Nintedanib (Ofev)

Coverage Criteria:
Ofev is reserved for patients meeting the following criteria:

For mild-to-moderate idiopathic pulmonary fibrosis:

1. Reserved for prescribing by Pulmonary; and,
2. Patient has been diagnosed with idiopathic pulmonary fibrosis (IPF) per ATS/ERS/JRS/ALAT criteria, confirmed by:
    a. Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity); and either:
        i. The presence of the high-resolution CT (HRCT) pattern of usual interstitial pneumonia (UIP) as defined by ATS/ERS/JRS/ALAT criteria; or,
        ii. Combinations of HRCT patterns and histopathology patterns indicative of IPF as defined by ATS/ERS/JRS/ALAT criteria in patients subjected to lung tissue sampling; and,
3. Patient has FVC greater than or equal to 50% at baseline; and,
4. Patient has a percent predicted diffusing capacity of the lungs for carbon monoxide (%DLCO) greater than or equal to 30%; and,
5. Patient does not have underlying liver disease; and,
6. Ofev has been prescribed at the FDA-approved dosing regimen.

For chronic fibrosing interstitial lung diseases with a progressive phenotype:

1. Reserved for prescribing by Pulmonary; and,
2. Patient has been diagnosed with chronic fibrosing interstitial lung disease with the following features:
    a. Fibrosis (greater than 10% fibrotic features) on high-resolution CT (HRCT); and,
    b. Clinical signs of progression (defined as FVC decline ≥10%, FVC decline ≥ 5% and <10% with worsening symptoms or imaging, or worsening symptoms and worsening imaging all in the 24 months prior to screening); and,
3. Patient has FVC greater than or equal to 45% at baseline; and,
4. Patient has a percent predicted diffusing capacity of the lungs for carbon monoxide (%DLCO) greater than or equal to 30%; and,
5. Patient does not have underlying liver disease; and,
6. Ofev has been prescribed at the FDA-approved dosing regimen.

For systemic sclerosis associated interstitial lung disease:

1. Prescribed by a specialist (pulmonologist or rheumatologist); and,
2. Patient has been diagnosed with systemic sclerosis-associated interstitial lung disease (SSc-ILD); and,
3. Patient has early diffuse SSc and ILD, and early evidence of ILD progression (may include FVC<65%, DLCO<55%, HRCT showing ILD affecting >20% of the lung, and/or anti-topoisomerase I antibodies); and,
4. Patient has tried and failed mycophenolate for at least 6 months (or has medical contraindications to mycophenolate); and,

5. Patient has tried and failed Actemra SQ for at least 6 months (or has medical contraindications to Actemra SQ); and,
6. Patient does not have underlying liver disease; and,
7. Ofev has been prescribed at the FDA-approved dosing regimen.

Coverage Duration:
Approvals will be granted for a 12 months duration.

Renewal Criteria:
1. Patient continues to meet the criteria above; and,
2. Patient has been seen within the past 14 months by the prescribing specialist; and,
3. Documentation that the medication continues to be effective has been submitted.