AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Esbriet	Page:	1 of 2
Effective Date:	8/10/2023	Last Review Date:	5/25/2023

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

Intent:

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

Description:

FDA-Approved Indication
Indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

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

Applicable Drug List:

Esbriet
pirfenidone

Policy/Guideline:

Documentation:
Submission of the following information is necessary to initiate the prior authorization review (where applicable):

A. Result of a chest high-resolution computed tomography (HRCT) study.
B. If a lung biopsy is conducted, submit the associated pathology report.

Criteria for Initial Approval:
Idiopathic Pulmonary Fibrosis (IPF)
Authorization of 12 months may be granted for treatment of idiopathic pulmonary fibrosis when the member has undergone a diagnostic work-up which includes the following:[2]

A. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded

   AND

B. The member has completed a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy which reveals a result consistent with the usual interstitial pneumonia (UIP) pattern, OR has completed an HRCT study of the chest which reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported by a lung biopsy. If a lung biopsy has not been previously

conducted, the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.

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 treatment with the requested medication, excluding when the requested medication is obtained as samples or via manufacturer's patient assistance programs.

Other:

Note: If the member is a current smoker, they should be counseled on the harmful effects of smoking on pulmonary conditions and available smoking cessation options.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit:

- Esbriet (pirfenidone) capsules 267 mg in 14-day titration blister pack: 63 capsules per 14 days
- Esbriet (pirfenidone) capsules 267 mg in 4-week maintenance blister pack: 252 capsules per 28 days
- Esbriet (pirfenidone) capsules 267 mg: 270 per 30 days
- Esbriet (pirfenidone) tablets 267 mg: 270 per 30 days
- pirfenidone tablets 534 mg: 90 per 30 days
- Esbriet (pirfenidone) tablets 801 mg: 90 per 30 days

References:

1. Esbriet [package insert]. South San Francisco, CA: Genentech USA, Inc.; February 2022.
2. Pirfenidone [package insert.] Berkeley Heights, NJ: Laurus Labs Limited; July 2022
3. Raghu G, Remy-Jardin M, Myers JL, et al. Diagnosis of Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. *Am J Respir Crit Care Med.* 2018 Sep 1;198(5):e44-e68.
4. Vancheri C, Kreuter M, Richeldi L, et al. Nintedanib with add-on pirfenidone in idiopathic pulmonary fibrosis: results of the Injourney trial. *Am J Respir Crit Care Med.* 2017 Sept 10. doi: 10.1164/rccm.201706-1301OC. [Epub ahead of print].