

Pirfenidone (generic Esbriet)
Effective 06/01/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Pirfenidone (generic Esbriet) is a pyridine indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following criteria are met:

1. Diagnosis of idiopathic pulmonary fibrosis (IPF)
2. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded
3. ONE of the following:
 - a. 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
 - b. BOTH of the following:
 - i. Member has completed an HRCT study of the chest which reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP, alternative diagnosis)
 - ii. ONE of the following:
 1. Diagnosis is supported by a lung biopsy
 2. 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

Continuation of Therapy

Requests for reauthorization may be approved when all of the following criteria are met:

1. Member demonstrates a positive clinical response to therapy

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

2. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Pirfenidone 267 mg tablet	9 tablets per day
Pirfenidone 267 mg capsule	9 capsules per day
Pirfenidone 534 mg capsule	3 capsules per day
Pirfenidone 801 mg capsule	3 capsules per day

References

1. Esbriet (pirfenidone) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; February 2023.
2. Raghu G, Remy-Jardin M, Richeldi L, et al. Idiopathic Pulmonary Fibrosis (an Update) and Progressive Pulmonary Fibrosis in Adults: An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. Am J Respir Crit Care Med. 2022;205(9):e18-e47. doi:10.1164/rccm.202202-0399ST

Review History

12/13/2023 - Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

03/11/2026 – Reviewed and updated at March P&T. Administrative update to language for members who are new to the Plan and added quantity limits to the policy. Updated reauthorization criteria to require that the member has had a positive clinical response to therapy. Effective 06/01/2026.

