Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Tzield (teplizumab-mzwv)

Effective: October 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0988

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists..

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Type 1 diabetes mellitus (T1D) is an auto immune condition in which the pancreas does not produce enough insulin. It is one of the most common chronic diseases in childhood caused by insulin deficiency following destruction of the insulin-producing pancreatic beta cells. It most commonly presents in childhood, but one-fourth of cases are diagnosed in adults. The incidence of childhood T1D varies based upon geography, age, sex, family history, and ethnicity. There are approximately 64,000 new cases of T1D in the US per year; and 5 million people are expected to have T1D by 2040, including 60,000 youth.

There is currently no cure for Type 1 diabetes and standard treatment approaches include measuring blood glucose concentrations, administering insulin and recognizing and treating hypoglycemia. T1D has 4 stages. Stage 1 includes beta cell autoimmunity with >2 islet autoantibodies with normal blood sugar and no symptoms. Stage 2 includes beta cell autoimmunity with >2 islet autoantibodies with abnormal glucose tolerance and no symptoms. Stage 3 includes beta cell autoimmunity and raised blood glucose above diagnostic thresholds usually with symptoms which includes polydipsia, weight loss, fatigue, and diabetic ketoacidosis. Stage 4 presents as established and longstanding T1D.

Food and Drug Administration (FDA) Approved Indications:

Tzield (teplizumab-mzwv) is a CD3-directed antibody indicated to:

- Delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients 1 year of age and older with Stage 2 type 1 diabetes.
- Delay the decline in endogenous insulin production in pediatric patients aged 8 to 17 years recently diagnosed with Stage 3 T1D. This indication is approved under accelerated approval based on evidence of reduced C-peptide decline. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Limitations of Use:

- There is limited evidence of safety and effectiveness in patients aged 45 years and older with Stage 2 T2D.
- Tzield is not effective as a disease modifying therapy in non-autoimmune dysglycemia conditions.

Clinical Guideline Coverage Criteria

The Plan may cover Tzield (teplizumab-mzwv) when **ALL** the following clinical criteria is met:

Stage 2 T1D

1. The Member has documentation of stage 2 pre-type1 diabetes* as evidenced by **Both** (a and b) of the following:

a. Lab results confirming the presence of two or more positive pancreatic islet autoantibodies (Glutamic acid decarboxylase 65 (GAD) autoantibodies, Insulin autoantibody (IAA), Insulinoma-associated antigen 2 autoantibody (IA-2A), or Zinc transporter 8 autoantibody (ZnT8A) Islet cell autoantibody) within the last 6 months

AND

b. Evidence of dysglycemia** without overt hyperglycemia using an Oral Glucose Tolerance Test (OGTT), or alternative method if appropriate and OGTT is not available or clinically inappropriate

AND

2. The Provider attests that the member's clinical history does not suggest Type 2 diabetes

AND

3. The Member is 1 year of age or older

AND

4. Tzield is being prescribed by an endocrinologist

***Note:** Stage 2 pre- type 1 diabetes includes beta cell autoimmunity with >2 islet autoantibodies with abnormal glucose tolerance and no symptoms.

****Note**: Dysglycemia is defined as an FG level of 110 to 125 mg/dl (6.1 to 6.9 mmol/L), a 2-hour postprandial plasma glucose level of at least 140 mg/dl (7.8mmol/L) and less than 200 mg/dl (1.1mmol/L), or an intervening postprandial glucose level at 30,60, or 90 minutes of greater than 200 mg/dl on two occasions

Stage 3 T1D

1. Documentation the member has been recently (i.e., within the previous 8 weeks) diagnosed with Stage 3 type 1 diabetes as evidenced by **Both** (a and b) of the following:
   a. Lab results confirming the presence of at least one positive pancreatic islet autoantibody (Glutamic acid decarboxylase 65 (GAD) autoantibodies, Insulin autoantibody (IAA), Insulinoma-associated antigen 2 autoantibody (IA-2A), or Zinc transporter 8 autoantibody (ZnT8A) Islet cell autoantibody) within the last 8 weeks

   AND

   b. Peak C-peptide ≥0.2 pmol/mL on a mixed-meal tolerance test (MMTT), or alternative method if appropriate and MMTT is not available or clinically inappropriate

AND

5. The Provider attests that the member's clinical history does not suggest Type 2 diabetes

AND

6. The Member is 8 to 17 years of age

AND

7. Tzield is being prescribed by an endocrinologist

Limitations

- For Stage 2 T1D, authorization of Tzield will be limited to one 14-day treatment course per lifetime.
- For Stage 3 T1D, authorization of Tzield will be limited to two 12-day treatment courses 6 months apart (up to 12 months apart), per lifetime. The second 12-day treatment course should be administered 6 months after the first treatment course; if the second course is delayed, administer the second treatment course within 6 to 12 months after first treatment course.

Codes

Table 1: HCPCS Codes

HCPCS Codes	Description
J9381	Injection, teplizumab-mzwv, 5 mcg

References:

1. Tzield (teplizumab-mzwv) [prescribing information]. Redbank, NJ; Provention Bio, Inc.; June 2026.
2. Tzield™ (teplizumab-mzwv) approved by FDA as the first and only treatment indicated to delay the onset of stage 3 type 1 diabetes(T1D) in adult and pediatric patients aged 8 years and older with Stage 2 T1D. Provention Bio Investor news accessed November 18, 2022 at https://investors.proventionbio.com/2022-11-17- TZIELD™ (teplizumab-mzwv) approved by FDA as the first and only treatment indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and pediatric patients aged 8 years and older with Stage 2 T1D - Nov 17, 2022 (proventionbio.com)
3. FDA approves first drug can delay onset of stage 3 type 1 diabetes accessed November 30,2022 at https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-can-delay-onset-type-1
4. Prevention of Type 1 Diabetes in Relatives at risk. Clinical Trials accessed November 30, 2022, at Teplizumab for Prevention

of Type 1 Diabetes in Relatives "At-Risk" - Full Text View - ClinicalTrials.gov
5. Management of Diabetes Type1 in children. UpToDate accessed November 30, 2022 at Overview of the management of type 1 diabetes mellitus in children and adolescents - UpToDate
6. Diabetes staging Type 1. American Diabetes Association accessed December 4,2022 Staging Presymptomatic Type 1 Diabetes: A Scientific Statement of JDRF, the Endocrine Society, and the American Diabetes Association - PMC (nih.gov)

Approval And Revision History

February 14, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

March 15, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved March 15, 2023 by P&T and February 14, 2023 by MPAC committees effective April 1, 2023
- Coding update per HCPCS level II quarterly release. Effective date July 1, 2023, the following HCPCS code has been added: J9381 replacing C9149
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- March 12, 2024: Removed the Limitations Tzield will only be approved for an FDA approved indication as per the product label. All other uses are considered experimental or investigational. Minor wording update to clarify that authorization of Tzield will be limited to one 14-day treatment course per lifetime (effective 6/1/2024).
- March 11, 2025: No changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 3/11/25).
- March 10, 2026: No changes
- September 15, 2026: For Stage 2 T1D, expanded age requirement of Tzield to at least 1 year of age based on expanded indication. Added coverage criteria for pediatric patients aged 8 to 17 years recently diagnosed with Stage 3 T1D based on expanded indication. Administrative update: Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.” (eff 10/1/26)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.