Tzield (teplizumab-mzwv)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Tzield (teplizumab-mzwv) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Tzield is indicated to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients aged 8 years and older with Stage 2 type 1 diabetes.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Presence of two or more pancreatic islet cell autoantibodies
B. Abnormal oral glucose tolerance test (OGTT) results

Prescriber Specialty

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

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 or older
B. Member has a family member diagnosed with Type 1 Diabetes
C. Member has two or more of the following pancreatic islet cell autoantibodies:
    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)
D. Member has an abnormal oral glucose tolerance test (or alternative glycemic test if an oral glucose-tolerance test is not available) confirming dysglycemia without overt hyperglycemia 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)
E. Member does not have symptoms associated with type 1 diabetes (e.g., increased urination, excessive thirst, weight loss)
F. Member's clinical history does not suggest Type 2 Diabetes
G. 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

Continuation of Therapy
Approval is limited to one 14-day treatment course per lifetime.

Tzield is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits
Treatment is limited to one 14-day treatment course per lifetime.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3590: Unclassified biologics (when specified as [Tzield] (teplizumab-mzwv))
- C9399: Unclassified drugs or biologicals (when specified as [Tzield] (teplizumab-mzwv))
- C9149: Inj, teplizumab-mzwv, 5 mcg (termed 7/1/2023)
- J9381: Injection, teplizumab-mzwv, 5 mcg (effective 7/1/2023)

REFERENCES

- Tzield [Package Insert]. Red Bank, NJ: Provention Bio, Inc.; November 2022.
- Herold KC, Bundy BN, Long SA, et al. Type 1 Diabetes TrialNet Study Group. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. N Engl J Med. 2019 Aug 15;381(7):603-613.
- ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. Standards of Care in Diabetes—2023. Diabetes Care 2023;46(Suppl. 1):S1–S280.

POLICY HISTORY

Policy #: 05.04.89
Original Effective Date: April 10, 2023
Reviewed: April 2023
Revised: April 2023
Current Effective Date: May 18, 2023