I. Medication Description

Ofev (nintedanib) is a small molecule that inhibits multiple receptor tyrosine kinases (RTKs) and non-receptor tyrosine kinases (nRTKs). Nintedanib inhibits the following RTKs: platelet-derived growth factor receptor (PDGFR) α and β, fibroblast growth factor receptor (FGFR) 1-3, vascular endothelial growth factor receptor (VEGFR) 1-3, colony stimulating factor 1 receptor (CSF1R), and Fms-like tyrosine kinase-3 (FLT-3). These kinases except for FLT-3 have been implicated in pathogenesis of interstitial lung diseases (ILD). Nintedanib binds competitively to the adenosine triphosphate (ATP) binding pocket of these kinases and blocks the intracellular signaling cascades, which have been demonstrated to be involved in the pathogenesis of fibrotic tissue remodeling in ILD. Nintedanib also inhibits the following nRTKs: Lck, Lyn and Src kinases. The contribution of FLT-3 and nRTK inhibition to nintedanib efficacy in ILD is unknown.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided for the following conditions when supportive documentation has been provided and when listed criteria are met:

- Idiopathic pulmonary fibrosis (IPF):
  - Medication is prescribed by a pulmonologist AND
  - Member is confirmed to be a current non-smoker.

- Systemic sclerosis-associated interstitial lung disease (SSc-ILD):
  - Medication is prescribed by a pulmonologist or a rheumatologist AND
  - Member is confirmed to be a current non-smoker.

IV. Quantity Limitations

100mg and 150mg capsules are covered at up to 60 per each 30 days.

V. Coverage Duration

Coverage is granted for six months and may be renewed.
VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
- Liver enzymes are provided and dosing is still appropriate according to the FDA-approved dosage guidance AND
- Member is confirmed to be a current non-smoker AND
- Member continues to derive clinical benefit from the drug as shown in a reduction of disease signs and symptoms AND
- There is an absence of unacceptable toxicity from the drug.

VII. Billing/Coding Information

Ofev is available as 100mg and 150mg oral capsules.

VIII. Summary of Policy Changes

- 3/15/15: new policy
- 7/1/15: formulary distinctions made
- 3/15/16: no policy changes
- 1/1/17: removed liver function testing requirements from criteria
- 1/1/18: no policy changes
- 1/15/19: no policy changes
- 1/30/20: added new indication: treatment of systemic sclerosis-associated interstitial lung disease

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.