

## 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 TA507 - Sofosbuvir–velpatasvir–voxilaprevir for treating chronic hepatitis C

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

New

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

This guidance provides evidence-based recommendations on sofosbuvir–velpatasvir–voxilaprevir (Vosevi) for treating chronic hepatitis C in adults.

Sofosbuvir–velpatasvir–voxilaprevir is recommended as an option for treating chronic hepatitis C in adults, only if it is used as specified in table 1 of the guidance and the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.

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 chronic hepatitis C, only if it is used as specified in table 1 of the guidance and the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.

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/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, it was noted that chronic hepatitis C disproportionately affects certain populations such as certain <b>immigrant populations</b>, prison populations, and drug users, in terms of accessing the healthcare system and having access to innovative new treatments, however the committee discussed these issues in previous hepatitis C appraisals and concluded that its recommendations were fair for these groups of people.</p> <p>Having decided that sofosbuvir–velpatasvir–voxilaprevir should be recommended for all the groups for whom there was evidence presented, the committee agreed that its recommendations were fair. It concluded that no further consideration of potential equality issues was needed to meet NICE’s obligation to promote equality of access to treatment.</p>
Age	This guidance is aimed at adult patients as an option for treating chronic hepatitis C, only if it is used as specified in table 1 of the guidance and the company provides the drug at the same price or lower than that agreed with

	<p>the Commercial Medicines Unit.</p> <p>Clinical experts noted that sofosbuvir-velpatasvir-voxilaprevir would not be recommended for patients with severe renal impairment (as sofosbuvir is contra-indicated in such patients) or those with decompensated liver disease (as NS3/4 protease inhibitors which as a class are contra-indicated in such patients even though there is no specific data for voxilaprevir in this scenario).</p> <p>This was not considered to be a potential equality issue because the marketing authorisation for sofosbuvir-velpatasvir-voxilaprevir does not include patients with decompensated cirrhosis, and patients with severe liver impairment (SPC). The committee can only give recommendations within the marketing authorisation.</p> <p>In addition, the Haemophilia Society suggested that due to the nature of the infection route for people with bleeding disorders (via NHS treatment) with potentially multiple genotypes, people with a bleeding disorder should be seen as priority for this treatment.</p> <p>Again having decided that sofosbuvir–velpatasvir–voxilaprevir should be recommended for all the groups for whom there was evidence presented, the committee agreed that its recommendations were fair. It concluded that no further consideration of potential equality issues was needed to meet NICE’s obligation to promote equality of access to treatment.</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)	Disability will have no bearing on the guidance

Dependants (with or without)	Dependant status will have no bearing on the guidance
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\* 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 adult patients as an option for treating chronic hepatitis C, only if it is used as specified in table 1 of the guidance and the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.
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.
<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 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)</b>		
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 Are there opportunities to better promote good relations between people of different religious belief, political opinion or racial group?</b>		
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	23/03/2018
Approved by <sup>1</sup>	Steven White	DP	26/03/2018
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.