Provention Bio COMPASS™ | proventionbio

TZIELD™ (teplizumab-mzwv) PATIENT START FORM: INSTRUCTIONS

For more information about **Provention Bio COMPASS™**, call 1-844-778-2246 Monday through Friday, 8 AM-8 PM ET.

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 doctor will each fill out a section of the START Form. The **Patient Consent Form**, provided on pages 4 and 5 of the START Form, can be submitted with pages 2 and 3 of the START Form by fax from the prescriber's office or mail to Provention Bio COMPASS at Provention Bio, 55 Broad Street, 2nd Floor Red Bank, NJ 07701. A signed Patient Consent Form is needed in order to receive support through Provention Bio COMPASS.

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. Be sure to always contact your physician if you have any questions about your health or treatment with TZIELD. Provention Bio COMPASS and your COMPASS Navigator will not provide medical or treatment advice. Provention Bio COMPASS services are available only to those who have been prescribed TZIELD and are intended for US residents only.

INSTRUCTIONS FOR HEALTHCARE PROVIDERS

ACQUISITION METHOD

- Choose your distribution pathway from a Specialty Distributor or selected network of Specialty Pharmacies.

1 PATIENT INFORMATION

- Required patient and guardian/caregiver information is composed of patient name and address and patient or guardian/caregiver phone number and email address.
- Please give the Patient Consent Form, provided on pages 4 and 5, to the patient or parent/legal guardian as appropriate. If the patient or parent/legal guardian is not available to sign the consent form, it will be provided to them separately by Provention Bio COMPASS.

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 that the patient is uninsured by checking the corresponding box.

3 HOUSEHOLD INCOME (optional)

Only required if applying to the Patient Assistance Program.

- If a patient is interested in learning more about potential financial support programs, include the number of people living in the patient's household and the total annual household income to inform potential eligibility for financial support programs.

4 PRESCRIBER/INFUSION SITE OF CARE INFORMATION

- Prescriber and infusion site of care contact information is in this section. The prescriber is the HCP prescribing TZIELD. Infusion site of care is the treating facility where the infusion will take place. In some instances, these are the same if you are infusing the patient 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.
- Include infusion site details or check the "Yes, please provide assistance from Provention Bio COMPASS to select an infusion site" box.

5 CLINICAL INFORMATION/LABS COMPLETED

- Required ICD-10 code and relevant lab testing.

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 fax the form to 908-425-4840.

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

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.

Before prescribing TZIELD, please read the accompanying Prescribing Information, including Medication Guide.

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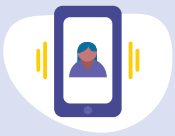

PATIENT START FORM

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.

***Indicates required.**

***Please Select Acquisition Method:** **Specialty Distributor:** ☐ Cardinal Specialty Distribution
Specialty Pharmacy: ☐ Orsini ☐ Amber and its affiliated entity Hy-Vee Pharmacy Solutions ☐ No preference

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

1 PATIENT INFORMATION

*Patient Last Name: _____ *Patient First Name: _____

*Patient Address: _____ *City: _____ *State: _____ *ZIP: _____

*Sex Assigned at Birth: ☐ Male ☐ Female *Date of Birth (mm/dd/yyyy): ____/____/_____ Date Recorded (mm/dd/yyyy): ____/____/_____

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

*Home/Work Phone #: _____ *Cell Phone #: _____ Email: _____

Preferred Form of Communication: Phone, Text, Email
Best Time to Contact: Morning, Afternoon, Night
Preferred Language: English, Spanish, Other _____

2 INSURANCE INFORMATION

☐ *Patient has no insurance

***(Please attach a copy of both sides of the patient's medical and pharmacy insurance card(s) via fax with this prescription form. If secondary insurance is available, please include the information with submission.)**

*Primary Insurance: _____ *Patient has secondary insurance coverage: ☐ Yes ☐ No

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

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

3 HOUSEHOLD INCOME (optional, only required if enrolling in the Patient Assistance Program)

Number of people who live in your household: _____

Total annual household income (includes salary/wages, Social Security income, unemployment insurance benefits, disability income, any other income for the household): _____

4 PRESCRIBER AND INFUSION SITE OF CARE INFORMATION

*Prescriber Name (First Name Last Name): _____ *Prescriber NPI: _____

*Prescriber Address: _____ *City: _____ *State: _____ *ZIP: _____

*Prescriber Email: _____ *Office Contact Name: _____

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

Infusion Site of Care Information

First Infusion Date (mm/dd/yyyy): ____/____/_____ (if known)

☐ Yes, please provide assistance from Provention Bio COMPASS to select an infusion site. Please coordinate directly with the: ☐ Prescriber ☐ Patient

☐ No, assistance is not needed. Patient will be infused at:

☐ Prescriber's office (SECTION 4) ☐ 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: _____ doses to be infused at facility
_____ doses to be infused at home

Infusion Site (if applicable)

Contact infusion site to set up infusion training: ☐ Yes ☐ No

Infusion Site Name: _____ Tax ID #: _____

Address: _____ City: _____ State: _____ ZIP: _____

Before prescribing TZIELD, please read the accompanying Prescribing Information, including Medication Guide.

