

Elevating *T1D Care in a Pediatric* Health System

Real-World Experience in
Early Screening and
Treatment Implementation

T1D = type 1 diabetes.



INDICATION

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

Limitations of Use:

- There is limited evidence of safety and effectiveness in patients aged 45 years and older with Stage 2 T1D.
- TZIELD is not effective as a disease modifying therapy in non-autoimmune dysglycemic conditions.

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. Serious cases have also been reported in adults with higher body surface area or comorbid conditions, such as adrenal insufficiency or cardiovascular disease. The majority of serious cases occurred in patients who continued TZIELD treatment despite persistent, severe lymphopenia. Severe lymphopenia may be prolonged in adults.
- Test patients for active EBV and CMV infection prior to starting treatment. TZIELD is contraindicated in patients who are immunocompromised or have active viral infection (such as 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.

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Please see additional Important Safety Information on pages 16 and 17 and full [Prescribing Information](#), including Boxed WARNING and patient selection criteria.

Executive Summary

A large regional pediatric health system in the southern region of the United States successfully implemented a comprehensive screening and infusion program to identify appropriate patients with Stage 2 T1D and treat them with teplizumab-mzwv.

This document provides general best practices and can serve as a framework for other institutions ready to institute T1D early-detection screening and monitoring and bring teplizumab-mzwv treatment to their patients where appropriate.

This case study was paid for and commissioned by Sanofi.

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Early Detection

The Opportunity

To identify individuals at risk for Stage 3 T1D earlier through a structured screening program and establish an integrated treatment pathway for eligible patients with Stage 2 T1D to access treatment with teplizumab-mzwv.

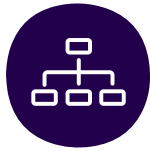
The Institution



Size

Large pediatric health system

Established pediatric endocrinology program



Structure

IDN with a multisite care network



Provider Network Scale

Extensive team of providers that includes pediatric endocrinologists



EHR

Epic

Results at a Glance

(September 2024-September 2026)¹

319

at-risk individuals* screened with available autoantibody data

~30%

autoantibody-positive rate (n=96)

~3%

of screened individuals were identified with Stage 2 T1D (n=11)



7 patients treated with teplizumab-mzwv through the health system's infusion pathway

Treatment decisions were made by each patient's care team based on clinical evaluation, eligibility criteria, and patient and family preferences.

*At-risk patients included first- and second-degree relatives of patients with established T1D, patients with celiac disease, and patients with elevated HbA1c/dysglycemia.¹

EHR = electronic health record; HbA1c = glycated hemoglobin; IDN = integrated delivery network.



Building the Foundation

The Clinical Champion: Your Program's North Star

A strong internal champion was critical to the screening and infusion program's success. Due to their clinical experience and standing within the organization, the program champion engaged leadership, secured institutional buy-in, and collaborated with internal and external stakeholders to move the program forward.

Key Champion Characteristics

Institutional Credibility:

Clinical experience and organizational standing, which enable effective advocacy

Cross-Functional Leadership:

- Ability to engage C-suite and division chief, and coordinate pharmacy, nursing, IT, administration, and clinical teams for clinical, operational, and financial buy-in
- Bridges screening, operational implementation, and treatment access





Building the Foundation (cont'd)

Critical Infrastructure Requirements



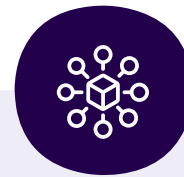
Formulary Approval

P&T committee presentation, formulary review, clinical and operational assessment, and approval to establish protocols for treatment with teplizumab-mzww



Protocol Development

Premedication and treatment administration, monitoring for adverse effects, including viral reactivation, active infections, abnormal blood counts and liver enzyme elevations, and missed-dose workflows²



EHR Integration

Note templates, SmartForms, registries, and Therapy Plans for standardized workflows



Staff Training

Multidisciplinary training on treatment workflows, patient counseling, monitoring requirements, and adverse-event management



Insurance Process

Benefit investigation, statement of medical necessity submission, prior authorization, and appeal workflows



Infusion Capacity and Coverage

Dedicated staffing to support 14-day consecutive infusion schedules, including weekends²

Key Success Factor

Infusion space was secured at a secondary campus by leveraging excess infusion center capacity before it was fully allocated—demonstrating the value of early stakeholder engagement.



