

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 28, 2023

TZIELD™ (teplizumab-mzwv)

LENGTH OF AUTHORIZATION: One treatment course per lifetime

REVIEW CRITERIA:

- Patient must be ≥ 8 years of age.
- Patient must have a confirmed diagnosis of Stage 2 Type 1 diabetes by both of the following:
 - Two 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); **AND**
 - Dysglycemia on an oral glucose tolerance test (OGTT) or alternative method if appropriate and OGTT is not available.
- Clinical history of the patient must **NOT** suggest Type 2 diabetes.
- Patient has baseline complete blood count (CBC) with Lymphocytes $> 1,000$ cells per mL.
- Patient has baseline liver enzyme tests.
- Documentation that all age-appropriate vaccinations have been administered prior to starting TZIELD.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Administer by intravenous infusion (over a minimum of 30 minutes) once daily for 14 days.
- Available as 2 mg per 2 mL (1 mg/mL) single-dose vial for injection.