Generic Name: N/A

Therapeutic or Brand Name: N/A

Applicable Drugs (if Therapeutic Class):
Esbriet® (pirfenidone), Ofev® (nintedanib)

Preferred: generic pirfenidone

Non-preferred: Esbriet (pirfenidone), Ofev (nintedanib)

Date of Origin: 8/30/2016

Date Last Reviewed / Revised: 2/24/2025

PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of one of the following conditions A through C and must meet all criteria under the applicable diagnosis:

   A. Idiopathic pulmonary fibrosis (IPF)

      i. Documented high resolution computed tomography (HRCT) or lung biopsy confirming diagnosis.

   B. Chronic fibrosis interstitial lung diseases (ILDs)

      i. Documented high resolution computed tomography (HRCT) or lung biopsy confirming diagnosis.

      ii. Documented development into a progressive phenotype (i.e., self-sustaining fibrosis, worsening quality of life).

      iii. The request is for Ofev.

   C. Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

      i. Documented high resolution computed tomography (HRCT) or lung biopsy confirming diagnosis.

      ii. Documented treatment failure, intolerance, or contraindication to BOTH cyclophosphamide and mycophenolate.

      iii. The request is for Ofev.

II. Documented assessment of the pattern and severity of respiratory impairment on pulmonary function testing (PFT), such as forced vital capacity (FVC), lung diffusion testing (D_{LCO}), and six-minute walk testing (6MWD).

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 the 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 both Esbriet/generic pirfenidone and Ofev.
- Esbriet:
    - Severe hepatic impairment (Child Pugh Class C).
    - End-stage renal disease requiring dialysis.
- Ofev:
    - Moderate or severe hepatic impairment (Child Pugh B or C).
    - Anticipated or current pregnancy.
    - Severe renal impairment (less than 30 mL/min CrCl) or end-stage renal disease.

OTHER CRITERIA

- Elevated liver enzymes and liver induced injury: Monitor ALT, AST, and bilirubin prior to initiation of treatment, at regular intervals during the first three months of treatment, and periodically thereafter or as clinically indicated. Temporary dosage reductions or discontinuations may be required.
- Gastrointestinal disorders: Temporary dosage reductions or discontinuations may be required if severe diarrhea, nausea, or vomiting occurs.
- Esbriet:
    - Severe cutaneous adverse reactions (SCAR), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported in association with the use of ESBRIET. If signs or symptoms of SCAR occur, interrupt ESBRIET treatment until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, permanently discontinue ESBRIET.
- Ofev:
    - Gastrointestinal perforation has been reported. Use OFEV with caution when treating patients with recent abdominal surgery, previous history of diverticular disease or receiving concomitant corticosteroids or NSAIDs. Discontinue OFEV in patients who develop gastrointestinal perforation.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Esbriet (see Appendix for dose titration and adjustments):
  - 267 mg: Up to 270 capsules/tablets per 30 days.
  - 534 mg: Up to 90 tablets per 30 days.
  - 801 mg: Up to 90 tablets per 30 days.
- Ofev: 60 capsules 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

- Esbriet dosing
  - Dosage titration:

Treatment days	Dosage
Days 1 through 7	267 mg three times daily (801 mg/day)
Days 8 through 14	534 mg three times daily (1602 mg/day)
Days 15 onward	801 mg three times daily (2403 mg/day)

  - Concomitant strong CYP1A2 Inhibitors (e.g., fluvoxamine, enoxacin):
    - Reduce to 267 mg three times a day (801 mg/day).
  - Concomitant moderate CYP1A2 Inhibitors (e.g., ciprofloxacin):
    - With the use of ciprofloxacin at a dosage of 750 mg twice daily, reduce to 534 mg three times a day (1602 mg/day).

REFERENCES

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.