Reference number(s)
5678- A

Specialty Guideline Management
Tzield

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tzield	teplizumab-mzwv

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication[1]

Tzield is indicated to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients 8 years of age and older with Stage 2 type 1 diabetes.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Presence of two or more pancreatic islet cell autoantibodies within the past 6 months.
- Abnormal oral glucose tolerance test (OGTT) results within the past 2 months.

Prescriber Specialties

This medication must be prescribed by or in consultation with an endocrinologist.

Coverage Criteria

Delay of Stage 3 Type 1 Diabetes[1-3]

Authorization of 1 month may be granted for members with Stage 2 type 1 diabetes to delay the onset of Stage 3 type 1 diabetes when all of the following criteria are met:

- Member is 8 years of age and older.
- Member has two or more of the following pancreatic islet cell autoantibodies detected in two samples obtained within the past 6 months:
  - 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)
- Member has an abnormal oral glucose tolerance test (OGTT) confirming dysglycemia within the past 2 months when any of the following are met:
  - Fasting blood glucose level of 100 to 125 mg/dL (5.6 to 6.9 mmol/L)
  - 2-hour postprandial plasma glucose level of at least 140 mg/dL (7.8 mmol/L) and less than 200 mg/dL (11.1 mmol/L)
  - Intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200 mg per deciliter (11.1 mmol/L) on two occasions
- Member does not have symptoms associated with type 1 diabetes (e.g., increased urination, excessive thirst, weight loss).
- Member will not exceed a one-time 14-day treatment course consisting of the following dosing schedule:
  - Day 1: 65 mcg/m^2
  - Day 2: 125 mcg/m^2
  - Day 3: 250 mcg/m^2
  - Day 4: 500 mcg/m^2
  - Days 5 through 14: 1,030 mcg/m^2

References

1. Tzield [package insert]. Red Bank, NJ: Provention Bio, Inc.; April 2025.
2. Herold KC, Bundy BN, Long SA, et al. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. N Engl J Med 2019; 381:603-613. https://www.nejm.org/doi/full/10.1056/nejmoa1902226.
3. American Diabetes Association Professional Practice Committee; 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes-2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S27–S49.