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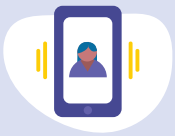

PATIENT START FORM

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.

Indicates required.

*Patient Last Name: _____ *Patient First Name: _____ *Date of Birth (mm/dd/yyyy): ____/____/_____

5 CLINICAL INFORMATION/LABS COMPLETED

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

Patient Allergies: _____

Prior/Current Medications: _____

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 antibody test results.

*Please confirm which tests have been completed, if any:

- Dysglycemia testing (CPT® Codes: 82947, 82948, 82962, 86341)
- Insulin autoantibody (IAA) (CPT Code: 86337)
- Glutamic acid decarboxylase 65 (GAD) autoantibodies (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)
- Other: _____

6 TZIELD™ (teplizumab-mzwv) PRESCRIPTION INFORMATION

***Patient Last Name:** _____ ***Patient First Name:** _____

***Date of Birth (mm/dd/yyyy):** ____/____/_____ ***Height:** ____ft ____in OR ____cm ***Weight:** _____lb OR _____kg ***Date Obtained:** ____/____/_____

***Patient Body Surface Area (BSA):** ☐

BSA Equation:

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

Example: Male, 8 years old = 120 cm, 26 kg

$$BSA\ (m^2) = \sqrt{\frac{(120)(26)}{3600}} = 0.931\ m^2$$

When calculating BSA round to the 100th using standard rounding rules

TZIELD (2 mg/2 mL, single-dose vial) *Infuse according to the dosing regimen in the Prescribing Information for TZIELD.*

***Please select the appropriate TZIELD quantity based on BSA for patients aged ≥8 years.**

Dispense:

☐ **Patient with BSA <1.94 m²: 14 cartons of 2 mg/2 mL, single-dose vials** ☐ **Patient with BSA ≥1.94 m²: 10 cartons of 2 mg/2 mL, single-dose vials**

(Provider, only select BOTH the 14-carton and the 10-carton options for patients with body surface area ≥1.94 m²)

Refills: No refills

SIGN

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

		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 Provention Bio and its agents, 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 Provention Bio in connection with this application.

I understand that I am under no obligation to prescribe any Provention Bio therapies or to participate in Provention Bio COMPASS, and that I have not received, nor will I receive, any benefit from Provention Bio for prescribing a Provention Bio therapy. I certify that I am a legal resident of the United States (and US territories).

I authorize Provention Bio and its agents to convey the above prescription by any means allowed under applicable law to the dispensing pharmacy.

Before prescribing TZIELD, please read the accompanying Prescribing Information, including Medication Guide.

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Enroll in Provention Bio COMPASS today by sending this signed Patient Consent Form by fax from prescriber's office to 908-425-4840, or mail to Provention Bio COMPASS at Provention Bio, 55 Broad Street, 2nd Floor Red Bank, NJ 07701.

PATIENT CONSENT FORM

Consent to share health information for the purpose of providing patient support and/or marketing or other communication:

Who may see and use my personal health information

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 to Provention Bio and its agents and representatives, including Provention Bio's commercial and field-based teams and third parties authorized by Provention Bio 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); **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 **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 Provention Bio product(s).

Provention Bio COMPASS and Provention Bio agree to protect my (and/or my child's) health information by using and disclosing such information only for the reasons listed above, pursuant to the requirements imposed under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). I understand that federal privacy laws may no longer protect my (and/or my child's) health information after its disclosure to Provention Bio COMPASS and that it may be subject to redisclosure.

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 Provention Bio, 55 Broad Street, 2nd Floor Red Bank, NJ 07701. 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.

Please see Medication Guide and Prescribing Information.

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 Provention Bio 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.

If I am completing Section 3 of the Patient START Form, I certify that the information I have set forth in Section 3 of the Patient START Form, including my household income, is true and accurate to the best of my knowledge. 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.

PATIENT INFORMATION

Indicates required.

_____ _____/_____/_____

*Patient Name *Patient Date of Birth

_____ _____

*Parent/Legal Guardian Name *Relationship to Patient

SIGN

_____ _____/_____/_____

***Patient/Parent/Legal Guardian Signature** ***Date**

☐ **Yes** ☐ **No** ***I give permission to Provention Bio to use my or my child's individually identifying health information for the access and reimbursement services listed above and consent to receiving phone calls about the program and its services.**

☐ Yes ☐ No I give permission to Provention Bio to provide me with informational and promotional materials relating to Provention Bio products and services and/or my or my child's condition or treatment.

☐ Yes ☐ No By checking this box, I consent to receive recurring text messages from Provention Bio COMPASS, including service updates and medication reminders, to the number I have provided. Message and data rates may apply. I am not required to consent or provide my consent as a condition of receiving any goods or services. I can text STOP to unsubscribe any time.

☐ Yes ☐ No By checking this box, I understand that the personal data I provide on this form may be shared with third parties operating on behalf of Provention Bio to conduct market research. I authorize Provention Bio and these third parties to contact me for market research purposes. *Note that your personal data will not be sold to any third party.*

_____ _____ _____

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

Please see Medication Guide and Prescribing Information.