

# 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<sup>1</sup>

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<sup>1-3</sup>

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<sup>2</sup>
  - Day 2: 125 mcg/m<sup>2</sup>
  - Day 3: 250 mcg/m<sup>2</sup>
  - Day 4: 500 mcg/m<sup>2</sup>
  - Days 5 through 14: 1,030 mcg/m<sup>2</sup>

## References

1. Tzield [package insert]. Red Bank, NJ: Provention Bio, Inc.; December 2023.

Reference number(s)
5678-A

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—2024*. *Diabetes Care* 1 January 2024; 47 (Supplement\_1): S20–S42.