AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Adempas	Page:	1 of 5
Effective Date:	10/25/2023	Last Review Date:	10/2023

Applies to:	☐Illinois	☐Florida	☐Florida Kids
	☒New Jersey	☐Maryland	☐Michigan
	☐Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Adempas under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

A. Pulmonary Arterial Hypertension (PAH)
   Adempas is indicated for the treatment of adults with pulmonary arterial hypertension (PAH), (World Health Organization [WHO] Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening. Efficacy was shown in patients on Adempas monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominately patients with WHO functional class II-III and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.
B. Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
   Adempas is indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class.

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

Applicable Drug List:

Adempas

Policy/Guideline:

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

Criteria for Initial Approval:

A. Pulmonary Arterial Hypertension (PAH)
Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:

1. Member has PAH defined as WHO Group 1 class of pulmonary hypertension (Refer to Appendix)
2. PAH was confirmed by right heart catheterization with all of the following pretreatment results:
   i. mPAP > 20 mmHg
   ii. PCWP ≤ 15 mmHg
   iii. PVR ≥ 3 Wood units
3. Patient is unable to take the required number of formulary alternatives (2) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication

B. Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

Authorization of 12 months may be granted for treatment of CTEPH when ALL of the following criteria are met:

1. Member has CTEPH defined as WHO Group 4 class of pulmonary hypertension (Refer to Appendix)
2. Member meets either criterion (i) or criterion (ii) below:
   i. Recurrent or persistent CTEPH after pulmonary endarterectomy (PEA)
   ii. Inoperable CTEPH with diagnosis confirmed by BOTH of the following (a. and b.):
      a. Computed tomography (CT)/magnetic resonance imaging (MRI) angiography or pulmonary angiography
      b. Pretreatment right heart catheterization with all of the following results:
         1. mPAP > 20 mmHg
         2. PCWP ≤ 15 mmHg
         3. PVR ≥ 3 Wood units

Criteria for Continuation of Therapy:

Authorization of 12 months may be granted for members with an indication listed in criteria for initial approval 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
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

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit:

- Adempas 0.5 mg tablets: 90 per 30 days
- Adempas 1 mg tablets: 90 per 30 days
- Adempas 1.5 mg tablets: 90 per 30 days
- Adempas 2 mg tablets: 90 per 30 days
- Adempas 2.5 mg tablets: 90 per 30 days

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