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IN BRIEF

An Expanded Indication for Teplizumab *(Tzield)*

The CD3-directed monoclonal antibody teplizumab (*Tzield* – Provention Bio), which was previously approved by the FDA to delay the onset of stage 3 type 1 diabetes in patients ≥8 years old with stage 2 type 1 diabetes, has now been approved for such use in children 1-7 years old.[1,2]

TYPE 1 DIABETES — Type 1 diabetes is an autoimmune disorder characterized by gradual destruction of insulin-producing pancreatic beta cells. Persons with a first-degree relative with type 1 diabetes are at increased risk of developing the disease. There are three stages of type 1 diabetes. Patients in stage 1 have euglycemia and ≥2 diabetes-related autoantibodies. Those in stage 2 have asymptomatic dysglycemia, but other metabolic indices are normal, and insulin treatment is not required. Patients in stage 3 have symptomatic clinical disease. The lifetime risk of patients in stage 2 developing stage 3 disease is almost 100%. Screening for autoantibodies to identify patients with stage 1 or 2 type 1 diabetes is not routinely performed.

MECHANISM OF ACTION — Infiltration of lymphocytes, particularly CD8+ T cells, causes pancreatic beta cell destruction in type 1 diabetes. Teplizumab binds to CD3, an antigen on the surface of T lymphocytes, deactivating autoreactive T lymphocytes and increasing the proportion of regulatory T cells in peripheral blood that help moderate the immune response.

A CLINICAL STUDY — FDA approval of the expanded indication was based on the results of an open-label trial in 23 children <8 years old (mean age 4.8 years) with stage 2 type 1 diabetes who received teplizumab IV once daily for 14 days. In an interim analysis, two patients progressed to stage 3 disease at 1 year of follow-up; the estimated probability of lack of progression to stage 3 type 1 diabetes was 89.6%.[3]

ADVERSE EFFECTS — No new safety risks of teplizumab were identified in the open-label trial. The most common adverse effects reported up to 28 days after the last dose were vomiting (52.2%), rash (43.5%), diarrhea (30.4%), decreased lymphocyte count (30.4%), decreased white blood cell count (26.1%), and maculopapular rash (26.1%). Cytokine release syndrome (fever, nausea, fatigue, headache, myalgia, arthralgia, and increased liver enzyme and bilirubin levels) has been reported. Serious bacterial and viral infections have been reported; teplizumab should not be used in patients with active serious infections or with chronic infections other than localized skin infections. The label contains a boxed warning about a risk of reactivation of viruses such as Epstein-Barr virus (EBV) and cytomegalovirus (CMV); patients should be tested for active EBV and CMV infection before starting treatment.

DOSAGE, ADMINISTRATION, AND COST — Teplizumab is administered intravenously once daily for 14 days. The recommended dosage is 65 mcg/m^2 on day one, 125 mcg/m^2 on day two, 250 mcg/m^2 on day three, 500 mcg/m^2 on day four, and 1030 mcg/m^2 on days 5-14. The drug is administered over ≥30 minutes in patients ≥8 years old and over ≥2 hours in children 1-7 years old. Premedication with an NSAID or acetaminophen, an antihistamine, and an antiemetic is recommended before each dose for at least the first 5 days of treatment to decrease the risk of cytokine release syndrome. Complete blood counts and liver function tests should be performed before starting the drug and during treatment; the drug should be stopped in patients with ALT or AST levels >5 times or bilirubin levels >3 times the upper limit of normal. The label recommends dosage adjustments that should be made if adverse effects occur. All age-appropriate vaccinations should be completed before starting teplizumab (live vaccines should be given at least 8 weeks before and inactivated vaccines at least 2 weeks before). The wholesale acquisition cost of a 14-day course of *Tzield* is $209,904.[4] ■

1. Teplizumab (Tzield) to delay onset of type 1 diabetes. Med Lett Drugs Ther 2023; 65:7.
2. KC Herold et al. An anti-CD3 antibody, teplizumab, in relatives at risk for type 1 diabetes. N Engl J Med 2019; 381:603.
3. SE Gitelman et al. Safety and pharmacokinetics of teplizumab in children less than 8 years of age with stage 2 type 1 diabetes. Diabetologia 2026; 69:330.
4. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. May 5, 2026. Reprinted with permission by First Databank, Inc. All rights reserved. ©2026. www.fdbhealth.com/drug-pricing-policy.

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