Teplizumab-mzwv (TZIELD)
Criteria for Use
March 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive teplizumab.

- ☐ Has type 1 or type 2 diabetes
- ☐ Lymphocyte count less than 1,000 lymphocytes/mcL
- ☐ Hemoglobin less than 10 g/dL
- ☐ Platelet count less than 150,000 platelets/mcL
- ☐ Absolute neutrophil count less than 1,500 neutrophils/mcL
- ☐ Elevated ALT or AST greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN
- ☐ Laboratory or clinical evidence of acute infection with Epstein-Barr virus or cytomegalovirus
- ☐ Active serious infection or chronic active infection other than localized skin infections
- ☐ Requires inactivated or mRNA vaccinations within the 2 weeks prior to teplizumab treatment, during treatment, or 6 weeks after completion of treatment.^1
- ☐ Requires live-attenuated vaccinations within the 8 weeks prior to teplizumab treatment, during treatment, or up to 52 weeks after treatment.^1

1 The safety of immunization with live-attenuated vaccines in teplizumab-treated patients has not been studied. Additionally, teplizumab may interfere with the immune response to vaccination and decrease vaccine efficacy. Administer all age-appropriate vaccinations prior to starting teplizumab. Administer live-attenuated (live) vaccines at least 8 weeks prior to treatment. Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment.

Inclusion Criteria

All of the following criteria must be met.

- ☐ Provider is a VA or VA Community Care endocrinologist
- ☐ Has relative with type 1 diabetes. If relative is a parent, sibling, or offspring, the veteran is less than or equal to 45 years of age. If relative is a second or third degree relative the veteran is less than or equal to 20 years of age.
- ☐ At least two positive pancreatic islet cell autoantibodies (Anti-GAD65, insulin autoantibody, anti-IA-2, islet cell autoantibody, anti-ZnT8)
- ☐ Dysglycemia without overt hyperglycemia on TWO occasions during an oral glucose tolerance test ^2

2 Dysglycemia during OGTT defined as 1 or more of the following: a fasting glucose level of 110 to 125 mg/dL, a 2-hour postprandial plasma glucose level of 140 mg/dL and less than 200 mg/dL, or a postprandial glucose level at 30, 60, or 90 minutes of greater than or equal to 200 mg/dL

Additional Inclusion Criteria

- ☐ For patients who can become pregnant: Pregnancy has excluded prior to receiving teplizumab. Do not use during pregnancy and at least 30 days (6-half-lives) prior to planned pregnancy
- ☐ For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy

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