ALBERTA BLUE CROSS®

Please complete all required sections to allow your request to be processed.

NINTEDANIB/PIRFENIDONE SPECIAL AUTHORIZATION REQUEST FORM

Patients may or may not meet eligibility requirements as established by Alberta Government-sponsored drug programs.

PATIENT INFORMATION				**COVERAGE TYPE:**
PATIENT LAST NAME	FIRST NAME		INITIAL	☐ Alberta Blue Cross ☐ Alberta Human Services ☐ Other
DATE OF BIRTH (YYYY-MM-DD)	ALBERTA PERSONAL HEALTH NUMBER			
STREET ADDRESS	CITY	PROV	POSTAL CODE	ID/CLIENT/COVERAGE NUMBER

PRESCRIBER INFORMATION			
PRESCRIBER LAST NAME	FIRST NAME	INITIAL	PRESCRIBER PROFESSIONAL ASSOCIATION REGISTRATION
			☐ CPSA ☐ ACO REGISTRATION NUMBER ☐ CARNA ☐ ADA+C ☐ ACP ☐ Other
STREET ADDRESS			
CITY , PROVINCE			PHONE / FAX
POSTAL CODE			FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED

Drug requested (choose *ONE only) ☐ **Nintedanib (e.g. Ofev)** ☐ **Pirfenidone (e.g. Esbriet)**

*Note: Combination use of pirfenidone and nintedanib will not be funded.

Please provide the following information for ALL requests

Diagnosis
- ☐ Mild to moderate idiopathic pulmonary fibrosis (IPF)
- ☐ For nintedanib only: chronic fibrosing interstitial lung disease with a progressive phenotype (PF-ILD)
- ☐ Other (please specify) _____

Section I: Please provide the following information for NEW requests

Initial approval period for patients meeting criteria: seven months for IPF (allow four weeks for repeat pulmonary function tests) and 12 months for PF-ILD.

a) Has the diagnosis been confirmed by a respirologist? ☐ Yes ☐ No (explain)

b) Please provide the pre-treatment Forced Vital Capacity (FVC) (% predicted):	Date

c) For IPF only

Has the diagnosis been confirmed by a high-resolution CT scan within the previous 24 months?	☐ Yes	☐ No (explain)
Have all other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) been excluded?	☐ Yes	☐ No (explain)

Section II: Initial RENEWAL (at six months) for IPF requests

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial six-month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted four weeks later. Approval period for patients meeting criteria is six months.

Forced Vital Capacity (FVC) (% predicted)	Date
In the case of disease progression as defined above, please provide a confirmatory Forced Vital Capacity (FVC) conducted four weeks later (% predicted)	Date

Section III: Second and subsequent RENEWAL for IPF and all RENEWALS for PF-ILD

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12-month period for ILD or during the preceding year of treatment for PF-ILD. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted four weeks later. Approval period for patients meeting criteria is 12 months.

Forced Vital Capacity (FVC) (% predicted)	Date
In the case of disease progression as defined above, please provide a confirmatory Forced Vital Capacity (FVC) conducted four weeks later (% predicted)	Date

Additional information relating to request

PRESCRIBER'S SIGNATURE	DATE (YYYY-MM-DD)	Please forward this request to ▪ **Alberta Blue Cross, Clinical Drug Services** **10009 108 Street NW, Edmonton, Alberta T5J 3C5** ▪ **FAX**: **780-498-8384** in Edmonton • **1-877-828-4106** toll free all other areas

ONCE YOUR REQUEST HAS SUCCESSFULLY TRANSMITTED, PLEASE DO NOT MAIL OR RE-FAX YOUR REQUEST

ALBERTA BLUE CROSS®

NINTEDANIB/PIRFENIDONE SPECIAL AUTHORIZATION CRITERIA

Patients may or may not meet eligibility requirements as established by Alberta Government-sponsored drug programs.

Criteria for coverage

NINTEDANIB (e.g. Ofev) and PIRFENIDONE (e.g. Esbriet) for idiopathic pulmonary fibrosis

Initial approval criteria:

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):
- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion Criteria:

Combination use of pirfenidone and nintedanib will not be funded.

Notes:

Patients who have experienced intolerance or failure to pirfenidone or nintedanib will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria.

NINTEDANIB (e.g. Ofev) for chronic fibrosing interstitial lung disease with a progressive phenotype

Initial approval criteria:

Adult patients with a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype:
- Diagnosis confirmed by a respirologist.
- Patient has a forced vital capacity (FVC) greater than or equal to 45% of predicted.
- Patient is under the care of a physician with experience in interstitial lung diseases.

Special authorization may be granted for 12 months.

For renewal of coverage:
Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% during the preceding year of treatment with nintedanib. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Exclusion Criteria:

Combination use of pirfenidone and nintedanib will not be funded."