Ofev

Description

Ofev (nintedanib)

Background
Idiopathic pulmonary fibrosis is a progressive condition in which the lungs develop abnormal tissue changes (fibrosis) over time. As a result, patients with IPF experience shortness of breath, and worsening lung function (1).

Ofev is a kinase inhibitor that blocks multiple pathways that may be involved in the development of fibrotic of lung tissue. It targets various growth factor receptors that affect the fibroblast cells thought to be responsible for disease progression (1).

Regulatory Status
FDA-approved indication: Ofev is a kinase inhibitor indicated for: (1)

- Treatment of idiopathic pulmonary fibrosis (IPF)
- Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Ofev is not recommended for patients who have moderate to severe liver problems. The safety and efficacy of Ofev have not been studied in patients with severe renal impairment and end-stage renal disease. Ofev can cause birth defects or death to an unborn baby. Women should not become pregnant while taking Ofev. Women who are able to get pregnant should use adequate contraception during and for at least three months after the last dose of Ofev. Liver function tests in all patients and a pregnancy test in females of reproductive potential should be conducted prior to initiating treatment with Ofev (1).
Eligible patients for clinical studies were to have percent forced vital capacity (%FVC) greater than or equal to 50% at baseline and a percent predicted diffusing capacity of the lungs for carbon monoxide (%DLCO) greater than or equal to 30%. The primary endpoint was the annual rate of decline in forced vital capacity (FVC) from baseline to study end (1-2).

Ofev is metabolized primarily (70 to 80%) via CYP1A2 with minor contributions from other CYP isoenzymes including CYP2C9, 2C19, 2D6 and 2E1. A drug interaction assessment needs to be performed before the start of the medication (1).

Safety and effectiveness of Ofev in pediatric patients have not been established (1).

**Related policies**

Esbriet

**Policy**

| This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims. |

Ofev may be considered **medically necessary** in patients 18 years of age or older with idiopathic pulmonary fibrosis (IPF) and if the conditions indicated below are met.

Ofev is considered **investigational** in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

- Idiopathic pulmonary fibrosis (IPF)

**AND ALL** of the following:

1. Idiopathic (i.e., no identifiable cause for pulmonary fibrosis) diagnosis confirmed by **ALL** of the following:
   a. Physical exam
   b. Pulmonary Function Tests
Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Respiratory Agents  Original Policy Date: November 7, 2014
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i. \( \%FVC \leq 82\% \) of predicted
ii. \%DLCO
iii. \%TLC\leq 80\% \) of predicted
  c. CT with classic findings of usual interstitial pneumonitis (UIP)

2. Must be prescribed by a pulmonologist
3. **NOT** to be used concurrently with other medications for idiopathic pulmonary fibrosis
4. Drug interaction assessment has been performed by the physician
5. **NO** known cause of the interstitial lung disease / fibrosis
6. Patient has had baseline liver function tests performed

**Age**
18 years of age or older

**Diagnosis**

Patient must have the following:

Systemic sclerosis-associated interstitial lung disease (ILD)

AND ALL of the following:
1. \%FVC \geq 40\% \) of predicted
2. \%DLCO 30-89\% \) of predicted
3. Prescribed or recommended by a pulmonologist or rheumatologist
4. Drug interaction assessment has been performed by the physician
5. Patient has had baseline liver function tests performed

**Prior – Approval Renewal Requirements**

**Age**
18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Idiopathic pulmonary fibrosis (IPF)
   a. **NOT** to be used concurrently with other medications for idiopathic pulmonary fibrosis
2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

AND ALL of the following:
a. Assessment by the healthcare professional that the medication is helping the patient by meeting at least ONE of the following criteria (while taking this medication):
   i. Slowed the rate of decline of lung function
   ii. Improved (or no decline in) symptoms of cough or shortness of breath
   iii. Improved sense of well-being
b. Drug interaction assessment has been performed by the physician

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

Duration 6 months

**Prior – Approval Renewal Limits**

Duration 12 months

**Rationale**

**Summary**

Ofev is a kinase inhibitor that blocks multiple pathways that may be involved in the development of fibrotic of lung tissue. It targets various growth factor receptors that affect the fibroblast cells thought to be responsible for disease progression. Safety and effectiveness of Ofev in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Ofev while maintaining optimal therapeutic outcomes.

**References**

Subject: Ofev

Policy History

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<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>November 2014</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>December 2014</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>April 2015</td>
<td>Addition of Idiopathic diagnosis confirmed by the following: CT, Pulmonary Function Test, and Physical exam; no known cause of the interstitial lung disease / fibrosis; also drug interaction assessment has been performed; must be prescribed by a pulmonologist; assessment by the healthcare professional that the medication is helping the patient by meeting at least ONE of the following criteria (while taking this medication): slowed the rate of decline of lung function, improved (or no decline in) symptoms of cough or shortness of breath, improved sense of well-being. Removal of predicted diffusing capacity for carbon monoxide (%DLCO) greater than or equal to 30% per SME</td>
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<tr>
<td>June 2015</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>February 2016</td>
<td>Change of the FVC from 80% to 82%</td>
</tr>
<tr>
<td>March 2016</td>
<td>Annual review</td>
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<tr>
<td>September 2016</td>
<td>Policy number changed from 5.13.05 to 5.45.05</td>
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<td>March 2017</td>
<td>Annual editorial review and reference update.</td>
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<td>March 2019</td>
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<tr>
<td>September 2019</td>
<td>Addition of indication: SSc-ILD. Addition of baseline liver function tests requirement</td>
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<tr>
<td>November 2019</td>
<td>Revised requirement for SSc-ILD to “prescribed or recommended by a pulmonologist or rheumatologist”</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.