

The Medical Letter[®]

on Drugs and Therapeutics

Volume 68

June 22, 2026

ISSUE No.

1757

IN THIS ISSUE

In Brief: An Expanded Indication for Teplizumab (*Tzield*) p 100

Important Copyright Message

FORWARDING OR COPYING IS A VIOLATION OF U.S. AND INTERNATIONAL COPYRIGHT LAWS

The Medical Letter, Inc. publications are protected by U.S. and international copyright laws. Forwarding, copying, or any distribution of this material without permission to a nonsubscriber is prohibited.

Sharing a password with a nonsubscriber or otherwise making the contents of this site available to third parties is prohibited.

By accessing and reading the attached content I agree to comply with U.S. and international copyright laws and these terms and conditions of The Medical Letter, Inc.

For further information click: [Subscriptions](#), [Site Licenses](#), [Reprints](#)
or call customer service at: 800-211-2769

The Medical Letter[®]

on Drugs and Therapeutics

Volume 68 (Issue 1757)

June 22, 2026

Take CME Exam

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/m² on day one, 125 mcg/m² on day two, 250 mcg/m² on day three, 500 mcg/m² on day four, and 1030 mcg/m² 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.

PRESIDENT, EDITOR IN CHIEF: Jean-Marie Pflomm, Pharm.D.; **EDITOR IN CHIEF EMERITUS:** Mark Abramowicz, M.D.; **VICE PRESIDENT, ADMINISTRATION:** Gianna Zuccotti, M.D., M.P.H., F.A.C.P., Harvard Medical School; **ASSOCIATE EDITORS:** Susan M. Daron, Pharm.D., Amy Faucard, MLS, Corinne Z. Morrison, Pharm.D., Michael P. Viscusi, Pharm.D. **CONSULTING EDITORS:** Joanna Esterow, PA-C, Mordechai Sacks, DMSc, PA-C, Brinda M. Shah, Pharm.D., F. Peter Swanson, M.D.

CONTRIBUTING EDITORS: Carl W. Bazil, M.D., Ph.D., Columbia University College of Physicians and Surgeons; Ericka L. Crouse, Pharm.D., B.C.P.P., B.C.G.P., F.A.S.H.P., F.A.S.C.P., Virginia Commonwealth University; Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School; Eric J. Epstein, M.D., Dartmouth Hitchcock Medical Center; David N. Juurlink, BPhm, M.D., Ph.D., Sunnybrook Health Sciences Centre; Richard B. Kim, M.D., University of Western Ontario; Sandip K. Mukherjee, M.D., F.A.C.C., Yale School of Medicine; Dan M. Roden, M.D., Vanderbilt University School of Medicine; Esperance A.K. Schaefer, M.D., M.P.H., Harvard Medical School; Arthur M. F. Yee, M.D., Ph.D., F.A.C.R., Weill Medical College of Cornell University

MANAGING EDITOR AND DIRECTOR OF CONTENT OPERATIONS: Susie Wong; **EDITORIAL ASSISTANT:** Karrie Ferrara

FULFILLMENT AND SYSTEMS MANAGER: Cristine Romatowski; **EXECUTIVE DIRECTOR OF SALES:** Elaine Reaney-Tomaselli

EXECUTIVE DIRECTOR OF MARKETING AND COMMUNICATIONS: Joanne F. Valentino; **INTERIM PUBLISHER:** Jean-Marie Pflomm, Pharm.D.

Founded in 1959 by Arthur Kallet and Harold Aaron, M.D.

Copyright and Disclaimer: The Medical Letter, Inc. is an independent nonprofit organization that provides healthcare professionals with unbiased drug prescribing recommendations. The editorial process used for its publications relies on a review of published and unpublished literature, with an emphasis on controlled clinical trials, and on the opinions of its consultants. The Medical Letter, Inc. does not sell advertising or receive any commercial support. No part of the material may be reproduced or transmitted by any process in whole or in part without prior permission in writing. The Medical Letter, Inc. does not warrant that all the material in this publication is accurate and complete in every respect. The Medical Letter, Inc. and its editors shall not be held responsible for any damage resulting from any error, inaccuracy, or omission.

Subscription Services

Address:

The Medical Letter, Inc.
2 Madison Ave, Ste 211
Larchmont, NY 10538

Customer Service:

Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
E-mail: custserv@medicalletter.org

Permissions:

To reproduce any portion of this issue,
please e-mail your request to:
permissions@medicalletter.org
Reprints – \$45 per issue or article

Subscriptions (US):

1 year – \$179; \$65 per year
for students, interns, residents,
and fellows in the US and Canada.
subscriptions.

Site License Inquiries:

E-mail: SubQuote@medicalletter.org
Call: 800-211-2769
Special rates available for bulk

www.medicalletter.org



Copyright 2026. ISSN 1523-2859

