Updated: 07/2017
PARP Approved: 08/2017

Gateway Health
Prior Authorization Criteria
Esbriet (pirfenidone capsules)

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

Esbriet (pirfenidone 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**
- The prescriber attests that the member will have LFTs completed monthly for the first 6 months and every 3 months thereafter, and as clinically indicated **AND**
- The member does not have end-stage renal disease requiring dialysis or severe hepatic impairment (Child Pugh C) **AND**
- The requested dose and frequency is appropriate for the member's liver function according to package labeling and does not exceed 801mg orally three times daily **AND**
- The member is being monitored for the potential adverse events of photosensitivity and/or weight loss **AND**
- The member is currently not smoking **AND**
- The member is not on any medications that can decrease exposure to Esbriet by strongly inducing (CYP1A2) liver enzymes such as carbamazepine **AND**
- The member is not on any medications that can increase exposure to Esbriet by strongly inhibiting (CYP1A2) liver enzymes such as fluvoxamine **AND**
- 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 increase or decrease exposure to Esbriet by inhibiting or inducing (CYP1A2) liver enzymes **AND**
- The member has had repeat LFTs (ALT, AST and bilirubin) since starting therapy **AND**
- The member does not have end-stage renal disease requiring dialysis or severe hepatic impairment (Child Pugh C) **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