PATIENT START FORM: INSTRUCTIONS

TZIELD® (teplizumab-mzwv) Injection 2 mg/2 mL

To submit the START Form online, click here, fax to 908-425-4840, or email COMPASS@sanofi.com.

For questions or to learn more about TZIELD COMPASS, call 1-844-778-2246 Monday through Friday, 8 AM–8 PM ET.

INDICATION

TZIELD® (teplizumab-mzwv) is a CD3-directed monoclonal antibody indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D.

Now that you have decided to prescribe TZIELD for your patient, please review the helpful guide below before you complete the Patient START Form. Note that all fields must be completed in order to receive support through TZIELD COMPASS.

Instructions for Healthcare Providers

To prevent delays in support, be sure to confirm the following before submitting the START Form

Patient and Prescriber Information

- ☐ All fields have been completed and clinical labs are attached
- ☐ Patient or Parent/Legal Guardian has signed Patient Consent. If not, COMPASS will reach out to obtain eConsent

Required Clinical Labs to Confirm Clinical Eligibility

- ☐ Patient has tested positive for at least 2 of the following pancreatic islet cell autoantibodies within the past 6 months*
  - Glutamic acid decarboxylase 65 autoantibody (GADA)
  - Insulin autoantibody (IAA)
  - Insulinoma-associated antigen 2 autoantibody (IA-2A)
  - Zinc transporter 8 autoantibody (ZnT8A)
  - Islet cell autoantibody (ICA)
- ☐ Patient has been diagnosed with dysglycemia without overt hyperglycemia, such as*,†
  - Fasting plasma glucose (FPG) of 100–125 mg/dL
  - 2-hour plasma glucose (2-h PG) during an oral glucose tolerance test (OGTT) of 140–199 mg/dL
  - Intervening plasma glucose level at 30, 60, or 90 minutes of ≥200 mg/dL during an OGTT
  - A1C of 5.7%–6.4% or ≥10% increase in A1C
- ☐ Complete blood count (CBC) and liver enzyme tests have been run to confirm patient has adequate hematologic function, adequate hepatic function, does not have evidence of acute infection with Epstein-Barr virus or cytomegalovirus, and does not have active serious infection

Patient Engagement

Be sure to discuss the following with your patient and/or their parent/legal guardian prior to completing the START Form

- What the patient can expect during their 14-day infusion, including options as to where the patient can receive their infusion. TZIELD COMPASS can provide support during these conversations
- Patient consent is required for enrollment. If the patient or parent/legal guardian does not sign while in the office, a COMPASS Navigator will reach out to obtain eConsent

*Timelines for lab requirements may vary by individual plan. †If an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate.

CD3 = cluster of differentiation 3.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Cytokine Release Syndrome (CRS):** CRS occurred in TZIELD-treated patients during the treatment period and through 28 days after the last drug administration. 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.

Please see additional Important Safety Information on page 6 and full Prescribing Information, including Medication Guide.

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

Tzield® COMPASS

PATIENT START FORM

TZIELD® (teplizumab-mzwv) Injection 2 mg/2 mL

To submit the START Form electronically, click here.

Please sign, date, and submit the form via fax (908-425-4840) or email (COMPASS@sanofi.com).
Form must be submitted by prescriber's office only.

For questions or to learn more about TZIELD COMPASS, call 1-844-778-2246 Monday through Friday, 8 AM–8 PM ET.

Indicates required field

Patient Information

***Patient First Name:** _____ ***Patient Last Name:** _____ ***Sex Assigned at Birth:** ☐ Male ☐ Female

***Date of Birth** (mm/dd/yyyy): _____ ***Patient Address:** _____ ***City:** _____

***State:** _____ ***ZIP:** _____ ***Primary Phone #:** ☐ Mobile ☐ Home (leave blank if patient is under 18 years old) _____

Email (leave blank if patient is under 18 years old): _____

Preferred Form of Communication: ☐ Phone ☐ Text ☐ Email ☐ Do not contact patient Best Time to Contact: ☐ Morning ☐ Afternoon ☐ Evening

Preferred Language: ☐ English ☐ Spanish ☐ Other _____

Parent/Legal Guardian information, if applicable (required for patients under 18 years old)

***Parent/Legal Guardian Name:** _____ ***Relationship to Patient:** _____

***Parent/Legal Guardian Primary Phone #:** ☐ Mobile ☐ Home _____ Email: _____

Secondary Parent/Legal Guardian or Caregiver Name: _____ Relationship to Patient: _____

Secondary Parent/Legal Guardian or Caregiver Primary Phone #: ☐ Mobile ☐ Home _____ Email: _____

Patient Consent

Section 7: I have read and agree to the Authorizations to Use and Disclose Health Information.

