POTENTIAL HEALTH PLAN PRIOR AUTHORIZATION CRITERIA GUIDE

Consider the criteria below when you complete a Prior Authorization (PA) form

Your practice or facility may need to obtain Prior Authorization from a health plan before it will cover TZIELD™ (teplizumab-mzwv). This guide is meant to help you as you complete a PA form and provides an overview of criteria that may be required for coverage by most health plans.

Coverage policies and PA forms vary by health plan and may require additional and/or different documentation than what is listed below. First, check whether your patient's health plan has a coverage policy in place for TZIELD, or if there will be coverage by medical necessity only.

A Provention Bio COMPASS™ Navigator can help your patient understand their coverage for TZIELD, based on the patient's individual health plan and its benefit structure.

Anticipated PA Requirements:

TZIELD 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

Confirmation of stage 2 T1D

≥2 of the following pancreatic islet cell autoantibodies as evidenced by lab results[1-3]:

- Glutamic acid decarboxylase 65 (GAD) autoantibodies
- Insulin autoantibodies (IAA)
- Insulinoma-associated antigen 2 autoantibodies (IA-2A)
- Zinc transporter 8 autoantibodies (ZnT8A)
- Islet-cell autoantibodies (ICA)

AND

Dysglycemia without overt hyperglycemia as evidenced by[1-3]:

- A 2-hour plasma glucose (2-h PG) level of 140-199 mg/dL (7.8-11.0 mmol/L) during a 75-g oral glucose tolerance test (OGTT)

Note: if an OGTT is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate[3]; check health plan requirements to confirm whether alternative methods are acceptable.

Ensure the clinical history of the patient does not suggest type 2 diabetes[3]

Patient must be at least 8 years of age[3]

If applicable, documentation that prescriber is a specialist

If applicable, attestation that patient has a relative with T1D

Please see Important Safety Information on the next page and full Prescribing Information, including patient selection criteria, and Medication Guide.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Cytokine Release Syndrome (CRS):** CRS occurred in TZIELD-treated patients during the treatment period and through 28 days after the last drug administration. Prior to TZIELD treatment, premedicate with antipyretics, antihistamines and/or antiemetics, and treat similarly if symptoms occur during treatment. If severe CRS develops, consider pausing dosing for 1 day to 2 days and administering the remaining doses to complete the full 14-day course on consecutive days; or discontinue treatment. Monitor liver enzymes during treatment. Discontinue TZIELD treatment in patients who develop elevated alanine aminotransferase or aspartate aminotransferase more than 5 times the upper limit of normal (ULN) or bilirubin more than 3 times ULN.
- **Serious Infections:** Use of TZIELD is not recommended in patients with active serious infection or chronic infection other than localized skin infections. Monitor patients for signs and symptoms of infection during and after TZIELD administration. If serious infection develops, treat appropriately, and discontinue TZIELD.
- **Lymphopenia:** Lymphopenia occurred in most patients. For most patients, lymphocyte levels began to recover after the fifth day of treatment and returned to pretreatment values within two weeks after treatment completion and without dose interruption. Monitor white blood cell counts during the treatment period. If prolonged severe lymphopenia develops (<500 cells per mcL lasting 1 week or longer), discontinue TZIELD.
- **Hypersensitivity Reactions:** Acute hypersensitivity reactions including serum sickness, angioedema, urticaria, rash, vomiting and bronchospasm occurred in TZIELD-treated patients. If severe hypersensitivity reactions occur, discontinue TZIELD and treat promptly.
- **Vaccinations:** The safety of immunization with live-attenuated (live) vaccines in TZIELD-treated patients has not been studied. TZIELD may interfere with immune response to vaccination and decrease vaccine efficacy. Administer all age-appropriate vaccinations prior to starting TZIELD.
  - Administer live vaccines at least 8 weeks prior to treatment. Live vaccines are not recommended during treatment, or up to 52 weeks after treatment.
  - Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment. Inactivated vaccines are not recommended during treatment, or 6 weeks after completion of treatment.

ADVERSE REACTIONS: Most common adverse reactions (>10%) were lymphopenia, rash, leukopenia, and headache.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** May cause fetal harm.
- **Lactation:** A lactating woman may consider pumping and discarding breast milk during and for 20 days after TZIELD administration.

Before prescribing TZIELD, please read the accompanying Prescribing Information, including Medication Guide.

For any health plan-specific PA criteria questions,
call Provention Bio COMPASS at 1-844-778-2246 Monday through Friday, 8 am-8 pm ET

References: 1. American Diabetes Association Professional Practice Committee; 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2022. Diabetes Care 1 January 2022; 45 (Supplement_1): S17–S38. **2.** Couper JJ, Haller MJ, Greenbaum CJ, et al. ISPAD clinical practice consensus guidelines 2018: stages of type 1 diabetes in children and adolescents. *Ped Diabetes*. 2018;19(suppl 27):20-27. **3.** TZIELD Prescribing Information. Provention Bio, Inc.

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