THE MERCK ACCESS PROGRAM ENROLLMENT FORM



Please read the accompanying <u>Medication Guide</u> for WELIREG, including an important warning about harm to an unborn baby, and discuss it with your doctor. The physician <u>Prescribing Information</u> also is available.

Phone: 855-257-3932 Fax: 855-755-0518 • The Merck Access Program, PO Box 2349, Columbus, OH 43216

Prescriptions for WELIREG can be filled through EITHER the specialty pharmacy network or certain physician practices with dispensing capabilities and certain hospital pharmacies. Please select the appropriate option below for how your patients can obtain WELIREG.

Complete the following information only if using one of the network specialty pharmacies to obtain WELIREG. If you are obtaining WELIREG through certain physician practices with dispensing capabilities and certain hospital pharmacies, please fill out the next section below.

Complete the following information only if your facility is dispensing WELIREG. If you are obtaining WELIREG through one of the above specialty pharmacies, please fill out the previous section.

Option 1: If a specialty pharmacy has referred your patient to The Merck Access Program (MAP) to determine eligibility for PAP, **Specialty** please select which pharmacy made the referral: Check off the box for the selected **Pharmacy** ☐ Biologics Pharmacy ☐ Onco360 Oncology Pharmacy specialty pharmacy. **Network** Please complete sections 2–9, as applicable, to have your patient referred to the Merck PAP for eligibility determination. Certain Option 2: If your facility is dispensing WELIREG, please check all boxes below that apply. **Physician Practices With** ☐ Patient Benefit Investigation and/or information about **Dispensing** the Prior Authorization or Appeals Process Check off the relevant box(es). Capabilities & Referral to the Merck PAP for eligibility determination **Certain Hospital** (provided through the Merck Patient Assistance Program, Inc.) **Pharmacies** Please complete sections 1–9, as applicable, to enroll your patient in The Merck Access Program (MAP).

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Complete the information for the patient's insurance and supplemental **Section 1: Insurance Information** insurance (if applicable). Include a copy of the front and back of any **INSURANCE INFORMATION (REQUIRED)** insurance card(s). Please complete all that apply and include a front and back copy of insurance card for each type of insurance PA Approval Dates: ____ Patient has no insurance If the patient has insurance through Patient has insurance through Medicare: Yes No Medicare, check off the appropriate Medicare plan(s). (If yes:) Part A Part B Part D Medicare Advantage **PRIMARY INSURANCE SECONDARY INSURANCE PLAN NAME AND STATE** NAME OF POLICYHOLDER POLICYHOLDER DATE OF BIRTH POLICYHOLDER RELATION TO PATIENT PHONE NUMBER FOR CUSTOMER SERVICE **GROUP NO. POLICY ID NO.** Fill out patient information **Section 2: Patient Information** completely. **PATIENT INFORMATION** Check off the box applicable to the Patient is a US resident: Yes No patient. Patient name: ______ Date of birth (mm/dd/yy): _____ Sex: __ M __ F Address: _____ City/state/zip: _____ (Street address only, no PO boxes) Phone (home): ______ (work/other): _____ Email: _____

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Please be sure that the plan name and policy ID number match what is

on the patient's ID card.

Section 3: Patient Authorization

PATIENT AUTHORIZATION

I understand that, before I may have communications with The Merck Access Program, sponsored by Merck Sharp & Dohme LLC ("Merck"), a subsidiary of Merck & Co., Inc., or receive assistance from the Merck Patient Assistance Program ("Merck PAP"), sponsored by the Merck Patient Assistance Program, Inc. (individually, "a Program"; collectively, "the Programs"), the administrators of the Programs, including their contractors or other representatives, will need to obtain, review, use, and disclose my personal health information ("PHI"), including information relating to my medical condition and prescription medications and the information included in this patient enrollment form.

I therefore authorize each of my physicians, pharmacies, and health plans to disclose my PHI, as necessary, to (i) Merck and the Programs; (ii) the administrators of the Programs, their contractors, third-party service providers, and representatives (collectively, "Program Administrators"); and (iii) the administrator of Merck's field access and reimbursement support team, its contractors, representatives, and third-party services partners (collectively, the "Field Access and Reimbursement Support Administrator") in order to (i) verify my eligibility to enroll in the Programs; (ii) enroll me in the Programs for which I am eligible; (iii) provide reimbursement support; and (iv) investigate insurance coverage in connection with The Merck Access Program.

