Provention Bio COMPASS™ | sanofi

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

PATIENT START FORM: INSTRUCTIONS

For more information about **Provention Bio COMPASS**, call 1-844-778-2246 Monday through Friday, 8 AM-8 PM ET. Click here to enroll your patient online.

Now that you have decided to prescribe TZIELD for your patient, complete this Patient START Form with all the necessary information for the TZIELD prescription and to initiate the enrollment process for Provention Bio COMPASS. Provention Bio COMPASS is a patient support program that provides helpful tools and resources, information about financial assistance options, and one-on-one support every step of the way.

To enroll in Provention Bio COMPASS, you and your patient will each fill out a section of the START Form. The START Form can be submitted by fax from the prescriber's office or mail to Provention Bio COMPASS at Sanofi US, PO Box 4996, Trenton, NJ 08650. You may also email the completed form to PRVB-Compass@sanofi.com. A signed START Form is needed in order to receive support through Provention Bio COMPASS. Online enrollment is also available. Please see START Form for more information.

You and your patient should expect to hear from the COMPASS Navigator within 1 business day after submitting the START Form. If you have any questions, call 1-844-778-2246.

Provention Bio COMPASS is a patient support program that helps patients to gain access to TZIELD and provides patients with education and resources related to TZIELD. Provention Bio COMPASS is not a healthcare service or an insurance provider and does not provide care coordination. Provention Bio COMPASS and the COMPASS Navigator will not provide medical or treatment advice. Provention Bio COMPASS services are available only to those who have been prescribed TZIELD for an FDA-approved indication and are intended for US residents only.

INSTRUCTIONS FOR HEALTHCARE PROVIDERS

1 PATIENT INFORMATION & CONSENT

- ❑ Required patient and guardian/caregiver information is composed of patient name and address and patient or guardian/caregiver phone number and email address.
- ❑ Please have the patient or parent/legal guardian sign Section 1 of the START Form, after carefully reading Sections 7, 8, and 9.

2 INSURANCE INFORMATION

- ❑ Provide the patient's primary insurance information, indicate if the patient has secondary insurance coverage, and include both sides of the patient's medical and pharmacy insurance cards when returning the START Form. If secondary insurance is available, please provide that information with submission; **OR**
- ❑ Indicate if the patient is uninsured by checking the corresponding box.

ACQUISITION METHOD

- ❑ If known, please indicate the preferred acquisition method. TZIELD may be acquired through a Specialty Distributor via buy-and-bill, or through a select network of Specialty Pharmacies.

3 PRESCRIBER INFORMATION

- ❑ Prescriber contact information is in this section. The prescriber is the HCP prescribing TZIELD.
- ❑ Include NPI and Tax ID numbers to help facilitate the benefits investigation process.

4 INFUSION SITE OF CARE INFORMATION

- ❑ Infusion site of care contact information is in this section. Infusion site of care is the treating facility where the infusion will take place. In some instances, this is the same as the prescriber contact information, if you are infusing in your office. If you are not infusing in your office, these will be different.
- ❑ Include NPI and Tax ID numbers to help facilitate the benefits investigation process.
- ❑ If known, include infusion site details. If you would like assistance with infusion site identification, please indicate so by checking the corresponding box.

5 CLINICAL DIAGNOSIS

- ❑ Indicate which tests have been conducted to confirm the patient's diagnosis, and attach recent clinical documentation of the test results.

6 TZIELD PRESCRIPTION INFORMATION

This section serves as the official prescription for TZIELD. The prescriber is to comply with state-specific prescription requirements, such as e-prescribing, state-specific prescription form(s), fax language, etc. Noncompliance with state-specific requirements may result in outreach to the prescriber.

- ❑ All fields in this section are required. Please sign, date, and return the form by email or fax (908-425-4840).

Please fax the signed TZIELD Patient START Form to 908-425-4840 as soon as it has been completed.

You may also email the form to PRVB-Compass@sanofi.com. Online enrollment is also available. If you have any questions or would like to learn more about Provention Bio COMPASS, call 1-844-778-2246 Monday through Friday, 8 AM-8 PM ET.

Please see the Prescribing Information, including Medication Guide.

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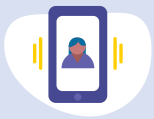
PATIENT START FORM

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

Please sign, date, and fax the form to 908-425-4840

Form must be submitted by prescriber's office only



For more information about **Provention Bio COMPASS**, call 1-844-778-2246 Monday through Friday, 8 AM-8 PM ET. Click here to enroll your patient online.

Indicates required field.

1 PATIENT INFORMATION

❑ ***I certify that as the prescriber, I have engaged in a comprehensive discussion about the therapy with the patient, and the patient has given their consent to begin treatment.**

***Patient First Name:** _____ ***Patient Last Name:** _____ ***Sex Assigned at Birth:** ❑ Male ❑ Female ***Date of Birth:** ____/____/____

***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 _____

Guardian/Caregiver information is required for patients under 18 years old (leave blank if patient is over 18 years old):

***Guardian/Caregiver Name:** _____ ***Relationship to Patient:** _____

***Guardian/Caregiver Primary Phone #** ❑ Mobile ❑ Home: _____ Email: _____

Secondary Caregiver Name: _____ Relationship to Patient: _____

Secondary Caregiver Primary Phone # ❑ Mobile ❑ Home: _____ Email: _____

PATIENT CONSENT

Indicates required.

