Draft Revised Policy: Do Not Implement

Sotatercept-csrk (WINREVAIR™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Winrevair is 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.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for initial requests: Chart notes, medical record documentation, or claims history supporting current pulmonary arterial hypertension (PAH) therapy.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~

Pulmonary Arterial Hypertension (PAH)

Authorization of 12 months may be granted for treatment of PAH in members 18 years of age and older when ALL of the following criteria are met:

- Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by right heart catheterization with all of the following pretreatment (before any PAH therapy) results:
  - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
  - ~~•~~ Pulmonary vascular resistance (PVR) >2 ~~≥ 5~~ Wood units ~~while member is stable on at least two PAH medications~~

- The requested medication will be used as add-on therapy.
- Member is currently receiving PAH therapy with medications from at least two of the following drug classes:
  - Endothelin receptor antagonist (e.g., Letairis, Opsumit, Tracleer)
  - Phosphodiesterase-5 inhibitor (e.g., Adcirca, Revatio)
  - Soluble guanylate cyclase stimulator (e.g., Adempas)
  - Prostacyclin analog (e.g., Flolan, Orenitram, Remodulin, Tyvaso, Veletri, Ventavis)
  - Prostacyclin receptor agonist (e.g., Uptravi)

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section ~~IV~~ who are currently receiving the requested medication through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

APPENDIX

WHO Classification of Pulmonary Hypertension (PH)

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic ~~PAH~~
  - Long-term responders to calcium channel blockers
- Heritable ~~PAH~~
- Associated with drugs and toxins~~-induced PAH~~
- ~~PAH~~ Associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

~~1.5 PAH long-term responders to calcium channel blockers~~

- PAH with ~~overt~~ features of venous/capillary(pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn~~-syndrome~~

Group 2: PH associated with ~~due to~~ Left Heart Disease

- Heart Failure:
  - ~~PH due to heart failure~~ With preserved ~~left ventricular~~ ejection fraction ~~(LVEF)~~
  - ~~PH due to heart failure~~ With reduced or mildly reduced ejection fraction ~~LVEF~~
  - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
  - Aortic valve disease
  - Mitral valve disease
  - Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

Group 3: PH associated with ~~due to~~ Lung Diseases and/or Hypoxia

- Chronic Obstructive pulmonary ~~lung~~ disease (COPD) and/or emphysema
- Interstitial ~~Restrictive~~ lung disease
- Combined pulmonary fibrosis and emphysema
  ~~3.3 Other lung disease with mixed restrictive/obstructive pattern~~
- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
  - Hypoventilation syndromes
  - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases ~~disorders~~

Group 4: PH associated with ~~due to~~ Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions
  - Sarcomas (high-or intermediate-grade) or angiosarcoma)
  - Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)

~~Renal carcinoma~~
~~Uterine carcinoma~~
~~Germ cell tumors of the testis~~
~~Other tumors~~

  - Non-malignant tumors (e.g. uterine leiomyoma)

~~Uterine leiomyoma~~

  - Arteritis without connective tissue disease
  - Congenital pulmonary artery stenosis

~~Parasites~~

  - Hydatidosis

Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematologic disorders, including inherited and acquired ~~:~~ chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic ~~and metabolic~~ disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and ~~Gaucher disease, glycogen storage disease,~~ neurofibromatosis type 1 ~~, sarcoidosis~~
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- ~~Others:~~ Chronic renal failure with or without hemodialysis, ~~fibrosing mediastinitis~~
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex

Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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EFFECTIVE DATE

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