Skipton House
80 London Road
London
SE1 6LH

Sent by Email

PA Email: [redacted]

23 March 2015

Dear Sir

Please find enclosed NHS England's response to the ACD consultation on the hepatitis C drug combination Ledipasvir–sofosbuvir.

The consultation response has been prepared by the specialised services commissioning team and incorporates comments from clinical members of the hepatitis subgroup of the Infectious Diseases Clinical Reference Group. These comments do not describe a consensus view from the clinical body as this has not been reached due to the variety of issues facing the decision-making around hepatitis C and we expect clinicians to respond to the appraisal consultation as individuals from their own organisation. The Infectious Diseases Clinical Reference Group, under the chairmanship of Peter Moss, will be able to provide any further direct advice to the NICE appraisal process through NHS England as requested.

The introduction of the oral treatments for hepatitis C is a major change in the management of this disease and NHS England is supporting the implementation of these treatments in a stepwise fashion with our previous early access scheme for decompensated cirrhosis, the second access scheme for all patients with cirrhosis soon to be available, and the formation of the work programme to establish access to oral drugs for patients with F3 liver fibrosis in conjunction with an effective program of surveillance for other patients and a focus on the specific needs of the complex patient groups with hepatitis C.

The potential publication of the NICE guidance as a single technology appraisal has led to a number of concerns that are described in the consultation response. This is a rapidly changing field of medicine with new evidence emerging and NHS England would want to implement through modifications of its early access scheme policies. All stakeholders who have advised NHS England have indicated the importance of forming a multiple technology appraisal evaluating the new suite of medications, their combinations, the previously available treatments and the potential for shorter treatment durations. It is understood that a multiple technology appraisal would be best achieved in approximately 18 months time when the full range of these new medications have been licensed.

In the meantime NHS England is confident that treatment strategies through commissioning policy can be formed to substantially reduce the burden of liver disease associated with hepatitis C.

The potential impact of not adopting the stepwise implementation approach described above needs to be considered explicitly in terms of both suboptimal treatment of those with hepatitis C and the impact on the ability of the NHS to meets its wider obligations. Using the prices described within the ACD and an estimated population of non-cirrhosis G1 & G4 subtypes of circa 34000, the potential budget impact of the ACD (in excess of planned access schemes) is circa £1,300M. NHS England is clear that affordability is not part of the consideration of the Technology Appraisal process. However, as the potential financial impact is so high, there is minimal room for uncertainties in the assumptions taken to reach a position.

Until a NICE multiple technology appraisal can be carried out, NHS England would support with their Access Scheme Programmes a NICE ‘Recommended with Research’ position for patients without cirrhosis. These schemes would harness substantial ‘real world’ data on the effectiveness of treatments and their combinations to deliver much greater value for money for the NHS than proceeding with a NICE recommendation through a single technology appraisal at this stage.

Yours sincerely

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