

Tziel[™] (teplizumab-mzwv intravenous infusion)

When requesting Tziel[™] (teplizumab-mzwv intravenous infusion), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

Tziel (teplizumab-mzwv intravenous infusion) is 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.

Coverage Guidelines

Delay the Onset of Type 1 Diabetes (Clinical/Stage 3)

The individual must meet **all** of the following criteria for initial approval:

- Is ≥ 8 years of age;
- Does not have a clinical diagnosis of T1D (i.e., Stage 3 T1D); (Note: Clinical T1D is also referred to as Stage 3 T1D. “Stage 1 type 1 diabetes” and “Stage 2 type 1 diabetes” are considered preclinical states and would not fall into the category of clinical T1D);
- Does not have type 2 diabetes;
- Has at least one biological relative with a diagnosis of T1D;
- Has tested positive for at least TWO of the following T1D-related autoantibodies on two separate occasions: 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);
- Results of an oral glucose tolerance test taken within the preceding 2 months indicated dysglycemia by meeting at least one of the following:
 - Fasting plasma glucose level ≥ 110 to < 126 mg/dL;
 - 2-hour postprandial plasma glucose level ≥ 140 to < 200 mg/dL;
 - Intervening postprandial glucose level at 30, 60, or 90 minutes > 200 mg/dL;
- Prior to the initiation of Tziel, patient has:
 - Lymphocyte count $\geq 1,000$ lymphocytes/mcL; AND
 - Hemoglobin ≥ 10 g/dL; AND
 - Platelet count $\geq 150,000$ platelets/mcL; AND
 - Absolute neutrophil count $\geq 1,500$ neutrophils/mcL; AND
- Prior to the initiation of Tziel, patient has:
 - Alanine aminotransferase (ALT) ≤ 2 times the upper limit of normal (ULN); AND
 - Aspartate aminotransferase (AST) ≤ 2 times the ULN; AND
 - Bilirubin ≤ 1.5 times the ULN; AND
- Does not have the following:

- Laboratory or clinical evidence of acute infection with Epstein-Barr Virus or cytomegalovirus; OR
- Active serious infection; OR
- Chronic active infection (other than localized skin infection)
- Has not received Tzield in the past;
- Tzield will be prescribed by an endocrinologist.

Approval duration: One 14-day course

Dosing Recommendations

Recommended to administer by intravenous infusion (over a minimum of 30 minutes), using a body surface area-based dosing, once daily for 14 consecutive days as follows:

- 65 mcg/m² body surface area (BSA) on Day 1;
- 125 mcg/m² BSA on Day 2;
- 250 mcg/m² BSA on Day 3;
- 500 mcg/m² BSA on Day 4;
- 1,030 mcg/m² BSA once daily on Days 5 through 14.

References

1. Tzield™ intravenous infusion [prescribing information]. Red Bank, NJ: Provention; November 2022.
2. Herold KC, Bundy BN, Long SA, et al; Type 1 Diabetes TrialNet Study Group. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. *N Engl J Med*. 2019 Aug 15;381(7):603-613.
3. American Diabetes Association. Standards of medical care in diabetes – 2022. *Diabetes Care*. 2022;45(Suppl 1):S1-S258.