Interstitial Lung Disease (ILD) Prior Authorization with Quantity Limit

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL
Target agents:

Pirfenidone tab 267 mg
pirfenidone tab 801 mg

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND ALL of the following: 1. Other known causes of interstitial lung disease (ILD) have been excluded (e.g., domestic, and occupational environmental exposures, connective tissue diseases, drug toxicities, alternative diagnoses, etc) **AND** 2. ONE of the following: A. The patient had a high-resolution computed tomography (HRCT) scan with results showing a pattern for usual interstitial pneumonia (UIP) **OR** B. The patient had a surgical lung biopsy with pathology confirming UIP **OR** C. The patient had a HRCT scan with results showing a pattern for probable UIP AND a surgical lung biopsy with pathology indicating probable UIP **OR** B. The patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) AND ALL of the following: 1. The requested agent is Ofev **AND** 2. The patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to ONE conventional agent (i.e., mycophenolate mofetil, cyclophosphamide, azathioprine) **OR** B. The patient has an intolerance or hypersensitivity to ONE conventional agent **OR** C. The patient has an FDA labeled contraindication to ALL conventional agents **OR** C. The patient has a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND ALL of the following: 1. The requested agent is Ofev **AND** 2. The patient has greater than 10% fibrotic features on HRCT **AND** 3. The patient presented with clinical signs of progression, defined by at least ONE of the following: A. FVC decline greater than or equal to 10% **OR** B. FVC decline greater than or equal to 5% and less than 10% with worsening symptoms or imaging **OR**

Module	Clinical Criteria for Approval
	C. Worsening symptoms and worsening imaging within the past 24 months **AND** 4. The patient has an FVC greater than or equal to 45% of predicted **AND** 5. The patient has a diffusion capacity of the lungs for carbon monoxide (DLCO) between 30% to less than 80% of predicted **AND** 6. The patient does NOT meet any of the following: A. A diagnosis of IPF B. Relevant airway obstructions (i.e., pre-bronchodilator FEV1/FVC less than 0.7) C. Significant pulmonary hypertension D. Greater than 1.5 times the upper limit of normal for ALT, AST, or bilirubin E. Known risk or predisposition to bleeding F. Receiving full dose anticoagulation treatment G. Recent history of MI or stroke **OR** D. The patient has another FDA approved indication for the requested agent **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient will NOT be using the requested agent in combination with another agent included in this prior authorization program **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with another agent included in this prior authorization program **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND**

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	B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** 12 months