Tzield® (teplizumab-mzwv)
(Intravenous)

Document Number: IC-0687

Last Review Date: 05/05/2026
Date of Origin: 01/03/2023
Dates Reviewed: 01/2023, 1/2024, 1/2025, 01/2026, 05/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 14 doses.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 5600 billable units over a 14-day course of therapy

III. Initial Approval Criteria [1,6]

Prior authorization validity is provided in the following conditions:

- Member is at least 1 year of age; **AND**
- Member has not received prior therapy with teplizumab; **AND**
- Provider will confirm that member is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member has been evaluated for the absence of active Epstein-Barr virus (EBV) or cytomegalovirus (CMV) infection and has been confirmed to have an undetectable viral load (e.g., polymerase chain reaction [PCR] testing); **AND**
- Member does not have any of the following laboratory indices:
    - Lymphocyte count less than 1,000 lymphocytes/mcL
    - Hemoglobin less than 10 g/dL
    - Platelet count less than 150,000 platelets/mcL
    - Absolute neutrophil count less than 1,500 neutrophils/mcL
    - Elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than 2 times the upper limit of normal (ULN)
    - Bilirubin greater than 1.5 times ULN; **AND**
- Provider will confirm that member will not receive live or live-attenuated vaccines within 8 weeks OR inactivated or mRNA vaccines within 2 weeks, prior to or during treatment; **AND**

- Provider will confirm that the member's diagnosis is of autoimmune origin and does not suggest Type 2 Diabetes Mellitus or other forms of diabetes *(including, but not limited to, genetic forms of diabetes, maturity-onset diabetes of the young [MODY], latent autoimmune diabetes in adults [LADA], or diabetes secondary to medications or surgery)*; **AND**
- Used as single agent therapy**; AND**

Type 1 Diabetes Mellitus † Φ [1,6]

- Member will receive treatment to delay the onset of Stage 3 type 1 diabetes: **AND**
- Member has a confirmed diagnosis of Stage 2 type 1 diabetes as documented by the following:
    - Member has two or more of the following pancreatic islet cell autoantibodies:
        - 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); **AND**
    - Dysglycemia without overt hyperglycemia using an oral glucose tolerance test *(if an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate)* defined as one of the following:
        - Fasting glucose 100-125 mg/dL
        - 2-hour postprandial plasma glucose 140-199 mg/dL
        - An intervening postprandial glucose level at 30, 60, or 90 minutes of ≥ 200 mg/dL
        - A1C 5.7-6.4% or ≥ 10% increase in A1C

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded *(refer to Section I)*

V. Dosage/Administration [1]

Indication	Dose
T1DM	Administer Tzield by intravenous infusion over a minimum of: • 30 minutes in adult and pediatric members aged 8 years and older • 2 hours in pediatric members aged 1 to less than 8 years Calculate the dosage using body surface area (BSA) and administer TZIELD once daily for 14 consecutive days as follows: • 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 Do not administer two doses on the same day. Refer to the prescribing information regarding missed doses.
Prior to each of the first 5 days of Tzield infusion: • Premedicate with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen • Premedicate with an antihistamine, and • Consider premedication with an antiemetic. If needed, administer additional premedication doses.	

VI. Billing Code/Availability Information

HCPCS Code:

- J9381 – Injection, teplizumab-mzwv, 5 mcg; 1 billable unit = 5 mcg

NDC:

- Tzield 2 mg/2 mL solution for injection as a single-dose vial: 73650-0316-xx

VII. References

1. Tzield [package insert]. Morristown, NJ; Provention Bio, Inc.; April 2026. Accessed April 2026.
2. Leung SS, Borg DJ, McCarthy DA, et al. Soluble RAGE Prevents Type 1 Diabetes Expanding Functional Regulatory T Cells. Diabetes. 2022 Sep 1;71(9):1994-2008. doi: 10.2337/db22-0177.
3. Herold KC, Bundy BN, Long SA, Type 1 Diabetes TrialNet Study Group, et al. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. N Engl J Med. 2019 Aug 15;381(7):603-613. doi: 10.1056/NEJMoa1902226. Epub 2019 Jun 9. Erratum in: N Engl J Med. 2020 Feb 6;382(6):586.
4. Insel RA, Dunne JL, Atkinson MA, et al. Staging presymptomatic type 1 diabetes: a scientific statement of JDRF, the Endocrine Society, and the American Diabetes Association. Diabetes Care. 2015 Oct;38(10):1964-74. doi: 10.2337/dc15-1419.
5. American Diabetes Association Professional Practice Committee; 3. Prevention or Delay of Diabetes and Associated Comorbidities: Standards of Care in Diabetes—2024. Diabetes Care 1 January 2024; 47 (Suppl._1): S43–S51. https://doi.org/10.2337/dc24-S003
6. American Diabetes Association Professional Practice Committee for Diabetes; 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes—2026. Diabetes Care 2026; 49 (Supplement_1): S27–S49. https://doi.org/10.2337/dc26-S002
7. American Diabetes Association Professional Practice Committee for Diabetes; 3. Prevention or Delay of Diabetes and Associated Comorbidities: Standards of Care in Diabetes—2026. Diabetes Care January 2026; 49 (Supplement_1): S50–S60. https://doi.org/10.2337/dc26-S003

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E10.A2	Type 1 diabetes mellitus, presymptomatic, Stage 2

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC