Nintedanib (OFEV®)
Criteria for Use
September 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.
See the VA National PBM-MAP-VPE Monograph on this drug at the PBM INTRAnet site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive Nintedanib.

- ☐ Patient is a current smoker
- ☐ Patient has Child Pugh B or C hepatic impairment*
- ☐ For the diagnosis of IPF, patient is on pirfenidone (ESBRIET®)
- ☐ There is documented ongoing nonadherence to prior medications or medical treatment
- ☐ Patient is pregnant or has not received contraceptive counseling on potential risk vs. benefit of taking nintedanib if patient were to become pregnant.

Inclusion Criteria

The answers to ALL of the following per diagnosis must be fulfilled in order to meet criteria.

- ☐ For Idiopathic Pulmonary Fibrosis
  - ☐ Treatment is initiated and followed by VA/VA Community Care Pulmonologist experienced in the diagnosis and management of interstitial lung disease
  - ☐ The diagnosis of idiopathic pulmonary fibrosis has been confirmed preferably through multidisciplinary evaluation (e.g. pulmonologist, radiologist, pathologist evaluation)
- ☐ For Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
  - ☐ Treatment is initiated and followed by VA/VA Community Care Pulmonologist or Rheumatologist experienced in the diagnosis and management of SSc-ILD.
  - ☐ The diagnosis of SSc-ILD has been confirmed preferably through multidisciplinary discussion (e.g. pulmonologist, rheumatologist, radiologist, pathologist evaluation)
  - ☐ Patient with SSc-ILD who demonstrates disease progression, defined as an absolute decline in either FVC% predicted of $\geq$10% from baseline or diffusing capacity of the lung for carbon monoxide (DL_{CO}) levels of $\geq$15% from baseline while on mycophenolate or cyclophosphamide or patient is unable to take mycophenolate or cyclophosphamide.

☐ For Chronic Fibrosing Interstitial Lung Disease – Progressive Phenotype (CFILD)

☐ Treatment is initiated and followed by VA/VA Community Care Pulmonologist experienced in the diagnosis and management of CFILD.

☐ The diagnosis of CFILD has been confirmed preferably through multidisciplinary discussion (e.g. pulmonologist, rheumatologist, radiologist, pathologist evaluation)

☐ Patients meeting any of the following criteria for disease progression within a 24-month period:

☐ worsening symptoms and a relative decline of $\geq$ 10% in FVC,

☐ worsening symptoms and a relative decline of $\geq$ 15% in DLCO, or

☐ worsening symptoms and radiological appearance accompanied by a $\geq$ 5 – < 10% relative decrease in FVC.

*** Footnote:**

Dose modifications for liver chemistry abnormalities:

- For AST or ALT >3 but ≤5x upper limit of normal (ULN), without symptoms or hyperbilirubinemia, after starting nintedanib therapy:
  - Discontinue confounding medications, exclude other causes, and monitor the patient closely.
  - Reduce nintedanib to 100mg twice daily, or place on temporary hold.
  - Repeat liver chemistry tests as clinically indicated.
  - Resume at 100mg twice daily or at full-dosage, as applicable, when liver chemistry tests have normalized
- Nintedanib should be permanently discontinued
  - If AST or ALT >3 but ≤5x ULN and accompanied by symptoms or hyperbilirubinemia
  - For AST or ALT >5x ULN, regardless of symptoms or hyperbilirubinemia

Prepared: September 2020. Previous versions: August 2020, March 2015. Contact: Mitchell Nazario, PharmD, CPE, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

**The VA Medical Advisory Panel of the Pharmacy Benefits Management Services is comprised of PBM clinical pharmacy specialists and practicing internist and specialist VA physicians from across the country.*