NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Sofosbuvir for treating chronic hepatitis C

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name:
Dr Richard Aspinall

Name of your organisation
British Society of Gastroenterology

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? **Yes.**

- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? **Yes**

- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc.)? **Committee member, Liver Section, British Society of Gastroenterology**

- other? (please specify)

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What is the expected place of the technology in current practice?

Sofosbuvir is one of several highly anticipated new drugs for the treatment of Hepatitis C virus (HCV). The major advances of this new technology are potentially on several fronts:

1. It increases the rate of sustained virological response (SVR) compared to current standards of care in most genotypes of HCV
2. It may allow a shorter course of antiviral therapy
3. It appears to be associated with fewer significant adverse effects than current treatments
4. Consequently, it may reduce the requirement for side effect monitoring
5. In conjunction with other direct acting antivirals (such as ledipasvir, simeprevir or daclatasvir) it offers the potential of interferon-free therapy for individuals in whom interferon is poorly-tolerated or contrainidicated, potentially expanding the number of individuals who can access therapy

Current HCV therapy based on interferon alpha 2a/2b plus ribavirin (for genotypes 2 & 3) or those drugs plus a first-generation protease inhibitor telaprevir or boceprevir (for genotype 1) are able to achieve an SVR in the majority of treatment-naive patients. However, these regimens have considerable side effects, require close monitoring and are potentially hazardous in patients with decompensated liver cirrhosis. Their efficacy is also reduced in previous poor responders to combination antiviral therapy.

It is likely that sofosbuvir will be a particular advantage for these and other “niche” groups, potentially allowing more cirrhotic patients to be treated and prevent the development of decompensation with the accompanying risk of transplantation or death.

The choice of the appropriate antiviral regimen for the individual patient will require specialist input in secondary care with a multidisciplinary assessment of patient and virological factors. Use of this technology should be restricted to care providers with the necessary expertise given the expense of sofosbuvir.

The advantages and disadvantages of the technology

The major potential disadvantage of sofosbuvir is its considerable expense when compared to the existing standards of care. Consequently, NICE may wish to specifically examine individual areas where this technology may be applied with the best incremental improvement over existing therapies: For example, this may mean previous treatment failures or patients with more advanced liver disease or those whose personal characteristics (such as IL-28r genotype) may indicate a lower likelihood of response to current interferon-based therapy.

As stated above, the major advantages of sofosbuvir are its potential to improve efficacy, shorten duration, induce fewer adverse effects and have fewer drug-drug interactions than current antivirals. The potential for interferon and ribavirin-free therapies would be a major advance in tolerability of antiviral therapy for HCV.

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The published phase 2 and phase 3 clinical trials have used a mixture of patient and virological characteristics that have reflected UK patient populations. Indeed, some of the trials were conducted in multiple centres in the UK.

Equality and Diversity

HCV infection disproportionately affects ethnic minorities in the UK, particularly those of South Asian origin but the virus is also at increased prevalence in people from the Middle East, Africa and Eastern Europe. It is also of higher prevalence in the socioeconomically deprived and there is emerging data of frequent sexual transmission in men who sex with men.
Given the high prevalence in people who inject drugs or have a personal history of drug use, HCV services must ensure that they are easily accessible and that they use outreach programmes to enable these distinct populations to access potentially curative therapy.

Any additional sources of evidence

There will be additional evidence from current clinical trials presented at the forthcoming International Liver Congress (European Association for the Study of the Liver) meeting in London in April 2014.

Implementation issues

Implementation of this technology should be relatively straightforward, given its ease of use. The major training requirement would be to ensure optimum personalisation of therapy in individual patients and it is recommended that HCV treatment centres should hold minuted MDT meetings to discuss choice of antiviral therapy. NHS England is currently proposing specialist commissioning standards that would include such arrangements and treatment units should be in position to adopt sofosbuvir without too much difficulty if approved.