



Title	Policy for the Prescription and administration of Pirfenidone
Document Type	Guideline
Issue no	<i>Clinical Governance Support Team Use</i>
Issue date	August 2014
Review date	August 2017
Distribution	NHS Borders
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Developed by	JFF and Scottish ILD network/NICE guidance.
Equality & Diversity Impact Assessed	N/A

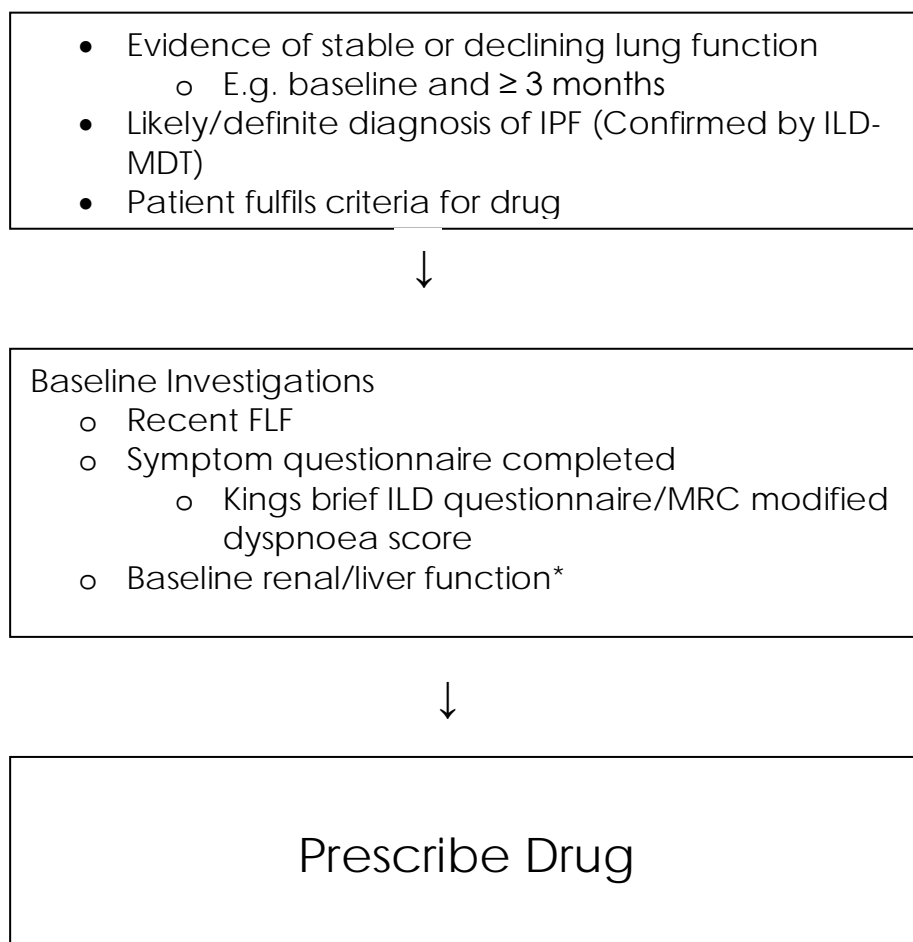
Pirfenidone Esbriet®

Licensed in mild to moderate idiopathic pulmonary fibrosis.

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive fibrotic interstitial lung disease of unknown origin. It is a difficult disease to diagnose and often requires the collaboration of a consultant respiratory physician, consultant radiologist and consultant histopathologist to reach a consensus diagnosis. Most patients with IPF experience symptoms of breathlessness and or cough. Symptoms progress over time associated with a decline in lung function, reduced quality of life and ultimately death.

In the UK median survival from diagnosis is 3 years. Approximately 20% will survive more than 5 years. The rate of progression varies greatly.

Patient decision tool

***Renal**

No dose adjustment in mild to moderate renal impairment

If creatine clearance <30mls/min do not prescribe

If ESRF on dialysis do not prescribe

***Liver**

No dose adjustment in mild to moderate hepatic impairment

If severe hepatic impairment do not prescribe

If end stage liver disease do not prescribe

Monitor bloods monthly for first 6 months then 3 monthly thereafter

- Renal function
- Hepatic function (AST/ALT/Alk Phos/Bili)

To prescribe Pirfenidone

1. Start with initiation pack

Covers first 2 weeks with dose escalation

267mg tds for 1 week, then 534mg tds for second week

2. Clinic review at this time to ensure drug tolerated and increase dose to 801mg tds
Option to dose reduce if tolerance is an issue

Follow up thereafter by clinical review and monitoring FLF and symptoms by way of questionnaire

See at 3 months, 6 months and 12 months if well. FLF and symptoms questionnaire used at each visit.

Cessation

NICE suggest stopping drug if FVC reduced by >10% in 12 months as this suggests lack of efficacy

Record reason for stopping e.g. intolerance, patient preference, etc

Yellow card any side effects.

Safety checklist

Liver function

- Pirfenidone is contraindicated in patients with severe hepatic impairment or end stage liver disease.
- There is a need to monitor liver function tests prior to initiation of treatment with Pirfenidone and at regular intervals thereafter – monthly for the first six months then 3 monthly thereafter.
- Elevations of serum transaminases can occur during treatment with Pirfenidone.
- In the event of significant elevation of liver aminotransferases the dose of Pirfenidone should be adjusted or treatment discontinued according to the guidelines in the Summary of Product
 - If a patient exhibits an aminotransferase elevation to >3 to ≤ 5 x upper limit of normal after starting Pirfenidone therapy, confounding medicinal products should be discontinued, other causes excluded, and the patient monitored closely.
 - If clinically appropriate the dose of Pirfenidone should be reduced or interrupted.
 - Once liver function tests are within normal limits Pirfenidone may be reintroduced and titrated up to the recommended daily dose if tolerated.
 - If a patient exhibits an aminotransferase elevation to ≤ 5 x upper limit of normal accompanied by symptoms or hyperbilirubinaemia, Pirfenidone should be discontinued and the patient should NOT be re-challenged.
 - If a patient exhibits an aminotransferase elevation to >5 x upper limit of normal, Pirfenidone should be discontinued and the patient should not be re-challenged.

Ongoing Monitoring

- Weight loss: Weight loss has been reported in patients treated with Pirfenidone.
- Physicians should monitor patients' weight, and when appropriate encourage increased caloric intake if weight loss is considered to be of clinical significance.
- Consumption of **grapefruit juice** is associated with inhibition of CYP1A2 and should be avoided during treatment with Pirfenidone.

Photosensitivity

- Patient should be informed that Pirfenidone is known to be associated with photosensitivity reactions and that preventative measures have to be taken
- Patients are advised to avoid or reduce exposure to direct sunlight

(including sunlamps)

- Patients should be instructed to use a sunblock daily, to wear clothing that protects against sun exposure and to avoid other medications known to cause photosensitivity.

Key warnings: please check

Before starting Pirfenidone check:

- For relevant drug interactions
- Whether the patient is hypersensitive to Pirfenidone
- Whether the patient has underlying hepatic disease
- Arrange monitoring for abnormal liver functions tests (including bilirubin): monthly for 1st six months of treatment , then 3 monthly thereafter
- Advise the patient to avoid the sun and all sources of U.V. light, to wear clothing that protects against sun exposure and what other measures can be taken such as taking extra care during the summer months
- Advise the patient to avoid grapefruit juice

Once Pirfenidone 267mg capsules have been administered patients are told to contact their GP or respiratory team if they experience:

- Any new and significant skin rash or any blistering or marked peeling of the skin
- If the skin or the whites of the eyes turn yellow or if they experience dark urine
- Any worrying or alarming symptoms or signs which might be related to Pirfenidone

Patient Information Sheet: Pirfenidone (Esbriet)

What is my medication?

Capsules containing 267mg of Pirfenidone

Why am I getting this drug?

This medicine has been shown to slow the formation of scar tissue (fibrosis) in the lung. It can be used for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).

How will this drug help you?

It is important to realise that this drug does not reverse or cure IPF. The aim is to slow the progression of the scarring (fibrosis) in your lungs.

How long does it take for Pirfenidone to work?

Treatment with Pirfenidone often takes 3-6 months to work as scar tissue forms gradually. It is important to understand that you may not feel any different while on treatment and it may not work in every patient.

When should I not take Pirfenidone?

- If you are allergic (hypersensitive) to it or any of the other ingredients in the medicine e.g. develop swelling of face, lips and/or tongue, new difficulty in breathing or wheezing.
- If you experience a severe skin reaction to sunlight or sunlamps (which you should NOT use) such as blistering and or marked peeling of the skin. Severe photosensitivity reactions are uncommon.
- If you are taking a medication called fluvoxamine (used to treat depression and obsessive compulsive disorder).
- If you have severe liver disease.
- If you have severe kidney disease.

- Pirfenidone can cause weight loss so your weight will be monitored at clinic.

How should I take Pirfenidone?

- Always take as directed by your doctor. If you are uncertain about your dose you should check with your doctor.
- Always take Pirfenidone with food and water as this reduced the risk of side effects like nausea (feeling sick) or dizziness
- Do NOT drink grapefruit juice whilst taking Pirfenidone as it may prevent it working properly.
- Swallow capsules whole- do not chew.
- Treatment with Pirfenidone usually begins with a lower dose, then increases over several weeks to the maintenance dose.
 - One capsule 3 times a day for first week
 - Two capsules 3 times a day for the second week
 - Three capsules three times a day thereafter
- The capsules are blue and gold in colour and have 'Intermurine 267mg' written in brown on them.
- You should continue taking the full dose unless your doctor advises otherwise
- Never take more than the dose that your doctor prescribes for you.

What to avoid whilst taking Pirfenidone?

- The following may reduce the effectiveness of Pirfenidone:
- Smoking- for advice about quitting speak to your GP or pharmacist
- Avoid grapefruit juice.
- Some medication- the team looking after you will review your medications as the drug is started. If you are in any doubt ask your pharmacist. Remember to tell your doctor all the medications that you are taking including all non prescription (over the counter) medications.

- Medicines that reduce the effectiveness of Pirfenidone include:
 - Omeprazole
 - Rifampacin
- Medication that may increase the side-effects of Pirfenidone include:
 - Ciprofloxacin
 - Tetracyclines
 - Amioderone
 - Propafenone
 - Fluoxetine
 - Paroxetine
 - Fluconazole

Pregnancy and breastfeeding?

Do not take Pirfenidone if you are pregnant or planning to become pregnant or think you might be pregnant. The risk to the unborn child is unknown. If you are breastfeeding you need to discuss the benefits and risks of taking Pirfenidone with the prescribing doctor.

Side-effects?

Like all medication Pirfenidone may cause side-effects in some patients. If you experience side-effects, talk to your doctor, pharmacist or respiratory specialist nurse. They can advise what options are available to manage side effects. Side-effects are generally mild to moderate in severity and often are manageable and reversible. Not everyone will experience side-effects, or to the same intensity. Taking Pirfenidone with food reduces some of the side effects. Your doctor may reduce the dose if you experience stomach problems, skin reactions to sunlight or significant changes in your liver blood tests.

Very common side effects:

- Skin reactions after going out in sunlight
- Feeling sick (nausea)
- Tiredness
- Diarrhoea
- Indigestion or stomach upset

Common side effects:

- Infections of the throat or airways going into the lungs
- Bladder infections
- Weight loss
- Loss of appetite
- Difficulty sleeping
- Dizziness, headache
- Feeling sleepy
- Changes in taste
- Hot flushes
- Shortness of breath
- Cough
- Indigestion, vomiting feeling bloated abdominal pain/discomfort, constipation, increased wind.
- Blood tests may show changes in the liver tests
- Skin problems- itch/redness/dry skin/rashes
- Muscle pain, aching joints/joint pain
- Chest pain
- Sunburn

Tips on managing side effects

1. Digestive problems:

- Take Pirfenidone with water and food

- Eating smaller [portions may help
- Your doctor may alter the dose of Pirfenidone for a period.

2. Skin problems:

- Use SPF50 sunblock daily- this can be provided on prescription- ask your GP
- Avoid excessive sun exposure
- Try and stay in the shade
- Be aware artificial light can also give reactions
- Avoid sunlamps
- Cover up when outside e.g. long sleeves and hat
- Avoid medicines that cause photosensitivity e.g. doxycycline
- Your doctor may reduce the Pirfenidone dose temporarily

3. Fatigue

This can be a common problem in people with IPF, including those taking Pirfenidone. You may have good days and bad days and it can help to pace yourself. Other ways you can help manage fatigue include:

- Keep a diary of how you are feeling and look for patterns in activity and tiredness
- If you feel overwhelmed by fatigue, speak to your doctor about your symptoms. Your doctor may reduce your Pirfenidone dose temporarily.

4. Liver Function

You will need a blood test before starting Pirfenidone and then at monthly intervals for the first 6 months, then 3 monthly thereafter while you are taking this medication. It is important that your liver blood tests are closely monitored whilst you are taking this drug.

5. Weight loss

Pirfenidone can cause weight loss. Your weight will be monitored whilst you are on this drug in the clinic.

How to store Pirfenidone?

Keep all medicines out of the reach of children.

Do not use Pirfenidone after the expiry date

Do not store above 30 degrees Celsius

For disposal of the drug when no longer required return to pharmacist, do not put into wastewater or household waste.

GP Information Sheet

Your patient is under the care of the Respiratory Medicine Team at Borders General Hospital.

Your patient has been started on a new oral anti-fibrotic drug called **Pirfenidone** (trade name Esbriet) for the treatment of idiopathic pulmonary fibrosis (IPF). It is licensed for use in patients with mild to moderate IPF i.e. those with a forced vital capacity of <80% predicted but > 50% predicted. You will not need to prescribe nor supervise treatment- the drug will be supplied via the BGH pharmacy- however we have created detailed information sheets for you and your patient which we hope are of help, and are grateful for your help with the blood monitoring. Any issues surrounding the patient on this drug please contact us either directly by phone 01896 826000 or via the respiratory medicine in box: respiratorymedicine@borders.scot.nhs.uk

For information

- The target maintenance dose is 3 capsules 3 times daily. Side effects are relatively common (skin rashes, GI upset and fatigue) and we know these are most likely to develop early on in treatment, particularly as the dose is titrated up, around 3-4 weeks of starting treatment.
- These symptoms often settle following dose reduction or temporary discontinuation of the drug. Please let us know if our patient becomes unwell and you think it might be related to the Pirfenidone.
- To avoid skin rashes we would be grateful if you could prescribe sun block which provides an UVB protection SPF50.
- We will arrange to see our patient at monthly intervals for the first 3

months in the clinic. Telephone/e-mail advice can be easily provided 01896 826000 asking to bleep the relevant person; or by e-mail from respiratorymedicine@borders.scot.nhs.uk

- At clinic visits we will monitor liver function and check if the patient is tolerating the treatment and alter dose as necessary. If you are doing the blood tests in the community and identify a rise in LFT's >2 times the upper limit of normal please let us know.
- There are some potential drug interactions detailed on the information sheets including commonly prescribed drugs such as omeprazole, doxycycline and ciprofloxacin.
- Medication should be taken with food and patients should avoid grapefruit juice whilst on treatment.
- Smoking can reduce the drugs efficacy and should be avoided.

If you have any questions or concerns please contact the respiratory team directly.

King's Brief ILD Questionnaire (K-BILD)

This questionnaire is designed to assess the impact of your lung disease on various aspects of your life. Read each question carefully and answer by CIRCLING the response that best applies to you. Please answer ALL questions, as honestly as you can.

PATIENT INFORMATION:

Name

Date:

Thank you for taking time to complete the following questionnaire.

1. In the last 2 weeks, I have been breathless climbing stairs or walking up an incline or hill.

1. Every time
2. Most times
3. Several Times
4. Some times
5. Occasionally
6. Rarely
7. Never

2. In the last 2 weeks, because of my lung condition, my chest has felt tight.

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

3. In the last 2 weeks have you worried about the seriousness of your lung complaint?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

4. In the last 2 weeks have you avoided doing things that make you breathless?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

5. In the last 2 weeks have you felt in control of your lung condition?

1. None of the time
2. Hardly any of the time
3. A little of the time
4. Some of the time
5. A good bit of the time
6. Most of the time
7. All of the time

6. In the last 2 weeks, has your lung complaint made you feel fed up or down in the dumps?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

7. In the last 2 weeks, I have felt the urge to breathe, also known as 'air hunger'.

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

8. In the last 2 weeks, my lung condition has made me feel anxious.

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

9. In the last 2 weeks, how often have you experienced 'wheeze' or whistling sounds from your chest?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

10. In the last two weeks how much of the time have you felt your lung disease is getting worse?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

11. In the last 2 weeks has your lung condition interfered with your job or other daily tasks?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

12. In the last 2 weeks have you expected your lung complaint to get worse?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

13. In the last 2 weeks, how much has your lung condition limited you carrying things, for example, groceries?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

14. In the last 2 weeks, has your lung condition made you think more about the end of your life?

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

15. Are you financially worse off because of your lung condition?

1. A significant amount
2. A large amount
3. A considerable amount
4. A reasonable amount
5. A small amount
6. Hardly at all
7. Not at all

The MRC Breathlessness Scale

Grade	Degree of breathlessness related to activities
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying on the level or walking up a slight hill
3	Walks slower than most people on the level, stops after a mile or so, or stops after 15 minutes walking at own pace
4	Stops for breath after walking about 100 yds or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when undressing

ILD MDT

Form completed by: Date:.....

Team present

Respiratory Physician JFF/SWW/other- please specify.....

Radiologist LF/LH/CR/JR/other – please specify.....

Specialist Nurse EF/ED/DC

Other- please specify

Patient label

Age.....

Drugs

.....
.....
.....
.....
.....

Occupational History:

Asbestos Exposure Y/N

ILD screening bloods Y/N results.....

Significant co-morbidities/PMH:

Smoking history:

Radiology review

Definite ILD	<input type="checkbox"/>	Possible ILD	<input type="checkbox"/>
Inconsistent with UIP	<input type="checkbox"/>	Sarcoidosis	<input type="checkbox"/>
HP acute/chronic	<input type="checkbox"/>	NSIP	<input type="checkbox"/>
Other	<input type="checkbox"/>		

Other please specify

Pathology Y/N Details:

Lung Function

FEV1 and % _____

FVC and % _____

DLCO % _____

DVCO/VA% _____

SpO2 % _____

SpO2% with exertion _____

6MWT _____

ECHO Y/N Result _____

Treatment plan

Pirfenidone candidate Y/N

Transplant candidate Y/N

Other treatment please specify

Needs discussion/referral to tertiary centre Y/N

Follow up plan

Copy for case notes; for GP; for RSN's, for ILD file.

TABLE 4. HIGH-RESOLUTION COMPUTED TOMOGRAPHY CRITERIA FOR UIP PATTERN

UIP Pattern (All Four Features)	Possible UIP Pattern (All Three Features)	Inconsistent with UIP Pattern (Any of the Seven Features)
<ul style="list-style-type: none"> ● Subpleural, basal predominance ● Reticular abnormality ● Honeycombing with or without traction bronchiectasis ● Absence of features listed as inconsistent with UIP pattern (see third column) 	<ul style="list-style-type: none"> ● Subpleural, basal predominance ● Reticular abnormality ● Absence of features listed as inconsistent with UIP pattern (see third column) 	<ul style="list-style-type: none"> ● Upper or mid-lung predominance ● Peribronchovascular predominance ● Extensive ground glass abnormality (extent > reticular abnormality) ● Profuse micronodules (bilateral, predominantly upper lobes) ● Discrete cysts (multiple, bilateral, away from areas of honeycombing) ● Diffuse mosaic attenuation/air-trapping (bilateral, in three or more lobes) ● Consolidation in bronchopulmonary segment(s)/lobe(s)

Definition of abbreviation: UIP = usual interstitial pneumonia.

TABLE 5. HISTOPATHOLOGICAL CRITERIA FOR UIP PATTERN

UIP Pattern (All Four Criteria)	Probable UIP Pattern	Possible UIP Pattern (All Three Criteria)	Not UIP Pattern (Any of the Six Criteria)
<ul style="list-style-type: none"> ● Evidence of marked fibrosis/ architectural distortion, ± honeycombing in a predominantly subpleural/ paraseptal distribution ● Presence of patchy involvement of lung parenchyma by fibrosis ● Presence of fibroblast foci ● Absence of features against a diagnosis of UIP suggesting an alternate diagnosis (see fourth column) 	<ul style="list-style-type: none"> ● Evidence of marked fibrosis / architectural distortion, ± honeycombing ● Absence of either patchy involvement or fibroblastic foci, but not both ● Absence of features against a diagnosis of UIP suggesting an alternate diagnosis (see fourth column) <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> ● Honeycomb changes only[‡] 	<ul style="list-style-type: none"> ● Patchy or diffuse involvement of lung parenchyma by fibrosis, with or without interstitial inflammation ● Absence of other criteria for UIP (see UIP PATTERN column) ● Absence of features against a diagnosis of UIP suggesting an alternate diagnosis (see fourth column) 	<ul style="list-style-type: none"> ● Hyaline membranes* ● Organizing pneumonia** ● Granulomas[†] ● Marked interstitial inflammatory cell infiltrate away from honeycombing ● Predominant airway centered changes ● Other features suggestive of an alternate diagnosis

Definition of abbreviations: HRCT = high-resolution computed tomography; UIP = usual interstitial pneumonia.

* Can be associated with acute exacerbation of idiopathic pulmonary fibrosis.

