Provention Bio COMPASS™ | proventionbio

GUIDANCE FOR COMPLETING THE PROVENTION BIO COMPASS™ PATIENT START FORM

To enroll your patient in Provention Bio COMPASS, you will complete the Patient START Form. Submitting the completed START Form will enroll your patient in Provention Bio COMPASS, enable patient support, and initiate treatment with TZIELD™ (teplizumab-mzwv).

Filling out the START Form is simple. The following guide highlights key points to keep in mind. Any item marked with an asterisk (*) on the form is required. Include all required information to avoid delays.

Indicate the intended product acquisition method.

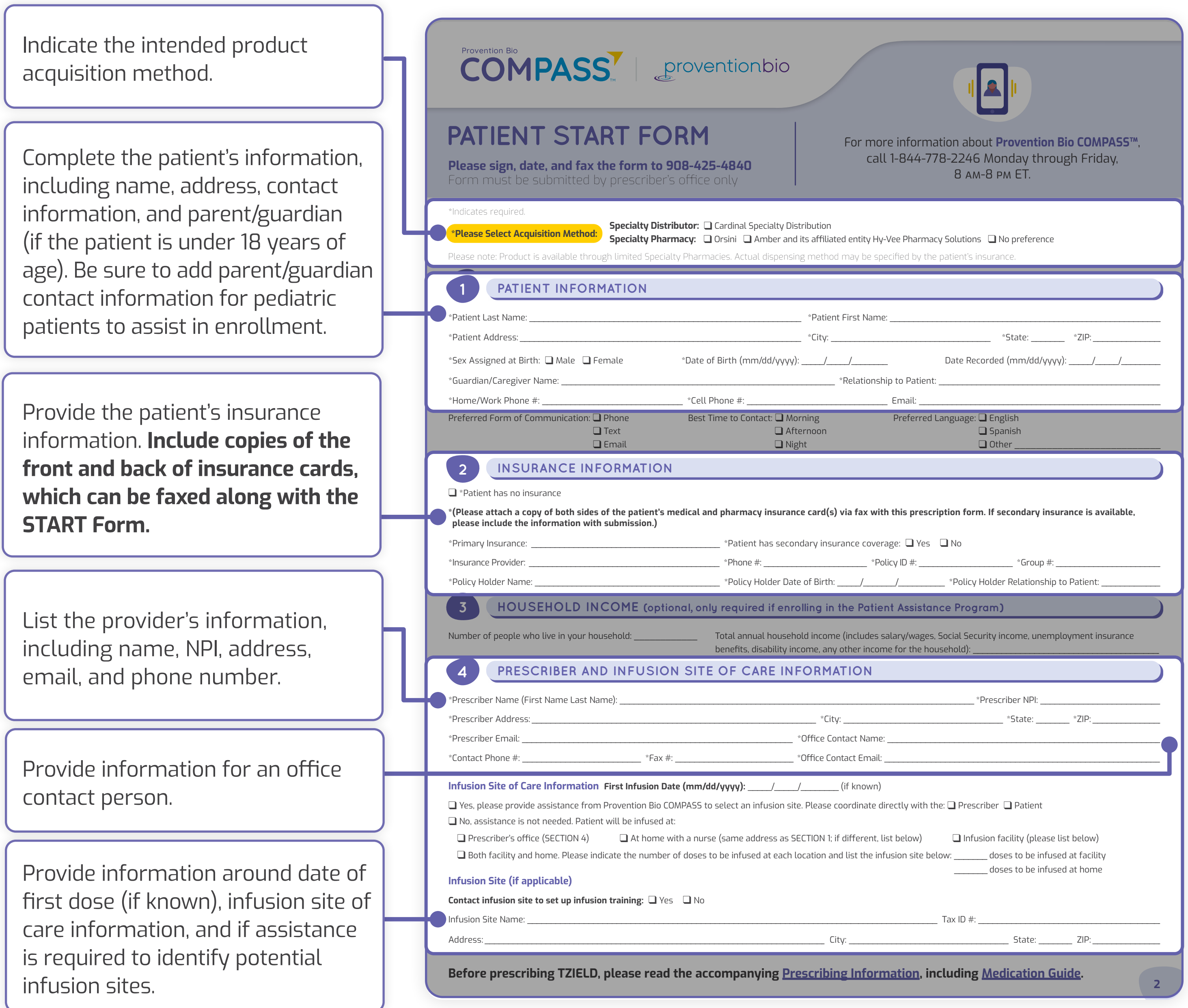
Complete the patient's information, including name, address, contact information, and parent/guardian (if the patient is under 18 years of age). Be sure to add parent/guardian contact information for pediatric patients to assist in enrollment.

Provide the patient's insurance information. **Include copies of the front and back of insurance cards, which can be faxed along with the START Form.**

List the provider's information, including name, NPI, address, email, and phone number.

Provide information for an office contact person.

Provide information around date of first dose (if known), infusion site of care information, and if assistance is required to identify potential infusion sites.



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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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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 and are intended for US residents only.

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GUIDANCE FOR COMPLETING THE PROVENTION BIO COMPASS PATIENT START FORM (cont.)

Fill in the patient's name and date of birth.

Provide the clinical information, including the ICD-10 diagnosis code, patient allergies, prior/current medications, and indicate any tests that have been completed.

Complete the TZIELD prescription information, including patient's name, date of birth, body surface area, and check box for appropriate TZIELD quantity.

Sign and date the form on the appropriate lines in the boxed area.

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*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 m^2: 14 cartons of 2 mg/2 mL, single-dose vials** ❑ **Patient with BSA ≥1.94 m^2: 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 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 ______ OR *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.

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

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Please review the form to ensure all required fields have been completed. With your submission, include copies of

The completed Patient START Form

The front and back of any applicable insurance cards

Fax the completed Patient START Form to 908-425-4840 to enroll your patient in Provention Bio COMPASS.

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