From Vision
to Reality

Building the Foundation (cont'd)

The Multidisciplinary Screening Team

Successful screening programs for early detection of T1D require collaboration across clinical, operational, and support teams to deliver coordinated patient care.

Patient

Scheduler

Appointment coordination, triage management, clinic flow optimization



APPs (NPs, PAs)

Patient assessments, care coordination, protocol execution, clinical support, patient education



Physicians

Clinical oversight, Stage 2 diagnosis confirmation, treatment decisions



Certified Diabetes Educators

Patient and caregiver education, lifestyle counseling, CGM training



Extended care team

Registered dietitian

Nutrition assessment and education



Social worker

Psychosocial support and resource navigation



Psychologist

Emotional support and behavioral healthcare



Research Coordinator

Program coordination, data collection, registry management



Key Success Factor

Successful implementation required organizational commitment from leadership to prioritize screening, staffing, IT support, and long-term program development.



Screening Program for T1D

The Key Step to
Program Success

Robust Screening Pathways: Critical to Successful Program Implementation

Effective screening is the foundation of a successful Stage 2 T1D program. Without effective screening, eligible patients cannot be identified; therefore, continued awareness and referral generation on the part of a multidisciplinary screening team are essential to sustaining the program.

The screening clinic for early-stage diabetes was established using **Quality Improvement (QI) methodology** to systematically plan the clinic setup.

The clinical champion worked closely with C-suite executives and the Chief Medical Officer (CMO) to secure organizational commitment, align the screening program with institutional strategic priorities, and ensure the necessary resources—dedicated clinic slots, staffing, and IT support—were allocated to support the initiative.

The Patient Diagnosis Journey: Pediatric Screening Program Overview

The program implemented a dedicated screening clinic supported by a separate triage workflow.

1. Populations the institution considered for screening^{3,4*}

- Family history of T1D, including first- and second-degree relatives of patients with established T1D
- Patients with elevated HbA1c/dysglycemia
- Personal history of autoimmune disease, including celiac disease, Hashimoto's thyroiditis, or Graves' disease

2. Screening measurements and stage determination^{3,4}

- **Initial screening:** HbA1c and islet autoantibody testing (GADA, IAA, IA-2A, ZnT8A)
- **Further evaluation (≥2 positive autoantibodies):** OGTT, C-peptide, and CGM assessment
- **Stage determination:** Results reviewed to confirm Stage 2 T1D

When the screening clinic launched, a triage pathway was established with several appointment slots reserved to support patient scheduling and evaluation. The program expanded in less than a year.

*Guided by ADA and ISPAD recommendations.^{3,4}



QI methodology helped increase the number of referrals

The screening clinic used QI PDSA cycles to refine the screening program, which increased the number of referrals. Refinements included educating the endocrinology, PCP, and gastroenterology teams and making the research coordinator available to screen siblings in the clinic.

ADA = American Diabetes Association; GADA = glutamic acid decarboxylase 65 autoantibody; GI = gastroenterologist; IA-2A = insulinoma-associated antigen 2 autoantibody; IAA = insulin autoantibody; ISPAD = International Society for Pediatric and Adolescent Diabetes; OGTT = oral glucose tolerance test; PCP = primary care provider; PDSA = Plan-Do-Study-Act; ZnT8A = zinc transporter 8 autoantibody.



Screening Program for T1D (cont'd)

The Key Step to
Program Success

Internal Awareness and Referral Activation: Multi-Channel Education and Engagement Strategy



HCP education

- Grand rounds presentations
- Education of pediatric endocrinologists and children's internal primary care team on screening pathways, referral processes, and treatment urgency
- Wellness articles on organization website
- Patient story podcasts
- CME opportunities and peer-to-peer outreach

Collaborative program structure

- Partnership with T1D research network for broader awareness
- Private endocrinologist and pediatrician referrals
- GI clinic partnership for patient screening for celiac disease
- Establishment of in-person TrialNet clinic to address low follow-through with online screening once per month; staffed by a research coordinator and offered at no cost to families



Key Success Factor

Expanded screening capacity and alignment with ADA guidance on early detection and referrals.

CME = continuing medical education.



