Ofev (nintedanib)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Ofev (nintedanib) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. 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. Idiopathic Pulmonary Fibrosis
   Ofev is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).
2. Systemic Sclerosis-Associated Interstitial Lung Disease
   Ofev is indicated to slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).
3. Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype
   Ofev is indicated for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.

POLICY

Documentation

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

- Result of a chest high-resolution computed tomography (HRCT) study.
- If a lung biopsy is conducted, submit the associated pathology report.

Criteria for Initial Approval

A. Idiopathic Pulmonary Fibrosis (IPF)

Authorization of 12 months 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 (ILDs) with a Progressive Phenotype

Authorization of 12 months may be granted for the treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype when the following criteria are met:

1. The member has completed a high-resolution computed tomography (HRCT) study of the chest which reveals fibrosing lung disease, defined as reticular abnormality with traction bronchiectasis, with or without honeycombing, with fibrosis affecting more than 10% of the lungs.
2. HRCT study does not show widespread consolidation or progressive massive fibrosis
3. The member meets at least one of the following criteria for progression of interstitial lung disease within the last 24 months, despite standard treatment with an agent other than nintedanib (Ofev) or pirfenidone (Esbriet):
   a. A relative decline in the FVC of at least 10% of the predicted value
   b. A relative decline in the FVC of 5% to less than 10% of the predicted value combined with at least one of the following:
      - Worsening of respiratory symptoms
      - Increased extent of fibrosis on HRCT
   c. Worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only

C. Systemic Sclerosis-Associated Interstitial Lung Disease

Authorization of 12 months may be granted for treatment of systemic sclerosis-associated interstitial lung disease when 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.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy for an indication listed in the Criteria for Initial Approval may be granted an authorization of 12 months when the member is currently receiving treatment with Ofev, excluding when Ofev is obtained as samples or via manufacturer's patient assistance programs.

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.

Ofev is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

- Ofev = 300 mg per day

REFERENCES

- Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. March 2020.
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- Vancheri C, Kreuter M, Richeldi L, et al. Nintedanib with add-on pirfenidone in idiopathic pulmonary fibrosis: results of the Injourney trial. Am J Respir Crit Care Med. 2017 Sept 10. doi: 10.1164/rccm.201706-1301OC. [Epub ahead of print].
- 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. Ann Rheum Dis. 2013; 72: 1747-55.
- Flaherty K, Wells A, Cottin V, et al. Nintedanib in Progressive Fibrosing Interstitial Lung Diseases. N Engl J Med 2019; 381:1718-1727

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POLICY HISTORY

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