SIGN

*Patient or Parent/Legal Guardian Signature	*Relationship to Patient	*Date (mm/dd/yyyy)

Section 8: I have read and agree to the Patient Certifications.

Check here ☐ I have read the Text Messaging Consent in Section 8 and expressly consent to receive text messages by or on behalf of the Program.

SIGN

*Patient or Parent/Legal Guardian Signature	*Relationship to Patient	*Date (mm/dd/yyyy)

Additional Parent/Legal Guardian or Caregiver Name (optional)	Relationship to Patient (optional)	Phone Number (optional)

2 Insurance Information

☐ Patient has no insurance (proceed to Section 3)

Please attach a copy of both sides of the patient's medical and pharmacy insurance card(s) via fax with this prescription form.

***Primary Insurance:** _____

***Insurance Provider:** _____ ***Phone #:** _____ ***Policy ID #:** _____

***Group #:** _____ ***Policy Holder Name:** _____ ***Policy Holder Date of Birth** (mm/dd/yyyy): _____

***Policy Holder Relationship to Patient:** _____ ***RxBIN:** _____ ***RxPCN:** _____

Secondary Insurance: _____ Insurance Provider: _____

Phone #: _____ Policy ID #: _____ Group #: _____ Policy Holder Name: _____

Policy Holder Date of Birth (mm/dd/yyyy): _____ Policy Holder Relationship to Patient: _____

Please see the Prescribing Information, including Medication Guide.

***Patient First Name:** _____ ***Patient Last Name:** _____ ***Patient Date of Birth:** _____

****Indicates required field***

***Please note:** Product is available through limited specialty pharmacies. Actual dispensing method may be specified by the patient's insurance.*

Please Select Acquisition Method

Specialty Distributor: ☐ Cardinal Specialty Distribution

Specialty Pharmacy: ☐ Orsini Specialty Pharmacy ☐ Amber Specialty Pharmacy ☐ No preference ☐ Unsure

3 Prescriber Information

***Clinic Name:** _____ ***First Name:** _____ ***Last Name:** _____

***Prescriber NPI:** _____ ***Prescriber Tax ID#:** _____ ***Address:** _____

***City:** _____ ***State:** _____ ***ZIP:** _____ ***Office Contact Name:** _____

***Office Contact Phone #:** _____ ***Fax #:** _____ ***Office Contact Email:** _____

4 Infusion Site of Care Information

☐ I would like assistance from TZIELD COMPASS in identifying infusion site options. My preferred site of care setting(s) include

☐ At home with a nurse ☐ Infusion facility ☐ Both facility and home

☐ I have already identified an infusion site for my patient. Patient will be infused at

☐ Prescriber's office (SECTION 3)

☐ At home with a nurse (if address is different than SECTION 1, please list below)

☐ Infusion facility (please list below)

☐ Both facility and at home (please list infusion site below, as well as number of doses to be infused at each location)

_____ days to be infused at facility _____ days to be infused at home

Infusion Site (if unknown, TZIELD COMPASS can provide support with infusion site identification/options)

Infusion Site Name: _____ Infusion Site NPI: _____

Tax ID #: _____ Address: _____

City: _____ State: _____ ZIP: _____ Infusion Center Contact Name: _____

Infusion Center Contact Phone #: _____ Fax #: _____

5 Clinical Diagnosis

***Primary Diagnosis ICD-10-CM Code:** ☐ E10.9 ☐ E10.8 ☐ Other (Include ICD-10-CM): _____

***Please indicate which tests have been conducted to confirm patient's diagnosis (please attach clinical documentation of these test results)**

***Confirmation of dysglycemia without overt hyperglycemia**

☐ Oral glucose tolerance test (OGTT) (CPT® Code: 82951) **Level:** _____ **Date test completed:** _____

☐ 2-hour plasma glucose 140-199 mg/dL *and/or* ☐ Intervening plasma glucose level at 30, 60, or 90 minutes ≥200 mg/dL

☐ Fasting plasma glucose (FPG) 100-125 mg/dL (CPT® Code: 82947) **Level:** _____ **Date test completed:** _____