The Patient Infusion Journey

From Diagnosis to Treatment and Monitoring

Pre-Infusion Workflow

1 Treatment Discussion³

- Discussed treatment with teplizumab-mzwv following Stage 2 diagnosis

2 Pre-Infusion Labs & Documentation^{2,5}

- Completed baseline CBC, liver enzyme, pregnancy, QuantiFERON, and viral panels (IgG, IgM, PCR) for EBV, CMV, and HSV
- Confirmed vaccination status, repeated islet autoantibody testing, and completed the statement of medical necessity

3 Insurance Authorization

- Therapy plan submitted in the EHR, which automatically triggers notification to the authorization team for benefit investigation
- Coordinated prior authorization, peer-to-peer review, and appeals as needed to support treatment access

4 Infusion Scheduling

- Coordinated infusion dates, medication procurement, and family scheduling for the 14-day treatment course²
- Reviewed IV access options (daily IV, midline, or PICC) and arrange Day 1 placement with the vascular access team⁵
- Checked EBV and CMV PCR viral loads 3 to 4 days* prior to the infusion start date²

Key Success Factor

Higher acceptance of treatment was observed among families familiar with T1D.



100% Insurance Authorization:

All patients who pursued therapy successfully obtained coverage approval and initiated treatment.

*A 3-4 day testing interval was utilized by this institution. Timing of pretreatment testing should be determined independently by each institution using their best medical judgment.

CBC = complete blood count; HSV = herpes simplex virus; IgG = Immunoglobulin G; IgM = Immunoglobulin M; IV = intravenous; PCR = polymerase chain reaction; PICC = peripherally inserted central catheter.



The Patient Infusion Journey (cont'd)

From Diagnosis to Treatment and Monitoring

Prior to each of the first 5 days, patients were premedicated with a nonsteroidal anti-inflammatory drug or acetaminophen, an antihistamine, and also an antiemetic as appropriate.²

Infusion Once Daily for 14 Consecutive Days²

All patients who initiated treatment with TZIELD® (teplizumab-mzwv) completed the 14-day course.*

A coordinated care team supported the families throughout the treatment process.

Core operational components required to support the **14-day infusion therapy** include:



Trained Team

Infusion nurses experienced with monoclonal antibody administration and monitoring for side effects

Code team available if needed



Weekend Coverage

Dedicated hospital staff to support continuous 14-day treatment²



Physician Oversight

On-call endocrinologist to meet with family Day 1, lab days, and for questions about side effects



Vascular Access Planning

Discussion with vascular access team and families about daily IV, midline, and PICC line options, with access placed on Day 1 of treatment⁵

Monitoring for Patients Taking Teplizumab-mzwv²

- Monitor lymphocyte count regularly (every 2-3 days) during teplizumab-mzwv infusion and monitor for lymphocyte recovery following completion of teplizumab-mzwv
- If prolonged severe lymphopenia (<500 cells per mcL lasting 1 week or longer) develops, permanently discontinue teplizumab-mzwv
- Monitor patients for signs and symptoms of viral reactivation during teplizumab-mzwv treatment and for at least 2 months following the last infusion. If viral reactivation is suspected, discontinue teplizumab-mzwv
- Monitor liver enzymes and bilirubin during treatment. Discontinue teplizumab-mzwv treatment in patients who develop elevated ALT or AST more than 5 times the ULN or bilirubin more than 3 times ULN
- Monitor patients for signs and symptoms of infection during and after teplizumab-mzwv treatment. If serious infection develops, treat appropriately, and discontinue teplizumab-mzwv
- If severe hypersensitivity reactions occur, discontinue use of teplizumab-mzwv and treat promptly

Follow-Up: Every 3 to 6 months

Monitoring components

- HbA1c
- Oral glucose tolerance test⁵
- CGM device prescribed for ongoing monitoring⁵

Care team members required

- Physicians
- APPs (NPs, PAs)
- Diabetes educators
- Registered dietitians
- Social workers
- Psychologist

*Some families from outside the area stayed locally throughout treatment.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; ULN = upper limit of normal.



