Generic Name: Teplizumab-mzwv

Therapeutic Class or Brand Name: Tzield™

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/27/2023

Date Last Reviewed / Revised: 11/18/2024

PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of the following condition AND must meet ALL criteria listed under applicable diagnosis:
   A. Stage 2 type 1 diabetes (T1D)
      1. At least two of the following pancreatic islet autoantibodies:
         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 ≥ 110 mg/dL and ≤ 125 mg/dL
         b) 2-hour post-prandial plasma glucose level ≥ 140 mg/dL and < 200 mg/dL
         c) 30-, 60-, or 90-minute post-prandial glucose level ≥ 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).

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

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
- Absolute neutrophil count less than 1,500 neutrophils/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

- Fourteen 2 mg/ 2 ml single-dose vials for injection/14 days

APPROVAL LENGTH

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

APPENDIX

N/A

REFERENCES

1. Tzield. Prescribing information. Provention Bio; 2023. Accessed November 7, 2024. https://products.sanofi.us/tzield/tzield.pdf
2. Keam SJ. Teplizumab: First Approval. *Drugs.* 2023;83(5):439-445. doi:10.1007/s40265-023-01847-y
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, Aleppo G, Aroda VR, et al. Classification and diagnosis of diabetes: standards of care in diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1):S19-S40. doi:10.2337/dc23-S002
5. 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(7):603-613. doi:10.1056/NEJMoa1902226
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