☐ A1C 5.7%-6.4% or ≥10% increase in A1C (CPT® Code: 83036) **Level:** _____ **Date test completed:** _____

***Confirmation of at least 2 pancreatic islet cell autoantibodies (select positive autoantibodies below)**

☐ Glutamic acid decarboxylase 65 (GAD) (CPT® Code: 86341) **Date test completed:** _____

☐ Insulin autoantibody (IAA) (CPT® Code: 86337) **Date test completed:** _____

☐ Insulinoma-associated antigen 2 autoantibody (IA-2A) (CPT® Code: 86341) **Date test completed:** _____

☐ Zinc transporter 8 autoantibody (ZnT8A) (CPT® Code: 86341) **Date test completed:** _____

☐ Islet cell autoantibody (ICA) (CPT® Code: 86341) **Date test completed:** _____

☐ **Complete blood count (CBC) and liver enzyme tests have been run to confirm patient has adequate hematologic function, adequate hepatic function, does not have evidence of acute infection with Epstein-Barr virus or cytomegalovirus, and does not have active serious infection**

☐ **I certify that the patient's clinical history demonstrates dysglycemia without overt hyperglycemia per an OGTT or alternative method if appropriate and OGTT is not available**

☐ ***I certify that the patient's clinical history and associated diagnosis do not suggest type 2 diabetes**

Patient allergies: _____

Prior (within the last 12 months) and current medications, including diabetic medications: _____

Please see the Prescribing Information, including Medication Guide.

*Patient First Name: _____ *Patient Last Name: _____ *Patient Date of Birth: _____

*Indicates required field

6 TZIELD® (teplizumab-mzwv) Injection 2 mg/2 mL Prescription Information

Infuse according to the body surface area-based dosing regimen in the Prescribing Information for TZIELD for patients aged ≥8 years old.
To calculate BSA, click here.

Mosteller formula $BSA\ (m^2) = \sqrt{\frac{[\text{height (cm)} \times \text{weight (kg)}]}{3600}}$

***Patient Height (cm):** _____ ***Patient Weight (kg):** _____

***Body Surface Area (BSA):** _____
Calculate using the Mosteller formula (see above)

***Date measured:** _____

*Quantity to Dispense	BSA
☐ **14** TZIELD 2 mg/2 mL, single-dose vials	≤1.94 m^2
☐ **24** TZIELD 2 mg/2 mL, single-dose vials	>1.94 m^2

Refills: No refills

By signing below, I certify that the above therapy is medically necessary and that I will supervise the patient's treatment accordingly.

SIGN

_____ _____
***Prescriber Signature—Dispense as Written (No Stamp Allowed)** ***Date (mm/dd/yyyy)**

OR

SIGN

_____ _____
***Prescriber Signature—Generic Substitution Allowed (No Stamp Allowed)** ***Date (mm/dd/yyyy)**

By signing above, I certify that (1) the information contained in this application is current, complete, and accurate to the best of my knowledge; (2) the above therapy is medically necessary and in the best interest of the patient identified above and that I will supervise the patient's treatment accordingly; (3) I have obtained any consent required under federal and state law for the release and use of the patient's personal health information including diagnosis, treatment, medical, and insurance information contained on this form to Sanofi and its agents, service providers, and affiliates, including commercial and field-based teams, for purposes of benefits verification and coordination of dispensing therapy, or to otherwise assist the patient to initiate or continue the prescribed therapy and/or to evaluate the patient's eligibility for TZIELD COMPASS or other programs for TZIELD; and (4) I will not seek payment from any payer, patient, or other source for free product provided directly to the patient. I have obtained patient's permission to enroll them in TZIELD and for them to be contacted by Sanofi in connection with this application. I understand that I am under no obligation to prescribe any Sanofi therapies or to participate in TZIELD COMPASS, and that I have not received, nor will I receive, any benefit from Sanofi for prescribing a Sanofi therapy. I certify that I am a legal resident of the United States (and US territories). I authorize Sanofi and its agents to convey the above prescription by any means allowed under applicable law to the dispensing pharmacy.

