ALASKA MEDICAID
Prior Authorization Criteria

Tzield®
(teplizumab-mzwv)

FDA INDICATIONS AND USAGE[1]

Tzield is a CD3-directed monoclonal antibody indicated to delay the onset of Stage 3 Type 1 diabetes in adults and pediatric patients aged 8 years and older with stage 2 Type 1 diabetes.

APPROVAL CRITERIA[1,2,3]

1. Patient is 8 years of age or older; **AND**
2. Patient has a documented diagnosis of stage 2 type 1 diabetes confirmed by:
   a. Presence of **TWO** or more of the following pancreatic islet cell antibodies:
      i)Islet cell autoantibody (ICA)
      ii) Insulinoma-associated antigen 2 autoantibody (IA-2A)
      iii) Insulin autoantibody (IAA)
      iv) Zinc transporter 8 autoantibody (ZnT8A)
      v)Glutamic acid decarboxylase 65 (GAD) autoantibodies; **AND**
   b. Dysglycemia on an oral glucose tolerance test (or alternative glycemic test if oral GTT not available).
3. Patient has a complete blood count and liver enzyme panel prior to initiation; **AND**
4. Provider must submit documentation of patient body surface area in M^2.

DENIAL CRITERIA[1]

1. Failure to meet approval criteria; **OR**
2. Patient currently has stage 3 type 1 diabetes; **OR**
3. Patient has a clinical history consistent with type 2 diabetes; **OR**
4. Patient has an active serious infection or chronic infection, including but not limited to Epstein-Barr virus (EBV) or cytomegalovirus (CMV); **OR**
5. Patient laboratory results show any of the following:
   a. Lymphocyte count less than 1,000 lymphocytes/mcl
   b. Hemoglobin less than 10g/dl
   c. Platelet count less than 150,000 platelets/mcl
   d. Elevated ALT or AST greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN

CAUTIONS[1]

- Monitor liver enzymes throughout course of treatment. If patient develops AST or ALT greater than 5 times ULN, discontinue treatment.
- Monitor patient white blood cell counts during treatment. If prolonged severe lymphopenia (<500 cells per mcL lasting 1 week or longer) develops, discontinue treatment.
- Monitor patients for signs/symptoms of infection. If a serious infection develops, discontinue treatment.

- Tzield is contraindicated during pregnancy and at least 30 days prior to planned pregnancy.

DURATION OF APPROVAL

- Initial Approval: 3 months
- Reauthorization not approved. The treatment is 14 infusions total given once daily for 14 days.

QUANTITY LIMIT[1]

- Administer TZIELD by intravenous infusion (over a minimum of 30 minutes), using a body surface area-based dosing, once daily for 14 consecutive days as follows:
  - Day 1: 65 mcg/m^2
  - Day 2: 125 mcg/m^2
  - Day 3: 250 mcg/m^2
  - Day 4: 500 mcg/m^2
  - Days 5 through 14: 1,030 mcg/m^2

- HCPCS –J3490, J3590, C9399

REFERENCES / FOOTNOTES:

1. Tzield [package insert]. Red Bank, NJ; Provention Bio, 2022. Accessed December 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. Available at: https://www.nejm.org/doi/10.1056/NEJMoa1902226. Accessed: Dec 27, 2022.
3. Hirsch IB. Prediction of type 1 diabetes mellitus. Last updated: January 21, 2022. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: December 27, 2022