The Merck Access Program

ENROLLMENT & PRESCRIPTION FORM

WINREVAIR™ (sotatercept-csrk) for injection 45 mg, 60 mg

Please see the Indication, Selected Dosage and Administration Information, and Selected Safety Information for WINREVAIR on page 5.

Phone: 888-637-2502, Fax: 877-219-7579 • The Merck Access Program, PO BOX 592188, Orlando, FL 32859

INSTRUCTIONS

Step 1: Complete pages 1-2 of this Form and sign and date on page 2. If your Patient is in the office, please ask your Patient to read and sign pages 3-4, as applicable, or Patient may visit merckaccessprogram-WINREVAIR.com to submit their consent electronically.

Step 2: Once all required fields are completed and the Form has been signed and dated, fax the document with a copy of the Patient's prescription insurance card to 877-219-7579.

By submitting this Form, you are requesting that The Merck Access Program assist your Patient with initiating a Benefits Investigation and/or obtaining information about the Prior Authorization or Appeals Process.

PATIENT INFORMATION

*Required Field

Patient is a US Resident*: ◯ Yes ◯ No **Sex*:** ◯ M ◯ F

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

Address*: _____ **City/State/Zip*:** _____
(Street Address Only, No PO Boxes)

Phone (Home)*: _____ **(Mobile):** _____

Email: _____ **Best time to contact:** _____

Preferred Language: ◯ English ◯ Spanish ◯ Other: _____

Please indicate Patient's preferred communication method: ◯ Phone ◯ Email ◯ Mail

INSURANCE INFORMATION

Prescription Insurance (Including Medicaid, Medicare, and Private Insurers) ◯ **Patient Has No Insurance**

Is this a Medicare Part D Plan? ◯ Yes ◯ No

Plan Name: _____

Policy ID #: _____ **Group #:** _____ **BIN #:** _____ **PCN #:** _____

Note: If Patient has insurance benefits through Veteran Affairs (VA), please complete the VA Enrollment Form located at merckaccessprogram-WINREVAIR.com

HEALTHCARE PROVIDER INFORMATION

Practice/Facility Name: _____ **Office Contact Name*:** _____

Healthcare Provider Name*: _____ **Direct Phone #*:** _____

Healthcare Provider NPI No.*: _____ **Fax*:** _____

Healthcare Provider State License No.: _____ **Email:** _____

Address*: _____ **Preferred Communication:** ◯ Phone ◯ Fax ◯ Email
(Street Address Only, No PO Boxes)

City/State/Zip*: _____ **Specialty Pharmacy Preference:** ◯ Accredo Health Group, Inc. ◯ CVS Specialty Pharmacy

Does the Facility use a Third-Party Administrator (TPA) to administer and manage its Patient assistance programs? ◯ Yes ◯ No

DIAGNOSIS INFORMATION

Product use is consistent with labeled indications for WINREVAIR*: ◯ Yes ◯ No

The following ICD-10 codes do not suggest approval, coverage, or reimbursement for specific uses or indications.

Check the box for the appropriate code below*:

◯ **I27.0 Primary Pulmonary Hypertension**[1]

◯ **I27.21 Secondary Pulmonary Arterial Hypertension**[1]

◯ **Other:** _____

_____

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

PRESCRIPTION INFORMATION (REQUIRED FOR REFERRAL TO SPECIALTY PHARMACY)

Ship to: ◯ **Patient's Address** ◯ **Prescriber's Address (If shipping to Prescriber Office is for initial doses only, please indicate number of doses)** _____

◯ **Other (Specify):** _____

Patient Weight: _____kg Date Weight Taken: _____

Select the applicable NDC(s) for the Patient's starting dose and target dose of WINREVAIR (sotatercept-csrk). Administration is subject to monitoring of hemoglobin and platelet count. Please refer to the Prescribing Information for additional dosing information.

NDC 0006-5090-01	NDC 0006-5091-01	NDC 0006-5087-01	NDC 0006-5088-01
WINREVAIR 45 mg kit (1 x 45 mg vial)	**WINREVAIR 60 mg kit** (1 x 60 mg vial)	**WINREVAIR 90 mg kit** (2 x 45 mg vials)	**WINREVAIR 120 mg kit** (2 x 60 mg vials)
◯ Starting dose (0.3 mg/kg)	◯ Starting dose (0.3 mg/kg)	◯ Target dose (0.7 mg/kg)	◯ Target dose (0.7 mg/kg)
◯ Target dose (0.7 mg/kg)	◯ Target dose (0.7 mg/kg)		

Directions (select and complete one):

◯ Inject _____ mL subcutaneously for one dose then increase to _____ mL for target dose after 3 weeks. Dosing interval is every 3 weeks.