I also authorize Merck, the Programs, the Program Administrators, and Field Access and Reimbursement Support Administrator, and their respective contractors to use, share, and disclose my PHI for the following purposes: (i) to provide the services described in this enrollment form; (ii) to communicate with me by U.S. postal mail, telephone, text, or email; (iii) to prepare summaries that do not include my PHI for statistical purposes; (iv) to conduct analyses to help Merck evaluate, improve, and/or provide its services, customer support, and educational and/or promotional materials for patients prescribed Merck medications; and (v) to share my PHI with one another and with my physicians and pharmacists as well as with Medicare, my health plans, and their administrators, contractors, or representatives, in order for them to coordinate my benefits, provide, when applicable, reimbursement support, and investigate my insurance coverage.

I also authorize the Program Administrators and Field Access and Reimbursement Support Administrator to disclose my PHI to authorized representatives of Merck and the Programs as necessary to ensure compliance with the rules of the Programs. I also authorize Merck's authorized representatives to use my PHI to communicate with the Program Administrators, Field Access and Reimbursement Support Administrator, my physicians, pharmacies, and me for compliance purposes.

If I have designated a Legal Representative, I authorize Merck, the Programs, Program Administrators, and Field Access and Reimbursement Support Administrator to use my PHI to contact the person I have designated as my Legal Representative for the purpose of verifying the information I have provided in this form and/or coordinating the provision of benefits that may be available to me under the Programs, and to disclose my PHI to my Legal Representative for the purposes described in this authorization.

I understand that the PHI disclosed pursuant to this authorization, once disclosed, may not be governed by the same privacy laws and may be subject to re-disclosure, but I also understand that the administrators of the Programs and their contractors and other representatives intend to use and disclose my PHI only for the purposes described in this authorization. I further understand that if I choose not to provide this authorization, it will not affect my eligibility for, or receipt of, treatment, including Merck products, or healthcare insurance benefits, but that I will not be able to receive any assistance from the Programs for which I may be eligible.

Section 3: Patient Authorization (continued)

PATIENT AUTHORIZATION

I understand that I may cancel this authorization at any time by telephoning The Merck Access Program at (855) 257-3932 or by mailing a written request for cancellation to The Merck Access Program, PO Box 2349, Columbus, OH 43216. I understand that canceling my authorization will mean that my physicians, pharmacies, and health plans, as well as the Field Access and Reimbursement Support Administrator, Merck, the Programs, and the Program Administrators may no longer rely on the authorization to use or disclose my PHI, but that any use or disclosure of such information that occurs before my cancellation is received will be unaffected by my cancellation.

I understand that if I do not cancel this authorization, the authorization will expire 15 months from the date of signature (or the maximum period allowed by applicable state law, if less than 15 months). The administrators of the Programs will retain the information I have submitted in accordance with Merck's records retention policy.

I understand that I am entitled to receive a copy of this authorization once it has been signed and may request a copy by contacting The Merck Access Program at the contact information provided above.

I have requested.	NT SIGNATURE
Signature of patient or legal repres	sentative*: Date:
*A legal representative is a person who has legal at enrollment form.	authority under applicable state law to bind you (the patient) by signing each authorization or declaration in the
Name of signing party (please prin	nt):
DECLARATION OF LEGAL REPRESI	ENTATIVE (If Applicable)
	entative of the patient and that I have the legal authority under applicable state law athorization or declaration in this enrollment form.
Phone number of legal representa	ative:

Section 4: The Merck Patient Assistance Program (Merck PAP) Terms And Conditions

To be eligible for enrollment in the Merck PAP for the Program Product, Patient must request referral to the Merck PAP (see checkbox on page 1) and meet the following Merck PAP eligibility requirements, as determined by the Merck PAP:

- Patient is a US resident and has a prescription for the Program Product from a doctor or prescriber licensed in the US.
- Patient does not have insurance or other coverage for the Program Product.
- Patient meets certain financial eligibility criteria.

The patient or legal representative must sign here.

Date is required.

The patient should complete this section if requesting a referral to the Merck Patient Assistance Program.

