Clinical Policy Title:	pirfenidone
Policy Number:	RxA.378
Drug(s) Applied:	Esbriet®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of Business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Idiopathic Pulmonary Fibrosis (must meet all):

1. Diagnosis of idiopathic pulmonary fibrosis (IPF);
2. Member meets the following (a and b);
   a. Exclusion of other known cases of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity);
   b. Member meets one of the following (i or ii);
      i. In patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF;
      ii. In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF;
3. Esbriet is not prescribed concurrently with Ofev®.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Idiopathic Pulmonary Fibrosis (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. Am J Respir Crit Care Med. 2011; 183: 788-824. Available at: https://pubmed.ncbi.nlm.nih.gov/21471066/. Accessed August 28, 2024.
2. 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;198(5): e44-e68. Available at: https://pubmed.ncbi.nlm.nih.gov/30168753/. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date

Policy established.	01/2020	03/06/2020
1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. References were updated.	07/22/2020	09/14/2020
Policy was reviewed: 1. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	05/31/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated to include new diagnostic criteria Member has a baseline forced vital capacity (FVC) ≥ 50% of predicted. 2. Initial Approval Criteria, I.A.5: Updated to include new diagnostic criteria Member has a baseline carbon monoxide diffusing capacity (DL_{CO}) ≥ 30% of predicted. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.	03/23/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of Idiopathic Pulmonary Fibrosis (IPF) to Diagnosis of Idiopathic Pulmonary Fibrosis (IPF) as documented by all of the following criteria (a and b); a. Exclusion of other known cases of interstitial lung disease (ILD)(eg, domestic and occupational environmental exposures,	04/17/2023	07/13/2023

connective tissue disease, drug toxicity); b. Member meets one of the following (I or ii); i. In patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF; ii. In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. 2. Initial Approval Criteria, I.A.4: Updated to remove prior diagnostic criteria "Member has a baseline forced vital capacity (FVC) ≥ 50% of predicted". 3. Initial Approval Criteria, I.A.5: Updated to remove prior diagnostic criteria "Member has a baseline carbon monoxide diffusing capacity (DLCO) ≥ 30% of predicted". 4. Initial Approval Criteria, I.A.4: Updated to include new concurrent therapy criteria Esbriet is not prescribed concurrently with Ofev®. 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024