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

# GUIDE TO BENEFITS REVERIFICATION AND PRIOR AUTHORIZATION (PA) REAUTHORIZATION

## Indication

WINREVAIR is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, Group 1 pulmonary hypertension) to improve exercise capacity and World Health Organization (WHO) functional class (FC), and reduce the risk of clinical worsening events including hospitalization for PAH, lung transplantation and death.

## Selected Safety Information

**Erythrocytosis:** WINREVAIR may increase hemoglobin (Hgb). Severe erythrocytosis may increase the risk of thromboembolic events or hyperviscosity syndrome. 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. 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.

**Selected Safety Information continues on page 3.**

This information is intended for healthcare professionals in the United States, including Puerto Rico.

# Ensuring Continued Coverage for WINREVAIR

It is important to obtain prior authorization (PA) reauthorizations when an authorization expires or if your patient has a change in insurance. Many insurance companies require PA reauthorization to continue accessing WINREVAIR after the initial coverage period. By reverifying the patient's insurance benefits and coverage, you may help patients to continue WINREVAIR therapy.

Your enrolled patients may have received a communication from The Merck Access Program (MAP) about health insurance benefits reverification and PA reauthorization processes for WINREVAIR. This guide is intended to support you with the health insurance benefits reverification and PA reauthorization processes for your patients on WINREVAIR.

### The following information is included in this guide:

- Information about health insurance benefits reverification and PA reauthorization, including recommended actions to support these processes
- Support offered by The Merck Access Program and how to get in contact with the Program

**Please contact your Merck Access and Reimbursement Manager (ARM) or MAP at 888-637-2502 with any questions.**



# Overview of Benefits Reverification and PA Reauthorization

### What is health insurance benefits reverification?

**Benefits reverification** is conducted after the initial health insurance benefit verification and confirms that the patient's insurance coverage has not changed, or that changes will not impact the patient's ability to access WINREVAIR. Patients can experience changes in their insurance coverage at varying times, such as at the start of a new year or because of a job change. Medications like WINREVAIR are typically covered under the pharmacy benefit pathway. Remind patients to inform their specialty pharmacy and healthcare provider of any insurance changes as early as possible. These changes can affect their healthcare provider and pharmacy networks, coverage requirements, and out-of-pocket costs.

### What is PA reauthorization?

**PA reauthorization** is the resubmission of a PA request to ensure continued coverage of WINREVAIR after the initial PA authorization has expired or lapsed. Many insurance companies require a PA to cover WINREVAIR. The authorization is often approved for a maximum of 1 year. Some insurance companies have shorter approval periods (eg, 3 or 6 months). The PA approval letter will indicate your patient's coverage length. You can also confirm this information with the patient's insurance company.

## Selected Safety Information (*continued*)

**Serious Bleeding:** In clinical studies, serious bleeding (e.g., gastrointestinal, intracranial hemorrhage) was reported in 4% vs 1% (STELLAR) and 7% vs 5% (ZENITH) of patients taking WINREVAIR vs placebo, respectively. 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. Do not administer WINREVAIR if the patient is experiencing serious bleeding.

**Embryo-Fetal Toxicity:** 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.

**Selected Safety Information continues on next page.**

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# Continued Coverage for WINREVAIR

Below is an outline of the common options to confirm continued coverage and access to WINREVAIR for your patients.

## Reverify benefit coverage

**Reverify benefit coverage of WINREVAIR before the authorization expires and at the beginning of each new plan year**

- Obtain the patient's pharmacy and medical insurance information (eg, plan name, sponsor/employer, policy/group number, member ID, insurance address, and phone number)
- Confirm patient's demographic information (eg, address, phone number)
- Determine any pharmacy network changes, as the patient may need to transfer their prescription or get a new prescription
- Resubmit your patient's PA if required due to benefit plan changes
- If you need additional support reverifying your patient's benefits, contact your patient's specialty pharmacy

## Prepare for PA reauthorization

**Beginning about 45 days before the authorization for WINREVAIR expires, you may be contacted by MAP and/or the patient's specialty pharmacy notifying you of the upcoming PA expiration date**

# Overview of PA Reauthorization

## Submit PA reauthorization

**PA reauthorizations should be submitted in advance of the expiration date to ensure the prescription refill can be processed and the patient's therapy is uninterrupted**

- PA reauthorization criteria may require you to attest to the need for and/or submit documentation verifying that WINREVAIR should be continued for the patient because there is clinical benefit. You should check with the insurance company for their individual requirements for PA reauthorization
- MAP and your patient's specialty pharmacy can also assist with verifying PA reauthorization requirements
- Request a copy of the Continuation of Therapy Letter from your Merck ARM to support health insurance benefits reverification and PA reauthorization efforts for WINREVAIR
- Your Merck ARM may be able to provide additional education regarding the reauthorization process

**If PA reauthorization is approved**, send a copy of approval to dispensing specialty pharmacy and they will coordinate with your patient to ship WINREVAIR.

**If PA reauthorization is denied**, send a copy of denial to dispensing specialty pharmacy and letter of appeal/additional support documentation to request reconsideration.

**If you have questions about the PA reauthorization process, please contact your Merck ARM or your patient's dispensing specialty pharmacy. If your patient's insurance is changing, it is imperative they contact the dispensing specialty pharmacy and provide the new insurance information.**

**Specialty Pharmacy Contact Information:**

**Accredo Health Group, Inc.**
**866-344-4874**
**Fax: 800-711-3526**
**accredo.com**

**or**

**CVS Specialty Pharmacy**
**877-242-2738**
**Fax: 877-943-1000**
**cvsspecialty.com**

## Selected Safety Information (*continued*)

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

**Selected Safety Information continues on next page.**

## Selected Safety Information (*continued*)

**Adverse Reactions:** The most common adverse reactions (≥10% for WINREVAIR and at least 5% more than placebo) occurring in the STELLAR phase 3 clinical trial 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 6.3%), and erythema (13.5% vs 3.1%). The most common adverse reactions in the ZENITH trial were infections (67.4% vs 44.2%), epistaxis (45.3% vs 9.3%), diarrhea (25.6% vs 17.4%), telangiectasia (25.6% vs 3.5%), increased hemoglobin (15.1% vs 1.2%), rash (10.5% vs 4.7%), erythema (10.5% vs 3.5%), and gingival bleeding (10.5% vs 2.3%).

**Selected Safety Information continues on next page.**

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## How to contact The Merck Access Program

**CALL**
**888-637-2502**
[MONDAY- FRIDAY, 8 AM to 8 PM ET]

**FAX**
**877-219-7579**
[TO SUBMIT ENROLLMENT AND PRESCRIPTION FORM]

**VISIT**
WWW.MERCKACCESSPROGRAM-WINREVAIR.COM

**If you have any questions, please contact your Merck Access and Reimbursement Manager (ARM).**

## Selected Safety Information (*continued*)

**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.

**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.**

This information is intended for healthcare professionals in the United States, including Puerto Rico.

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