Reference number(s)
5682-A

STANDARD MEDICARE PART B MANAGEMENT

TZIELD (teplizumab-mzwv)

POLICY

I. 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
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 policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Presence of two or more pancreatic islet cell autoantibodies within the past 6 months
B. Abnormal oral glucose tolerance test (OGTT) results within the past 2 months

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

Delay of Stage 3 Type 1 Diabetes
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:
A. Member is 8 years of age and older
B. Member has two or more of the following pancreatic islet cell autoantibodies detected in two samples obtained within the past 6 months:
    1. Glutamic acid decarboxylase 65 (GAD) autoantibodies
    2. Insulin autoantibody (IAA)
    3. Insulinoma-associated antigen 2 autoantibody (IA-2A)
    4. Zinc transporter 8 autoantibody (ZnT8A)
    5. Islet cell autoantibody (ICA)
C. Member has an abnormal oral glucose tolerance test (OGTT) confirming dysglycemia within the past 2 months when any of the following are met:
    1. Fasting blood glucose level of 110 to 125 mg/dL (6.1 to 6.9 mmol/L)

2. 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)
3. Intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200 mg per deciliter (11.1 mmol/L) on two occasions

D. Member does not have symptoms associated with type 1 diabetes (e.g., increased urination, excessive thirst, weight loss)
E. Member will not exceed a one-time 14-day treatment course consisting of the following dosing schedule:
1. Day 1: 65 mcg/m^2
2. Day 2: 125 mcg/m^2
3. Day 3: 250 mcg/m^2
4. Day 4: 500 mcg/m^2
5. Days 5 through 14: 1,030 mcg/m^2

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Tzield.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

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

VI. EXPLANATION OF RATIONALE

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

VII. REFERENCES

1. Tzield [package insert]. Red Bank, NJ: Provention Bio, Inc.; November 2022.
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.