NHS England

NHS England Response to NICE ACD – Sofosbuvir for treating chronic hepatitis C (ID654)

NHS England would like to provide the following response to the ACD – Sofosbuvir for treating chronic hepatitis C.

NHS England is generally supportive of the recommendations contained within the ACD. Whilst we recognise some of the limitations of the RCTs performed in some genotypes we also recognise that sofosbuvir within the recommendations falls well within the accepted QALY threshold. We would like to raise the following points for consideration by NICE:

1. The wording in a number of the conclusions is that 'sofosbuvir is recommended *as an option* for…' but it is essential that treatment decisions are made by clinicians experienced in the management of hepatitis C (preferably working as a team through MDT meetings), to ensure that the most appropriate and cost effective treatments are used.

NHS England would expect that this is included in the recommendations.

2. The criteria relating to sofosbuvir with ribivirin needs to be more explicit. Given the cost of such treatment could be circa £70k per patient course we are concerned that the definition of *'interferon unsuitable – includes people who are intolerant to and ineligible for interferon'* could lead to wide interpretation and would lead to overuse of this combination. This regimen should clearly be seen as a second line therapy, for patients who are truly unable to take interferon.

NHS England would expect the criteria to be changed to exclude naïve patients unless they have a specific contraindication to pegylated interferon and that there is further refinement of the definition of 'interferon unsuitable'.

3. We note that Genotype 2 is not mentioned at all in the summary of treatment recommendations for sofosbuvir/pegylated interferon/ribivirin. Whilst we appreciate that evidence is limited in this group, for completeness there should be some statement as to whether or not NICE recommends this treatment as an option in Genotype 2.

NHS England asks that a statement as to the suitability of sofosbuvir for Genotype 2 is included in the recommendations.

4. NHS England would like to seek a waiver to the period within which NICE TA's are funded (ie within 3 months). The first reason for the request for an extension relates partly to the capacity of the NHS to meet what is expected to be an increased demand for drugs such as sofosbuvir. In other words, NHS England believes that the health technology cannot be appropriately administered until other appropriate health services resources, including staff, are in place. This includes the ability to monitor the results of treatment ie recording and reporting of a sustained virological response rate. The second reason is because at the prices proposed by the manufacturer in their NICE submission, this technology is not affordable at the quantum of new expenditure it would represent (particularly if the backlog of prevalent cases become immediately eligible for funding alongside incidence cases). The third reason is because further therapies for Hepatitis C are likely to become available in the foreseeable future, and the NHS would wish to see their comparative cost effectiveness assessed before selecting one particular option for hundreds of millions of pounds of new public investment.

NHS England formerly requests a waiver or substantial extension over several years to the normal implementation period for the reasons given above.