Implementation Steps

Screening and treating individuals with Stage 2 T1D requires a structured, multidisciplinary approach. The following steps guided this center's planning:



Phase 1: Align and Secure Buy-In



Screening

- ✓ **Identify a clinical champion** to lead screening program development
- ✓ **Secure C-suite and CMO buy-in** for screening as a strategic priority
- ✓ Apply a QI framework to **identify barriers, prioritize interventions, and establish measurable program goals**
- ✓ **Assemble multidisciplinary team** (physicians, APPs, diabetes educators, scheduler, research coordinator)
- ✓ **Conduct stakeholder meetings** for space
- ✓ **Define target populations** using ADA/ISPAD guidelines
- ✓ **Explore screening support** through advocacy organizations such as Breakthrough T1D



Treatment Implementation

- ✓ **Initiate P&T committee review** of teplizumab-mzwv
- ✓ **Write protocols for screening and infusion** using best practices from other centers
- ✓ **Develop premedication and emergency plans**
- ✓ **Outline monitoring labs** for adverse reactions
- ✓ **Create protocols** for monitoring side effects, abnormal blood counts, active infections, elevated liver enzymes, missed doses²
- ✓ **Present therapy plan** for approval



Implementation Steps (cont'd)



Phase 2: Build the Infrastructure



Screening

- ✓ **Develop triage process** and allocate dedicated clinic slots for screening
- ✓ **Build standardized note templates, SmartSets, and SmartForms in EHR**
- ✓ **Create screening protocol:** islet autoantibodies (GADA, IAA, IA-2, ZnT8A) → OGTT for those with ≥2 positive autoantibodies^{2,3}
- ✓ **Conduct stakeholder meetings** for staffing and weekend coverage
- ✓ **Train staff** on screening protocols and patient education
- ✓ **Develop patient educational materials** (handouts, wellness articles, podcasts)



Treatment Implementation

- ✓ **Develop clinic workflows** for teplizumab-mzwv infusion
- ✓ **Build EHR therapy plans and treatment registry dashboard**
- ✓ **Deliver in-service training** to educators and staff
- ✓ **Present to physician team** on indications, workflow, best practices
- ✓ **Establish insurance benefit process** (30-100 days) including prior authorizations and appeals



Implementation Steps (cont'd)



Phase 3: Launch the Program



Screening

- ✓ **Launch screening clinic** and activate internal/external referral pathways
- ✓ **Present at grand rounds** and launch marketing/awareness campaigns
- ✓ **Establish in-person research clinic** if online follow-through is low
- ✓ **Track QI metrics** (volumes, positivity rates, referral sources) and refine based on data



Treatment Implementation

- ✓ **Specialty pharmacy orders teplizumab-mzwv** from manufacturer
- ✓ **Create visit note templates** with SmartPhrases
- ✓ **Launch therapy plan** in EHR
- ✓ **Establish baseline labs** (CBC, liver enzymes, pregnancy test, QuantiFERON, autoantibodies, and viral panels for EBV, HSV, and CMV) and protocols for the 3- to 4-day* pre-infusion safety viral clearance check^{2,5}
- ✓ **Confirm vaccination status**²
- ✓ **Premedicate prior to each of the first 5 days** of teplizumab-mzwv infusion²
- ✓ **Schedule appropriate monitoring and testing** for patients receiving teplizumab-mzwv during and after treatment²
- ✓ **Schedule 3- to 6-month follow-ups** (HbA1c, OGTT)⁵
- ✓ **Provide diabetes education and prescribe CGM** for ongoing monitoring⁵

*A 3-4 day testing interval was utilized by this institution. Timing of pretreatment testing should be determined independently by each institution using their best medical judgment.



Navigating Challenges and Solutions

Insights from
Real-World
Implementation

Institution-Specific Challenges and Implemented Solutions

Challenges		Solutions
Development of screening program policies and enforcing them across the organization	➤	Appointment of a clinical champion to establish protocols, best practices, and monitoring plans
Setup of infusion capabilities, including space, nursing staff, and weekend coverage	➤	C-suite support, early stakeholder buy-in and leveraging excess infusion center capacity before fully allocated; voluntary weekend sign-ups for nursing team
Coordination of once-daily 14-day infusion therapy ²	➤	Patient/caregiver education; EHR builds and smart sets for pre-ordering; hospital-staffed weekend coverage
Side effect monitoring. Serious side effects include viral reactivation, CRS, serious infections, lymphopenia and hypersensitivity reactions. Common adverse reactions include lymphopenia, vomiting, rash, leukopenia, diarrhea, neutropenia, increased liver transaminase and headache ²	➤	Robust premedication protocols; in-service training for diabetes educators and infusion staff
Low patient volume relative to capacity	➤	Multi-channel marketing; partnership with T1D research network; summer scheduling for teens

Key Areas of Focus

Awareness

Lack of urgency among families of high-risk patients unfamiliar with T1D

Time Constraints

Limited discussion time during visits

Patient Follow-Through

14-day commitment is a hurdle for caregivers and teens



Considerations:

As T1D screening and monitoring expands, health systems should consider how referral pathways, treatment evaluation, and infusion capacity can support timely access to treatment for eligible Stage 2 T1D patients.

