Clinical Pharmacy Program Guidelines for Idiopathic Pulmonary Fibrosis

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
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</thead>
<tbody>
<tr>
<td>Medication</td>
<td>Esbriet (pirfenidone), Ofev (nintedanib)</td>
</tr>
<tr>
<td>Issue Date</td>
<td>11/2014</td>
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<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>9/2017</td>
</tr>
<tr>
<td>Effective Date</td>
<td>11/2017</td>
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1. **Background:**

   Esbriet (pirfenidone) is a pyridone and Ofev (nintedanib) is a kinase inhibitor that are indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

2. **Coverage Criteria:**

   A. **Initial Authorization**

   1. **Esbriet or Ofev** will be approved based on **all** of the following criteria:

   a. Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by **all** of the following criteria:

      (1) Exclusion of other known causes of interstitial lung disease (e.g. domestic and occupational environmental exposures, connective tissue disease, and drug toxicity). As documented by the following:

      i. ICD-10 Code J84.112 (Idiopathic pulmonary fibrosis)

      -AND-

      (2) **One** of the following:

      i. In patients **not** subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF

      -OR-

      ii. In patients subjected to a lung biopsy, both HRCT and surgical lung

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biopsy pattern reveal IPF or probable IPF

-AND-

b. The agent is not being used in combination with Esbriet or Ofev.

-AND-

c. The prescriber is a pulmonologist

Authorization will be issued for 12 months

B. Reauthorization

1. Ofev and Esbriet will be approved based on the following criterion:

   a. Documentation of positive clinical response to Esbriet or Ofev therapy.

Authorization will be issued for 12 months

3. References:


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<tr>
<th>Program</th>
<th>Prior Authorization - Esbriet (pirfenidone), Ofev (nintedanib)</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>11/2014</td>
<td>New policy</td>
</tr>
<tr>
<td>12/2015</td>
<td>Annual review; no change</td>
</tr>
<tr>
<td>9/2016</td>
<td>Removed ICD-9 code. Updated background, references, and policy template.</td>
</tr>
<tr>
<td>9/2017</td>
<td>Annual Review. Updated background and references.</td>
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