nintedanib (OFEV)

Diagnosis Considered for Coverage:

- Idiopathic pulmonary fibrosis (IPF)
- Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
- Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype

Coverage Criteria:

For idiopathic pulmonary fibrosis:

Initial Treatment

- Being prescribed by or in consultation with a pulmonologist, and
- Not being used in combination with Esbriet, and
- Dose does not exceed 300 mg per day, and
- Patient has the following pulmonary function tests:
 - Forced Vital Capacity (FVC) ≥ 50% of predicted value, and
 - Diffusing Capacity of carbon monoxide (DL_{CO}) ≥ 30% of predicted value.

Coverage Duration: 1 year

Reauthorization

- Being prescribed by or in consultation with a pulmonologist, and
- Patient has not received lung transplant, and
- Not being used in combination with Esbriet, and
- Dose does not exceed 300 mg per day.

Coverage Duration: 1 year

For diagnosis of interstitial lung disease (ILD):

- Dose does not exceed 300 mg per day, and
- One of the following (A or B):
 - A. Patient has systemic sclerosis, and
 - Being prescribed by or in consultation with a pulmonologist or rheumatologist, and
 - Inadequate response, intolerable side effect, or contraindication with cyclophosphamide or mycophenolate
 - B. Patient has chronic progressive fibrosis, and



• Being prescribed by or in consultation with a pulmonologist.

Coverage Duration: 1 year

Effective Date: 5/31/2023