Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Ofev (nintedanib capsules)

Policy Number: 5.01.606
Origination: 10/2015
Last Review: 10/2018
Next Review: 10/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Ofev (nintedanib) when it is determined to be medically necessary because the following criteria are met.

When Policy Topic is covered

Food and Drug Administration (FDA)-Approved Indications

1. **Idiopathic Pulmonary Fibrosis (IPF)**. Approve if the patient meets the following criteria (a, b, c and d).

a) The patient is aged ≥ 40 years; AND
b) The agent has been prescribed by, or in consultation with, a pulmonologist; AND
c) At baseline (before therapy initiation), patients have an FVC ≥ 50% of the predicted value; AND
d) The diagnosis of IPF is confirmed by one of the following (i or ii):
- **i.** Findings on high-resolution computed tomography (HRCT) indicates usual interstitial pneumonia (UIP); OR
- **ii.** A surgical lung biopsy demonstrates usual interstitial pneumonia (UIP).

Ofev is indicated for the treatment of IPF.[1] Patients included in the trial were aged ≥ 40 years and the disease mainly impacts older adults.[1-4] The safety and efficacy of Ofev have not been established in pediatric patients.[1] For inclusion in the pivotal studies patients were required to have an FVC ≥ 50% of the predicted value, indicating mild to moderate disease severity. It is uncertain if patients with lower percent predicted FVC values, indicating worse disease, would benefit from Ofev therapy.[1-3] The 2011 American Thoracic Society (ATS), European Respiratory Society (ERS), the Japanese Respiratory Society (JRS), and Latin American Thoracic Association (ALAT) guideline for the diagnosis and management of IPF notes that the accuracy of the diagnosis of IPF increases with multidisciplinary interactions between pulmonologists, radiologists, and pathologists experienced in the diagnosis of interstitial lung disease (ILD). The guidelines also state that the diagnosis of IPF requires exclusion of other known causes of ILD; the presence of a usual interstitial pneumonia pattern on HRCT in patients not subjected to surgical lung biopsy; and specific combinations of HRCT and surgical lung biopsy pattern in patients subjected to surgical lung biopsy. The criteria are recommended based on the professional opinion of specialized physicians.

When Policy Topic is not covered

Conditions Not Recommended for Approval

Ofev has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.) Not medically necessary.

1. **Ofev is Being Used Concomitantly with Esbriet® (pirfenidone capsules)**. Esbriet is another medication indicated for IPF.[5] The effectiveness and safety of concomitant use of Ofev with Esbriet have not been established.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Considerations

Ofev requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Ofev, a kinase inhibitor, is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).[1] The recommended dose of Ofev is 150 mg twice daily (BID) with food given approximately 12 hours apart. Liver function tests should be performed prior to Ofev initiation. Dose modifications are recommended for adverse events (AEs) such as liver enzyme elevations. The most common AEs with Ovef are diarrhea (62%), nausea (24%), abdominal pain (15%), liver enzyme elevation (14%), vomiting (12%), decreased appetite (11%), decreased weight (10%), headache (8%), and hypertension (5%). AEs leading to permanent dose reductions occurred in 16% of Ofev-treated patients. Ofev discontinuation due to AEs occurred in 21% of patients.

The clinical efficacy of Ofev has been studied in 1,231 patients with IPF in one Phase II study and two Phase III studies that were identical in design.[1-3] The trials were randomized, double-blind, placebo-controlled studies comparing treatment with Ofev 150 mg BID with placebo for 52 weeks. For all three studies, a statistically significant reduction in the annual rate of decline of forced vital capacity (FVC) was observed in patients receiving Ofev compared with patients receiving placebo. Also, data shows that the proportion of patients that demonstrated categorical declines in lung function was lower for patients given Ofev compared with placebo. Acute IPF exacerbations were also reduced.

Prior authorization is recommended for prescription benefit coverage of Ofev. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ofev, initial approval requires Ofev to be prescribed by or in consultation with a physician who specializes in the condition being treated

Rationale

Ofev is indicated for the treatment of IPF.[1] Patients included in the trial were aged ≥ 40 years and the disease mainly impacts older adults.[1-4] The safety and efficacy of Ofev have not been established in pediatric patients.[1] For inclusion in the pivotal studies patients were required to have an FVC ≥ 50% of the predicted value, indicating mild to moderate disease severity. It is uncertain if patients with lower percent predicted FVC values, indicating worse disease, would benefit from Ofev therapy.[1-3] The 2011 American Thoracic Society (ATS), European Respiratory Society (ERS), the Japanese Respiratory Society (JRS), and Latin American Thoracic Association (ALAT) guideline for the diagnosis and management of IPF notes that the accuracy of the diagnosis of IPF increases with multidisciplinary interactions between pulmonologists, radiologists, and pathologists experienced in the diagnosis of interstitial lung disease (ILD). The guidelines also state that the diagnosis of IPF requires exclusion of other known causes of ILD; the presence of a usual interstitial pneumonia pattern on HRCT in patients not subjected to surgical lung biopsy; and specific combinations of HRCT and surgical lung biopsy pattern in patients subjected to surgical lung biopsy. The criteria are recommended based on the professional opinion of specialized physicians.

References

1. Ofev® capsules [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; October 2014.

2. Richeldi L, du Bois RM, Raghu G, et al, for the INPULSIS Trial Investigators. Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis. *N Engl J Med*. 2014;370(22):2071-2082.
3. Richeldi L, Costabel U, Selman N, et al. Efficacy of a tyrosine kinase inhibitor in idiopathic pulmonary fibrosis. *N Engl J Med*. 2011;365(12):1079-1087.
4. Raghu G, Collard HR, Egan JJ, et al, on behalf of the ATS/ERS/JRS/ALAT Committee on Idiopathic Pulmonary Fibrosis. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J Respir Crit Care Med*. 2011;183:788-824.
5. Esbriet® capsules [prescribing information]. Brisbane, CA: InterMune, Inc.; October 2014.

Billing Coding/Physician Documentation Information

NA Ofev is a Specialty pharmacy benefit

Additional Policy Key Words

5.01.606

Policy Implementation/Update Information

10/2015 New policy titled Ofev (nintedanib)
10/2016 Annual revision; no changes to policy statement
10/2017 Annual revision; no changes to policy statement
10/2018 No changes made
