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> Guide to Appeals and Medical Exceptions

- How to Use This Guide
- Understanding Appeals and Medical Exceptions
- Payer Submission Checklist
- The Merck Access Program

To get started with The Merck Access Program, call (888) 637-2502 to speak with a representative, Monday through Friday, 8 AM to 8 PM ET.

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

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

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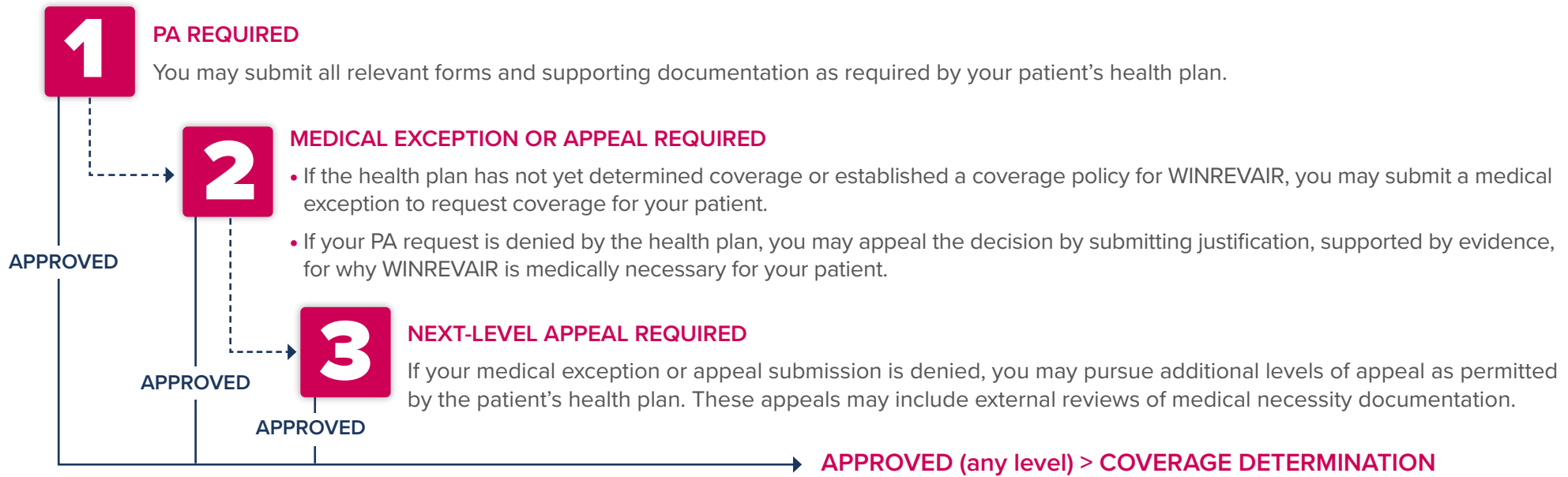
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How to Use This Guide

This guide is intended to provide general information regarding prior authorization (PA), medical exceptions, and appeals, which may support your patient in accessing WINREVAIR after an independent prescribing decision has been made.

Any or all of the steps below may be applicable depending on your patient's health plan. The information below can be used to navigate the payer coverage process prior to your patient receiving WINREVAIR.



IF WINREVAIR IS COVERED
on a high-formulary tier or is not on the patient's health plan formulary, you may submit a tiering or formulary exception request demonstrating that WINREVAIR is medically necessary for your patient.

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About WINREVAIR™ (sotatercept-csrk)

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 $<50,000/\text{mm}^3$. 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.

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About WINREVAIR™ (sotatercept-csrk) *(continued)*

SELECTED SAFETY INFORMATION *(continued)*

Adverse Reactions: The most common adverse reactions ($\geq 10\%$ 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.

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Understanding Payer Requirements for Coverage

Types of Coverage Requests

PA¹

PAs are a tool used by payers to enable case-specific assessments of coverage for prescribed therapies. PA procedures and requirements for coverage are based on clinical need and therapeutic rationale. The PA process applies to medications that are included as part of the payer's formulary.

PA Denial/Appeal²

If a PA is denied, you and your patient may choose to pursue an appeal to request coverage for the medication. Appeal requirements may vary by health plan and can require a letter supporting the request with accompanying documentation.

