

## Part 1. Policy scoping

### 1.1 Information about the policy / decision

1.1.1 What is the name of the policy / decision?

NICE Technology Appraisal TA504 - Pirfenidone for treating idiopathic pulmonary fibrosis (review of TA282)

1.1.2 Is this an existing, revised or a new policy / decision?

Revised

1.1.3 What is it trying to achieve? (intended aims/outcomes)

This guidance provides evidence-based recommendations on pirfenidone (Esbriet) for idiopathic pulmonary fibrosis in adults.

Pirfenidone is recommended as an option for treating idiopathic pulmonary fibrosis in adults only if:

- the person has a forced vital capacity (FVC) between 50% and 80% predicted
- the company provides pirfenidone with the discount agreed in the patient access scheme and
- treatment is stopped if there is evidence of disease progression (an absolute decline of 10% or more in predicted FVC within any 12-month period).

1.1.4 If there are any Section 75 categories which might be expected to benefit from the intended policy, please explain how.

This guidance should benefit adult patients as an option for treating idiopathic pulmonary fibrosis only if the person has a forced vital capacity (FVC) between 50% and 80% predicted, the company provides pirfenidone with the discount agreed in the patient access scheme and treatment is stopped if there is evidence of disease progression (an absolute decline of 10% or more in predicted FVC within any 12-month period).

1.1.5 Who initiated or wrote the policy?

National Institute for Health and Care Excellence (NICE)

1.1.6 Who owns and who implements the policy?

NICE owns the policy. The Department determines whether the policy should be endorsed for Northern Ireland, and, if endorsed, the HSCB / HSC Trusts implement it.

## 1.2 Implementation factors

Are there any factors which could contribute to/detract from the intended aim/outcome of the policy/decision? If yes, are they

Financial

Legislative

Other

Please explain:

## 1.3 Main stakeholders affected

Who are the internal and external stakeholders (actual or potential) that the policy will impact upon?

Staff

Service users

Other public sector organisations

Voluntary/community/trade unions

Other, please specify

Families/Carers

## 1.4 Other policies with a bearing on this policy / decision. If any:

Policy	Owner(s) of the policy
NICE Technology Appraisal TA282 - Pirfenidone for treating idiopathic pulmonary fibrosis (endorsed by DoH in May 2013).	NICE/DoH

## 1.5 Available evidence

What evidence/information (both qualitative and quantitative\*) have you gathered to inform this policy? Specify details for each of the Section 75 categories.

In developing this guidance, NICE have assessed its equality impact in scoping, consulting and before issuing the final guideline. This process is designed to mitigate the impact on equality. In addition, DoH locally consult on equality and human rights issues.

Section 75 category	Details of evidence/information
Religious belief	Religion will have no bearing on the guidance
Political opinion	Political opinion will have no bearing on the guidance
Racial group	<p>During the scoping process, consultees suggested that restricting treatment based on percent predicted forced vital capacity (FVC) (in line with the recommendations in previous NICE technology appraisal guidance for treating idiopathic pulmonary fibrosis) could discriminate against minority ethnic people, particularly people of south Asian family origin.</p> <p>The committee discussed these issues with the clinical experts during its first meeting, noting that the Global Lung Initiative has introduced equations to predict FVC values in minority ethnic groups and, when these equations were used, FVC values for minority ethnic people were comparable to the FVC values of people in clinical trials (most of whom were white). Thus, when using the newer equations, people would not be denied treatment because of their ethnicity.</p>
Age	This guidance is aimed at adult patients as an option for treating idiopathic pulmonary fibrosis only if the person has a forced vital capacity (FVC) between 50% and 80% predicted, the company provides pirfenidone with the

	<p>discount agreed in the patient access scheme and treatment is stopped if there is evidence of disease progression (an absolute decline of 10% or more in predicted FVC within any 12-month period).</p> <p>During the scoping process, consultees suggested that restricting treatment based on percent predicted forced vital capacity (FVC) (in line with the recommendations in previous NICE technology appraisal guidance for treating idiopathic pulmonary fibrosis) could discriminate against older people, because the reference tables are derived from populations under the age of 70 years, whereas the average age of people with idiopathic pulmonary fibrosis is 72 years.</p> <p>The committee discussed these issues with the clinical experts during its first meeting, noting that according to clinical experts, it is difficult to compare the predicted FVC values of older people with the FVC values of people in clinical trials because older people show a wide range of predicted FVC.</p> <p>The committee recognised the limitations of FVC but understood that, in clinical practice, wider patient characteristics would be taken into account when interpreting percent predicted FVC. It concluded that its recommendations did not discriminate against any groups of people protected by the Equality Act.</p>
Marital status	Marital status will have no bearing on the guidance
Sexual orientation	Sexual orientation will have no bearing on the guidance
Gender (Men and women generally)	Gender will have no bearing on the guidance
Disability (with or without)	During the scoping process, consultees suggested that restricting treatment based on percent predicted forced vital capacity (FVC) (in line with the recommendations in previous NICE technology appraisal guidance for treating idiopathic pulmonary fibrosis) could discriminate

