Wellmark Advantage Health Plan

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Effective Date: 01/01/2023

Tzield™ (teplizumab-mzwv)

HCPCS: J3590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Patient must be a nondiabetic at high risk for developing clinical Type 1 diabetes as evidenced by ALL of the following:
      i. Patient must have a direct relative with Type 1 diabetes
         1. If first-degree relative (parent, sibling, offspring), patient must be between 8 and 45 years old
         2. If a second- or third-degree relative (niece, nephew, aunt, uncle, cousin, grandchild), patient must be between 8 and 20 years old.
      ii. Documentation of abnormal glucose tolerance by oral glucose tolerance test (OGTT), defined as any of the following occurring at least once for patients under 18 years of age or on two occasions for patients 18 years of age and older within the last 2 months:
         1. Fasting blood glucose level of 110mg/dL to < 126 mg/dL, OR
         2. 2-hour postprandial glucose > 140 mg/dL and < 200 mg/dL, OR
         3. Postprandial glucose level at 30, 60, or 90 minutes > 200 mg/dL
      iii. Presence of at least two of the following diabetes-related autoantibodies on two occasions within the previous 6 months: anti-GAD65, anti-ICA512, anti-insulin (MIAA), ZnT8, and/or ICA
         1. Autoantibodies found on the second occasion do not need to involve the same autoantibodies found on the first occasion
   b. Prescribed by or in consultation with an endocrinologist
   c. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the Wellmark Advantage Health Plan medical utilization management drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: Align with FDA recommended dosing
   b. Initial Authorization Period: Align with FDA recommended duration of treatment
   c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- T1D is an autoimmune condition that leads to the destruction of insulin-secreting beta-cells which are responsible for insulin production.

- Over 1.6 million people in the United States are living with T1D, and approximately 64,000 people are newly diagnosed with T1D each year.

- Diagnosis often occurs in children and young adults but can occur at any age.

- The incidence rate for T1D peaks at approximately 12 years of age, and those diagnosed by 10 years of age have a reduced life expectancy by 16 years.

- The American Diabetes Association Standards of Medical Care in Diabetes (2022) recommends individuals with T1D be treated with multiple daily injections of prandial and basal insulin, or continuous subcutaneous insulin infusion.

- There are no disease-modifying or preventative therapies currently available for T1D.

References:

1. Sims EK, Bundy BN, et al. Teplizumab improves and stabilizes beta cell function in antibody-positive high-risk individuals. Science Translational Medicine. 3 Mar 2021. 13:583. Available at: https://doi.org/10.1126/scitranslmed.abc8980
2. Herold KC, et al. An anti-CD3 antibody, teplizumab, in relatives at risk for type 1 diabetes [published correction appears in N Engl J Med. 2020 Feb 6;382(6):586]. N Engl J Med. 2019;381(7):603-613. doi:10.1056/NEJMoa1902226
3. Manufacturer Press Release. Provention Bio's Teplizumab Continued to Significantly Delay the Onset of Insulin-Dependent Type 1 Diabetes (T1D) in Presymptomatic Patients. June 15, 2020. Accessed on June 27, 2022. Available at: https://investors.proventionbio.com/2020-06-15-Provention-Bios-Teplizumab-Continued-to-Significantly-Delay-the-Onset-of-Insulin-Dependent-Type-1-Diabetes-T1D-in-Presymptomatic-Patients
4. IPD Analytics. Teplizumab New Drug Preview. August 5, 2022. Accessed August 31, 2022. https://www.ipdanalytics.com

Policy History		
#	Date	Change Description
1.1	Effective Date: 01/01/2023	New Policy
1.0	Effective Date: 10/06/2022	Preliminary drug review

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*