Medical Exception³

When the medication is not included on the health plan's formulary or is not in a preferred tier, a medical exception can be pursued to potentially gain access to the therapy. A medical exception is used to request coverage for a product and will require a Letter of Medical Necessity and accompanying documentation.



How to Submit Commercial Coverage Requests

Each patient's health plan will have different requirements for submission of coverage requests. Typically, these types of requests may be submitted using the appropriate channels (mail, fax, electronic) to the appropriate department at the health plan. The health plan will follow up with the prescriber and patient once a decision has been reached.



How a Medicare Part D Plan Processes an Exception Request

- A notice of the health plan's decision on a benefits request must be provided within 24 hours for an expedited request or 72 hours for a standard request⁴
- A health plan must provide notice of its decision and make payment, if appropriate, within 14 calendar days after receiving a request for reimbursement for benefits already received⁴
- If the health plan responds with an unfavorable determination for coverage, their decision notice will contain relevant information to file a request for appeal

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Medical Necessity and Exception Process

If your patient's health plan has denied coverage of WINREVAIR on the basis that it does not meet the plan formulary requirements, you may be able to submit a medical exception request. You may wish to complete and submit a Letter of Medical Necessity and/or Appeal Letter depending on the specific payer requirements.

1 STEP 1

Benefits investigation is conducted to determine your patient's coverage.

2 STEP 2

The investigation determines that WINREVAIR is not covered.

3 STEP 3

You may wish to complete and submit a Letter of Medical Necessity (you can refer to the MAP website, merckaccessprogram-WINREVAIR.com, under Coverage and Access resources where you can find the Example Letter of Medical Necessity) depending on the specific payer requirements.

4 STEP 4

If coverage for WINREVAIR is not granted based on the Letter of Medical Necessity, you may wish to submit a Letter of Appeal to your patient's health plan (you can refer to the MAP website, merckaccessprogram-WINREVAIR.com, under Coverage and Access resources where you can find the Example Appeal Letter).

5 STEP 5

If the appeal is denied, you may wish to request a peer review with a medical director from your patient's health plan.

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Common Payer Requirements

Medicare Part D and Medicare Advantage

Medicare coverage for WINREVAIR depends on what type of Medicare plan the patient is enrolled in (standalone Medicare Part D or Medicare Advantage) and the benefits available under their specific Medicare plan.

It may be possible for a patient to receive coverage for a medication that is not listed on the plan's formulary by submitting an exception request.



For Medicare Part D and Medicare Advantage patients, an exception request may need to be submitted to the patient's health plan.⁴

- The health plan must notify the patient (and the prescribing physician or other prescriber involved, as appropriate) of its coverage decision no later than 72 hours after receiving the request for standard cases, or no later than 24 hours for expedited cases



Exception requests can be submitted to the Medicare Part D or Medicare Advantage plan by the prescribing physician.⁴

- Requests can be submitted verbally by calling the health plan or through a written request submitted to the health plan
- The request should include the prescriber's supporting statement and or documentation that indicates the drug is medically necessary
- Providers should contact the plan directly to determine the specific plan requirements for submitting a formulary exception request

Patients can refer to their health plan's website to view the status of their Medicare Part D coverage requests.



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Common Payer Requirements (continued)

Commercial Payers

Payer coverage policies differ for each payer and plan. You should refer to the payer's website and review payer-specific coverage policies to understand the appeals and/or medical exceptions process and the unique payer coverage requirements.

Timing for requests will vary by health plan. You should refer to the payer's website for specific timelines for expedited and non-expedited requests.

While specific payer coverage criteria varies by payer, payers may take into account the following general coverage considerations:



Provider Specialty:

Due to the specialized skills required for evaluating, diagnosing, and monitoring of certain diseases, health plans may require PAH medications to be prescribed by, or in consultation with, a physician who specializes in the condition being treated (ie, a cardiologist or pulmonologist).

