The example letter on page 2, regarding medical necessity, is for demonstration purposes only. Use of this example letter or the information in this example letter does not guarantee coverage. It is not intended to be a substitute for, or to influence, the independent clinical decision of the prescribing healthcare professional.

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

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.

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.

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 (≥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%).

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.

Continue to page 2 for an example Letter of Medical Necessity that can be completed and submitted to the payer.

MERCK

<Date>

ATTENTION: <Medical Director Name and/or Medical Review/Appeals>
<Payer/Health Plan Name>
<Payer Address>

REGARDING: Medical necessity for WINREVAIR™ (sotatercept-csrk) for injection 45 mg, 60 mg

PATIENT NAME: <Patient Name>
DATE OF BIRTH: <Patient Date of Birth>
POLICY ID NUMBER: <Policy ID Number>
PROVIDER ID NUMBER: <Provider ID Number>

MEMBER NAME: <Member Name>
MEMBER NUMBER: <Member Number>
GROUP NUMBER: <Group Number>
DIAGNOSIS: <ICD-10 code>
PATIENT DOSAGE: <Patient Dosage>

☐ **STANDARD** ☐ **URGENT**

Dear <Medical Director Name and/or Medical Review/Appeals>,

I am writing to request authorization for WINREVAIR for my patient, <Patient Name>.
I have prescribed WINREVAIR because this patient has been diagnosed with Pulmonary Arterial Hypertension (PAH, World Health Organization [WHO] Group 1), and I believe that therapy with WINREVAIR is appropriate for this patient. Attached to this request are clinical notes regarding this patient's disease state, the US Food and Drug Administration (FDA) approval letter for WINREVAIR, and the WINREVAIR package insert.

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.

<In this rationale for treatment, you may wish to include a statement of medical need and the reason WINREVAIR™ (sotatercept-csrk) is being requested:

- Summary of patient's PAH diagnosis, including:
  - Diagnosis (ICD-10-CM) and date of diagnosis
  - WHO group and subtype
  - Relevant test results, which may include right heart catheterization results that detail mean PAP, PCWP, PVR, 6MWD, echo, and acute vasoreactivity challenge
  - Patient's current clinical condition (ie, WHO functional class)
- Any relevant PAH therapies the patient is currently using or has previously used, including any contraindications to PDE5is, ERAs, sGC stimulator, and prostacyclins
- Laboratory and other test results:
  - Recent complete blood count with hemoglobin and platelets
  - Confirmation that patient is not pregnant (when applicable)
- Provide your professional opinion on potential implications for your patient's condition if they do not receive treatment with WINREVAIR
- Consider including your medical credentials for treating patients with PAH>

Thank you for taking the time to read this letter. I look forward to your prompt review of this request. My office may be reached at <office phone number> if any additional information is required.

Best regards,

<Physician Name>

<6MWD, 6-minute walk distance; ERAs, endothelin receptor antagonists; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; PAP, pulmonary artery pressure; PCWP, pulmonary capillary wedge pressure; PDE5is, phosphodiesterase type 5 inhibitors; PVR, pulmonary vascular resistance; sGC, soluble guanylate cyclase; WHO, World Health Organization.>