STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NINTEDANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NINTEDANIB	OFEV	41489		GPI-10 (4555405020)	

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
   - Therapy is prescribed by or 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

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   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
   - Therapy is prescribed by or 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
   - The patient does NOT have 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 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient's lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities e.g., infection, heart failure)
   - The patient has ≥ 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing)
   - The patient has a baseline forced vital capacity (FVC) at least 45% of predicted value

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)
   B. **If you have idiopathic pulmonary fibrosis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
      3. You have a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
      4. You do NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
      5. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50 percent at baseline

   (Initial denial text continued on next page)

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

C. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You have systemic sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40 percent of predicted value
   6. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

D. **If you have chronic fibrosing interstitial lung disease with progressive phenotype, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   3. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (not caused by comorbidities such as infection, heart failure)
   4. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 45 percent of predicted value

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NINTEDANIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF), systemic sclerosis-associated interstitial lung disease (SSc-ILD), or chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD) **AND** meet the following criterion?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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