NHS England

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NHS England
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16th December 2014

Dear Mr Boysen,

Waiver for implementation of NICE TA for Treatment for Hepatitis C

In October 2014 NHS England wrote to you requesting a waiver on the 90 day implementation of the NICE TAs for Sofosbuvir (mainly in conjunction with pegylated interferon) (ID654), and for Simeprevir (in conjunction with pegylated interferon and ribavirin) (ID668). Since then there have been a number of changes in the progress of new drugs for treating hepatitis C, and in the agreement of NHS England interim policies. There have also been further discussions with the clinicians on the Clinical Reference Group HCV subgroup. In the light of these changes NHS England would like to provide further information in support of a waiver for the NICE TA on Sofosbuvir.

NHS England has, since the previous letter, approved an interim policy document for the use of simeprevir in conjunction with pegylated interferon and ribavirin, for introduction early in 2015. This policy has dealt with the concerns about the introduction of this drug, and there is no longer a need to delay implementation of NICE TA ID668.

NHS England still believe that a delay in implementation of NICE TA ID654 (Sofosbuvir) is required to allow necessary infrastructure to be put in place to ensure equity of access to treatment and quality of care. This is in accordance with the requirements of the Health and Social Care Act 2012 and The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

b. The health technology cannot be appropriately administered until certain health service infrastructure requirements including goods, materials or other facilities are in place;

NHS Capacity to deliver implementation of the guidance

Although the new drugs for treating hepatitis C infection are less toxic than earlier regimens, selecting the most appropriate agents and course length remains highly complex. It is therefore important that expert clinicians are involved in prescribing decisions (while maintaining local delivery of care). NHS England is committed to putting appropriate systems in place to ensure that patients get the best quality of care, which we believe will be best provided by a combination of a network model and clinical guidelines. The networks will encompass MDT decision-making by teams experienced in the treatment of hepatitis C and in the appropriateness of initiation of treatment or continued surveillance of infected patients. MDTs including experienced clinicians will support the best quality of clinical care, and allow the most clinically and cost effective prescribing of high cost drug treatments in accordance with NHS England policy / NICE TAs. These innovations will take some time to develop and implement.

The network model will also ensure better equity of access. Many patients with chronic hepatitis C infection come from marginalised groups who do not engage well with health care, and there is a risk that without proper structures in place a significant proportion of patients in need will not get access to care. Mechanisms are needed to encourage outreach and engagement with patients outside traditional health care settings: these will be much easier to set up as part of formal clinical networks than with uncoordinated local commissioning. It is recognised that treatment with new drugs could be introduced without such systems, but this is likely to disadvantage many patients.

At the same time NHS England recognises that there is a substantial group of patients (mainly but not exclusively those with cirrhosis) who run the risk of serious harm if treatment is delayed. Patients with compensated HCV-related cirrhosis have a significant risk of developing hepatocellular carcinoma, or decompensated liver disease; this risk can be reduced dramatically by successful antiviral treatment.

By these means patients at greatest need will get rapid access to the best possible therapy, while a delay in implementation of NICE guidance will allow systems to be put in place to provide the most equitable and effective treatment for those patients who have less severe disease and so less urgent need for treatment.

The procurement advice to NHS England is that a competitive procurement route would be required to commission Hepatitis C Networks. This process would take about 4 to 5 months to complete. A key part of the model is partnership working and the preferred procurement model allows bidders the opportunity to develop their proposals jointly with others e.g. DGHs, prison health, LAs etc. The network proposal includes costings to support the need to increase core staff and to facilitate network partnerships and co-ordination of care.

As you will know, there IS a range of very promising developments in the treatment of hepatitis C expected in the near future, and we do have a concern that implementation of all new treatments should be managed holistically so as to leave clinicians with a coherent set of guidelines covering the full range of new and existing treatments, rather than being potentially distorted by the order in which products

come to market. We are concerned that there are potential ethical difficulties if we cannot take an overview of all available and soon to be available treatments. We would suggest that the availability of additional new treatments which are known to be coming to market, and the associated policy and decision making clinical networks, amounts to "health service infrastructure" without which implementation of a recommendation for Sofosbuvir in isolation would be problematic.

In order to ensure that the services we provide are both fit for purpose and can deliver these new treatments that ensure best outcomes for our patients we feel it is imperative that we are given sufficient time to implement the networks outlined above, before we are required to fund drugs that may otherwise be used inappropriately (having regard in particular to the need for specialist expertise and the imminent arrival of further new treatments for hepatitis C). This will also ensure systems are in place to collect outcomes data to inform future clinical practice. We are not making a case not to commission Sofosbuvir or Simeprevir prior to your recommendation taking effect. In recognition of the delay in implementation publication of the guidance if the waiver is granted NHS England will expect to have interim policies in place from April 2015 to cover key patient groups.

In summary NHS England will:

- Fast track for approval the service specification allowing the formation of clinical networks for the management of hepatitis C infection, and take the steps necessary to implement the specification within the 2015-16 year;

- Fast track for consideration by April 2015 for approval of an interim policy document (currently under development) to provide oral antiviral therapy to all cirrhotic patients (plus a small number with severe non-hepatic complications of HCV);

- Bring together as soon as possible a clinical body that will publish (non - statutory) clinical guidance to ensure the populations with the greatest need receive early treatment and that all patients receive the most appropriate and cost-effective therapy. This will incorporate both NICE guidance and any published NHS England interim clinical policies; and

- Implement the NICE TA ID654 on Sofosbuvir within 180 days of publication of the guidance, allowing treatment to be expanded to a wider group of patients.

NHS England requests that NICE:

- Agree to a waiver in the implementation of NICE TA ID654 as previously requested; and

- Include reference in their TA to the clinical guidance produced on behalf of NHS England to ensure that as far as possible all clinicians follow a national standard of care.

These proposals have the full support of the NHS England Clinical Reference Group subgroup on hepatitis C infection.

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National Medical Director