I have read and agree to the Authorization to Use and Disclose Health Information in Section 7.

SIGN

_____ *Patient/Parent/Legal Guardian Signature

_____ *Relationship to Patient

_____/_____/_____ *Date

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

❑ I have read the Text Messaging Consent in Section 9 and expressly consent to receive text messages by or on behalf of the Program.

SIGN

_____ *Patient/Parent/Legal Guardian Signature

_____ *Relationship to Patient

_____/_____/_____ *Date

_____ Additional Caregiver/Legal Guardian Name (optional)

_____ Relationship to Patient (optional)

_____ Phone Number (optional)

2 INSURANCE INFORMATION

***Primary Insurance:** _____

❑ Patient has no insurance (proceed to Section 3)

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

***Policy Holder Name:** _____ ***Policy Holder Date of Birth:** _____/_____/_____ ***Policy Holder Relationship to Patient:** _____

***RxBIN #:** _____ ***PCN #:** _____

Secondary Insurance: _____

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

Policy Holder Name: _____ Policy Holder Date of Birth: _____/_____/_____ Policy Holder Relationship to Patient: _____

Please see the Prescribing Information, including Medication Guide.

*Indicates required field.

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

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® ❑ Amber™ and its affiliated entity Hy-Vee® Pharmacy Solutions ❑ 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 have discussed infusion site of care preferences with patient. ❑ I have not discussed infusion site of care preferences with patient.

❑ I would like assistance from Provention Bio COMPASS to advise on a potential infusion site.

❑ I will provide infusion site information. Patient will be infused at:

- ❑ Prescriber's office (SECTION 3)
- ❑ At home with a nurse (same address as SECTION 1; if different, list below)
- ❑ Infusion facility (please list below)
- ❑ Both facility and home. Please indicate the number of doses to be infused at each location and list the infusion site below: _____ days to be infused at facility _____ days to be infused at home

Infusion Site (if unknown, Provention Bio 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 Code:** ❑ E10.9 ❑ E10.8 ❑ Other (Include ICD-10): _____

***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)
- ❑ Fasting Plasma Glucose (FPG) (CPT® Code: 82947)
- ❑ A1C (CPT® Code: 83036)

***Glucose/A1C level:** _____

***Date test completed:** _____

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

- ❑ Insulin autoantibody (IAA) (CPT® Code: 86337)
- ❑ Glutamic acid decarboxylase 65 (GAD) (CPT® Code: 86341)
- ❑ Insulinoma-associated antigen 2 autoantibody (IA-2A) (CPT® Code: 86341)
- ❑ Islet cell autoantibody (ICA) (CPT® Code: 86341)
- ❑ Zinc transporter 8 autoantibody (ZnT8A) (CPT® Code: 86341)

***Date test completed:** _____

❑ ***I certify that the patient's clinical history and associated diagnosis do not suggest Stage 3 type 1 diabetes (clinical symptoms and overt hyperglycemia).**

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

Please call Provention Bio COMPASS at 1-844-778-2246 Monday through Friday, 8 AM-8 PM ET, if you have questions about the required tests.

Patient Allergies: _____

Prior/Current Medications: _____

6 TZIELD® (teplizumab-mzwv) INJECTION 2mg/2mL PRESCRIPTION INFORMATION

Infuse according to the body surface area-based dosing regimen in the Prescribing Information for TZIELD for patients aged ≥ 8 years old.

*Patient Height: _____ *Patient Weight: _____ *Body Surface Area (BSA): _____ m^2 *Date Measured: _____

Calculate using the Mosteller formula†

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

Refills: No refills

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

To calculate BSA, click here.

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

SIGN

_____ _____ OR _____ _____

Prescriber Signature—Dispense as Written (No Stamp Allowed) ***Date*** ***Prescriber Signature—Generic Substitution Allowed (No Stamp Allowed)*** ***Date***

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 Provention Bio 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 Provention Bio COMPASS 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 Provention Bio 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 1

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 Provention Bio 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 2mg/2mL; 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 Provention Bio 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 Provention Bio COMPASS at 908-425-4840, or by mailing such request to Sanofi US, 55 Corporate Drive, Bridgewater NJ, 08807. Provention Bio 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.

If I revoke this Authorization, I will no longer be able to receive Provention Bio COMPASS support services. This Authorization shall be valid for one (1) year from the date indicated next to my signature below unless earlier revoked by my written request or if state law deems it valid for a lesser period. 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 Provention Bio 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 Provention Bio 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.

8 PATIENT CERTIFICATIONS

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

I am enrolling in the 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").

Provention Bio 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 Provention Bio 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, Provention Bio 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 Provention Bio 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 Provention Bio 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. The terms and conditions can be found here: https://www.tzield.com/pdf/compass-program-mobile-terms-and-conditions.pdf. I 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.

9 TEXT MESSAGING CONSENT

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 48023 from my mobile phone, and that I can get help for text messages by texting HELP to 48023. 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. I understand that my consent is not required as a condition of purchasing any goods or services from Sanofi.

Please see the Prescribing Information, including Medication Guide.