NICE CONSULTATION RESPONSE

The British Society of Gastroenterology (BSG) welcomes the latest revisions but is concerned that genotype 4,5 and 6 pts have been denied access when the data for this group is as strong as that for other groups that are included. For the remaining genotypes, this evaluation appears, a sensible and appropriate approach to the use of Sofosbuvir given the experience and published data. Patients infected with the two major genotypes, 1 and 3, will be able to access Sofosbuvir where appropriate, and specifically where the results of conventional PEG-interferon plus Ribavirin can be improved upon:

- The excellent outcome of G1 naives with 12/52 PEG-Interferon/Ribavirin/Sofosbuvir will deliver cure to most recipients with a reduced period of interferon exposure.
- Non-cirrhotic genotype 3 naives will continue to receive PEG/Riba in the clinic, whereas treatment exposed and/or cirrhotic 3's will have Sofosbuvir added unless they are Interferon intolerant, when they will just receive Sofosbuvir and ribavirin.
- Treatment experienced genotype 1's will also be eligible.

Genotype2 patients rarely fail short-course PEG/Ribavirin therapy and this will remain the mainstay of treatment. However those unable to tolerate PEG and the tiny number of treatment failures can access Sofosbuvir with Ribavirin. HIV co-infected and liver transplant patients, whilst small in number, represents a considerable challenge to conventional hep c therapy. Drug-drug interactions, frailty of liver and side-effects reduces acceptability and success of PEG based therapy. Access to Sofosbuvir for this group is a rational decision.

Reviewing the data and submission for genotype 4,5 & 6, minority subtypes in UK, it does appear that there is some inconsistency in the recommendations. The Neutrino study (page 8 and 9) of treatment naïve patients included 28 G4's, a single G5 and 6 G6's. An SVR was seen in 27/28 G4, and all G5 and G6's. In addition the Gilead ICER calculation is below the NICE threshold. Sofosbuvir would therefore appear cost-effective for these rare genotypes. Thus, genotype ,4,5 and 6 patients, logically, should be allowed access to Sofosbuvir.

In conclusion, the BSG would be broadly supportive of this evaluation. However, the BSG would advocate strongly for patients with genotypes 4,5 and 6 also being allowed access to Sofosbuvir. Exclusion of this small, but important group of patients disregards the limited, but indubitable evidence and detracts from what is otherwise a balanced and apposite judgement.