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CENTRAL HEALTH MEDICARE PLAN

Medical Policy

Pulmonary Arterial Hypertension **Remodulin®** (Treprostinil) **Tyvaso®** (Treprostinil) **Veletri®** (epoprostenol) **Ventavis®** (iloprost)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-056
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Remodulin® (treprostinil), Tyvaso® (treprostinil), Veletri® (epoprostenol), and Ventavis® (iloprost) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Remodulin, Tyvaso, Veletri, or Ventavis will be provided for 12 months and may be renewed.

Remodulin, Tyvaso, Veletri, and Ventavis:

1. The requested medication will be prescribed by, or in consultation with a pulmonologist

Pulmonary Arterial Hypertension (PAH)

or cardiologist; **AND**

2. Patient has a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with documentation of right heart catheterization [defined as a mean pulmonary arterial pressure (mPAP) >25mm Hg at rest or >30mm Hg during exercise, with a normal pulmonary capillary wedge pressure (PCWP)]; **AND**
3. Patient exhibits NYHA-WHO Functional Class III or IV symptoms (**Tyvaso, Veletri, and Ventavis ONLY**); **OR**
4. Patient exhibits NYHA-WHO Functional Class II to IV symptoms (**Remodulin ONLY**); **AND**
5. Patient has had an intolerance to, or treatment failure of a calcium channel blocker after favorable response to acute vasoreactivity testing.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Chronic use in patients with congestive heart failure due to severe left ventricular systolic dysfunction is therefore contraindicated – **Veletri ONLY**

BACKGROUND

Pulmonary arterial hypertension (PAH) is a progressive disease characterized by elevated pressure in
the vessels that carry blood between the heart and the lungs. This results in ventricular dysfunction,
reduced exercise capacity, the potential for right sided heart failure, and even death.

Several mechanisms have been identified in the pathogenesis of PAH, leading to the development of
four classes of medications to treat the disorder. Endothelin receptor antagonists (ERAs), phosphodiesterase-5 (PDE-5) inhibitors, prostacyclin analogs, and soluble guanylate cyclase (sGC) stimulators may be used as monotherapy, sequential combination therapy, or simultaneous combination therapy to treat PAH.

Remodulin (trepostinil), Tyvaso (treprostinil), Veletri (epoprostenol), Ventavis (iloprost) are prostacyclin analogs administered as inhalation solutions.

Remodulin is indicated for the treatment of pulmonary hypertension (WHO Group 1) to diminish symptoms associate with exercise; to diminish the rate of clinical deterioration in patients with PAH requiring transition from epoprostenol.

Tyvaso is indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) to diminish symptoms associated with exercise

Veletri is indicated for the treatment of pulmonary hypertension (WHO Group 1) to improve exercise capacity.

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Ventavis is indicated for the treatment of pulmonary hypertension (WHO Group 1) with NYHA class III or IV symptoms to improve a composite endpoint consisting of exercise tolerance, symptoms and lack of Deterioration.

New York Heart Association functional classification:
Class 1: No symptoms with ordinary physical activity.
Class 2: Symptoms with ordinary activity. Slight limitation of activity.
Class 3: Symptoms with less than ordinary activity. Marked limitation activity.
Class 4: Symptoms with any activity or event at rest

DEFINITIONS

1. REMODULIN (treprostinil) Injection, for subcutaneous or intravenous use. Initial U.S. Approval: May 2002
    a. Remodulin is supplied in 20-mL multidose vials as sterile solutions in water for injection, individually packaged in cartons.
2. TYVASO (treprostinil) inhalation solution, for oral inhalation only. Initial U.S. Approval: 2002
    a. Tyvaso (treprostinil) inhalation solution is supplied in 2.9 mL clear LDPE ampules packaged as four ampules in a foil pouch.
    b. Tyvaso is a clear colorless to slightly yellow solution containing 1.74 mg treprostinil per ampule at a concentration of 0.6 mg/mL.
3. VELETRI (epoprostenol) for injection, for intravenous use. Initial U.S. Approval: 1995
    a. VELETRI is supplied as a sterile lyophilized material in 10 mL vials.
4. VENTAVIS® (iloprost) inhalation solution, for oral inhalation use. Initial U.S. Approval: 2004
    a. VENTAVIS (iloprost) Inhalation Solution is supplied in cartons of 30 × 1 mL clear glass single-use ampules as follows:
        i. 1 mL ampule containing iloprost 10 mcg per mL
        ii. 1 mL ampule containing iloprost 20 mcg per mL

CODING

Applicable NDC Codes	
66302-0105-01	REMODULIN- treprostinil injection, solution 5 mg/1 ml
66302-0101-01	REMODULIN- treprostinil injection, solution 1mg/1 ml
66302-0102-01	REMODULIN- treprostinil injection, solution 2.5 mg/1 ml
66302-0110-01	REMODULIN- treprostinil injection, solution 10 mg/1 ml
66302-0206-XX	TYVASO- treprostinil inhalant
66215-0403-01	VELETRI- epoprostenol injection 0.5 mg
66215-0402-01	VELETRI- epoprostenol injection 1.5 mg
66215-0401-01	VELETRI- epoprostenol injection 1.5 mg
66215-0302-XX	VENTAVIS- iloprost inhalation solution 10 mcg/1 ml
66215-0303-XX	VENTAVIS- iloprost inhalation solution 20 mcg/1 ml

Applicable Procedure Code	
J3285	Injection, treprosinil, 1 mg, (Remodulin) 1 billable unit = 1 mg
J7686	injection, treprosinil, 1 mg, (Tyvaso) 1 billable unit = 1 mg
J1325	Injection, epoprostenol, 0.5 mg (Veletri) 1 billable unit = 0.5 mg
Q4074	Inhalation solution, iloprost, (Ventavis) billable unit = up to 20 mcg

Applicable ICD-10 Codes	
I27.0	Primary pulmonary hypertension
I27.2	Other secondary pulmonary hypertension
I27.20	Pulmonary hypertension, unspecified
I27.21	Secondary pulmonary arterial hypertension
I27.22	Pulmonary hypertension due to left heart disease
I27.23	Pulmonary hypertension due to lung diseases and hypoxia
I27.24	Chronic thromboembolic pulmonary hypertension
I27.29	Other secondary pulmonary hypertension

EVIDENCE BASED REFERENCES

1. Product Information: REMODULIN(R) subcutaneous injection, intravenous injection, Treprostinil subcutaneous injection, intravenous injection. United Therapeutics Corp (per FDA), Research Triangle Park, NC, 2018.
2. Product Information: TYVASO inhalation solution, treprostinil inhalation solution. United Therapeutics Corp., Research Triangle Park, NC, 2009.
3. Product Information: VELETRI intravenous powder for injection, epoprostenol intravenous powder for injection. Actelion Pharmaceuticals US, Inc., South San Francisco, CA, 2011.
4. Product Information: VENTAVIS(R) inhalation solution, iloprost inhalation solution. Actelion Pharmaceuticals US, Inc. (per Manufacturer), South San Francisco, CA, 2013

POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021: Annual review – no changes made. November 8, 2022: Annual review – no changes made. March 01, 2023 – Adopted by MA UMC - no changes made. January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 11/8/2022