Potential Clinical Requirements:

Payers' requirements may include the following with supporting documentation submitted:

- Confirmed diagnosis, specifying PAH (WHO Group 1) and subtype, with right heart catheterization results that detail mean PAP, PCWP, and PVR
- Description of 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 such as recent complete blood count with hemoglobin and platelets and confirmation patient is not pregnant (when applicable)
- Relevant test results (eg, right heart catheterization, echocardiography, acute vasoreactivity challenge, 6-minute walk distance)
- Product Prescribing Information (if applicable)

The payer may require (1) documentation supporting the patient's current and prior therapies for this diagnosis, including any contraindications to previous treatments; and/or (2) a detailed treatment history that outlines classes of medications the patient has previously used.

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Common Payer Requirements (continued)

Common PAH Coverage Denials



Documentation

- Missing patient information or physician signature, and incomplete or incorrect information



Diagnosis and Coding

- Inaccurate or irrelevant ICD-10 codes used
- Absence of relevant test results



Incomplete Medical History

- Insufficient reasoning for duration of previous PAH therapy
- No documentation of current therapies or need for additional therapy

SELECTED SAFETY INFORMATION (continued)

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Payer Submission Checklist

If a PA request for a medication is denied, or if a PA is not an option due to formulary requirements, you may be able to submit an appeal or medical exception request. It is important to review any denial letter(s) (as applicable) and the specific payer guidelines, as the required documentation and submission process will differ depending on the payer and the patient.

If a plan denies a prior authorization or does not have a coverage policy for WINREVAIR, you may be able to submit a Letter of Appeal or a Letter of Medical Necessity to the payer for consideration:

- It may be beneficial to note the proposed treatment plan and include the Provider ID number in the letter
- Consider providing the rationale for the treatment decision, including a description of the patient's diagnosis and summary of the patient's relevant medical history

Before you start the request, you may wish to:

- Submit the Enrollment and Prescription Form to The Merck Access Program to identify your patient's insurance benefits and any PA/appeal/medical exception requirements
- Review the coverage policy for your patient's health plan for WINREVAIR to understand the requirements the patient must meet for coverage

It may be beneficial to check that:

- A PA was submitted and denied, if required by the patient's insurer
- Patient information was recorded correctly (eg, name, date of birth, insurance policy number)
- The correct National Drug Code(s) (NDC) was/were provided with the product name

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.

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Payer Submission Checklist *(continued)*

Depending on the payer, it may be beneficial to include:

- Consider including documentation that supports the treatment decision, such as:
 - Any relevant PAH therapies the patient is currently using or has previously used, including any contraindications to PDE5is, ERAs, sGC stimulator, and prostacyclins
 - Patient clinical notes detailing the relevant diagnosis, including PAH (WHO Group 1) confirmed by right heart catheterization, functional class, date of diagnosis, and patient's current condition
 - Relevant test results (eg, right heart catheterization, echocardiography, acute vasoreactivity challenge, 6-minute walk distance)
 - Product Prescribing Information (package insert)
- Additional relevant documentation (if available) regarding the treatment decision
 - Clinical trial data supporting the FDA approval
 - Administration and dosing information

Example Letters can be found on The Merck Access Program website at merckaccessprogram-WINREVAIR.com under "Resources."



SELECTED SAFETY INFORMATION *(continued)*

Adverse Reactions: The most common adverse reactions ($\geq 10\%$ 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%).

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The Merck Access Program

A representative from The Merck Access Program may be able to:

