Protocol for Winrevair® (sotatercept-csrk)

Approved October 2024

Winrevair *is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class) and reduce the risk of clinical worsening events.*

Criteria for approval:

1. Patient is of the FDA-labeled or compendial approved age
2. Documentation of pulmonary arterial hypertension (PAH) with WHO functional class II or III symptoms
3. Diagnosis is confirmed by right heart catheterization
4. Medication is prescribed by or in consultation with a pulmonologist, cardiologist, or another specialist with experience in treating PAH
5. Patient has had an inadequate response to at least **TWO** products for the treatment of PAH, unless contraindicated or not tolerated, such as:
    a. Phosphodiesterase type 5 (PDE5 inhibitor) [e.g., sildenafil, tadalafil]
    b. Endothelin receptor antagonist [e.g., bosentan (Tracleer), ambrisentan (Letairis)]
    c. Prostacyclin agonist [e.g., treprostinil (Remodulin, Tyvaso, Orenitram)]
    d. Soluble guanylate cyclase inhibitors
6. Patient has a platelet count greater than or equal to 50,000/mm^3
7. Prescriber attests the patient will be monitored for thromboembolic events and hyperviscosity syndrome, measuring at minimum hemoglobin and platelet count, before each dose
8. Weight will be provided for weight-based dosing
9. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of Therapy:

1. Documentation of positive clinical response
2. Weight will be provided for weight-based dosing
3. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established

indication and dosing regimens or in accordance with a medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Approval Duration: 12 months

Quantity limit: 1 kit (two vials) every 21 days

References

1. Winrevair. [package insert] Merck & Co., Inc., Rahway, NJ. March 2024
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2022. Updated periodically
3. Mayeux JD, Pan IZ, Dechand J, Jacobs JA, Jones TL, McKellar SH, Beck E, Hatton ND, Ryan JJ. Management of Pulmonary Arterial Hypertension. Curr Cardiovasc Risk Rep. 2021;15(1):2. doi: 10.1007/s12170-020-00663-3. Epub 2020 Nov 18. PMID: 33224405; PMCID: PMC7671829.
4. Klinger J, Elliott G, Levine D. et al. Therapy for Pulmonary Arterial Hypertension in Adults. CHEST 2019; 155 (3): 565-586. Accessed August 21, 2024, at https://journal.chestnet.org/article/S0012-3692(19)30002-9/pdf
5. Hopkins W, Rubin LJ. Treatment of pulmonary arterial hypertension (group 1) in adults: Pulmonary hypertension-specific therapy. In: UpToDate, Mandel J (Ed), Wolters Kluwer. (Accessed on August 21, 2024.)