Have all age-appropriate vaccinations been administered? _____ *If no, please provide full details in notes.*
- NOTE: The prescriber must order all laboratory testing for the patient through the course of treatment, including liver enzymes, white blood count and all other testing recommended by the manufacturer.

■ Premedication Order

Oral medications to be taken by the patient at least 60 minutes prior to start of infusion treatment. They may be taken by the patient at home.

Acetaminophen _____ mg Ibuprofen _____ mg Diphenhydramine _____ mg

IV medications to be administered 30 minutes prior to start of the infusion treatment.

Ondansetrom _____ mg Diphenhydramine _____ mg

For all premedications, select frequency of administration: First 5 treatments Each time, full course

■ Tzield (teplizumab) Medication Order

Provide patient's body surface area in meters squared: _____

Administer Tzield according to the following schedule: 65 mcg/m² on day 1, 125 mcg/m² on day 2, 250 mcg/m² on day 3, 500 mcg/m² on day 4, and 1,030 mcg/m² on days 5 through 14. The medication shall be diluted in 18ml of normal saline and administered over 30-60 minutes, one treatment per day, for 14 consecutive days.

■ Rescue Management in case of Infusion Therapy Reaction

These include fever, chills, rigors, headache, rash, itching, swelling, edema, nausea, vomiting, abdominal pain, hypotension, and respiratory distress.

- Stop medication infusion and start normal saline infusion at 50 ml/hr. Call ordering provider to report reaction.
- Follow standing reaction orders, including Diphenhydramine, Methylprednisolone, Albuterol and oxygen as needed.
- For severe reactions, administer Epi-pen (adult or child) or equivalent and call 911. Repeat if severe symptoms persist.

■ Ordering Provider Authorization

Provider Signature: _____ Name: _____ Date: _____

Address: _____

Phone: _____ Fax: _____ Indiv. NPI #: _____ License: _____

Best Contact Person in Office: _____ Direct Phone to Contact Person: _____

FAX THIS ORDER AND SUPPORTING DOCUMENTATION TO 201-266-0437 OR UPLOAD USING YOUR SECURE DEDICATED WEBPAGE – TO GET A PERSONAL LINK PLEASE CONTACT THE INTAKE TEAM.