NINTEDANIB

Generic	Brand	HICL	GCN	Exception/Other
NINTEDANIB	OFEV	41489		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nintedanib is prescribed by or given in consultation with a pulmonologist
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient does **NOT** have other known causes of interstitial lung disease (for example, connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus infection, viral hepatitis, or cancer)
   - The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline
   - The patient is NOT receiving therapy with Esbriet

   If yes, **approve for 12 months by HICL with a quantity limit of #2 capsules per day. APPROVAL TEXT:** Renewal requires that the patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline.

   If no, continue to #2.

2. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) and meet **ALL** of the following criteria?
   - The patient has a diagnosis of Systemic Sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - The patient is 18 years of age or older
   - Nintedanib is prescribed by or given in consultation with a pulmonologist or rheumatologist
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT)
   - The patient has a baseline forced vital capacity (FVC) of at least 40% of predicted value
   - Exclusion of other etiologies of interstitial lung disease (ILD) [e.g., Heart failure/fluid overload, Drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), Recurrent aspiration (such as from GERD), Pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]

   If yes, **approve for 12 months by HICL with a quantity limit of #2 capsules per day. APPROVAL TEXT:** Renewal requires that the patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline.

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

If no, do not approve.
INITIAL DENIAL TEXT: The guideline named **NINTEDANIB (Ofev)** requires a diagnosis of idiopathic pulmonary fibrosis (IPF) or systemic sclerosis-associated interstitial lung disease (SSc-ILD). In addition, the following must be met.
For a diagnosis of idiopathic pulmonary fibrosis (IPF), approval requires:

- The patient is 18 years of age or older
- Nintedanib is prescribed by or given in consultation with a pulmonologist
- The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
- The patient does NOT have other known causes of interstitial lung disease (for example, connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus infection, viral hepatitis, or cancer)
- The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline
- The patient is NOT receiving therapy with Esbriet

For a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval requires:

- The patient has a diagnosis of Systemic Sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
- The patient is 18 years of age or older
- Nintedanib is prescribed by or given in consultation with a pulmonologist or rheumatologist
- The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT)
- The patient has a baseline forced vital capacity (FVC) of at least 40% of predicted value
- Exclusion of other etiologies of interstitial lung disease (ILD) [e.g., Heart failure/fluid overload, Drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), Recurrent aspiration (such as from GERD), Pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]

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NINTEDANIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) or systemic sclerosis-associated interstitial lung disease (SSc-ILD) **AND** meet the following criterion?
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by HICL with a quantity limit of #2 capsules per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **NINTEDANIB (Ofev)** requires a diagnosis of idiopathic pulmonary fibrosis (IPF) or systemic sclerosis-associated interstitial lung disease (SSc-ILD). In addition, the following must be met.
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ofev.

REFERENCES
- Ofev [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 02/15
Client Approval: 11/19
P&T Approval: 10/19