

Medical Drug Clinical Criteria

Subject: Tzield (teplizumab-mzwv)

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Overview

This document addresses the use of Tzield (teplizumab-mzwv), a CD3-directed antibody approved by the Food and Drug Administration (FDA) to delay the onset of stage 3 type 1 diabetes in adults and pediatric individuals aged 8 years and older with stage 2 type 1 diabetes. Prior to initiating therapy, stage 2 type 1 diabetes must be confirmed by documenting at least two positive pancreatic islet cell autoantibodies as well as 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 may be appropriate. It is also important to ensure the clinical history does not suggest type 2 diabetes.

The efficacy of Tzield was studied in a randomized, double-blind, placebo-controlled phase 2 trial in 76 individuals 8 years of age or older. All participants were at risk for development of type 1 diabetes defined by having a relative with type 1 diabetes, presence of at least two diabetes autoantibodies in two samples and evidence of dysglycemia during an oral glucose tolerance test. Tzield was administered as a two week course of daily intravenous therapy. The median time to the diagnosis of type 1 diabetes was 48.4 months in the Tzield group and 24.4 months in the placebo group (95% confidence interval, 0.22 to 0.78; P = 0.006).

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tzield (teplizumab-mzwv)

Initial requests for Tzield (teplizumab-mzwv) may be approved if the following criteria are met:

- I. Individual is 8 years of age or older; AND
- II. Documentation is provided that individual has stage 2 type 1 diabetes confirmed by:
 - A. Presence of two or more of the following pancreatic islet cell autoantibodies:
 - 1. Glutamic acid decarboxylase 65 (GAD) autoantibodies;
 - 2. Insulin autoantibody (IAA);
 - 3. Insulinoma-associated antigen 2 autoantibody (IA-2A);
 - 4. Zinc transporter 8 autoantibody (ZnT8A);
 - 5. Islet cell autoantibody (ICA);
 - AND
 - B. Dysglycemia on an oral glucose-tolerance test (or alternative glycemic test if an oral glucose-tolerance test is not available).

Tzield (teplizumab-mzwv) requests may not be approved for the following:

- I. Individual with stage 3 type 1 diabetes; OR
- II. Individual with clinical history consistent with type 2 diabetes; OR
- III. Individual with an active serious infection or chronic infection, including but not limited to Epstein-Barr virus or cytomegalovirus; OR
- IV. May not be approved when the above criteria are not met and for all other indications.

Approval Duration: one treatment course per lifetime

Quantity Limits

Tzield (teplizumab-mzwv) Quantity Limit

<u>Drug</u>	<u>Treatment Day</u>	<u>Dose</u>
<u>Tzield (teplizumab-mzwv) 2 mg/2 mL vial</u>	<u>Day 1</u>	<u>65 mcg/m²</u>
	<u>Day 2</u>	<u>125 mcg/m²</u>
	<u>Day 3</u>	<u>250 mcg/m²</u>
	<u>Day 4</u>	<u>500 mcg/m²</u>
	<u>Day 5 - 14</u>	<u>1030 mcg/m²</u>

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

<u>J3490</u>	<u>Unclassified drugs (when specified as [Tzield] (teplizumab-mzwv))</u>
<u>J3590</u>	<u>Unclassified biologics (when specified as [Tzield] (teplizumab-mzwv))</u>

ICD-10 Diagnosis

All diagnoses pend

Document History

New: 11/22/2022

Document History:

- 11/22/2022 – Select Review: Add new clinical criteria and quantity limit for Tzield. Coding Reviewed: Added HCPCS J3490, J3590. All diagnoses pend.

References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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