Medical Policy:

Tzield (teplizumab-mzwv), Intravenous Injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.373	February 7, 2025	February 9, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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.

Length of Authorization

One (14 day) treatment course per lifetime

Dosing Limits [Medical Benefit]

400 billable units (2,000mcg) daily for 14 days

Approve a one-time, 14-day course of Tzield with the following regimen (A, B, C, D, and E):

A. 65 mcg/m2 body surface area (BSA) given intravenously on Day 1; AND
B. 125 mcg/m2 BSA given intravenously on Day 2; AND
C. 250 mcg/m2 BSA given intravenously on Day 3; AND
D. 500 mcg/m2 BSA given intravenously on Day 4; AND

E. 1,030 mcg/m2 BSA given intravenously once daily on Days 5 through 14.

Guideline

1. **Type 1 Diabetes (Clinical/Stage 3), Delay of Onset.** Approve for a one-time per lifetime course (14-day course) if the patient meets the following criteria (A, B, C, D, E, F, G, H, I, and J):
   A. Patient is ≥ 8 years of age; **AND**
   B. Patient does NOT have a clinical diagnosis of type 1 diabetes (i.e., Stage 3 type 1 diabetes); **AND**
      Note: Clinical type 1 diabetes is also referred to as Stage 3 type 1 diabetes. "Stage 1 type 1 diabetes" and "Stage 2 type 1 diabetes" are considered preclinical states and would not fall into the category of clinical type 1 diabetes.
   C. Patient does NOT have type 2 diabetes; **AND**
   D. Patient has tested positive for at least TWO of the following type 1 diabetes-related autoantibodies: anti-glutamic acid decarboxylase 65 (anti-GAD65); anti-islet antigen-2 (anti-IA-2); islet-cell autoantibody (ICA); micro insulin; anti-zinc transporter 8 (anti-ZnT8)
   E. 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*) by meeting at least one of the following (a, b, or c):
      a. Fasting plasma glucose level ≥ 100 to < 125 mg/dL; **OR**
      b. 2-hour postprandial plasma glucose level ≥ 140 to < 200 mg/dL; **OR**
      c. Patient has an HbA_{1c} ≥ 5.7% to < 6.5% in the preceding 2 months; **AND**
   F. At baseline (prior to the initiation of Tzield), patient does NOT have evidence of hematologic compromise, as defined by meeting the following (i, ii, iii, and iv)
      i. Lymphocyte count ≥ 1,000 lymphocytes/mcL; **AND**
      ii. Hemoglobin ≥ 10 g/dL; **AND**
      iii. Platelet count ≥ 150,000 platelets/mcL; **AND**
      iv. Absolute neutrophil count ≥ 1,500 neutrophils/mcL; **AND**
   G. At baseline (prior to the initiation of Tzield), patient does NOT have evidence of hepatic compromise, as defined by meeting the following (i, ii, and iii):
      i. Alanine aminotransferase (ALT) ≤ 2 times the upper limit of normal (ULN); **AND**
      ii. Aspartate aminotransferase (AST) ≤ 2 times the ULN; **AND**
      iii. Bilirubin ≤ 1.5 times the ULN; **AND**
   H. According to the prescriber, the patient does NOT have any of the following (i, ii, or iii):
      i. Laboratory or clinical evidence of acute infection with Epstein-Barr Virus or cytomegalovirus; **OR**
      ii. Active serious infection; **OR**
      iii. Chronic active infection (other than localized skin infection); **AND**
   I. Patient has NOT received Tzield in the past; **AND**
      Note: Verify through claims history that the patient has not previously received Tzield AND, if no claim for Tzield is present, the prescriber must attest that the patient has not previously received Tzield.
   J. The medication will be prescribed by, or in consultation with, an endocrinologist.

Applicable Procedure Codes

Code	Description
J9381	Injection, teplizumab-mzwv, 5 mcg; 1 billable unit = 5 mcg

Applicable NDCs

Code	Description
73650-0316-01	Teplizumab-mzwv 1mg/mL, 2mL
73650-0316-14	Teplizumab-mzwv 1mg/mL, 2mL 14s
73650-0316-10	Teplizumab-mzwv 1mg/mL, 2mL 10s

ICD-10 Diagnoses

Code	Description
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/7/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Initial Criteria: Type 1 Diabetes (Clinical/Stage 3), Delay of Onset. Fasting plasma glucose level: updated from ≥ 110 to ≥100 Removed: "Intervening postprandial glucose level at 30, 60, or 90 minutes > 200 mg/dL;" Added: "Patient has an HbA_{1c} ≥ 5.7% to < 6.5% in the preceding 2 months; AND"
EmblemHealth & ConnectiCare	9/22/2023	Initial Criteria: Type 1 Diabetes (Clinical/Stage 3), Delay of Onset. Removed "Patient meets both of the following (i and ii): i. Patient has taken an oral glucose tolerance test within the preceding 2 months; AND ii. The results of the oral glucose tolerance test indicated dysglycemia" Replaced with "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)"by meeting at least one of the following (a, b, or c): a. Fasting plasma glucose level ≥ 110 to < Removed" 126" Added " 125" mg/dL; OR Modified the statement "The medication will be prescribed by, an endocrinologist" to read "The medication will be prescribed by, or in consultation with, an endocrinologist" Removed code: J3590 Added code: J9381 and E10.8
EmblemHealth & ConnectiCare	02/09/2023	New Policy

References

1. Product Information: TZIELD™ intravenous injection, teplizumab-mzwv intravenous injection. Provention Bio Inc (per FDA), Red Bank, NJ, 2022.