MEDICATION POLICY:
Esbriet®

Generic Name: Pirfenidone

Therapeutic Class or Brand Name: Esbriet®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/30/2016

Date Last Reviewed / Revised: 1/6/2023

Prior Authorization Criteria

(May be considered medically necessary when criteria I through VII are met)

I. Documented diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by high resolution computed tomography (HRCT) or lung biopsy.

II. Documented assessment of the pattern and severity of respiratory impairment on pulmonary function testing (PFT).

III. Documentation of non-smoking status or plan for smoking cessation.

IV. Minimum age requirement: 18 years old.

V. Treatment is prescribed by or in consultation with a pulmonologist.

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

Exclusion Criteria

- Identifiable causes of interstitial lung disease have not been ruled out.
- Coadministration of with Ofev (nintedanib).
- End-stage renal disease requiring dialysis.
- Severe hepatic impairment (Child Pugh Class C).

Other Criteria

- N/A.

Quantity / Days Supply Restrictions

- 267 mg strength: Quantities of up to 270 capsules/tablets per 30 days.
- 801 mg strength: Quantities of up to 90 tablets per 30 days.

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A.

REFERENCES

1. Esbriet. Prescribing information. Genentech USA, Inc.; 2022. Accessed December 27, 2022. http://www.gene.com/download/pdf/esbriet_prescribing.pdf
2. Costabel U, Albera C, Glassberg MK, et al. Effect of pirfenidone in patients with more advanced idiopathic pulmonary fibrosis. *Respir Res*. 2019;20(1):55. Published 2019 Mar 12. doi:10.1186/s12931-019-1021-2
3. Cottin V, Wollin L, Fischer A, Quaresma M, Stowasser S, Harari S. Fibrosing interstitial lung diseases: knowns and unknowns. *Eur Respir Rev*. 2019;28(151):180100. Published 2019 Feb 27. doi:10.1183/16000617.0100-2018
4. 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(6):788-824. doi:10.1164/rccm.2009-040GL