NOW APPROVED EXPANDED PEDIATRIC INDICATION
in children as young as 1 year of age with Stage 2 T1D

Tzield®
(teplizumab-mzwv)
Injection | 2 mg/2mL

TZIELD® (teplizumab-mzwv)

Institutional Readiness Considerations

Disclaimer: This resource is provided for informational purposes only and does not constitute legal, clinical, or reimbursement advice.

INDICATION

TZIELD (teplizumab-mzwv) is indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients 1 year of age and older with Stage 2 T1D.

IMPORTANT SAFETY INFORMATION

WARNING: Viral Reactivation

- **Serious, life-threatening cases of viral reactivation, including Epstein-Barr virus (EBV) and cytomegalovirus (CMV) reactivation have been reported with TZIELD. Patients who are immunocompromised are at increased risk. The majority of serious cases occurred in patients who continued TZIELD treatment despite persistent, severe lymphopenia.**
- **Test patients for active EBV and CMV infection prior to starting treatment. TZIELD is not recommended in patients with laboratory or clinical evidence of active EBV or CMV infection. Adhere to lymphocyte count monitoring requirements and discontinuation recommendations. Monitor patients for signs and symptoms of viral reactivation following TZIELD treatment and for at least 2 months following the last infusion. If viral reactivation is suspected, discontinue TZIELD.**

Please see additional Important Safety Information throughout and see full Prescribing Information, including Boxed Warning and patient selection criteria.

Institutional Readiness Considerations

Best practices and considerations for institutional readiness

The guide is intended to serve as an educational resource to help cross-functional teams align on roles and identify operational dependencies to enable TZIELD infusions within their institution.

This resource outlines considerations for an implementation process and has been informed by published evidence and best practices from health systems that have already established early detection, staging, and treatment pathways for T1D.

This list has been organized into 5 phases that reflect important considerations when launching a TZIELD treatment program. Each phase suggests several steps to consider, along with possible stakeholders to involve.

Steps to consider	Cross-functional partners
Phase 1 — TZIELD Availability and Implementation	
1. Consider pharmacy leadership and P&T committee engagement Initiate formulary review process for TZIELD. Establish procurement, storage, and dispensing protocols with pharmacy.	• P&T committee • Chief of endocrinology • Clinical champion
2. Activate the protocol development team Form a cross-functional team to build protocols for screening, monitoring, referral, and initiation of TZIELD therapy. Protocols may include confirmatory AAb and metabolic testing, stage-specific utilization criteria, and referral pathways.	• Clinical operations • Endocrinology • Nursing
3. Prepare for TZIELD implementation support Define responsibilities (screening and monitoring), infusion locations and sites of care, and daily operational procedures (weekend infusion coverage, etc).	• Clinical operations • Nursing • Infusion administration
Phase 2 — Infusion Management	
4. Assess infusion capacity Evaluate chair capacity and ability to manage 14 consecutive daily sessions per patient.[1] Identify alternate sites of care for overflow. Define patient scheduling process, rescheduling policy, and documentation requirements.	• Infusion center director • Clinical operations
5. Weekend and extended-hours coverage considerations Establish a policy for weekend scheduling—dedicated staff, partner facility coverage, or home infusion* hybrid—to prevent treatment interruption.	• Infusion center director • Nursing leadership
6. Support infusion staff readiness for TZIELD administration and AE management Develop and deliver competency-based training on IV administration protocol, AE recognition and management, and escalation pathways. Before first patient, document that staff have been trained in TZIELD administration and understand the warnings and precautions (including BOXED WARNING), important pretreatment laboratory evaluations and vaccinations, premedication instructions, and monitoring during and after treatment.	• Endocrinology

*The Pediatric Endocrine Society recommends that, for at least the first week of therapy, infusion of TZIELD to pediatric patients should occur in a controlled clinical setting staffed by nurses trained in Pediatric Advanced Life Support or Advanced Cardiac Life Support.[2]

AAb = autoantibody; AE = adverse event; IV = intravenous; P&T = pharmacy and therapeutics.

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Steps to consider	Cross-functional partners
Phase 3 — EHR and Clinical Workflow Build	
7. Develop TZIELD order sets Create standardized order sets for pretreatment labs, premedication requirements, TZIELD dosing, treatment monitoring, and AE response protocols. Build structured note templates, discrete fields, 1-click referral pathways, and EHR alerts.	• EHR analyst • Endocrinology • Pharmacy IT • Nursing IT
8. Establish tracking in the EHR Configure dashboards to track patient-level metrics, including screening volumes, AAb positivity rates, TZIELD experiences, and equity indicators (race, insurance status, geography).	• Pharmacy IT • EHR analyst • Nursing IT
Phase 4 — Access and Coverage	
9. Establish PA workflow Build a standardized PA submission package with required clinical documentation. Assign a dedicated PA coordinator to manage authorization timelines proactively. Understand payer-specific documentation requirements, and develop sample letters of medical necessity and coding/billing or denial management workflows.	• Health system finance team • Pharmacy PA team • Revenue management
10. Identify patient financial assistance resources Establish relationships with manufacturer patient support programs and copay assistance options.	• Financial counseling • Social work • Infusion operations
11. Address access infrastructure Identify structural barriers that may limit access for publicly insured, rural, or non–English speaking patients. Develop transportation assistance protocols, language-concordant education materials, and navigator support roles.	• Health equity lead • Social work • Infusion operations
Phase 5 — Education, Outreach, and Continuous Improvement	
12. Develop and deploy staff education program Build role-specific training for endocrinologists, PCPs, nurses, diabetes educators, and infusion staff covering T1D staging, eligibility criteria, and shared decision-making principles.	• Medical education • Endocrinology • Nursing education
13. Establish referring provider outreach and referral network Conduct outreach to primary care, pediatrics, gastroenterology, and rheumatology practices to build awareness of screening protocols and referral pathways. Provide standardized referral templates and educational handouts for their offices.	• Endocrinology • Physician relations • Marketing
14. Consider patient education materials and processes Build T1D-related patient education content and resources for patients with Stage 2 T1D and their caregivers. Consider use of relevant Sanofi product-specific educational resources as needed.	• Endocrinology • Diabetes nurse educators • Infusion staff
15. Launch QI review cycle and continuous improvement process Develop a comprehensive set of metrics for T1D patient identification, monitoring, and outcomes. Conduct protocol compliance reviews. Assess workflow gaps, TZIELD experiences, and outcomes. Align protocols with evolving ADA and FDA guidance.	• Quality improvement • Program steering committee