	<p>against disabled people who have difficulty standing straight, because FVC is expressed as a percentage of the predicted normal value for a person of the same height.</p> <p>The committee discussed these issues with the clinical experts during its first meeting, noting that for people who cannot stand straight, their armspan (which approximates their height) can be used to calculate percent predicted FVC. Thus, when using this measure people would not be denied treatment because of their disability.</p>
<p>Dependants (with or without)</p>	<p>Dependant status will have no bearing on the guidance</p>

\* Qualitative data – refers to the experiences of individuals related in their own terms, and based on their own experiences and attitudes. Qualitative data is often used to complement quantitative data to determine why policies are successful or unsuccessful and the reasons for this.

Quantitative data - refers to numbers (that is, quantities), typically derived from either a population in general or samples of that population. This information is often analysed either using descriptive statistics (which summarise patterns), or inferential statistics (which are used to infer from a sample about the wider population).

## 1.6 Needs, experiences and priorities

Taking into account the information recorded in 1.1 to 1.5, what are the different needs, experiences and priorities of each of the following categories, in relation to the particular policy/decision? Specify details for each of the Section 75 categories

<b>Section 75 category</b>	<b>Details of needs/experiences/priorities</b>
Religious belief	There is no evidence that different religions will have any different needs, experiences, priorities or issues in relation to the guidance.
Political opinion	There is no evidence that different political opinions will have any different needs, experiences, priorities or issues in relation to the guidance.
Racial group	There is no evidence that different racial groups will have any different needs, experiences, priorities or issues in relation to the guidance.
Age	This guidance relates to adults patients as an option for treating idiopathic pulmonary fibrosis only if the person has a forced vital capacity (FVC) between 50% and 80% predicted, the company provides pirfenidone with the discount agreed in the patient access scheme and treatment is stopped if there is evidence of disease progression (an absolute decline of 10% or more in predicted FVC within any 12-month period).
Marital status	There is no evidence that those of different marital status will have any different needs, experiences, priorities or issues in relation to the guidance.
Sexual orientation	There is no evidence that different sexual orientation will have any different needs, experiences, priorities or issues in relation to the guidance.

<b>Section 75 category</b>	<b>Details of needs/experiences/priorities</b>
<b>Gender</b> (Men and women generally)	There is no evidence that different genders will have any different needs, experiences, priorities or issues in relation to the guidance.
<b>Disability</b> (with or without)	There is no evidence that people with disabilities will have any different needs, experiences, priorities or issues in relation to the guidance, however for people who cannot stand straight, their armspan (which approximates their height) can be used to calculate percent predicted FVC. Thus, when using this measure people would not be denied treatment because of their disability.
<b>Dependants</b> (with or without)	There is no evidence that those of different dependant status will have any different needs, experiences, priorities or issues in relation to the guidance.



## Part 2. Screening questions

2.1 What is the likely impact on equality of opportunity for those affected by this policy, for each of the Section 75 equality categories? (minor/major/none)		
Section 75 category	Details of policy impact	Level of impact? minor/major/none
Religious belief	No impact on equality of opportunity	None
Political opinion	No impact on equality of opportunity	None
Racial group	No impact on equality of opportunity	None
Age	No impact on equality of opportunity	None
Marital status	No impact on equality of opportunity	None
Sexual orientation	No impact on equality of opportunity	None
Gender (Men and women generally)	No impact on equality of opportunity	None
Disability (with or without)	No impact on equality of opportunity	None
Dependants (with or without)	No impact on equality of opportunity	None

**2.2** Are there opportunities to better promote equality of opportunity for people within the Section 75 equalities categories?

Section 75 category	If <b>Yes</b> , provide details	If <b>No</b> , provide reasons
Religious belief		No evidence to support this
Political opinion		No evidence to support this
Racial group		No evidence to support this
Age		No evidence to support this
Marital status		No evidence to support this
Sexual orientation		No evidence to support this
Gender (Men and women generally)		No evidence to support this
Disability (with or without)		No evidence to support this
Dependants (with or without)		No evidence to support this

<b>2.3</b> To what extent is the policy likely to impact on good relations between people of different religious belief, political opinion or racial group? (minor/major/none)		
Good relations category	Details of policy impact	Level of impact minor/major/none
Religious belief	The policy will not impact on good relations	None
Political opinion	The policy will not impact on good relations	None
Racial group	The policy will not impact on good relations	None

<b>2.4</b> Are there opportunities to better promote good relations between people of different religious belief, political opinion or racial group?		
Good relations category	If <b>Yes</b> , provide details	If <b>No</b> , provide reasons
Religious belief		No evidence to support this
Political opinion		No evidence to support this
Racial group		No evidence to support this

## 2.5 Additional considerations

### Multiple identity

Provide details of data on the impact of the policy on people with multiple identities (e.g. minority ethnic people with a disability, women with a disability, young protestant men, young lesbian, gay or bisexual persons). Specify relevant Section 75 categories concerned.

