Mass General Brigham
Health Plan

Ofev (nintedanib)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

FDA-Approved Indications

A. Idiopathic Pulmonary Fibrosis
   Ofev is indicated for the treatment of adults with idiopathic pulmonary fibrosis (IPF).
B. Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype
   Ofev is indicated for the treatment of adults with chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.
C. Systemic Sclerosis-Associated Interstitial Lung Disease
   Ofev is indicated to slow 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.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following diagnosis-specific criteria is met:

A. Idiopathic Pulmonary Fibrosis (IPF)
Authorization may be granted for treatment of idiopathic pulmonary fibrosis when the member has undergone a diagnostic work-up which includes the following:
1. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded AND
2. The member has completed a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy which reveals a result consistent with the usual interstitial pneumonia (UIP) pattern, OR has completed an HRCT study of the chest which reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported by a lung

biopsy. If a lung biopsy has not been previously conducted, the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.

B. Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype
Authorization may be granted for treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype when the member meets both of the following criteria:

1. 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.
2. 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).

C. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Authorization 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 above may be granted an authorization when the member is currently receiving treatment with Ofev.

Limitations

1. Approvals will be granted for 12 months.

References

1. Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. October 2022.
2. 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. doi:10.1164/rccm.202202-0399ST
3. 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. doi:10.1056/NEJMoa1903076
4. 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. doi:10.1002/art.38098
5. Flaherty KR, Wells AU, Cottin V, et al. Nintedanib in progressive fibrosing interstitial lung diseases. *N Engl J Med*. 2019;381(18):1718-1727. doi:10.1056/NEJMoa1908681

Review History
12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024