



## NINTEDANIB/PIRFENIDONE SPECIAL AUTHORIZATION REQUEST FORM

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

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

| PATIENT INFORMATION  |                                |  |  | COVERAGE TYPE:  |
|--|--------------------------------|--|--|---|
| PATIENT LAST NAME  | FIRST NAME                     | INITIAL  | <input type="checkbox"/> Alberta Blue Cross<br><input type="checkbox"/> Alberta Human Services<br><input type="checkbox"/> 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   |   |
| STREET ADDRESS   |                                |  | <input type="checkbox"/> CPSA  | <input type="checkbox"/> ACO      REGISTRATION NUMBER |
| CITY , PROVINCE  |                                |  | <input type="checkbox"/> CARNA   | <input type="checkbox"/> ADA+C                        |
| POSTAL CODE  |                                |  | <input type="checkbox"/> ACP   | <input type="checkbox"/> Other                        |
| FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED  |                                |  |  |   |
| Drug requested (choose *ONE only):   |                                | <input type="checkbox"/> Nintedanib (e.g. Ofev) <input type="checkbox"/> Pirfenidone (e.g. Esbriet)  |  |   |
| *Note: Combination use of pirfenidone and nintedanib will not be funded.   |                                |  |  |   |
| Please provide the following information for NEW requests: Initial approval period for patients meeting criteria: seven months (allow four weeks for repeat pulmonary function tests)  |                                |  |  |   |
| a) Diagnosis   |                                |  |  |   |
| <input type="checkbox"/> Mild to moderate idiopathic pulmonary fibrosis (IPF)<br><input type="checkbox"/> Other (please specify) _____   |                                |  |  |   |
| b) Has the diagnosis been confirmed by a respirologist and a high-resolution CT scan within the previous 24 months?  |                                | <input type="checkbox"/> Yes <input type="checkbox"/> No (explain) _____   |  |   |
| c) Have all other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) been excluded?  |                                | <input type="checkbox"/> Yes <input type="checkbox"/> No (explain) _____   |  |   |
| d) Please provide the following pre-treatment information for NEW requests   |                                |  |  |   |
| Forced Vital Capacity (FVC) (% predicted)  |                                | Date   |  |   |
| Initial Renewal (at six 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 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   |  |   |
| 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 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                           | Please forward this request to<br>▪ Alberta Blue Cross, Clinical Drug Services<br>10009 108 Street NW, Edmonton, Alberta T5J 3C5<br>▪ 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  |                                |  |  |   |

The information on this form is being collected and pursuant to sections 20, 21 and 22 of the Health Information Act, and sections 33 and 34 of the Freedom of Information and Protection of Privacy Act, for the purposes of determining or verifying eligibility to participate in a program or receive a benefit, product or health service. If you have any questions regarding the collection or use of this information, please contact an Alberta Blue Cross privacy matters representative toll-free at 1-855-498-7302 or write to Privacy Matters, Alberta Blue Cross, 10009 - 108 Street, Edmonton AB T5J 3C5.

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**Criteria for coverage****NINTEDANIB (e.g. Ofev) and PIRFENIDONE (e.g. Esbriet)**

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  $\geq 10\%$  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  $\geq 10\%$  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 piroxicam and nintedanib will not be funded.

Notes:

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