◯ Inject _____ mL subcutaneously for _____ dose(s) then increase to _____ mL for target dose after _____ weeks. Dosing interval is every 3 weeks.

◯ Alternative Directions: _____

Dispense 21 days of drug (1 kit), needles, syringes and ancillary supplies (eg, sharps container) necessary to administer medication.

Refills: _____ ◯ NKDA ◯ Known Drug Allergies: _____

Current Medications: _____ ◯ None

◯ **RN Visit for assessment and Nurse-Supported Patient Education on preparation and administration of WINREVAIR requested.**

Healthcare provider, in consultation with Patient, has determined that it would be appropriate for Patient to receive nurse-supported Patient education at therapy initiation. Nurse support is sponsored by Merck Sharp & Dohme LLC ("Merck"), a subsidiary of Merck & Co., Inc., the maker of WINREVAIR. It is limited to Patient education about the preparation and administration of WINREVAIR. It is intended to supplement a Patient's understanding of the therapy and the process to properly prepare and administer WINREVAIR. It is not intended to provide medical advice, replace any direction or training from the Patient's healthcare provider, or serve as a reason to prescribe WINREVAIR. Healthcare provider confirms that this request for nurse-supported Patient education is made with permission and agreement of the Patient. Program rules and limitations apply. Merck reserves the right in its sole discretion to modify or discontinue this program at any time.

By requesting support through this program, you certify that as a healthcare provider who made the decision to prescribe WINREVAIR to your Patient, you have provided training consistent with product label to the Patient and you have concluded, in your professional medical judgment, that the Patient or caregiver is capable of preparing and administering WINREVAIR independently.

HEALTHCARE PROVIDER ATTESTATION

By signing below, I represent and warrant the following:

- This Prescription Form has been prepared exclusively by the healthcare provider or healthcare provider office identified in this Form.
- By signing below, I represent and warrant that I am authorized pursuant to the laws of my state of license to prescribe WINREVAIR.
- 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 my 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 Syneos Market Access, and authorizes the Programs and Syneos Market Access (together with their respective administrators, contractors or other affiliates) to use and disclose the PHI for purposes of benefits investigation and reimbursement support.
- I understand that a Third-Party Administrator (TPA) may not sign any documents on behalf of the Patient.
- I represent and warrant that if my Practice uses a 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 certify that I 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.
- 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.
- Neither I nor my Practice will receive any reimbursement from Merck, whether for administration fees or otherwise.
- I understand that information concerning participants of the Programs 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.

By signing, I certify that I have read and agree to the above Healthcare Provider Attestation and that the information provided is complete and accurate to the best of my knowledge.

I authorize The Merck Access Program to act on my behalf to transmit the prescription to a contracted network Specialty Pharmacy.

Prescriber Signature (Dispense as Written) _____ **Prescriber Signature** (Substitution Allowed) _____ **Date** _____

Prescriber signature required to validate prescriptions. The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription Form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber. Prescriber attests that this is prescriber's legal signature (**NO STAMPS**).

Healthcare Provider Name (Please Print): _____

Healthcare Provider Designation: ◯ **MD** ◯ **DO** ◯ **NP** ◯ **PA** ◯ **Other:** _____

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

Patient Name*: _____ Date of Birth*: _____

PATIENT AUTHORIZATION

The Merck Access Program may provide information and support related to your insurance benefits for WINREVAIR (sotatercept-csrk), estimated out-of-pocket costs, and co-pay assistance options for which you may be eligible. The Merck Access Program will use your data only for the purposes listed below. Patient or Legal Representative signature is required for participation in The Merck Access Program.

I authorize each of my physicians, pharmacies, and health plans to obtain, use, share, and disclose my personal health information, such as my name, information relating to my medical condition, prescriptions, and other information in this Form or related to my health (collectively, "PHI"), as necessary, to and with The Merck Access Program, sponsored by Merck Sharp & Dohme LLC ("Merck"), a subsidiary of Merck & Co., Inc.; the Merck Patient Assistance Program ("Merck PAP"), sponsored by the Merck Patient Assistance Program, Inc. (individually, "a Program"; collectively, "the Programs"); RxCrossroads by McKesson and the administrators of the Programs, including their business partners and contractors (collectively with the Programs, the "Parties"). I understand that the Parties may need to obtain, use, share, and disclose my PHI for the following purposes:

1. To share my PHI with one another, with my physicians and pharmacists, Medicare, my health plans, and each of their administrators, contractors, or representatives, in order to verify my eligibility to enroll in the Programs, to coordinate my benefits, and to provide, when applicable, reimbursement support, administration of the Program, and investigate my insurance coverage;
2. To provide the services described in this enrollment Form, such as verifying my eligibility to enroll in the Programs and to enroll me in the Programs for which I am eligible;
3. To coordinate my prescription with Specialty Pharmacies for dispensing my Merck medication;
4. If I have a designated Personal Representative, 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, including information provided in this enrollment Form, to my Legal Representative for the purposes described above;
5. To ensure compliance with laws and the rules of the Programs;
6. To communicate with me by US postal mail, telephone, text, or email;
7. To prepare summaries that do not include my PHI for statistical purposes.
8. 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.

