

Specialty Guideline Management

nintedanib-Ofev

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ofev	nintedanib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2}

Treatment of adults with idiopathic pulmonary fibrosis (IPF).

Treatment of adults with chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.

Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review for initial requests (where applicable):

Reference number(s)
1882-A

Idiopathic Pulmonary Fibrosis (IPF)

- Chart notes or medical record documentation of result of a chest high-resolution computed tomography (HRCT) study.
- Chart notes or medical record documentation of pathology report of lung biopsy (if performed).
- Chart notes or medical record documentation of pathology report of transbronchial lung cryobiopsy (if performed).

Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype

- Chart notes or medical record documentation of result of a chest high-resolution computed tomography (HRCT) study.
- Chart notes or medical record documentation of progressive disease (e.g., forced vital capacity [FVC] decline greater than or equal to 10% of the predicted value, worsening respiratory symptoms, increased extent of fibrosis on HRCT).

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

Chart notes or medical record documentation of result of a chest high-resolution computed tomography (HRCT) study.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Idiopathic pulmonary fibrosis (IPF): pulmonologist or a specialist in the treatment of IPF.
- Chronic fibrosing interstitial lung disease with a progressive phenotype: pulmonologist or a specialist in the treatment of chronic fibrosing interstitial lung disease with a progressive phenotype.
- Systemic sclerosis-associated interstitial lung disease (SSc-ILD): pulmonologist, rheumatologist, or a specialist in the treatment of SSc-ILD.

Coverage Criteria

Idiopathic Pulmonary Fibrosis (IPF)^{1-3,9}

Authorization of 12 months may be granted for treatment of idiopathic pulmonary fibrosis when the member has undergone a diagnostic work-up which includes both of the following:

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- Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded.
- The member meets either of the following:
 - Member has completed a high-resolution computed tomography (HRCT) study of the chest, transbronchial lung cryobiopsy (TBLC), or a lung biopsy which reveals a result consistent with the usual interstitial pneumonia (UIP) or probable UIP pattern and the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.
 - Member has completed an HRCT study of the chest which reveals a result other than the UIP or probable UIP pattern (e.g. indeterminate for UIP) and meets both of the following:
 - The member had a lung biopsy or a TBLC with pathology confirming UIP or probable UIP.
 - The diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.

Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype^{1-3,6}

Authorization of 12 months may be granted for treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype (progressive pulmonary fibrosis [PPF]) when the member meets both of the following:

- The member has completed a high-resolution computed tomography (HRCT) study of the chest that shows fibrosis affecting at least 10 percent of the lungs.
- The member has progressive disease (e.g., forced vital capacity [FVC] decline greater than or equal to 10% of the predicted value, worsening respiratory symptoms, increased extent of fibrosis on HRCT).

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)^{1,2,4,5,7,8,10}

Authorization of 12 months may be granted for treatment of systemic sclerosis-associated interstitial lung disease when the member's diagnosis was confirmed by a high-resolution computed tomography (HRCT) study of the chest.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy for an indication listed in the coverage criteria may be granted an authorization of 12 months when the member is currently receiving treatment with the requested drug.

Reference number(s)
1882-A

Other

Note: If the member is a current smoker, they should be counseled on the harmful effects of smoking on pulmonary conditions and available smoking cessation options.

References

1. Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2025.
2. Nintedanib [package insert]. Princeton, NJ: Sandoz Inc.; January 2026.
3. Raghu G, Remy-Jardin M, Richeldi L, et al. Idiopathic pulmonary fibrosis (an update) and progressive pulmonary fibrosis in adults: An official ATS/ERS/JRS/ALAT clinical practice guideline. *Am J Respir Crit Care Med.* 2022;205(9):e18-e47.
4. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for systemic sclerosis-associated interstitial lung disease. *N Engl J Med.* 2019;380(26):2518-2528.
5. van den Hoogen F, Khanna D, Fransen J, et al. 2013 Classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative. *Arthritis Rheum.* 2013;65(11):2737-47.
6. Flaherty KR, Wells AU, Cottin V, et al. Nintedanib in progressive fibrosing interstitial lung diseases. *N Engl J Med.* 2019;381(18):1718-1727.
7. Rahaghi FF, Hsu VM, Kaner RJ, et al. Expert consensus on the management of systemic sclerosis-associated interstitial lung disease. *Respir Res.* 2023;24(1):6-16.
8. Galdo FD, Lescoat A, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. *Ann Rheum Dis.* 2024;0:1-12.
9. Korevaar DA, Colella S, Fally M et al. European Respiratory Society guidelines on transbronchial lung cryobiopsy in the diagnosis of interstitial lung diseases. *Eur Respir J.* 2022;60: 1-17.
10. Antoniou KM, Distler O, Gheorghiu et al. ERS/EULAR clinical practice guidelines for connective tissue disease-associated interstitial lung disease. *Eur Respir J.* 2025; 1-55.