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PARP Approved: 09/2017

Gateway Health
Prior Authorization Criteria
Ofev (nintedanib capsules)

All requests for Ofev (nintedanib capsules) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Ofev (nintedanib capsules) Prior Authorization Criteria:

Coverage may be provided for members 18 years of age or older with a diagnosis of **idiopathic pulmonary fibrosis (IPF)** when all of the following criteria is met:

- Documentation of a confirmed diagnosis of IPF **AND**
- Documentation of baseline liver function tests (LFTs; i.e. ALT, AST and bilirubin) prior to initiating treatment **AND**
- The treatment regimen is being prescribed by, or in consultation with, a pulmonologist **AND**
- Ensure the patient does not have moderate (Child Pugh B) or severe hepatic impairment (Child Pugh C) before starting therapy **AND**
- Will have LFTs completed monthly for 3 months and every 3 months thereafter, and as clinically indicated **AND**
- The member does not have any of the following:
  - Active bleeding
  - Recent history of myocardial infarction (MI) or stroke
  - Gastrointestinal perforation
  - Severe renal impairment or end-stage renal disease
  - AST or ALT elevations >5 times ULN or >3 times ULN with signs or symptoms of severe liver damage **AND**
- The requested dose and frequency is appropriate for the member's liver function according to package labeling and does not exceed 150mg orally twice daily **AND**
- Attestation by the provider the member will be monitored for signs of increased bleeding if on anticoagulation therapy and possibly, dosage adjustment **AND**
- The member is currently not smoking **AND**
- The member is not on any medications that can decrease exposure to Ofev by inducing (CYP3A4) liver enzymes such as rifampicin, St. John's wort, phenytoin, carbamazepine, etc. **AND**
- If female and of child bearing age, documentation of a negative pregnancy test prior to initiation of treatment **AND**
- The member is using adequate contraception to prevent pregnancy during treatment and for at least 3 months after taking their last dose of Ofev **OR**
- If applicable, the member must not be breastfeeding **AND**
- In all situations where initial coverage is approved, authorizations will be provided for 3 months.

Reauthorization may be provided when the following criteria is met:

- Documentation the member is not on any medications that can decrease exposure to Ofev by inducing (CYP3A4) liver enzymes **AND**

- The member has had repeat LFTs (ALT, AST and bilirubin) since starting therapy **AND**
- Attestation by the provider the member is being monitored for increased risk of bleeding if on anticoagulation treatment and possibly, dosage adjustment **AND**
- The member does not have any of the following:
    - Active bleeding
    - Recent history of myocardial infarction (MI) or stroke
    - Gastrointestinal perforation
    - Severe renal impairment or end-stage renal disease
    - AST or ALT elevations >5 times ULN or >3 times ULN with signs or symptoms of severe liver damage
    - Persistent severe diarrhea, nausea or vomiting despite symptomatic treatment **AND**
    - The member is using adequate contraception to prevent pregnancy during treatment and for at least 3 months after taking their last dose of Ofev **AND**
    - In all situations where reauthorization coverage is approved, authorizations will be provided for 6 months.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.