CVS Caremark®

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| 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 Indication1

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 Diabetes1-3

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/m2
  + Day 2: 125 mcg/m2
  + Day 3: 250 mcg/m2
  + Day 4: 500 mcg/m2
  + Days 5 through 14: 1,030 mcg/m2

## References

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