

Clinical Oversight Review Board (CORB) Criteria for Prescribing Teplizumab-mzwv (Tzielid)

Non-Formulary **teplizumab-mzwv (Tzielid)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary teplizumab-mzmv (Tzielid)) will be covered when the following criteria are met:

- Prescribed by an endocrinologist
- Patient aged 8 to 45 years
- Have a first or second degree relative with type 1 diabetes
 - If first degree (brother, sister, parent, or offspring), relative must be 8 to 45 years old
 - If second degree (niece, nephew, aunt, uncle, grandchild, or cousin), relative must be 8 to 20 years old
- Abnormal glucose tolerance by oral glucose tolerance test (OGTT) defined as
 - Fasting blood glucose 111 to 125 mg/dL OR
 - 2-hour glucose 140 to 199 mg/dL OR
 - 30-, 60-, or 90-minute value on OGTT greater than 200 mg/dL
- Presence of at least two of the following diabetes autoantibodies
 - Glutamic acid decarboxylase 65 (GAD) autoantibody
 - Zinc transporter 8 (ZnT8) autoantibody
 - Islet cell autoantibody (ICA)
 - Insulin autoantibody (IAA)
 - Insulinoma-associated antigen-2 (IA-2) autoantibody
- Not taking any immunosuppressant medications including corticosteroids
- No history of cardiovascular disease or coronary artery disease
- No history of gestational diabetes
- Complete blood cell count (CBC) with
 - Lymphocyte count 1,000 lymphocytes/mcL or greater
 - Hemoglobin 10 g/dL or greater
 - Platelet count 150,000 platelets/mcL or greater
 - Absolute neutrophil count 1,500 neutrophils/mcL or greater
- Liver enzymes with
 - Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) less than or equal to 2 times the upper limit of normal (ULN)
 - Total bilirubin less than or equal to 1.5 times ULN
 - Normal international normalized ratio (INR)

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Kaiser Foundation Health Plan of the Northwest

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- No history of type 1 diabetes that has been previously diagnosed or detected at baseline (fasting glucose greater than 126 mg/dL or 2-hour glucose greater than 200 mg/dL)
- Negative purified protein derivative (PPD) test for tuberculosis infection
- No live virus vaccination within 8 weeks of initiation
- No active serious infection or chronic active infection other than localized skin infections
- No past or current human immunodeficiency virus (HIV), Hepatitis B, or Hepatitis C infection
- Not currently pregnant or breastfeeding
 - A lactating person may interrupt breastfeeding and pump and discard breast milk during treatment and for 20 days after teplizumab administration to minimize drug exposure to a breastfed child
- No treatment in the past year of any monoclonal antibody
- No history of pancreatectomy or chronic pancreatitis
- No diagnosis of renal failure or chronic kidney disease
- No diagnosis of anemia
- No laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV)
- Caution in patients who have been treated with radiation for lymphatic disease
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication