

Ministry of Health and Long-term Care Ontario
Exceptional Access Program (EAP)
EAP Reimbursement Criteria for
Pirfenidone (Esbriet)
Updated: August 28, 2014

For a drug to be considered for funding, the EAP reimbursement criteria must always be met and the request approved prior to the initiation of treatment with the drug being requested, unless otherwise specified within the criteria. This includes:

- funding for continued treatment that was previously supplied through a clinical trial, or paid for by other means (such as a third party payer)
- Note: First time applications for the funding of ongoing treatments must meet both initial and renewal criteria for the drug being requested (unless otherwise specified)
- funding for a renewal beyond the previously approved initial period, unless otherwise specified.
- For a limited number of requests where expert opinion is required, the requests are reviewed by an external reviewer who is a medical expert in the field.

Initial requests

For the treatment of adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF)* confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.

* Mild-moderate IPF is defined as: a FVC between 50-80% predicted, and a Percent Carbon Monoxide Diffusing Capacity (%DLCO) between 30-90% predicted.

Initial renewal criteria:

Patients must NOT demonstrate progression of disease defined as an absolute decline in the 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.

Second renewal (12 months after initiation of therapy):

Patients must NOT demonstrate progression of disease defined as an absolute decline in the percent predicted FVC of $\geq 10\%$ since initiation of therapy (baseline). 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.

Comments from the Canadian Pulmonary Fibrosis Foundation

The above information is taken from the paper published by Minister of Health and Long Term Care. You can see it on **Page 155** of the original at:

http://www.health.gov.on.ca/en/pro/programs/drugs/pdf/frequently_requested_drugs.pdf

The Canadian Pulmonary Fibrosis Foundation accepts no responsibility for this information and you should always contact your physician for answers to medical questions

Patients are reminded to go through the Inspiration program and details are on the website at

<http://www.canadianpulmonaryfibrosis.ca/get-involved/advocacy/access-to-treatment/>

Your respirologist should be aware of the whole process you need to go through but if you need help please contact the Inspiration people at the link above