Tzield (teplizumab-mzwv)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Diabetes, or diabetes mellitus, is a chronic (long-term) disorder that disrupts the way the body uses sugar. Cells in the body need glucose (a type of sugar) to work normally. A hormone called insulin helps glucose enter cells. For patients with diabetes, glucose is not able to enter cells, causing high blood glucose (hyperglycemia).

Diabetes is commonly classified into four categories:

1. Type 1 diabetes - there is little to no production of insulin (by the pancreas)
2. Type 2 diabetes - there may be too little insulin made, and/or the cells in the body do not respond to insulin (insulin resistance)
3. Gestational diabetes - happens during pregnancy
4. Specific types of diabetes due to other causes (e.g., drug or chemical-induced diabetes)

Tzield (teplizumab-mzwv) is FDA-approved as treatment to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients 8 years of age and older with Stage 2 type 1 diabetes. Tzield is an

intravenously (IV) administered anti-CD3-directed antibody designed to bind to certain immune system cells and delay progression to stage 3 T1D. Tzield is administered by intravenous infusion once daily for 14 consecutive days.

While the exact cause of both type 1 and type 2 diabetes are not known, potential risk factors are known. For type 1 diabetes, these include but are not limited to known risk factors such as having a family member with type 1 diabetes, having a gene that makes it more likely to develop T1D, certain conditions where the body's immune system attacks itself, and various other genetic and environmental factors. People may develop T1D at any age, but more often than not, it is found in younger children, teens and young adults. The American Diabetes Association (ADA) has identified three distinct stages of type 1 diabetes with accompanying characteristics and diagnostic criteria.

Definitions

"Blood Glucose" is the main sugar found in the blood and the body's main source of energy. It is also called glucose or blood sugar. The blood level of glucose is noted in milligrams per deciliter (mg/dL).

"Fasting blood glucose (FG) test" is taken by blood sample after 8 hours of fasting (not eating).

"Hemoglobin A1c (HbA1c)" is a test that measures a person's average blood glucose level over the past 2 to 3 months. It is also known as "A1C" or "glycosylated hemoglobin". A1C should be measured at least twice annually for stable glycemic control and at least quarterly for unstable glycemic control. A1C test results may be affected by age, certain conditions, ethnicity, genetic traits, and pregnancy; the ADA recommends that treating providers review for discrepancies between A1c results and blood glucose results.

"Hyperglycemia" is excessive blood glucose. Fasting hyperglycemia is blood glucose above a desirable level after a person has fasted for at least 8 hours. Postprandial hyperglycemia is blood glucose above a desirable level 1 to 2 hours after a person has eaten.

"Insulin" is a hormone made by the beta cells of the pancreas. Insulin allows glucose to enter the cells in the body for use in energy production, and when it is inadequate, the sugar remains in the blood leading to diabetes. There are a variety of oral and parenteral medications that can increase insulin production, increase the body's sensitivity to existing insulin and reduce blood sugar. Insulin can also be injected or infused when lifestyle changes and non-insulin medications are inadequate.

"Oral glucose tolerance test (OGTT)" is a recommended test for diabetes screening performed using glucose load containing the equivalent of 1.75g/kg body weight to a maximum of 75 g of anhydrous glucose dissolved in water. The test measures blood glucose at baseline (e.g., after overnight fasting) and two hours after consuming the glucose-containing drink.

"Type 1 Diabetes" is an autoimmune condition that occurs when the beta cells of the pancreas are unable to produce enough insulin and therefore blood glucose cannot enter cells to be used for energy. Type 1 diabetes is often referred to as "insulin-dependent" because these patients require insulin daily to maintain their blood glucose at acceptable levels.

"Type 2 Diabetes" is a condition that occurs when either the pancreas doesn't produce enough insulin or the body cells become resistant to insulin. Type 2 diabetes is much more common than Type 1, and is often treated with combinations of lifestyle changes and non-insulin medications, although insulin can be required later in the disease course. Many individuals with Type 2 Diabetes are "insulin-requiring".

Medical Necessity Criteria for Authorization

The Plan considers **Tzield (teplizumab-mzwv)** medically necessary when **ALL** of the following criteria are met:

1. The member is between 8 to 65 years of age***; AND***
2. Is being given to delay the onset of Stage 3 type 1 diabetes***; AND***
3. The member has a documented diagnosis of Stage 2 type 1 diabetes, defined as having **BOTH**:
    a. Two or more of the following pancreatic islet autoantibodies:
        i. Glutamic acid decarboxylase 65 (GAD) autoantibodies***; and/or***
        ii. Insulin autoantibody (IAA)***; and/or***
        iii. Insulinoma-associated antigen 2 autoantibody (IA-2A)***; and/or***
        iv. Zinc transporter 8 autoantibody (ZnT8A)***; and/or***
        v. Islet cell autoantibody (ICA)***; and***
    b. Abnormal glucose tolerance, evidenced by **ONE** of the following within the past 90 days:
        i. Fasting plasma glucose ≥ 110 mg/dL (6.1 mmol/L), and <126 mg/dL (7 mmol/L)***; or***
        ii. 2-hour plasma glucose measurement ≥140 mg/dL (7.8 mmol/L), and <200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test***; or***
        iii. A1C ≥5.7% (39 mmol/mol), and <6.5% (48 mmol/mol)***; AND***

4. If member is a female of reproductive potential, documentation of a recent negative pregnancy test result (within the last 30 days)***; AND***
5. The member does **NOT** have evidence of **ANY** of the following:
    a. Clinical history suggesting type 2 diabetes***; or***
    b. Is currently pregnant***; or***
    c. Fasting plasma glucose level of 126 mg/dL or higher (7 mmol/L)***; or***
    d. 2-hour plasma glucose measurement ≥ 200 mg/dL (11.1 mmol/L)***; or***
    e. Hemoglobin A1C measurement of 6.5% or higher***; or***
    f. Previously diagnosed or clear clinical diagnosis of diabetes (e.g., patient in a hyperglycemic crisis or with classic symptoms of hyperglycemia and a random plasma glucose ≥200 mg/dL (11.1 mmol/L)***; or***
    g. Symptoms of diabetes plus casual plasma glucose concentration > 200 mg/dL (11.1 mmol/L). Casual is defined as any time of day without regard to time since the last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss***; or***
    h. Laboratory evidence of ANY of the following:
        i. Lymphocyte count less than 1,000 lymphocytes/mcL***; or***
        ii. Hemoglobin less than 10 g/dL***; or***
        iii. Platelet count less than 150,000 platelets/mcL***; or***
        iv. Absolute neutrophil count less than 1,500 neutrophils/mcL***; or***
        v. Elevated ALT or AST greater than 2 times the upper limit of normal (ULN) or bilirubin greater than 1.5 times ULN***; or***
        vi. Laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV)***; or***
        vii. Active serious infection or chronic active infection other than localized skin infections***; AND***
6. The member does not have a history of prior treatment with Tzield (teplizumab-mzwv)***; AND***
7. Will be administered at the FDA-approved and recommended dosage once daily for 14 consecutive days.

Experimental or Investigational / Not Medically Necessary

Tzield (teplizumab-mzwv) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

Applicable Billing Codes (HCPCS/CPT Codes)

Service(s) name	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
J9381	Injection, teplizumab-mzwv, 5 mcg
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus with unspecified complications

CPT/HCPCS Codes covered but may be subject to medical-necessity review:	
Code	*Description*
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)

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Clinical Guideline Revision / History Information

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