



MVP Health Care Medical Policy

Medicare Part B: Teplizumab-mzwv

Type of Policy:	Drug Therapy
Prior Approval Date:	02/01/2025
Approval Date:	02/01/2026
Effective Date:	04/01/2026
Related Policies:	N/A

Drugs Requiring Prior Authorization under the medical benefit

J9381 Tzielid (teplizumab-mzwv)

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 members 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.

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.

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 members with active serious infection or chronic infection, other than localized skin infections, or in members with laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV).
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References

1. Tzield (teplizumab-mzwv) injection package insert. Red Bank, NJ: Provention Bio, Inc.; 12/2023.
2. Berold KC, Bundy BN, Long SA, et al. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes [published correction appears in N Engl J Med. 2020 Feb 6;382(6):586]. N Engl J Med. 2019;381(7):603-613. doi:10.1056/NEJMoa1902226.