7 Authorization to Use and Disclose Health Information

PATIENT: PLEASE READ THE FOLLOWING CAREFULLY, THEN DATE AND SIGN WHERE INDICATED IN SECTION 1 ON PAGE 2

I hereby authorize my (and/or my child's) healthcare providers, health insurance carriers, and pharmacy providers to use and disclose my (and/or my child's) individually identifying health information, including health insurance information, medical diagnosis and condition (including lab test results related to such diagnosis or supportive testing), prescription information, and name, address, and telephone number ("My Information") to Sanofi, its affiliates, and its agents and representatives ("Sanofi"), including Sanofi's commercial and field-based teams and third parties authorized by Sanofi for the following purposes in order to administer the TZIELD COMPASS Patient Support Program, including: 1. Collecting, entering, and maintaining my (and/or my child's) health information in a database to gather information on my (and/or my child's) patient experience; 2. Verifying insurance coverage, reviewing reimbursement requirements, and coordinating coverage for TZIELD® (teplizumab-mzwv) Injection 2 mg/2 mL; 3. Determining eligibility for program offerings, including copay assistance, free drug or other financial assistance services, or to refer me (and/ or my child) to other programs or sources of funding; 4. Contacting me to provide education, information, and support services to me (and/or my child) related to TZIELD; 5. Contacting me to conduct market research and assess TZIELD COMPASS customer service, and to provide therapy support services designed for people prescribed TZIELD; 6. Performing data analytics with aggregated de-identified data to assess program efficiency; and contacting me about opportunities to participate in research related to TZIELD; 7. Providing me (and/or my child) with ongoing therapy support, including by communicating with healthcare professionals or service providers. All prescription-related support is limited to Sanofi product(s).

Once My Information has been disclosed to Sanofi, I understand that federal privacy laws may no longer protect it from further disclosure. However, I also understand that Sanofi has agreed to protect My Information by using reasonable efforts and disclosing it only for the purposes allowed by me in this Authorization or as otherwise required by law. I understand that I am entitled to a copy of this signed Authorization and may revoke (withdraw) this Authorization at any time by faxing a signed, written request to TZIELD COMPASS at 908-425-4840, or by mailing such request to Sanofi US, PO Box 4996, Trenton, NJ, 08650. TZIELD COMPASS will no longer seek disclosure of my (and/or my child's) health information from my (and/or my child's) healthcare providers and health insurance carriers once it has received and processed my revocation. However, revoking this Authorization will not affect any use and disclosure of the health information that has already occurred in reliance on my authorization.

Please see the Prescribing Information, including Medication Guide.

7 Authorization to Use and Disclose Health Information (cont.)

If I revoke this Authorization, I will no longer be able to receive TZIELD COMPASS support services. I understand that this Authorization expires 18 months from the date support is last provided under the TZIELD COMPASS Patient Support Program, or until my local state law requires expiration, subject to applicable law, unless and until I withdraw (take back) this Authorization before then, or as otherwise required by law. I understand that I do not have to sign this authorization to obtain healthcare treatment or benefits; however, in order to receive the services and communications described above, I must sign the authorization. Federal Law (including HIPAA) requires a signed authorization in order for TZIELD COMPASS to collect this information from my (and/or my child's) healthcare providers. I understand that my (and/or my child's) pharmacy, health insurers, and third-party vendors may receive remuneration (payment) from TZIELD COMPASS and Sanofi or its affiliates in exchange for providing me (and/or my child) with support services and that sharing my (and/or my child's) health information helps facilitate the support services I (and/or my child) will receive. I may reference the US Sanofi Privacy Policy at **https://www.sanofi.com/en/sanofi-us-privacy-policies** for further information regarding these rights with respect to Sanofi US.

I understand that Sanofi may de-identify My Information, including data obtained from accompanying clinical notes and/or documentation, and use it in performing research, education, business analytics, marketing studies, or for other commercial purposes, including linkage with other de-identified information Sanofi receives from other sources. I understand that members of Sanofi may share My Information, including identifiable health information, among themselves in order to de-identify it for these purposes and as needed to perform the Services or to communicate with me by mail, telephone, or email, or, if I indicate my agreement and consent in Section 1 on page 1, by text. I understand and agree that Sanofi may use My Information for these purposes and may share My Information with my healthcare providers, health insurers and specialty pharmacies.

I consent to have my data tokenized by Sanofi. Tokenization is the process of translating sensitive demographic information into a non-identifiable code called a "token" that can't be traced back to you as an individual. The demographic information needed to create a token (includes the participant's name, date of birth, gender, and address) will be collected. This token will allow linkage of your healthcare data from third-party data sets, including electronic medical records and claims databases. The tokenization software and process adhere to all appropriate data privacy and security standards and is encrypted and irreversible. This process allows Sanofi to better understand the health of participants in a comprehensive way, and thus supports more robust scientific/medical research and/or publications. Once you withdraw consent to link data, no further data links will be created. You can choose to withdraw your consent for tokenization of your data at any time by notifying Sanofi and both the token ID and patient ID would be deleted.

