NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient/carer organisation statement (STA)

Ledipasvir-sofosbuvir for treating chronic hepatitis C

Thank you for agreeing to give us your views on this treatment that is being appraised by NICE and how it could be used in the NHS. Patients, carers and patient organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of receiving NHS care for the condition
- the experience of having specific treatments for the condition
- the outcomes of treatment that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the acceptability of different treatments and how they are given
- expectations about the risks and benefits of the treatment.

To help you give your views, we have provided a questionnaire. You do not have to answer every question — the questions are there as prompts to guide you. The length of your response should not normally exceed 10 pages.

1. About you and your organisation

Your name: Charles Gore

Name of your organisation: The Hepatitis C Trust

Your position in the organisation: CEO

Brief description of the organisation: The Hepatitis C Trust is a patient organisation, started and run by patients (although not all of our staff have hepatitis C). It is the national hepatitis C charity and is funded approximately 60% by grant-making trusts, 20% by the pharma industry,10% by central government and 10% by individuals/events/other. We have about 4,000 members of our patients association

(For example: who funds the organisation? How many members does the organisation have?)

We are asking for your collective view as an organisation and will be asking patient experts for their individual input separately. If you have the condition, or care for someone with the condition, you may wish to complete a patient expert questionnaire to give your individual views as well.

1. Living with the condition

What is it like to live with the condition or what do carers experience when caring for someone with the condition?

This varies. Some people experience few if any symptoms, while others can be so debilitated that they cannot work and find much of their social/emotional/sexual life significantly impaired (by for example chronic fatigue, mood swings and sexual dysfunction). Equally some people encounter stigma (because of the association with drug use usually) and even discrimination, including loss of job. People who were infected through the NHS often feel extremely angry and bitter because they feel the government has never accepted responsibility or adequately compensated them. People living with hepatitis C are currently experiencing significant fear that interferon-free therapy and hence a cure will be denied to them on the grounds of affordability, simply because the NHS is overspent, rather than on the grounds of cost-effectiveness.

2. Current practice in treating the condition

Which treatment outcomes are important to patients or carers? (That is, what would patients or carers like treatment to achieve?) Which of these are most important? If possible, please explain why.

A cure

What is your organisation's experience of currently available NHS care and of specific treatments for the condition? How acceptable are these treatments and which are preferred and why?

Current treatments all contain interferon, which has a major side-effect profile. This is exacerbated with the addition of first generation protease inhibitors for those with genotype 1. As a result many patients find them very difficult to tolerate, although others experience few problems. They are also long (24-48 weeks) and only about 70% effective. This is preventing many people from trying treatment, one of the reasons treatment numbers are so low. The length of treatment is also preventing significant amounts of treatment in prisons and therefore wasting a perfect opportunity to treat people and allow them to exit prison with at least one aspect of their lives improved.

3. What do patients or carers consider to be the advantages of the treatment being appraised?

Benefits of a treatment might include its effect on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (such as lifestyle and work)
- other people (for example, family, friends and employers)
- ease of use (for example, tablets rather than injection)
- where the treatment has to be used (for example, at home rather than in hospital)
- any other issues not listed above

Please list the benefits that patients or carers expect to gain from using the treatment being appraised.

A cure (SVR) with consequent improvement in life expectancy, quality of physical, emotional, social, employment and sexual life

Please explain any advantages that patients or carers think this treatment has over other NHS treatments in England.

More chance of a cure

Far fewer side effects

Shorter duration of treatment

If you know of any differences in opinion between patients or carers about the benefits of the treatment being appraised, please tell us about them.

None

4. What do patients and/or carers consider to be the disadvantages of the treatment being appraised?

Disadvantages of a treatment might include:

- aspects of the condition that the treatment cannot help with or might make worse
- difficulties in taking or using the treatment (for example, injection rather than tablets)
- side effects (for example, type or number of problems, how often, for how long, how severe. Please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- where the treatment has to be used (for example, in hospital rather than at home)
- impact on others (for example, family, friends and employers)
- financial impact on the patient and/or their family (for example, the cost of travel to hospital or paying a carer)
- any other issues not listed above

Please list any concerns patients or carers have about current NHS treatments in England.