ADA = American Diabetes Association; EHR = electronic health record; FDA = US Food and Drug Administration; PA = prior authorization; PCP = primary care physician; QI = quality improvement.

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- **Test patients for active EBV and CMV infection prior to starting treatment. TZIELD is not recommended in patients with laboratory or clinical evidence of active EBV or CMV infection. Adhere to lymphocyte count monitoring requirements and discontinuation recommendations. Monitor patients for signs and symptoms of viral reactivation following TZIELD treatment and for at least 2 months following the last infusion. If viral reactivation is suspected, discontinue TZIELD.**

WARNINGS AND PRECAUTIONS

Viral Reactivation: Serious, life-threatening cases of viral reactivation, including EBV and CMV have been reported with TZIELD. During and within 2 months of TZIELD treatment, if primary infection or reactivation of EBV or CMV occurs, it may present with increased severity, including EBV-associated lymphoproliferative disease and organ failure. Patients who are immunocompromised, including patients with Down syndrome, may be at increased risk. The majority of serious viral reactivation cases occurred in patients who continued TZIELD despite persistent, severe lymphopenia. Prior to initiating treatment with TZIELD, evaluate patients for active EBV and CMV infection and confirm undetectable viral load (e.g., PCR testing). TZIELD is not recommended in patients with laboratory or clinical evidence of active EBV or CMV infection. During treatment with TZIELD, regularly monitor lymphocyte counts and monitor patients for signs and symptoms of viral reactivation during treatment and for at least 2 months following the last infusion. If viral reactivation is suspected, discontinue TZIELD and obtain viral load (e.g., PCR) promptly. If viral reactivation is confirmed, permanently discontinue TZIELD.

Cytokine Release Syndrome (CRS): CRS occurred in TZIELD-treated patients during the treatment period and through 28 days after the last drug administration. CRS manifestations in TZIELD-treated patients included fever, nausea (with or without vomiting), fatigue, headache, myalgia, arthralgia, increased ALT, increased AST, and increased total bilirubin. These manifestations typically occurred during the first 5 days of TZIELD treatment. Prior to TZIELD treatment, premedicate with antipyretics, antihistamines and/or antiemetics, and treat similarly if symptoms occur during treatment. If severe CRS develops, consider pausing dosing for 1 day to 2 days and administering the remaining doses to complete the full 14-day course on consecutive days; or discontinue treatment. Monitor liver enzymes during treatment. Discontinue TZIELD treatment in patients who develop elevated alanine aminotransferase or aspartate aminotransferase more than 5 times the upper limit of normal (ULN) or bilirubin more than 3 times ULN.

Serious Infections: Use of TZIELD is not recommended in patients with active serious infection or chronic infection other than localized skin infections. Monitor patients for signs and symptoms of infection during and after TZIELD administration. If serious infection develops, treat appropriately, and discontinue TZIELD.

Lymphopenia: Lymphopenia occurred in most TZIELD-treated patients. For most patients, lymphocyte levels began to recover after the fifth day of treatment and returned to pretreatment values within two weeks after treatment completion and without dose interruption. Obtain a CBC prior to starting TZIELD and monitor white blood cell counts during TZIELD treatment. If prolonged severe lymphopenia develops (<500 cells per mcL lasting 1 week or longer), permanently discontinue TZIELD.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity Reactions: Acute hypersensitivity reactions including serum sickness, angioedema, urticaria, rash, vomiting and bronchospasm occurred in TZIELD-treated patients. If severe hypersensitivity reactions occur, discontinue TZIELD and treat promptly

Vaccinations: The safety of immunization with live-attenuated (live) vaccines with TZIELD treated patients has not been studied. TZIELD may interfere with immune response to vaccination and decrease vaccine efficacy. Administer all age-appropriate vaccinations prior to starting TZIELD.

- Administer inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment. Inactivated vaccines are not recommended during treatment or 6 weeks after completion of treatment.
- Administer live vaccines at least 8 weeks prior to treatment. Live vaccines are not recommended during treatment, or up to 52 weeks after treatment.

ADVERSE REACTIONS

Most common adverse reactions were lymphopenia, vomiting, rash, leukopenia, diarrhea and headache.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** May cause fetal harm. To minimize exposure to a fetus, avoid use of TZIELD during pregnancy and at least 30 days prior to planned pregnancy. Report pregnancies to us at our Adverse Event reporting line at 1-800-633-1610 or visit https://ae.reporting.sanofi
- **Lactation:** A lactating woman may consider pumping and discarding breast milk during and for 20 days after TZIELD administration.

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References: 1. TZIELD Prescribing Information. Provention Bio, Inc. **2.** Mehta S, Ryabets-Lienhard A, Patel N, et al. Pediatric Endocrine Society statement on considerations for use of teplizumab (Tzield™) in clinical practice. *Horm Res Paediatr.* 2025;98(5):597-608. doi:10.1159/000538775.

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