VETERANS AFFAIRS (VA) 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 3.

INSTRUCTIONS

Please forward this completed Form to the VA Pharmacy. The VA Pharmacy will fax the completed Form to the dispensing Specialty Pharmacy.

Accredo Health Group, Inc. Fax: 800-711-3526 | Phone: 866-344-4874 **or CVS Specialty Pharmacy** Fax: 877-943-1000 | Phone: 877-242-2738

PATIENT INFORMATION

*Required Field

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

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

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

Email: _____ **Sex*:** ◯ **M** ◯ **F**

Preferred Language: ◯ **English** ◯ **Spanish** ◯ **Other:** _____

Patient Representative (if applicable): _____ **Alternate Phone:** _____

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*: _____

VA PHARMACY INFORMATION

Name of VA Facility

Address	**Suite**	**City**	**State**	**Zip**
Primary Purchasing Contact Name	**Telephone**	**Fax**	**Email**	
Primary Clinical Contact Name	**Telephone**	**Fax**	**Email**	
Secondary Purchasing Contact Name	**Telephone**	**Fax**	**Email**	
Secondary Clinical Contact Name	**Telephone**	**Fax**	**Email**	

Payment Method **Purchase Order #** **Ship To**

◯ Credit Card (Call pharmacy contact) ◯ E-invoice Tungsten Network _____ ◯ Patient ◯ VA Location

DIAGNOSIS INFORMATION (REQUIRED)

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. The medication kit does not include additional ancillary supplies. Those are provided at an additional charge.

Refills: _____ ◯ NKDA ◯ Known Drug Allergies: _____

Current Medications: _____ ◯ None

◯ **Optional 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, which is not a part of, endorsed by, or administered by the U.S. Department of Veterans Affairs. 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 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:

- 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.
- 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.
- This Prescription Form has been prepared exclusively by authorized personnel of the U.S. Department of Veterans Affairs.
- By signing below, I represent and warrant that I am licensed to prescribe WINREVAIR.
- 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 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.

_____ **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.

Please see WINREVAIR Indication, Selected Dosage and Administration Information, and Selected Safety Information on page 3.

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 increase 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 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 final 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.

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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.