By signing this authorization, I acknowledge my understanding that:

- The PHI disclosed pursuant to this authorization, once disclosed, may no longer be governed by federal privacy law 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.
- My Specialty Pharmacies receive compensation in connection with sharing my PHI with Merck as described in this Authorization.

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

PATIENT AUTHORIZATION (CONTINUED)

- 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 I understand that I will not be able to receive any assistance from the Programs for which I may be eligible.
- I may cancel this authorization at any time by telephoning The Merck Access Program at (888) 637-2502 or by mailing a written request for cancellation to The Merck Access Program, PO BOX 592188, Orlando, FL 32859. I understand that canceling my authorization will mean that my physicians, pharmacies, and health plans, as well as the Programs, their respective administrators, and their contractors and representatives, 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.
- 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 am entitled to receive a copy of this authorization once it has been signed and I can do so by telephoning The Merck Access Program at (888) 637-2502.

By signing, I certify that I have read and agree to the above Patient Authorization.

PATIENT SIGNATURE

Signature of Patient or Legal Representative*: _____ **Date:** _____

*A Legal Representative is a person who has legal authority under applicable state law to bind you (the Patient) by signing each authorization or declaration in the enrollment Form.

Name of Signing Party (Please Print): _____

DECLARATION OF LEGAL REPRESENTATIVE

◯ I declare that I am the Legal Representative of the Patient and that I have the legal authority under applicable state law to bind the Patient by signing each authorization or declaration in this enrollment Form.

Phone Number of Legal Representative: _____ **Relationship of Legal Representative to Patient:** _____

MOBILE AUTHORIZATION

Please provide your mobile number if you would like to receive text messages relating to your enrollment: _____

◯ By opting into texting, you authorize Merck and its service providers to contact you at the phone number provided above and send you communications about your enrollment in The Merck Access Program (MAP) via telephone and text message. Opting into text messaging for these purposes is not a condition of enrollment into MAP and is not required to receive MAP support. These calls or text messages may be generated using auto-dial or pre-recorded messages at the number you submit. The number and type of messages will be based upon your program selections, and message and data rates may apply. At any time, you may request to stop telephone calls or text messages by following the opt-out directions provided during those communications.

ADDITIONAL INFORMATION AND SUPPORT

◯ **Yes! I'd like to enroll in the WINREVAIR (sotatercept-csrk) Patient Support Program to receive educational resources, information, and other communications related to WINREVAIR.**

By checking this box, you give permission to Merck and others working on behalf of Merck to use your personal information to provide you with information, resources, services, and communications about WINREVAIR, as well as to improve such services, via email, text, phone, and mail using the contact information provided in this Form. Additionally, your information may be used for market research purposes.

At any time, you can request a copy of this permission and that the personal information about you be removed from the Merck contact list for WINREVAIR by calling 1-888-637-2502. Unless you change this selection sooner, your permission will expire 1 year after Merck no longer promotes WINREVAIR.

INDICATION

WINREVAIR (sotatercept-csrk) is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events.

SELECTED DOSAGE AND ADMINISTRATION INFORMATION

Recommended Starting Dosage: WINREVAIR is administered once every 3 weeks by subcutaneous injection according to patient body weight. The starting dose of WINREVAIR is 0.3 mg/kg. Obtain hemoglobin (Hgb) and platelet count prior to the first dose of WINREVAIR. Do not initiate treatment if platelet count is <50,000/mm^3 (<50x10^9/L).
Injection volume for starting dose is calculated based on patient weight as follows:

$$\textit{Injection Volume (mL)} = \frac{\textit{Weight (kg) x 0.3 mg/kg}}{\textit{50 mg/mL}}$$

Injection volume should be rounded to the nearest 0.1 mL.

For example: (70 kg x 0.3 mg/kg) ÷ 50 mg/mL = 0.42 mL, rounds to 0.4 mL

See Table 1 for selecting the appropriate kit based on calculated injection volume for starting dose.

Table 1: Kit Type Based on Injection Volume for Dose of 0.3 mg/kg

Injection Volume (mL)	Kit Type
0.2 to 0.9	45 mg kit (containing 1 x 45 mg vial)
1 to 1.1	60 mg kit (containing 1 x 60 mg vial)

Recommended Target Dosage: After verifying acceptable Hgb and platelet count, increase to the target dose of 0.7 mg/kg. Continue treatment at 0.7 mg/kg every 3 weeks unless dosage adjustments are required.
Injection volume for target dose is calculated based on patient weight as follows:

$$\textit{Injection Volume (mL)} = \frac{\textit{Weight (kg) x 0.7 mg/kg}}{\textit{50 mg/mL}}$$

Injection volume should be rounded to the nearest 0.1 mL.

