Reference number(s)
5682-A

Standard Medicare Part B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

- 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.

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Reference number(s)
5682-A

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

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Tzield.
- The available compendium

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- American Diabetes Association Professional Practice Committee; 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes-2025.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tzield are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for a fasting blood glucose level of 100 to 125 mg/dL can be found in the American Diabetes Association Standards of Care in Diabetes 2025 guidelines.

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.

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.