BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.30.084

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Endocrine and Metabolic Agents	**Original Policy Date:**	December 9, 2022
Subject:	Tzield	**Page:**	1 of 4

Last Review Date: March 8, 2024

Tzield

Description

Tzield (teplizumab-mzwv)

Background
Tzield (teplizumab-mzwv) binds to CD3 (a cell surface antigen present on T lymphocytes) and delays the onset of Stage 3 type 1 diabetes in adults and pediatric patients aged 8 years and older with Stage 2 type 1 diabetes. The mechanism may involve partial agonistic signaling and deactivation of pancreatic beta cell autoreactive T lymphocytes. Tzield leads to an increase in the proportion of regulatory T cells and of exhausted CD8+ T cells in peripheral blood (1).

Regulatory Status
FDA-approved indication: Tzield is a CD3-directed antibody indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D (1).

Select adult and patients and pediatric patients 8 years of age and older for Tzield treatment who have a diagnosis of Stage 2 type 1 diabetes. Stage 2 type 1 diabetes should be confirmed by documenting: (1)

- At least two positive pancreatic islet cell autoantibodies
- 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)

Prior to initiating Tzield, a complete blood count and liver enzyme tests should be obtained. Use of Tzield is not recommended in patients with certain laboratory abnormalities (1).

Cytokine release syndrome (CRS) has been observed in Tzield-treated patients. Patients should be premedicated with antipyretics, antihistamines, and/or antiemetics prior to Tzield treatment. Liver enzymes should be monitored during treatment (1).

All age-appropriate vaccinations should be administered prior to starting Tzield. Live-attenuate vaccines should be administered at least 8 weeks prior to treatment. Inactivated vaccines or mRNA vaccines should be administered at least 2 weeks prior to treatment (1),

The safety and effectiveness of Tzield have not been established in pediatric patients younger than 8 years of age (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tzield may be considered **medically necessary** if the conditions indicated below are met.

Tzield may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 8 years of age or older

Diagnosis

Patient must have the following:

Stage 2 type 1 diabetes (T1D)

AND ALL of the following:

1. Stage 2 T1D has been confirmed by **ALL** of the following:
    a. Presence of two or more of the following pancreatic islet cell autoantibodies

i. Glutamic acid decarboxylase 65 (GAD) autoantibodies
ii. Insulin autoantibody (IAA)
iii. Insulinoma-associated antigen 2 autoantibody (IA-2A)
iv. Zinc transporter 8 autoantibody (ZnT8A)
v. Islet cell autoantibody (ICA)

b. Dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) **OR** an alternative method if OGTT is not available

2. Used to delay the onset of Stage 3 T1D
3. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS)
4. Prescriber agrees to monitor complete blood count (CBC) and liver enzyme tests
5. Prescriber agrees to administer premedications as necessary, such as antipyretics, antihistamines, and antiemetics
6. Prescriber agrees that all age-appropriate vaccinations will be administered prior to starting Tzield

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Tzield is a CD3-directed antibody indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D. Patients should be

monitored for signs and symptoms of cytokine release syndrome (CRS) and patients should be premedicated with antipyretics, antihistamines, and/or antiemetics as necessary (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Tzield while maintaining optimal therapeutic outcomes.

References

1. Tzield [prescribing information]. Red Bank, NJ: Provention Bio, Inc.; December 2023.

Policy History

Date	Action
December 2022	Addition to PA
March 2023	Annual review. Per SME, added requirement “prescriber agrees that all age-appropriate vaccinations will be administered prior to starting Tzield”
September 2023	Annual review
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.