

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Tzielid (teplizumab-mzww)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Tzielid, approved by the FDA in 2022, 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. It is the first approved drug to delay progression to Stage 3 T1D, the stage at which patients become symptomatic. Tzielid is administered by IV infusion once daily for one cycle of 14 consecutive days. Side effects of note include cytokine release syndrome (CRS), lymphopenia, leukopenia, and rash.

T1D is a chronic, T-cell-mediated autoimmune condition that leads to destruction of insulin-producing beta cells and dependence on exogenous insulin for survival. It usually develops in children, teenagers, and young adults, at a peak age of 13-14 years, but could occur at any age.

Tzielid works by binding to CD3 (a cell surface antigen present on T lymphocytes). The mechanism may involve partial agonistic signaling and deactivation of pancreatic beta cell autoreactive T cells.

In the pivotal Phase 2 clinical trial, TN-10, treatment with Tzielid delayed the onset of Stage 3 T1D by approximately 2 years compared to placebo, which is statistically significant. An extended follow-up of this trial demonstrated a delay of 2.7 years.

Tzielid (teplizumab-mzww) will be considered for coverage when the following criteria are met:

Type 1 Diabetes (T1D)

For **initial** authorization:

1. Member is at least 8 years of age; AND
- 2.

If all the above requirements are met, the medication will be approved for 3 months.

For reauthorization:

1. Continuation beyond 1 course of 14-day treatment will not be authorized.

CareSource considers Tzield (teplizumab-mzvw) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/18/2023	New policy for Tzield created.

References:

1. Tzield [prescribing information]. Provention Bio, Inc.; 2022.
2. Herold KC, Bundy BN, Long SA, et al. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes [published correction appears in *N Engl J Med*. 2020 Feb 6;382(6):586]. *N Engl J Med*. 2019;381(7):603-613. doi:10.1056/NEJMoa1902226
3. Sims EK, Bundy BN, Stier K, et al. Teplizumab improves and stabilizes beta cell function in antibody-positive high-risk individuals. *Sci Transl Med*. 2021;13(583):eabc8980. doi:10.1126/scitranslmed.abc8980
4. Insel RA, Dunne JL, Atkinson MA, et al. Staging presymptomatic type 1 diabetes: a scientific statement of JDRF, the Endocrine Society, and the American Diabetes Association. *Diabetes Care*. 2015;38(10):1964-1974. doi:10.2337/dc15-1419
5. ElSayed NA, Aleppo G, Aroda VR, et al. 2. Classification and Diagnosis of Diabetes: Standards of Care in Diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1):S19-S40. doi:10.2337/dc23-S002
6. VanBuecken D, Lord S, Greenbaum CJ. Changing the Course of Disease in Type 1 Diabetes. [Updated 2022 Jan 6]. In: Feingold KR, Anawalt B, Boyce A, et al., editors. Endotext [Internet]. South Dartmouth (MA): MDText.com,