Effective date: 9/2017
Reviewed: 9/2017, 12/2018, 2/2019, 12/2019, 9/2020, 12/2021, 5/2022, 2/2023, 2/2024 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

Tyvaso (treprostinil inhalation solution)
Tyvaso DPI (treprostinil inhalation powder)

POLICY

I. CRITERIA FOR INITIAL APPROVAL

Pulmonary Hypertension (PH)
Authorization of 6 months may be granted for treatment of PH when both of the following criteria are met:

A. Prescriber is either one of the following:
    1. Prescriber is associated with an accredited Center of Comprehensive Care by the Pulmonary Hypertension Association for adult members
    2. Prescriber is a cardiologist, pulmonologist or physician specializing in PAH for pediatric members

B. Member has either of the following:
    1. WHO Group 1 class of pulmonary hypertension (refer to Appendix)
    2. Pulmonary hypertension associated with interstitial lung disease (WHO Group 3)

B. PH was confirmed by either criterion (1) or criterion (2) below:
    1. Pretreatment right heart catheterization with all of the following results:
        i. mPAP > 20 mmHg
        ii. PCWP ≤ 15 mmHg
        iii. PVR ≥ 3 Wood units
    2. For infants less than one year of age, PH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.

II. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members with an indication listed in Section I who are currently receiving the requested medication through a paid pharmacy benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

III. QUANTITY LIMITS

a. Tyvaso 0.6mg/ml – 2.9 ml (1 amp) per day
b. Tyvaso DPI 16mcg, 32mcg, 48mcg and 64mcg – 4 cartridges per day
c. Tyvaso DPI Titration Kit 16-32mcg – 7 cartridges per day
d. Tyvaso DPI Titration Kit 32-48mcg – 8 cartridges per day
e. Tyvaso DPI Titration Kit 16-32-48mcg – 9 cartridges per day

IV. APPENDIX

WHO Classification of Pulmonary Hypertension

1 PAH

1.1 Idiopathic (PAH)
1.2 Heritable PAH
1.3 Drug- and toxin-induced PAH
1.4. PAH associated with:
- 1.4.1 Connective tissue diseases
- 1.4.2 HIV infection
- 1.4.3 Portal hypertension
- 1.4.4 Congenital heart diseases
- 1.4.5 Schistosomiasis

1.5 PAH long-term responders to calcium channel blockers
1.6 PAH with overt features of venous/capillaries (PVOD/PCH) involvement
1.7 Persistent PH of the newborn syndrome

2 PH due to left heart disease

2.1 PH due to heart failure with preserved LVEF
2.2 PH due to heart failure with reduced LVEF
2.3 Valvular heart disease
2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH

3 PH due to lung diseases and/or hypoxia

3.1 Obstructive lung disease
3.2 Restrictive lung disease
3.3 Other lung disease with mixed restrictive/obstructive pattern
3.4 Hypoxia without lung disease
3.5 Developmental lung disorders

4 PH due to pulmonary artery obstruction

4.1 Chronic thromboembolic PH
4.2 Other pulmonary artery obstructions
- 4.2.1 Sarcoma (high or intermediate grade) or angiosarcoma
- 4.2.2 Other malignant tumors
  - Renal carcinoma
  - Uterine carcinoma
  - Germ cell tumours of the testis
  - Other tumours
- 4.2.3 Non-malignant tumours
  - Uterine leiomyoma
- 4.2.4 Arteritis without connective tissue disease
- 4.2.5 Congenital pulmonary artery stenosis
- 4.2.6 Parasites
  - Hydatidosis

5 PH with unclear and/or multifactorial mechanisms

5.1 Hematologic disorders: Chronic hemolytic anemia, myeloproliferative disorders

5.2 Systemic and metabolic disorders: Pulmonary Langerhans cell histiocytosis, Gaucher disease, glycogen storage disease, neurofibromatosis, sarcoidosis

5.3 Others: chronic renal failure with or without hemodialysis, fibrosing mediastinitis

5.4 Complex congenital heart disease

V. REFERENCES

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