Government of District of Columbia Department of Health Care Finance

Teplizumab-mzwv (Tzield™) injection, for intravenous use, **Prior Authorization Request**

REQUEST DATE: / /

PATIENT INFORMATION

PATIENT'S MEDICAID ID NUMBER

PATIENT'S DATE OF BIRTH / /

PATIENT'S FULL NAME

PRESCRIBER INFORMATION

PRESCRIBER'S FULL NAME

PRESCRIBER PHONE NUMBER: – –

PRESCRIBER FAX NUMBER: – –

PRESCRIBER SPECIALTY*:

PRESCRIBER NPI #: –

Must be prescribed by or in consultation with an endocrinologist

PHARMACY INFORMATION

PHARMACY NAME

PHARMACY PHONE NUMBER: – –

PHARMACY FAX NUMBER: – –

PHARMACY NPI #:

+

Summary of FDA Approved Prescribing Information TZIELD™ (teplizumab-mzwv) is a CD3-directed monoclonal antibody indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D.

PRIOR AUTHORIZATION REQUEST: Confirmation of diagnosis as per the ADA current clinical practice guidelines, and use per FDA approved labeling is required

1. **The patient is at least 8 years of age with Stage 2 Type I diabetes as confirmed by clinical markers.** ***Submit at least 2 supporting labs with request*** ☐ Yes ☐ No
   [(Glutamic acid decarboxylase 65 (GAD65) autoantibodies; Insulin autoantibody (IAA); Insulinoma-associated antigen 2 autoantibody (IA-2A) Zinc transporter 8 autoantibody (ZnT8A); Islet cell autoantibody (ICA)]
2. **The patient has presence of dysglycemia without overt hyperglycemia as confirmed by using an oral glucose tolerance test (OGTT) (or in the alternative, submit supporting labs** (i.e. Fasting plasma glucose, 2 hour post prandial plasma glucose level, A1C, or ≥ 10% increase in A1C.**)** ☐ Yes ☐ No
3. **The patient's clinical history does not suggest TYPE II diabetes, NOR has progressed to Stage 3 Type 1 diabetes (increased urination, excessive thirst, weight loss).** ☐ Yes ☐ No
4. **Patient has absence of acute infection, and is without hematologic or hepatic compromise** (**Submit supporting labs--**Liver enzymes-AST/ALT, Bilirubin, CBC (ANC, Platelets, Hgb, etc., please include baseline labs references and dates as clinically appropriate) ☐ Yes ☐ No
5. **Patient has not been previously treated with TZIELD™** and has no recent or planned live or inactivated vaccines, within (<8 weeks) or (< 2 weeks) of treatment, Respectively. Provider will monitor for Cytokine release syndrome (CRS), and premedicate patient with antipyretics, antihistamines, and or antiemetics ☐ Yes ☐ No

Approval is for one treatment course per lifetime. Please specify dosing schedule using patient's BSA(m^2) below: **Patient BSA(m^2)**_____

Patient's height _____ **cm/in** **Patient's weight** _____ **lbs/kg**

6.

Day 1: 65 mcg/m2	**Dose:**
Day 2: 125 mcg/m2	**Dose:**
Day 3: 250 mcg/m2	**Dose:**
Day 4: 500 mcg/m2	**Dose:**
Days 5 to 14: 1,030 mcg/m2	**Dose:**

Note: Pharmacy must be enrolled in DC Medicaid Mental Health Specialty Network and will deliver the medication to the clinic or physician office where the administration will take place. Tzield™ approved per these criteria shall be administered in an infusion center setting with appropriately trained personnel.

I certify that, to the best of my knowledge, all information I have provided on this request is complete and accurate and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PRESCRIBER'S SIGNATURE: _____ **DATE**: _____

FAX TO: District of Columbia Pharmacy Program
Phone: 1-800-273-4962
Fax: 1-866-535-7622