For example: (70 kg x 0.7 mg/kg) ÷ 50 mg/mL = 0.98 mL, rounds to 1 mL

See Table 2 for selecting the appropriate kit based on calculated injection volume for target dose.

Table 2: Kit Type Based on Injection Volume for Dose of 0.7 mg/kg

Injection Volume (mL)	Kit Type
0.4 to 0.9	45 mg kit (containing 1 x 45 mg vial)
1 to 1.2	60 mg kit (containing 1 x 60 mg vial)
1.3 to 1.8	90 mg kit (containing 2 x 45 mg vials)
1.9 to 2.4	120 mg kit (containing 2 x 60 mg vials)

Preparation and Administration: WINREVAIR is intended for use under the guidance of a healthcare professional. Patients and caregivers may administer WINREVAIR when considered appropriate and when they receive training and follow-up from the healthcare provider on how to reconstitute, prepare, measure, and inject WINREVAIR. Confirm at subsequent visits that the patient and/or caregiver can correctly prepare and administer WINREVAIR, particularly if the dose changes or the patient requires a different kit. Refer to Prescribing Information and Instructions for Use for information on the proper preparation and administration of WINREVAIR.

SELECTED SAFETY INFORMATION

Erythrocytosis: WINREVAIR may cause increases in hemoglobin (Hgb). Severe erythrocytosis may increase the risk of thromboembolic events or hyperviscosity syndrome. In clinical studies, moderate elevations in Hgb (>2 g/dL above upper limit of normal [ULN]) occurred in 15% of patients taking WINREVAIR while no elevations ≥4 g/dL above ULN were observed. Monitor Hgb before each dose for the first 5 doses, or longer if values are unstable, and periodically thereafter, to determine if dose adjustments are required.

Severe Thrombocytopenia: WINREVAIR may decrease platelet count. Severe thrombocytopenia may increase the risk of bleeding. In clinical studies, severe thrombocytopenia (platelet count <50,000/mm^3 [<50 x 10^9/L]) occurred in 3% of patients taking WINREVAIR. Thrombocytopenia occurred more frequently in patients also receiving prostacyclin infusion. Do not initiate treatment if platelet count is <50,000/mm^3. Monitor platelets before each dose for the first 5 doses, or longer if values are unstable, and periodically thereafter to determine whether dose adjustments are required.

Serious Bleeding: In clinical studies, serious bleeding (eg, gastrointestinal, intracranial hemorrhage) was reported in 4% of patients taking WINREVAIR and 1% of patients taking placebo. Patients with serious bleeding were more likely to be on prostacyclin background therapy and/or antithrombotic agents, or have low platelet counts. Advise patients about signs and symptoms of blood loss. Evaluate and treat bleeding accordingly. Do not administer WINREVAIR if the patient is experiencing serious bleeding.

Embryo-Fetal Toxicity: Based on findings in animal reproduction studies, WINREVAIR may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use an effective method of contraception during treatment with WINREVAIR and for at least 4 months after the final dose. Pregnancy testing is recommended for females of reproductive potential before starting WINREVAIR treatment.

Impaired Fertility: Based on findings in animals, WINREVAIR may impair female and male fertility. Advise patients on the potential effects on fertility.

Adverse Reactions: The most common adverse reactions occurring in the Phase 3 clinical trial (≥10% for WINREVAIR and at least 5% more than placebo) were as follows: headache (24.5% vs 17.5%), epistaxis (22.1% vs 1.9%), rash (20.2% vs 8.1%), telangiectasia (16.6% vs 4.4%), diarrhea (15.3% vs 10.0%), dizziness (14.7% vs 6.2%), and erythema (13.5% vs 3.1%).

Lactation: Because of the potential for serious adverse reactions in the breastfed child, advise patients that breastfeeding is not recommended during treatment with WINREVAIR, and for 4 months after the last dose.

Pediatric Use: The safety and effectiveness of WINREVAIR have not been established in patients less than 18 years of age.

Geriatric Use: A total of 81 patients ≥65 years of age participated in clinical studies for PAH, of which 52 (16%) were treated with WINREVAIR. Bleeding events occurred more commonly in the older WINREVAIR subgroup, but with no imbalance between age subgroups for any specific bleeding event.

Before prescribing WINREVAIR, please read the accompanying Prescribing Information. The Patient Information and Instructions for Use (1-vial kit, 2-vial kit) also are available.

MERCK

Reference: 1. CMS. ICD-10-CM Tabular List of Disease and Injuries. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm. Accessed February 28, 2024.