There will no impact on multiple identity

2.6 Was the original policy / decision changed in any way to address any adverse impacts identified either through the screening process or from consultation feedback. If so please provide details.

### Part 3. Screening decision

3.1 How would you summarise the impact of the policy / decision?

No impact  
Minor impact  
Major impact

X

Consider mitigation (3.4 – 3.5)

3.2 Do you consider that this policy / decision needs to be subjected to a full Equality Impact Assessment (EQIA)?

Yes - screened in  
No - screened out

X

3.3 Please explain your reason for making your decision at 3.2.

This guidance will impact on all sections of the community equally.

## Mitigation

If you have concluded at 3.1 and 3.2 that the likely impact is '**minor**' and an equality impact assessment is not to be conducted, you must consider mitigation (or scope for further mitigation if some is already included as per 2.6) to lessen the severity of any equality impact, or the introduction of an alternative policy to better promote equality of opportunity or good relations.

3.4 Can the policy/decision be amended or changed or an alternative policy introduced to better promote equality of opportunity and/or good relations?

Yes

No

3.5 If you responded "**Yes**", please give the **reasons** to support your decision, together with the proposed changes/amendments or alternative policy.

## Part 4. Monitoring

Monitoring is an important part of policy development and implementation. Through monitoring it is possible to assess the impacts of the policy / decision both beneficial and adverse.

4.1 Please detail how you will monitor the effect of the policy / decision?

To provide further assurance regarding implementation, the Regulation Quality Improvement Authority (RQIA) will extend its support of regional audits to cover some clinically based NICE guidance and will look at a sample of the technology appraisals each year.

4.2 What data will you collect in the future in order to monitor the effect of the policy / decision?

See above.

**Please note:** - For the purposes of the annual progress report to the Equality Commission you may later be asked about the monitoring you have done in relation to this policy and whether that has identified any Equality issues.

## Part 5. Disability Duties

5.1 Does the policy/decision in any way promote positive attitudes towards disabled people and/or encourage their participation in public life?

No

5.2 Is there an opportunity to better promote positive attitudes towards disabled people or encourage their participation in public life by making changes to the policy/decision or introducing additional measures?

No



## Part 6.Human Rights

6.1 Please complete the table below to indicate whether the policy / decision affects anyone's Human Rights?

ARTICLE	POSITIVE IMPACT	NEGATIVE IMPACT = human right interfered with or restricted	NEUTRAL IMPACT
Article 2 – Right to life			X
Article 3 – Right to freedom from torture, inhuman or degrading treatment or punishment			X
Article 4 – Right to freedom from slavery, servitude & forced or compulsory labour			X
Article 5 – Right to liberty & security of person			X
Article 6 – Right to a fair & public trial within a reasonable time			X
Article 7 – Right to freedom from retrospective criminal law & no punishment without law.			X
Article 8 – Right to respect for private & family life, home and correspondence.			X
Article 9 – Right to freedom of thought, conscience & religion			X
Article 10 – Right to freedom of expression			X
Article 11 – Right to freedom of assembly & association			X
Article 12 – Right to marry & found a family			X
Article 14 – Prohibition of discrimination in the enjoyment of the convention rights			X

ARTICLE	POSITIVE IMPACT	NEGATIVE IMPACT = human right interfered with or restricted	NEUTRAL IMPACT
1 <sup>st</sup> protocol Article 1 – Right to a peaceful enjoyment of possessions & protection of property			X
1 <sup>st</sup> protocol Article 2 – Right of access to education			X

6.2 If you have identified a likely negative impact who is affected and how?

*At this stage we would recommend that you consult with your line manager to determine whether to seek legal advice and to refer to Human Rights Guidance to consider:*

- *whether there is a law which allows you to interfere with or restrict rights*
- *whether this interference or restriction is necessary and proportionate*
- *what action would be required to reduce the level of interference or restriction in order to comply with the Human Rights Act (1998).*

6.3 Outline any actions which could be taken to promote or raise awareness of human rights or to ensure compliance with the legislation in relation to the policy/decision.

## Part 7 - Approval and authorisation

	<b>Name</b>	<b>Grade</b>	<b>Date</b>
Screening completed by	Jonathan Adair	Acting EO2	07/03/2018
Approved by <sup>1</sup>	Steven White	DP	
Forwarded to E&HR Unit <sup>2</sup>			

### Notes:

<sup>1</sup> The Screening Template should be approved by a senior manager responsible for the policy this would normally be at least Grade 7.

<sup>2</sup> When the Equality and Human Rights Unit receive a copy of the final screening it will be placed on the Department's website and will be accessible to the public from that point on. In addition, consultees who elect to receive it, will be issued with a quarterly listing all screenings completed during each three month period.