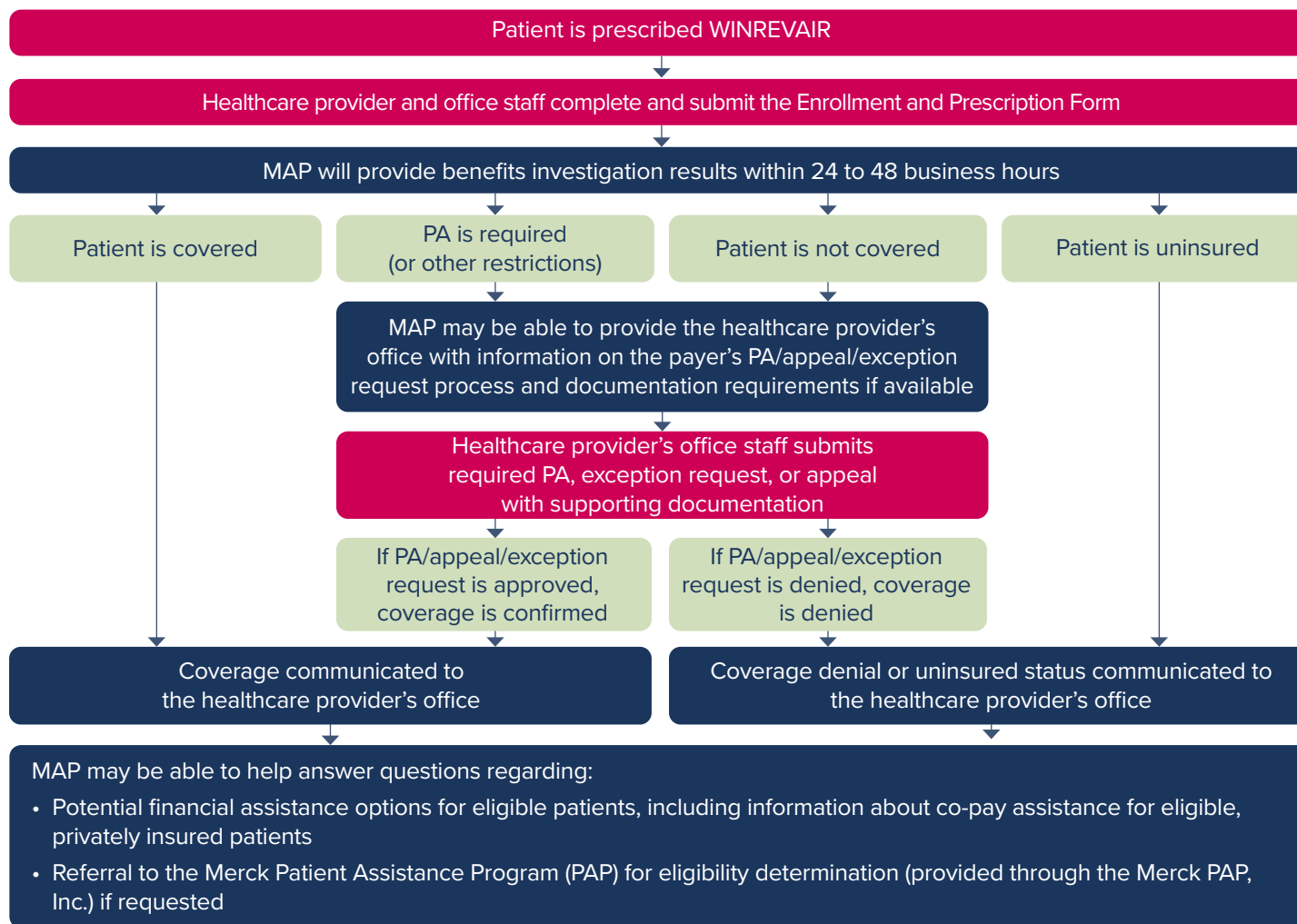
- 1** Identify and provide a summary of your patient's insurance benefits, including information about your patient's out-of-pockets costs
- 2** Provide information on co-pay assistance options, including the WINREVAIR coupon program for eligible, privately insured patients
- 3** Communicate status updates to your patient regarding their coverage and access for WINREVAIR
- 4** Send prescriptions to a Merck in-network Specialty Pharmacy based on your patient's insurance plan and preference
- 5** Refer your patients to the Merck Patient Assistance Program for eligibility determination (provided through the Merck Patient Assistance Program, Inc.)

The Merck Access Program may be able to contact insurers to request patient-specific coverage and benefits information for WINREVAIR. To get started, complete and submit an [Enrollment and Prescription Form](#) to The Merck Access Program.

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Benefits Investigation and Coverage Process



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1. Academy of Managed Care Pharmacy. Prior authorization. Accessed September 10, 2024. <https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/prior-authorization>
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ERA, endothelin receptor antagonist; ICD-10, International Classification of Diseases, Tenth Revision; MAP, The Merck Access Program; PAP, pulmonary artery pressure; PCWP, pulmonary capillary wedge pressure; PDE5i, phosphodiesterase type 5 inhibitor; PVR, pulmonary vascular resistance; sGC, soluble guanylate cyclase; WHO, World Health Organization.

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