HOUSEHOLD INCOME INFORMATION MUST BE PROVIDED FOR ENROLLMENT IN MERCK PAP

Current annual gross household income* (parent/guardian if patient is under age 18): \$

Number of household members (including patient):

*Total gross income before taxes, received within a 12-month period by all members of a household age 15 and older. (Please include before-tax wages, pension, interest/dividends, Social Security benefits, and any other

If Patient is accepted into the Merck PAP, the following Terms and Conditions apply:

sources of income.)

- Assistance will terminate if the Merck PAP becomes aware of any fraud or if the Program Product is no longer prescribed for Patient.
- Completing this Form does not guarantee that Patient will qualify for patient assistance.
- Patient will not seek reimbursement or credit for this prescription from any insurer, health plan, or government program. If
 Patient is a member of a Medicare Part D plan, patient will not seek to have the prescription or any cost associated with it
 counted as part of Patient's out-of-pocket cost for prescription drugs.
- Merck PAP reserves the right to modify or discontinue this program, or terminate assistance at any time and without notice.
- Patient authorizes Merck PAP and its affiliates to forward the prescription to a dispensing pharmacy, certain physician practices, or certain hospital pharmacies on Patient's behalf. Merck PAP is not acting as a dispensing pharmacy. Merck PAP is not responsible for verifying any information contained in the prescription forwarded as part of the enrollment process, including, without limitation, allergies, medical conditions, or other medications being taken by Patient.
- Patient will notify the Merck PAP immediately if anything changes with Patient's prescription, income, or insurance coverage.
- The Merck PAP reserves the right to request documentation to verify the information provided in this enrollment form for purposes of determining Patient eligibility for assistance, and to conduct periodic audits of Patient's enrollment, including the physician who will be supervising treatment, to verify the information provided herein.
- Assistance received through the Merck Patient Assistance Program is not insurance.

Section 5: Merck PAP Financial Hardship Exception

☐ Patient requests consideration for Merck PAP Financial Hardship Exception

If Patient does not meet the prescription drug coverage criteria, Patient may still request assistance if experiencing a financial hardship (i.e., cannot afford the deductible, co-pay, co-insurance, or other cost-sharing requirement of their insurance plan). Patient eligibility request and enrollment under the financial hardship exception is subject to the following terms and conditions:

- The decision of whether Patient is approved for a financial hardship exception resides exclusively with the Merck PAP.
- If Patient has Medicare coverage, eligibility will automatically expire on December 31 of the current calendar year and Patient must submit a new enrollment form before December 31 for eligibility determination for the following year. If Patient fails to re-enroll before December 31, Patient will no longer receive their medication from the Merck PAP.
- If Patient has private prescription drug coverage, eligibility will automatically expire one (1) year from date of enrollment and Patient must re-enroll for eligibility determination for the following year.

Section 6: Patient Acknowledgment And Signature

By signing, I certify that I have read and agree to the above terms and conditions of the Merck PAP and the Merck PAP Financial Hardship Exception, as applicable, based on the support I have requested. By signing, I also certify that all information that I have provided in this application is complete and accurate. PATIENT SIGNATURE Signature of patient or legal representative: Name of signing party (please print): _____ Relationship to patient (if other than patient signing): ____ **Section 7: Merck PAP Income Verification** The patient must authorize PAP to verify their current gross annual household income (household income before taxes are withdrawn) by either: a. OPTION 1: Authorizing PAP and other individuals involved in administering the PAP to obtain his/her consumer report and/or other information related to his/her credit report to determine the patient's eligibility to participate in the program. This verification will not affect the patient's credit rating. **b.** OPTION 2: Sending with this application, a COPY of only **ONE** of the following documents showing proof of the household income the patient provided on the application form: Social Security Benefits Letter
 Veteran Benefits Statement
 Unemployment Benefit Statement
 Disability Statement
 Pension Letter
 Letter from an employer - Most recent 1040 Federal Tax Form One month of pay stubs, prior to the application date If selecting Option 2, include a COPY of only ONE of these documents with your completed, signed, and dated enrollment form. Please do not send an original I understand the Merck Patient Assistance Program, Inc. (Merck PAP) will verify information about my current gross annual household income in order to ensure I am qualified for this program. By signing below, I am providing written authorization to Merck PAP and other individuals involved in administering the Merck PAP to obtain my consumer report and/or other information related to my credit report to determine my eligibility to participate in the program. This verification will not affect my credit rating. PATIENT SIGNATURE Signature of patient or legal representative: Date: Name of signing party (please print): Relationship to patient (if other than patient signing): Section 8: Healthcare Provider Information — **HEALTHCARE PROVIDER INFORMATION** (to be completed by healthcare provider) Healthcare provider name: Healthcare provider tax ID #: ______ Healthcare provider NPI #: _____ Practice/Facility name: _____ Practice tax ID #: ____ Practice NPI #: _____ _____ City/state/zip: _____ (Street address only, no PO boxes) Office contact person: ______ Office contact number: _____ Product use is consistent with labeled indications for WELIREG™ (belzutifan): ☐ Yes ☐ No