[†] An isolated or occasional granuloma and/or a mild component of organizing pneumonia pattern may rarely be coexisting in lung biopsies with an otherwise UIP pattern.

[‡] This scenario usually represents end-stage fibrotic lung disease where honeycombed segments have been sampled but where a UIP pattern might be present in other areas. Such areas are usually represented by overt honeycombing on HRCT and can be avoided by pre-operative targeting of biopsy sites away from these areas using HRCT.

PIRFENIDONE IN IDIOPATHIC PULMONARY FIBROSIS – NURSING PROTOCOL

Place patient addressograph here

Patient telephone number-

If pirfenidone STOPPED please document

Date: / /

Reason:

VISIT 1

Baseline forced vital capacity (FVC) - for pirfenidone to be prescribed FVC must be <80% predicted)

Date: / /

FVC: litres (actual)

FVC: litres (predicted)

FVC: % predicted

Sats % (state if on air or oxygen -)

Check

- No contraindications
- Patient has information sheet
- Patient understands about need for daily sunblock and to report if any worrying symptoms
- Patient has contact details of clinic team
- Baseline bloods (FBC, urea and electrolytes, LFTs including AST and ALT)
- Baseline MRC score
- Baseline KBILD (symptom) questionnaire
- If all of above fine, then issue prescription for PIRFENIDONE and SUNBLOCK, signed by consultant
- Schedule phone call for 2 weeks time

2 WEEK PHONE CALL

Date: / /

Check

- Tolerating treatment? Document any symptoms below

- Patient understands about need for daily sunblock and to report if any worrying symptoms
- They understand they may get side effects over the next few weeks on higher doses
- Patient has contact details of clinic team
- Schedule clinic visit in 2 weeks (1 month from Clinic Visit 1)

1 MONTH CLINIC REVIEW

Date: / /

Check

- Tolerating treatment? Document any symptoms below

- Patient understands about need for daily sunblock and to report if any worrying symptoms
- Patient has contact details of clinic team
- Bloods (FBC, urea and electrolytes, LFTs including AST and ALT)
- MRC score
- KBILD (symptom) questionnaire
- If all of above fine, then issue prescription for PIRFENIDONE and SUNBLOCK, signed by consultant
- Schedule clinic visit in 1 month

6 MONTH CLINIC REVIEW

Date: / /

Check

- Tolerating treatment? Document any symptoms below

- FVC: litres (actual)
- FVC: litres (predicted)
- FVC: % predicted
- Sats % (state if on air or oxygen -)
- Calculate relative change in FVC %

a] Difference between current FVC (litres) and baseline FVC (litre)

b] Divide this number by the baseline FVC

c] Multiply this by 100 to get the relative change in FVC %

For example if current FVC is 3 litres, baseline FVC was 4 litres, then the change between them is 1 litre, divided by the baseline FVC of 4 i.e. 0.25 and then multiplied by 100 = deterioration of 25%

- Let the consultant know if the relative change in FVC is >10% (since this suggests a deterioration despite pirfenidone). It may need to be stopped if so.
- Patient understands about need for daily sunblock and to report if any worrying symptoms
- Patient has contact details of clinic team
- Bloods (FBC, urea and electrolytes, LFTs including AST and ALT)
- MRC score
- KBILD (symptom) questionnaire
- If all of above fine, then issue prescription for PIRFENIDONE and SUNBLOCK, signed by consultant
- Schedule clinic visit in 3 months

12 MONTH CLINIC REVIEW

Date: / /

Check

- Tolerating treatment? Document any symptoms below

- FVC: litres (actual)
- FVC: litres (predicted)
- FVC: % predicted
- Sats % (state if on air or oxygen -)
- Calculate relative change in FVC %

a] Difference between current FVC (litres) and baseline FVC (litre)

b] Divide this number by the baseline FVC

c] Multiply this by 100 to get the relative change in FVC %

For example if current FVC is 3 litres, baseline FVC was 4 litres, then the change between them is 1 litre, divided by the baseline FVC of 4 i.e. 0.25 and then multiplied by 100 = deterioration of 25%

- Patient understands about need for daily sunblock and to report if any worrying symptoms
- Patient has contact details of clinic team
- Bloods (FBC, urea and electrolytes, LFTs including AST and ALT)
- MRC score
- KBILD (symptom) questionnaire
- If all of above fine, then issue prescription for PIRFENIDONE and SUNBLOCK, signed by consultant
- Schedule clinic visit in 3 months