8 Patient Certifications

PATIENT: PLEASE READ THE FOLLOWING CAREFULLY, THEN DATE AND SIGN WHERE INDICATED IN SECTION 1 ON PAGE 2

I am enrolling in the TZIELD COMPASS Patient Support Program (the "Program") and authorize Sanofi and their affiliates and agents to provide me services under the Program, as described in the Program Enrollment Form and as may be added in the future. Such services include medication and adherence communications and support, medication dispensing support, coverage and financial assistance support, disease and medication education, and other support services (the "Services"). TZIELD COMPASS is a patient support program that helps patients to gain access to TZIELD and provides patients with education and resources related to TZIELD.

I authorize TZIELD COMPASS under the Fair Credit Reporting Act to use my demographic information to access reports on my individual credit history from consumer reporting agencies. I understand that, upon request, TZIELD COMPASS will tell me whether an individual consumer report was requested and the name and address of the agency that furnished it. I further understand and authorize TZIELD COMPASS to use any consumer reports about me and information collected from me, along with other information they obtain from public and other sources, to estimate my income in conjunction with the Patient Assistance Program eligibility determination process, if applicable. I further understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid; and no free product may be sold, traded, or distributed for sale. If approved for the TZIELD COMPASS Patient Assistance Program, I will not seek to have the value of any medication provided to me under this program counted toward my true-out-of-pocket (TrOOP) cost for prescription drugs for my Medicare Part D Plan.

I understand that I may be contacted by Sanofi for follow-up information in case I report an adverse event.

I give permission to be referred by my COMPASS Navigator to a Therapeutic Education Manager (TEM) if I ask for clinical information regarding TZIELD. I acknowledge that a TEM will provide only information about TZIELD, not any medical advice or support, and that my doctor is the best resource for any medical questions or concerns about my treatment and my disease. I give permission to Sanofi to provide me with informational and promotional materials relating to Sanofi or its affiliates products and services and/or my or my child's condition or treatment (together, the "Communications"). I also understand that the personal data I provide on this form may be shared with third parties operating on behalf of Sanofi or its affiliates to conduct market research. I authorize Sanofi and these third parties to contact me for market research purposes, though I understand that my personal data will not be sold to any third party. I understand that I do not have to enroll in the Program or receive the Communications, and that I can still receive TZIELD, as prescribed by my Healthcare Provider. I can opt out of receiving the Communications, support services offered by the Program, or being subject to market research at any time by notifying a Program representative by telephone at 1-844-778-2246 or by sending a letter to Sanofi US, PO Box 4996, Trenton, NJ 08650.

Please see the Prescribing Information, including Medication Guide.

8 Patient Certifications (cont.)

I acknowledge that by checking the Text Messaging Consent box on page 1, I expressly consent to receive text messages from or on behalf of the Program at the mobile telephone number(s) that I provide. I confirm that I am the subscriber for the mobile telephone number(s) provided, and I agree to notify Sanofi promptly if any of my number(s) change in the future. I understand that my wireless service provider's message and data rates may apply. I understand that I can opt out of future text messages at any time by texting STOP to 1-908-206-7556 from my mobile phone, and that I can get help for text messages by calling TZIELD COMPASS at 1-844-778-2246. I also understand that additional text messaging terms and conditions may be provided to me in the future as part of an opt-in confirmation text message. Message and data rates may apply. I understand that my consent is not required as a condition of purchasing any goods or services from Sanofi. You may keep a copy of this form for your records.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

- **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. Monitor white blood cell counts during the treatment period. If prolonged severe lymphopenia develops (<500 cells per mcL lasting 1 week or longer), 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.
  - Administer live vaccines at least 8 weeks prior to treatment. Live vaccines are not recommended during treatment, or up to 52 weeks after treatment.
  - 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.

ADVERSE REACTIONS

Most common adverse reactions (>10%) were lymphopenia, rash, leukopenia, and headache.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** May cause fetal harm.
- **Lactation:** A lactating woman may consider pumping and discarding breast milk during and for 20 days after TZIELD administration.

Please see full Prescribing Information and Medication Guide.

TZIELD COMPASS is a patient support program that helps eligible patients gain access to TZIELD and provides them with education and resources related to TZIELD.

sanofi

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Tzield® COMPASS