The patient or legal representative

must sign here.

Date is required.

The patient or legal representative must sign here.

Date is required.

Please fill out the following fields as applicable for the healthcare provider.

Include the email address of the office contact person.

Section 9: Healthcare Provider Attestation

HEALTHCARE PROVIDER ATTESTATION

By signing below, I represent and warrant the following:

- This Enrollment Form has been prepared exclusively by the healthcare provider or healthcare provider office identified in this Enrollment Form
- By signing below, I represent and warrant that I am authorized pursuant to the laws of my state of license to prescribe WELIREG.
- I or others in my healthcare provider practice group ("my Practice") have obtained written authorization from the patient named in this Enrollment Form that complies with the requirements of the HIPAA Privacy Rule, 45 C.F.R. §164.508, and authorizes me and the Practice, as well as the patient's health insurance plan(s), to disclose the patient's personal health information ("PHI"), including information relating to the patient's medical condition and prescription medications and the information disclosed in this Enrollment Form to The Merck Access Program (the "Access Program"), and the Merck Patient Assistance Program ("Merck PAP") (collectively, "the Programs") and the administrator of Merck's field access and reimbursement support team, including its contractors, representatives, or third-party services partners (collectively, "Field Access and Reimbursement Support Administrator"), and authorizes the Programs and Field Access and Reimbursement Support Administrator (together with their respective administrators, contractors or other affiliates) to use and disclose the PHI for purposes of benefits investigation and reimbursement support.
- I represent and warrant that if my Practice uses a Third-Party Administrator (TPA), the TPA is authorized to act on my behalf to submit enrollment forms to Merck PAP and that the TPA has been trained on Merck PAP rules and requirements before providing services related to Merck PAP.
- I understand that a TPA may not sign on behalf of the patient.
- I certify that I, or a healthcare provider in my Practice, have determined that the prescribed product is medically appropriate for the patient identified above and that I, or a healthcare provider in my Practice, will be supervising the patient's treatment.
- I certify that the Program Product is being used in an outpatient setting only.
- If the patient receives product through the Merck PAP, neither I nor my Practice will seek reimbursement for such product administered to the patient from any source.
- I understand that any donated product from Merck PAP must be returned if the specific eligible patient is unable to receive treatment for any reason and may not be used for any other patient other than the Merck PAP patient for whom it was intended.
- Neither I nor my Practice will receive any reimbursement from Merck, whether for administrative fees or otherwise.
- I understand that information concerning Program participants may be summarized for statistical or other purposes and provided to Merck and/or the Programs only for use in an aggregated, de-identified format.
- I and my Practice grant the Programs the right to conduct periodic audits of my Practice's records to verify the information provided herein.
- I consent to receive communications related to the Programs by telephone, email, and/or fax.
- I understand that the Programs reserve the right to modify or discontinue this program at this facility/practice, or terminate assistance at any time and without notice.
- The information provided is complete and accurate to the best of my knowledge.

Does the Facility use a Third-Party Administrator (TPA) to administer and manage its patient assistance programs?

Yes No By signing, I certify that I have read and agree to the above Healthcare Provider Certification and Attestation (if applicable based on the support my patient requested). By signing, I also certify that all information that I have provided in this enrollment form is complete and accurate.

Date: <

The healthcare provider must indicate if their facility uses a Third-Party Administrator.

The healthcare provider must sign here.

Date is required.

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Healthcare provider signature: _

Healthcare provider name (please print):

Healthcare provider designation (MD, DO, NP, PA, other):

To report a suspected adverse event involving a specific Merck product, please contact the Merck National Service Center at 800-444-2080.



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