

I. Requirements for Prior Authorization of Idiopathic Pulmonary Fibrosis (IPF) Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for IPF Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an IPF Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the IPF Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Does not have a history of a contraindication to the prescribed medication; **AND**
5. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**
6. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**
7. If a current smoker, has documentation of being advised by the prescriber to stop smoking; **AND**
8. For a non-preferred IPF Agent, **one** of the following:
 - a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred IPF Agents approved or medically accepted for the beneficiary's indication
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred IPF Agent

See the Preferred Drug List (PDL) for the list of preferred IPF Agents at:
<https://papdl.com/preferred-drug-list>;

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN IPF AGENT: The determination of medical necessity of a request for renewal of a prior authorization for an IPF Agent will take into account whether the beneficiary:

1. Based on the prescriber's assessment, is benefitting from the requested medication; **AND**
2. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Does not have a history of a contraindication to the prescribed medication; **AND**
5. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.)

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an IPF Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

IDIOPATHIC PULMONARY FIBROSIS AGENTS PRIOR AUTHORIZATION FORM

<input type="checkbox"/> New request	<input type="checkbox"/> Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:			Specialty:	
Contact's phone number:			NPI:	State license #:
LTC facility contact/phone:			Street address:	
Beneficiary name:			Suite #:	City/State/Zip:
Beneficiary ID#:	DOB:	Phone:	Fax:	

CLINICAL INFORMATION

Drug requested:	Strength:	Formulation (powder, tablet, etc.):	
Dose/directions:		Quantity:	Refills:
Diagnosis (<i>submit documentation</i>):		Dx code (<i>required</i>):	
Is the medication being prescribed by or in consultation with a pulmonologist, rheumatologist, or other specialist?		<input type="checkbox"/> Yes <i>Submit documentation of consultation, if applicable.</i> <input type="checkbox"/> No	
Is the beneficiary currently being treated with the requested medication?		<input type="checkbox"/> Yes <i>If yes, submit documentation.</i> <input type="checkbox"/> No	
Will the beneficiary be taking any medications that interact with the requested IPF Agent? • Esbriet (pirfenidone) examples: ciprofloxacin, fluvoxamine • Ofev (nintedanib) examples: erythromycin, ketoconazole, anticoagulants		<input type="checkbox"/> Yes <i>Submit complete medication list.</i> <input type="checkbox"/> No	

INITIAL requests

Is the beneficiary a current smoker?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Submit documentation.</i>
If yes, did the prescriber advise the beneficiary to stop smoking?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>documentation.</i>

RENEWAL requests

Has the beneficiary experienced a positive clinical response to the requested medication?	<input type="checkbox"/> Yes <i>Submit documentation.</i> <input type="checkbox"/> No
Did the beneficiary experience any adverse reactions that require dose adjustment as described in the FDA-approved product labeling (e.g., liver enzyme elevations, GI reaction, photosensitivity reaction, rash)?	<input type="checkbox"/> Yes <i>Submit documentation.</i> <input type="checkbox"/> No

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	Date:
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