



## MVP Health Care Medical Policy

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### Medicare Part B: Teplizumab-mzwv

<b>Type of Policy:</b>	<b>Drug Therapy</b>
<b>Prior Approval Date:</b>	<b>02/01/2024</b>
<b>Approval Date:</b>	<b>02/01/2025</b>
<b>Effective Date:</b>	<b>04/01/2025</b>
<b>Related Policies:</b>	<b>N/A</b>

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### Drugs Requiring Prior Authorization under the medical benefit

**J9381** Tzielid (teplizumab-mzwv)

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#### Overview/Summary of Evidence

Tzielid is an IV administered anti-CD3 antibody, designed to bind to certain immune system cells, moderate the body's immune response, and delay progression to stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years of age and older with stage 2 T1D. T1D is an autoimmune disease resulting from inability to make insulin and requiring insulin replacement.

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#### Indications/Criteria

Teplizumab may be considered for coverage when the following criteria is met:

- Prescribed by, or in consultation with an endocrinologist
- Diagnosis of stage 2 type 1 diabetes with documentation of the **ALL** following:
  - At least TWO positive pancreatic islet cell autoantibodies (Glutamic acid decarboxylase 65 autoantibody, Insulin autoantibody, Insulinoma-associated antigen 2 autoantibody, Zinc transporter 8 autoantibody, or Islet cell autoantibody) confirmed within the past 6 months
  - Evidence of dysglycemia without overt hyperglycemia using an oral glucose tolerance test. Dysglycemia defined as a fasting glucose level of

110 to 125mg/dL, a 2-hour postprandial plasma glucose level of at least 140 mg/dL and less than 200mg/dL or an intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200mg/dL on two occasions within the past 60 days.

- Confirmation that member does not have type 2 diabetes
- Documentation of complete blood count confirming member has hemoglobin greater than 10 g/dL, lymphocyte count greater than 1,000 lymphocytes/mcL, platelet count greater than 150,000 platelets/mcL, and absolute neutrophil count greater than 1,500 neutrophils/mcL.
- Documentation that member does not have alanine aminotransferase (ALT) or aspartate aminotransferase (AST) concentrations greater than 2 times the upper limit of normal (ULN) or bilirubin concentration greater than 1.5 times the ULN.
- Member is 8 years of age or older

**Initial approval** will be for 14 consecutive infusions within two months. Additional courses and requests for replacement due to lost or damaged product will not be covered.

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### **Exclusions**

The use of teplizumab will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
  - Diagnosis of type 2 diabetes
  - In patients with active serious infection or chronic infection, other than localized skin infections, or in patients with laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV).
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### **References**

1. Tzielid (teplizumab-mzwv) injection package insert. Red Bank, NJ: Provention Bio, Inc.; 12/2023.