CRS = cytokine release syndrome.



Implementation

Ready to Implement Early T1D Screening and Treatment?

Implementation is feasible within a structured clinical program. With appropriate institutional support and multidisciplinary coordination, your center can implement an effective protocol.

Sanofi Support Throughout the Journey

The COMPASS Patient Support Program provides educational support around coverage requirements, sample letters of medical necessity and appeals, as well as sample coding and billing information.

The TZIELD (teplizumab-mzwv) Patient Ambassador & Mentor Program connects new patients with mentors who have firsthand experience with autoimmune T1D and treatment with teplizumab-mzwv. These real patients or caregivers share their personal stories to help others feel informed and supported as they begin their treatment journey.



Contact a Sanofi representative to learn more about TZIELD (teplizumab-mzwv)

References: 1. Data on file. Sanofi. 2. TZIELD. Prescribing information. Provention Bio, Inc. 3. American Diabetes Association Professional Practice Committee. *Diabetes Care*. 2026;49(suppl 1):S27-S49. 4. Haller MJ, et al. *Horm Res Paediatr*. 2024;97(6):529-545. 5. Mehta S, et al. *Horm Res Paediatr*. 2025;98(5):597-608.



Important Safety Information

INDICATION

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Limitations of Use:

- There is limited evidence of safety and effectiveness in patients aged 45 years and older with Stage 2 T1D.
- TZIELD is not effective as a disease modifying therapy in non-autoimmune dysglycemic conditions.

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. Serious cases have also been reported in adults with higher body surface area or comorbid conditions, such as adrenal insufficiency or cardiovascular disease. The majority of serious cases occurred in patients who continued TZIELD treatment despite persistent, severe lymphopenia. Severe lymphopenia may be prolonged in adults.**
- **Test patients for active EBV and CMV infection prior to starting treatment. TZIELD is contraindicated in patients who are immunocompromised or have active viral infection (such as 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.**

CONTRAINDICATIONS

TZIELD is contraindicated in patients who are immunocompromised or have active viral infection (such as EBV or CMV infection).

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. The duration of severe lymphopenia following TZIELD treatment may be prolonged in adults. Serious cases have also been reported in adults with higher body surface area or comorbid conditions, such as adrenal insufficiency or cardiovascular disease.

Prior to initiating treatment with TZIELD, evaluate patients for active EBV and CMV infection and confirm absence of active infection on assessment of viral load (e.g., PCR testing). 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.

Please see additional Important Safety Information on pages 1 and 17 and full [Prescribing Information](#), including Boxed WARNING and patient selection criteria.



Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Cytokine Release Syndrome (CRS): CRS occurred in TZIELD-treated patients during the treatment period and through 28 days after the last drug administration. Manifestation of CRS 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 if symptoms have resolved or significantly improved, subsequently administering the remaining doses on consecutive days to complete the full 14-day treatment course; 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: Bacterial and viral infections have occurred in TZIELD-treated patients. Adults may have a longer duration of severe lymphopenia following TZIELD treatment, which may increase the risk of 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. Severe lymphopenia (<500 cells per mL) lasting 1 week or longer has been reported in TZIELD-treated patients.

Severe lymphopenia following TZIELD treatment may be more prolonged in adults. Obtain a CBC prior to starting TZIELD and monitor lymphocyte counts during TZIELD treatment. If prolonged severe lymphopenia develops (<500 cells per mL lasting 1 week or longer), permanently discontinue TZIELD.

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.

- Inactivated or mRNA vaccinations are not recommended within the 2 weeks prior to the TZIELD treatment course, during treatment, or up to 6 weeks after completion of the treatment course.
- Live-attenuated vaccinations are not recommended within the 8 weeks prior to starting TZIELD treatment, during treatment, or up to 52 weeks after completion of the treatment course.

ADVERSE REACTIONS

Most common adverse reactions were lymphopenia, vomiting, rash, leukopenia, diarrhea, neutropenia, increased liver transaminase 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.

Please see full **Prescribing Information**, including **Boxed WARNING** and patient selection criteria.