Mass General Brigham
Health Plan

Tzield (teplizumab-mzwv)
Effective 07/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

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

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with Tzield, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for treatment when all the following criteria are met:

1. Member is 8 years of age or older
2. Member using requested medication who have Stage 2 type 1 diabetes to delay the onset of Stage 3 type 1 diabetes
3. Medical charts documenting member has an abnormal oral glucose tolerance test (OGTT) confirming dysglycemia within the past 2 months when ONE of the following are met:
    a. Fasting blood glucose level of 110 to 125mg/dL (6.1 to 6.9 mmol/L)
    b. 2-hour post prandial plasma glucose level of at least 140mg/dL (7.8 mmol/L) and less than 200mg/dL (11.1 mmol/L)
    c. Intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200mg/dL (11.1 mmol/L) on two occasions.
4. Medical charts documenting member has TWO or more of the following pancreatic islet cell autoantibodies detected in two samples obtained in the last 6 months:
    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)
5. Member will not exceed a one-time 14-day treatment course consisting of the following dosing schedule:

a. Day 1: 65mcg/m^2
b. Day 2: 125mcg/m^2
c. Day 3: 250mcg/m^2
d. Day 4: 500mcg/m^2
e. Day 5 through 14: 1,030mcg/m^2

6. Provider attestation that member does NOT have a diagnosis of type 2 diabetes
7. Provider attestation that member does NOT have a diagnosis of type 1 diabetes

Limitations

1. Initial approvals will be granted for 1 month

References

1. Tzield [package insert]. Red Bank, NJ: Provention Bio, Inc.; November 2022.
2. 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; 381:603-613. https://www.nejm.org/doi/full/10.1056/nejmoa1902226.

Review History

04/12/2023 – Reviewed and Created for April P&T; Effective 7/1/23