Dear NICE Technology Appraisal Team,

We as the UKCPA Hepatology and Gastroenterology Group would like to comment on the document circulated on the 21st November entitled**;** *Sofosbuvir for treating chronic hepatitis C [ID654] .Consultation on decision to amend the deferred funding*.

As stakeholders in the awaited NICE appraisal for sofosbuvir we were disappointed to see a request from NHSE to defer the funding of sofosbuvir at this very late stage of the process. We would ask that NICE consider the following in its decision making of this request

Cost of not treating patients with fibrosis

The suitable patient criteria for the NHSE Early Access Scheme for sofosbuvir was explicit and only those with Childs Pugh B and above were eligible. We are concerned that a large number of patients who did not fit the criteria for the scheme such as those with F3-F4 fibrosis will continue to advance towards cirrhosis whilst waiting for sofosbuvir to be NICE approved and funded. It is widely clinically acknowledge and supported by a robust evidence base that the presence or absence of cirrhosis has a clinically significant effect on the probability of achieving a sustained viral response.

If we wait for patients to become more advanced in their stage of liver disease before treating their hepatitis C then we increase the likelihood of treatment failure and hence the overall cost burden to the NHSE.

Cost of not treating cirrhotic patients

Although reference is made to extending the NHSE early access scheme we have yet no clarity on the specifics relating to this and whether it will broaden the patient criteria to include those with mild/moderate disease.

However if the scheme is not extended and/or the patient numbers are strictly capped then there inevitably will be a number of cirrhotic patients who will not be in a position to be treated. The cost modelling is available which indicates that the cost burden of patients with cirrhosis is significant. The sooner an intervention is made in a patient with hepatitis C then the lower the overall cost impact and importantly the greater the improvement in a patient's quality of life.

Waiting for specialist teams and networks to be assimilated

We welcome and fully support the comments made in point 10 of the document referencing increasing specialist pharmacist support to assist in the seamless delivery of sofosbuvir. However we do not feel the latter should be used as a time-limiting factor in terms of gaining access to sofosbuvir. The UKCPA Gastroenterology and Hepatology Group consists of a large number of pharmacists who are involved in the delivery of hepatitis C treatments and provides consistent support and education to its service users. This delivery of education can be tailored to meet increased interest and demand.

Services are 'fit for purpose'

Whilst we as a group acknowledge the reference made in point 11 around service pathways being 'fit for purpose' we would equally acknowledge that this is an unusual statement due to hepatitis C service pathways being in place for many years. These pathways have enabled patients to be successfully treated. Although national figures suggest we are treating < 5% of the infected population this is not soley due to services not being fit for purpose but due to multi-factorial logistical issues such as screening/diagnosis rates and centre capacities. We support the increased focus on solidifying these service pathways but would highlight that this will be a long term project and one that should not limit the introduction of sofosbuvir.

In summary; we support the creation of a robust and integrated hepatitis C delivery pathway as is outlined in the circulated document but would ask NICE to consider the points made above and to reconsider NHSEs request to defer funding. We would also ask you to take into account broadening the early access patient criteria if the decision is to approve NHSEs request. If funding is deferred then enabling a broader population to be treated via early access would be well received by this group.

Regards,

[redacted] on behlaf of the UKCPA Gastroenterology and Hepatology Committee

References

Health Protection Agency. The NHS Atlas of Variation in Healthcare for People with Liver Disease. Reducing unwarranted variation to increase value and improve quality. 2013