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 (NLX)		
Specialty Limitations	.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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