Insufficient efficacy

Side effects, both during and after treatment

Length of treatment

Please list any concerns patients or carers have about the treatment being appraised.

Availability

If you know of any differences in opinion between patients or carers about the disadvantages of the treatment being appraised, please tell us about them.

None

5. Patient population

Are there any groups of patients who might benefit more from the treatment than others? If so, please describe them and explain why.

The groups who would particularly benefit are vulnerable groups often considered 'difficult to treat' such as prisoners, people who inject drugs and the homeless. In particular the shorter course of treatment may make treatment now possible where it was not before (e.g. in prison)

Are there any groups of patients who might benefit less from the treatment than others? If so, please describe them and explain why.

No

6. Research evidence on patient or carer views of the treatment

Is your organisation familiar with the published research literature for the treatment?

✓ Yes ☐ No

If you answered 'no', please skip the rest of section 7 and move on to section 8.

Please comment on whether patients' experience of using the treatment as part of their routine NHS care reflects the experiences of patients in the clinical trials.

Not currently in routine care

Do you think the clinical trials have captured outcomes that are important to patients? Are you aware of any limitations in how the treatment has been assessed in clinical trials?

Cure (SVR) is the most important outcome. This is the key endpoint in trials.

No limitations other than the usual bias of trials towards (psychosocially)

easier to treat patients

If the treatment being appraised is already available in the NHS, are there any side effects that were not apparent in the clinical trials but have emerged during routine NHS care?

Not in use

Are you aware of any relevant research on patient or carer views of the condition or existing treatments (for example, qualitative studies, surveys and polls)?

✓ Yes ☐ No

If yes, please provide references to the relevant studies.

Max Hopwood 'Recovery from hepatitis C treatments' University of New South Wales 2009

http://www.hepctrust.org.uk/Resources/HepC%20New/Hep%20C%20Resources/Reports/Recovery_from_hepatitis_C_treatments.pdf

The Hepatitis C Trust 'Post-treatment survey report' 2010

http://www.hepctrust.org.uk/Resources/HepC%20New/Hep%20C%20Resources/Reports/Post%20Treatment%20Survey%20Report%202010.pdf

7. Equality

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Protected characteristics are: age; being or becoming a transsexual person; being married or in a civil partnership; being pregnant or having a child; disability; race including colour, nationality, ethnic or national origin; religion, belief or lack of religion/belief; sex; sexual orientation.

Please let us know if you think that recommendations from this appraisal could have an adverse impact on any particular groups of people, such as:

- excluding from full consideration any people protected by the equality legislation who fall within the patient population for which the treatment is/will be licensed;

- having a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the treatment;
- any adverse impact on people with a particular disability or disabilities.

Please let us know if you think that there are any potential equality issues that should be considered in this appraisal.

None

Are there groups of patients who would have difficulties using the treatment or currently available treatments? Please tell us what evidence you think would help the Committee to identify and consider such impacts.

8. Other issues

Do you consider the treatment to be innovative?

✓ Yes ☐ No

If yes, please explain what makes it significantly different from other treatments for the condition.

The key point is that it does not require interferon

Are there any other issues that you would like the Appraisal Committee to consider?

Yes. Providers have historically treated few if any people who inject drugs (PWID) on the grounds that they will become reinfected and/or will not adhere to treatment. The evidence does not bear this out. Please therefore make a clear statement that this guidance applies to people who inject drugs too.

9. Key messages

In no more than 5 bullet points, please summarise the key messages of your submission.

- The treatment is innovative and extremely effective
- It is interferon-free which will be a step-change for patients in terms of tolerability and allow less monitoring
- Its good side-effect profile should allow more treatment in the community
- Shorter duration will allow more people to be treated in the same time obviating any capacity restraints

- It may permit treatment of vulnerable groups who to date have been largely sidelined such as prisoners, PWID and the homeless