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: Richard Hall

Name of your organisation: Liver4Life (L4L)

Your position in the organisation: Co-Founder

Brief description of the organisation: L4L is a new charity that puts patient care and support at the centre of everything we do. We are a national charity that supports any adult (patient or carer) who is affected by a liver condition. We receive funding from a number of sources including individual giving, trust funding, corporate funding (including pharmaceutical companies) and gift in kind donations. We have no membership scheme but we are affiliated with a number of patient support groups.

(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.

2. 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?

As with many liver conditions, the Hepatitis C virus (HCV) has few outward symptoms for a number of years other than fatigue. However, the liver is still being damaged constantly, and in many cases fibrosis or even cirrhosis may have occurred before the condition is detected. Once HCV is detected, many people report a personal need to remove the virus from their body. This is to prevent the progression of liver disease, but also the psychological effect of having the virus can make many people change their social habits, and withdraw from society.

3. 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.

Unlike many liver conditions there is a 'cure' for HCV. Through the use of drugs people have the ability to remove the virus from their body. This is the most important outcome for people. However, secondary outcomes include receiving appropriate information about the person's condition, appropriate timings for treatment, and people being involved in the treatment options and decisions being made.

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 treatment options include dual and triple therapy regimes which all involve the use of ribavirin and interferon. Both of these treatments have many side effects, and it can be difficult for patients to complete the treatment with full adherence due to these side effects.

There are also regional variations on how people are tested to HCV, who is offered treatment, and what support they are offered when on treatment.

4. 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.

The removal of Interferon from the treatment equation (and therefore the reduction or removal of side effects) is greatly anticipated by many people affected by HCV. The ability to have an all-oral treatment is also of great benefit as many people who have HCV are (or were) people who inject drugs. All the current treatment options include the injecting of interferon on a weekly basis, and some people are adverse to this idea. Also, an all-oral treatment should increase the adherence due to the reduction in the length of treatment.

The new treatment also has higher 'cure' rates of HCV and therefore better outcomes for people with this condition.

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

See above

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

5. 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.

Current treatment options include dual and triple therapy regimes which all involve the use of ribavirin and interferon. Both of these treatments have many side effects, and it can be difficult for patients to complete the treatment with full adherence due to these side effects.

There are also regional variations on how people are tested to HCV, who is offered treatment, and what support they are offered when on treatment.

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

People with HCV have a concern about the availability for this new treatment option. Within the HCV community there is a growing fear that due to the perceived cost of these new treatments, patients will be prioritised and selected only if they have tried the more difficult treatment of triple therapy including interferon. While it would be logistically impossible to treat everyone at the same time, the availability of a revolutionary treatment should be made available to anyone with HCV.

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

6. 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.

Any groups that fit within the treatment criteria would benefit from this treatment. However, as mentioned previously, it is also important that treatment is offered with the correct education, information and support to ensure that adherence and treatment are successful.

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

None

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

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

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.

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?

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?

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.

8. 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.

None

9. Other issues

Do you consider the treatment to be innovative?

Yes

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

This is an all-oral interferon free treatment, with greatly reduced side effects.

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

No

10. Key messages

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

- The proposed treatment is far superior to current treatments
- Information and education on treatment at all points of the treatment pathways is important for adherence and clearance of HCV
- Reduction in side effects will be an important step forward
- This treatment should be made available for all who qualify for it