NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Ledipasvir-sofosbuvir for treating chronic hepatitis C

The impact on equality has been assessed during this appraisal according to the principles of the NICE equality scheme.

Consultation

1.	Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how?

During consultation of the draft scope, one consultee highlighted that NICE should be aware that HCV adversely affects certain populations, who could be considered at risk of being disadvantaged in terms of access to the healthcare system, and therefore at risk of inequity of access to innovative new treatments. For example:

- Certain immigrant populations
- Prison populations
- Intravenous drug users

Attendees at the scoping workshop agreed that this issue related to implementation and could not be addressed through technology appraisal recommendations.

2.	Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the Committee addressed these?

The Committee noted the potential equality issue raised by the company that minority ethnic groups and people with HIV co-infection are more highly represented in the HCV genotype 4 population than in the HCV genotype 1 or 3 populations. The Committee was satisfied that it had sufficiently considered the evidence available for people with HCV genotype 4 (albeit limited). In absence of mature data the Committee had attempted to bridge

this evidence gap by considering whether the evidence available for HCV genotype 1 was generalisable to the HCV genotype 4 population, and based on the cost effectiveness data had made recommendations that were aligned with the treatment duration stated in the marketing authorisation for genotype 4. Therefore, the Committee agreed that its recommendations were fair and did not constitute an equality issue.

3.	Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?
No.	

4.	Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
No.	

5.	Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No.	

6.	Are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?
N/A.	

7.	Have the Committee's considerations of equality issues been

described in the appraisal consultation document, and, if so, where?
Please see section 4.36 of the appraisal consultation document and the summary table.

Approved by Associate Director (name): Helen Knight

Date: 22 July 2015

Final appraisal determination

1.	Have any additional potential equality issues been raised during the consultation, and, if so, how has the Committee addressed these?

No. However, the Committee was aware of a comment made during the appraisal of daclatasvir for treating chronic hepatitis C that genotype 3 HCV is more prevalent in people of South Asian or Pakistani family origin than other genotypes of HCV. Another consultee stated that there is evidence supporting increased rates of steatosis, hepatocellular carcinoma, cirrhosis/decompensation and death in those infected with genotype 3 HCV compared to other genotypes. It noted that the data it had been presented with (see section 3.56 of the FAD) suggested that a small proportion of people with genotype 3 HCV were of Asian family origin and from other minority ethnic groups. It also noted that the proportion of people with this protected characteristic was not disproportionately higher in genotype 3 HCV compared with other genotypes (such as genotype 4 HCV). The Committee further acknowledged that the economic analysis had accounted for different rates of disease progression for each genotype. Based on the cost-effectiveness data it had made recommendations in line with the treatment duration and ribavirin co-administration stated in the marketing authorisation for each genotype population. Therefore, the Committee agreed that its recommendations were fair and did not constitute an equality issue.

2.	If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

N/A

3.	If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

N/A

4.	If the recommendations have changed after consultation, are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?
N/A	

5.	Have the Committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?
Please see section 4.37 of the final appraisal determination and the summary table.	

Approved by Centre or Programme Director (name): Meindert Boysen

Date: 13 October 2015