Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE

nintedanib (Ofev)

Notes:

- Quantity Limits: Yes
- Monitor liver enzymes (AST, ALT, and bilirubin) monthly for the first 3 months and every 3 months thereafter.
- Nintedanib is teratogenic. Women of childbearing potential should avoid becoming pregnant while taking nintedanib.
- Smoking reduces nintedanib exposure. Smoking should be avoided 3 months prior to starting nintedanib and during nintedanib treatment.

Initiation (new start) criteria: Non-formulary **nintedanib (Ofev)** will be covered for 12 months on the prescription drug benefit when the following criteria are met:

(1) Idiopathic Pulmonary Fibrosis:

- Prescriber is a Pulmonologist.
- Patient is at least 18 years of age.
- Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by consensus at multidisciplinary conference.
- ALL of the following:
  - Forced Vital Capacity (FVC) that is 40% to 90% of the predicted value
  - FEV_1/FVC ratio at least 0.7
  - Carbon monoxide diffusing capacity (DLco) of 30% to 90% of predicted
  - Able to walk at least 150 meters during a 6-minute-walk-test
- Patient is a non-smoker.
- Patient is not receiving treatment with pirfenidone.
- Patient does not have any of the following conditions:
  - Significantly impaired liver function (AST or ALT greater than three-times the upper limit of normal; total bilirubin greater than the upper limit of normal; alkaline phosphatase greater than three-times upper limit of normal)
  - Moderate (Child-Pugh class B) or severe liver impairment (Child-Pugh class C)
  - Significantly impaired kidney function (GFR or CrCl less than 30 mL/min), end-stage renal disease (ESRD) requiring dialysis.

(2) Systemic Sclerosis-Associated Interstitial Lung Disease:

- Prescriber is a Pulmonologist.
- Patient is at least 18 years of age.
- Diagnosis of Systemic Sclerosis.
- Diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) confirmed by consensus at multidisciplinary conference.
- High-resolution computed tomography (HRCT) imaging demonstrating pulmonary fibrosis involving at least 10% of the lungs.
- Patient has a pre-treatment FVC that is 40% to 90% of the predicted value
- Patient has a pre-treatment carbon monoxide diffusing capacity (DLco) of 30% to 90% of predicted value
- Patient has a history of prior treatment with mycophenolate prescribed for SSc-ILD, or is presently receiving treatment with mycophenolate, or patient has a documented intolerance or contraindication to mycophenolate.
- Patient is a non-smoker.
- Patient is not receiving treatment with pirfenidone.
- Patient does not have any of the following conditions:
  - Significantly impaired liver function (AST or ALT greater than three-times the upper limit of normal; total bilirubin greater than the upper limit of normal; alkaline phosphatase greater than three-times upper limit of normal)
  - Moderate (Child-Pugh class B) or severe liver impairment (Child-Pugh class C)
  - Significantly impaired kidney function (GFR or CrCl less than 30 mL/min), end-stage renal disease (ESRD) requiring dialysis.

(3) Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype:

- Prescriber is a Pulmonologist.
- Patient is at least 18 years of age.
- Diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype confirmed by consensus at multidisciplinary conference and documented by:
  - High-resolution computed tomography (HRCT) imaging demonstrating pulmonary fibrosis involving at least 10% of the lungs.
  - Relative decline in forced vital capacity (FVC) demonstrated by at least 3 spirometry measurements over the past 24 months of either:
    - 10% or more

  - 5% to 9.9% combined with worsening respiratory symptoms
  - 5% to 9.9% combined with increasing fibrotic changes on HRCT
  - 0% to 4% combined with worsening respiratory symptoms and increasing fibrotic changes on HRCT
- Patient has a pre-treatment FVC that is 40% to 90% of the predicted value
- Patient has a pre-treatment carbon monoxide diffusing capacity (DLco) of 30% to 90% of predicted value
- Patient has a history of treatment with, or was intolerant or did not have a clinical response to an immunosuppressive therapy (such as azathioprine, cyclosporine, tacrolimus, oral corticosteroids, rituximab, cyclophosphamide, or mycophenolate)
- Patient is a non-smoker.
- Patient is not receiving treatment with pirfenidone.
- Patient does not have any of the following conditions:
  - Significantly impaired liver function (AST or ALT greater than three-times the upper limit of normal; total bilirubin greater than the upper limit of normal; alkaline phosphatase greater than three-times upper limit of normal)
  - Moderate (Child-Pugh class B) or severe liver impairment (Child-Pugh class C)
  - Significantly impaired kidney function (GFR or CrCl less than 30 mL/min), end-stage renal disease (ESRD) requiring dialysis.

Continued use criteria: Non-formulary **nintedanib (Ofev)** will continue to be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Patient continues to be under the care of a pulmonologist.
- Liver function and spirometry are monitored (at least annually).
- Patient does not have contraindications to use of nintedanib (e.g., significantly impaired liver function, significantly impaired kidney function or ESRD requiring dialysis).
- Patient is a non-smoker.
- Patient is not receiving treatment with pirfenidone.