Appendix G – patient/carer organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Sofosbuvir for treating chronic hepatitis C

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: Charles Gore

Name of your organisation: The Hepatitis C Trust

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc) ✓ **Chief Executive**
- other? (please specify)

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What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. Advantages

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

Infection with the hepatitis C virus (HCV). Sofosbuvir plus interferon and/or ribavirin will result in a sustained virological response (SVR), meaning completely undetectable viral RNA, and now accepted as equivalent to cure.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above

A SVR/cure prevents progression of HCV-related liver disease and hence life-threatening conditions such as cirrhosis and liver cancer. It may even result in fibrosis regression and the restoration of a normal liver. It also removes the symptoms of HCV, such as (sometimes extreme) tiredness, joint pain, cognitive impairment, depression. As a result it can restore quality of life – HCV often significantly impairs people's social life, libido, ability to work because of the physical and mental symptoms. In addition many people experience stigma because of HCV's association with drug use and in some cases discrimination at work: we have documented cases of people being refused work or being fired because of their HCV

2. Disadvantages

Please list any problems with or concerns you have about the technology. Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or thier family (for example cost of travel needed to access the technology, or the cost of paying a carer)

The side effects of this treatment really relate to the side effects of interferon and ribavirin both of which for most genotypes still need to be taken with sofosbuvir. However, in each case there is a reduction in duration compared to current standard of care and hence less interferon and ribavirin are needed so side effects are reduced. Sofosbuvir itself has a relatively mild side effect profile. The disadvantages are therefore less than the disadvantages associated with current standard of care.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

None that we are aware of as the national hepatitis C patient charity

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

It will particularly benefit those who are likely to have, or have had, problems with interferon, and those with genotype 2 or 3 who are intolerant or unwilling to take it.

Not all genotypes will get the same benefit.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Pegylated interferon plus ribavirin (plus either Boceprevir or Telaprevir for genotype 1).

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:
- improvement of the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc)

Pegylated interferon is a difficult drug to tolerate for most but not all patients. Boceprevir and Telaprevir are also often hard to tolerate. There is some evidence that interferon induces long term side effects that persist after the end of treatment in an as yet undetermined sub-set of patients. The use of sofosbuvir will lessen the amount of interferon needed and in the case of genotype 2 and probably genotype 3 patients obviate it altogether.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:
- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

We think this technology represents an all-round improvement

Research evidence on patient or carer views of the technology
If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

The technology is not yet used in routine care

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

The technology is not yet used in routine care

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Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

These two reports look at long term effects of interferon treatment:
1. Recovery from hepatitis C treatments Max Hopwood, NCHSR 2009 (http://www.hepctrust.org.uk/Resources/HepC%20New/Hep%20C%20Resources/Reports/Recovery_from_hepatitis_C_treatments.pdf)
2. Post treatment survey report, The Hepatitis C Trust 2010 (http://www.hepctrust.org.uk/Resources/HepC%20New/Hep%20C%20Resources/Reports/Post%20Treatment%20Survey%20Report%202010.pdf)

Availability of this technology to patients in the NHS
What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

This technology offers a better chance of a cure than the current standard of care. It is also clear from talking to the Trust's staff, most of whom have HCV, and from the thousands of callers to our helpline that the length and difficulty of current standard of care is a major barrier to people undertaking treatment. Amongst current intravenous drug users the fewer people who do treatment (successfully), the higher the prevalence of HCV and the more transmission of the virus. The availability of this technology offering shorter, more tolerable treatment will mean more people doing it and, because of its improved efficacy, more people being cured and regaining their quality of life. We also believe that the improvements offered by this technology will encourage more people to get tested, potentially saving their lives (people do not get tested if they have decided that even if they are infected they will not do treatment because it is so difficult).

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

A significant number of patients who could be cured will not be, with the inevitable consequences for their health. It may also deter people from getting tested.

Are there groups of patients that have difficulties using the technology?

Generally speaking no, except for those for whom ribavirin is a problem (e.g. either partner in couples wishing to conceive a child), or for whom interferon is a problem. However this technology requires less use of both ribavirin and interferon than current standard of care

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Equality
NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- could lead to recommendations that have 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 technology;
- could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

There has been a reluctance to treat substance users, many of whom may have other comorbidities such as mental health issues, partly from erroneous beliefs that they do not adhere to treatment and/or become reinfected. There is evidence to show that neither of these happens to any significant degree. Although this appraisal will not of itself lead to exclusion of this group, a failure to specifically *include* them in some form in the text may lead to their continued exclusion.

Other Issues
Please consider here any other issues you would like the Appraisal Committee to consider when appraising this technology.

Hepatitis C is an infectious disease. Curing people therefore has the possibility of reducing transmission (e.g. Martin et al: HCV treatment for prevention among people who inject drugs: modeling treatment scale-up in the age of direct acting antivirals. Hepatology 2013) and thereby lowering the cost per QALY. Since this is not accounted for in NICE's model, it should be clearly stated that for this reason the estimated ICER may be an over-estimate