Applicable Drugs: Tzield (teplizumab-mzwv)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/27/2023

Date Last Reviewed / Revised: 8/26/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of the following condition AND must meet criteria listed under applicable diagnosis:

A. Stage 2 type 1 diabetes (T1D) and BOTH criteria 1 and 2 are met:

1. At least two of the following pancreatic islet autoantibodies on two separate occasions:

a) Glutamic acid decarboxylase 65 (GAD) autoantibodies

b) Insulin autoantibody (IAA)

c) Insulinoma-associated antigen 2 autoantibody (IA-2A)

d) Zinc transporter 8 autoantibody (ZnT8A)

e) Islet cell autoantibody (ICA)

2. Dysglycemia without overt hyperglycemia on an oral glucose tolerance test on (*two consecutive tests required for patients ≥ 18 years old*) defined by one of the following:

a) Fasting blood glucose level greater than or equal to 100 mg/dL and less than or equal to ≤125 mg/dL

b) 2-hour post-prandial plasma glucose level greater than or equal to 140 mg/dL and less than 200 mg/dL

c) 30-, 60-, or 90-minute post-prandial glucose level greater than or equal to 200 mg/dL

II. Minimum age requirement: 8 years old.

III. Treatment must be prescribed by or in consultation with an endocrinologist (pediatric endocrinologist for patients < 18 years old).

EXCLUSION CRITERIA

- Patient has Stage 3 T1D or type 2 diabetes
- Elevated ALT or AST > 2 times the upper limit of normal (ULN) or bilirubin > 1.5 times ULN
- Hemoglobin < 10 g/dL or platelet count < 150,000 platelets/mcL

- Lymphocyte count < 1,000 lymphocytes/mcL
- Active serious infection or acute infection with Epstein-Barr virus or cytomegalovirus
- Chronic active infection other than localized skin infections

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities of up to 14 single-dose vials for injection (2 mg/ 2 ml) total

APPROVAL LENGTH

- **Authorization:** 1 month
- **Re-Authorization:** N/A, total treatment consists of 14 infusions

APPENDIX

N/A

REFERENCES

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3. 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;38(10):1964-1974. doi:10.2337/dc15-1419
4. ElSayed NA, McCoy RG, Aleppo G, et al. Diagnosis and Classification of diabetes: standards of care in diabetes-2025. *Diabetes Care.* 2025;48(Suppl 1):S27-S50. doi:10.2337/dc25-S001
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6. Sims EK, Bundy BN, Stier K, et al. Teplizumab improves and stabilizes beta cell function in antibody-positive high-risk individuals. *Sci Transl Med.* 2021;13(583):eabc8980. doi:10.1126/scitranslmed.abc8980
7. Phillip M, Achenback p, Adala A, et al. Consensus guidance for monitoring individuals with islet autoantibody-positive pre-stage 3 type 1diabetes. Diabetes Care. 2024;47:1276-1298. doi:org/10.2337/dci24-0042.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.