

I. Requirements for Prior Authorization of Antifibrotic Respiratory Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Antifibrotic Respiratory Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

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

1. Is prescribed the Antifibrotic Respiratory 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. Is prescribed the Antifibrotic Respiratory Agent by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**
5. Does not have a contraindication to the prescribed drug; **AND**
6. If a current smoker, has documentation of being advised by the prescriber to stop smoking; **AND**
7. For a non-preferred Antifibrotic Respiratory Agent, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antifibrotic Respiratory 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 Antifibrotic Respiratory Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred).

See the Preferred Drug List (PDL) for the list of preferred Antifibrotic Respiratory 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 ANTIFIBROTIC RESPIRATORY AGENT: The determination of medical necessity of a request for renewal of a prior authorization for an Antifibrotic Respiratory Agent will take into account whether the beneficiary:

1. Is benefitting from the requested drug based on the prescriber's assessment; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Antifibrotic Respiratory Agent by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**
4. Does not have a contraindication to the prescribed drug; **AND**
5. For a non-preferred Antifibrotic Respiratory Agent with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug.

See the PDL for the list of preferred Antifibrotic Respiratory Agents at:
<https://www.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.

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 Antifibrotic Respiratory 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.

ANTIFIBROTIC RESPIRATORY 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:			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	
If applicable, has the dose of the requested medication been adjusted for the beneficiary's degree of liver impairment, concomitant medications, adverse effects, etc.?		<input type="checkbox"/> Yes <i>Submit documentation.</i> <input type="checkbox"/> No	

INITIAL requests

For a non-preferred Antifibrotic Respiratory Agent , does the beneficiary have a history of trial and failure of or a contraindication or an intolerance to the preferred Antifibrotic Respiratory Agents appropriate for the beneficiary's diagnosis or indication? Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.	<input type="checkbox"/> Yes <i>Submit documentation.</i> <input type="checkbox"/> No
Is the beneficiary a current smoker? If yes, did the prescriber advise the beneficiary to stop smoking?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Submit documentation.</i> <input type="checkbox"/> Yes <input type="checkbox"/> No

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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