Reference number
5678-A

SPECIALTY GUIDELINE 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 are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
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 100 to 125 mg/dL (5.6 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. 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.