



## **RX.PA.093.CCH TZIELD (TEPLIZUMAB-MZWV)**

The purpose of this policy is to define the prior authorization process for Tzield (teplizumab-mzwv) for pediatric patients aged 8 years and older and adults with Stage 2 type 1 diabetes.

### **DEFINITIONS**

N/A

### **POLICY**

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Tzield (teplizumab-mzwv), is subject to the prior authorization process.

### **PROCEDURE**

#### **Initial Authorization Criteria:**

*Must meet all the criteria listed below:*

- Must be age 8 years or older
- Must have documentation supporting the diagnosis of stage 2 Type 1 Diabetes, with BOTH of the following:
  - At least two of the following positive pancreatic islet cell autoantibodies
    - Glutamic acid decarboxylase 65 (GAD) autoantibodies
    - Insulin autoantibody (IAA)
    - Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - Zinc transporter 8 autoantibody (ZnT8A)
    - Islet cell autoantibody (ICA)
  - Dysglycemia on oral glucose testing confirmed within 7 weeks of baseline visit defined as one of the following:
    - Fasting blood glucose greater than 110mg/dL or and less than 126mg/dL OR
    - 2-hour glucose greater or equal to 140mg/dL and less then 200mg/dL OR
    - 30-, 60-, or 90-minute value greater than or equal to 200mg/dL
- Must not have the following:

- Lymphocyte count less than 1,000 lymphocytes/mcL
- Hemoglobin less than 10 g/dL
- Platelet count less than 150,000 platelets/mcL
- Absolute neutrophil count less than 1,500 neutrophils/mcL
- Elevated ALT or AST greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN
- Laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV)
- Must not have active serious infection other than localized skin infections
- Must not have received prior treatment with teplizumab

**Limitations:**

<b>Length of Authorization (if above criteria met)</b>	
Initial Authorization	Up to 6 months
Reauthorization	N/A (one course per lifetime)

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

**Codes:**

<b>CPT Codes / HCPCS Codes / ICD-10 Codes</b>		
Code	Brand	Description
J9381	Tzield	Injection, teplizumab-mzwv, 5 mcg

**References:**

1. Tzield [Package Insert] Red Bank, NJ: Provention Bio, Inc; 2022

**Revision History**

<b>DESCRIPTION OF REVIEW / REVISION</b>	<b>DATE APPROVED</b>
New Policy	01/2024

### **Record Retention**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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