British HIV Association
BHIVA

BASHH

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Meindert Boysen
Programme Director, Centre for Health Technology Evaluation
National Institute for Health and Care Excellence (NICE)
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By email to: TACommD@nice.org.uk

Dear Mr Boysen

Thank you for allowing us to comment on the **Consultation on decision to amend the deferred funding: Hepatitis C (chronic) - sofosbuvir [ID654]**

The British HIV Association (BHIVA) represents health-care professionals and community members involved in the care of people living with HIV-infection including those coinfected with HIV. The British Association for Sexual Health and HIV (BASHH) membership includes medical practitioners, other healthcare workers, scientists and epidemiologists working in sexual health. The Advisory Committee had access to the BHIVA Guidelines for the management of hepatitis viruses in adults infected with HIV (*HIV Medicine* (2013), **14** (Suppl. 4), 1–71) and members of BHIVA and the British Association of Sexual Health and HIV (BASHH) were involved in the original sofosbuvir consultations.

BHIVA and BASHH strongly disagree with the NHS England request to defer funding of sofosbuvir, and the rationale on which this request is based, for the following reasons:

- The role of sofosbuvir in hepatitis C management and the need for this new agent has been agreed – this is simply a request to delay access to an approved drug
- Concerns regarding hepatitis treatment networks are unfounded since NHS England has already 'designated' viral hepatitis treatment centres and most regions have responded by creating new networks or strengthening those already in place. The sofosbuvir expanded access programme (EAP) demonstrated clearly the effectiveness of these networks and that the infrastructure required to start using sofosbuvir is already in place.
- There is a huge need for sofosbuvir and there will undoubtedly be some increase in prescribing activity but this does not necessarily translate to an over-burdening of staff and services. Most of the patients currently in need already access specialist services on a regular basis for monitoring and management of complications. Those patients who are still being treated with the limited options we have available require frequent visits for additional monitoring, symptom control, dose adjustment and prescribing of complex supportive treatments. We have the capacity to manage complex patients and complex treatments so we also have the capacity to manage increased prescribing of a shorter, simpler and better tolerated treatment such as sofosbuvir.
- Any short-term increase in clinic/staff time (and we emphasise that we believe the service we represent have the structure, flexibility and capacity to manage this) will be more than counterbalanced by a reduction in monitoring and complications.
- We disagree with the notion that making sofosbuvir available would increase numbers coming forward to test for HCV. For HIV-infected patients in the UK, about 90% have already been tested for HCV (UK CHIC Cohort, unpublished data) and guidelines suggest annual testing.

- The uptake of sofosbuvir treatment, as per the draft guidance, would not be as high as projected by NHSE; most patients with mild liver disease would prefer to wait for IFN-free therapy. It would be unjustifiable to delay therapy for those with more severe forms of liver disease (Metavir F3/F4) any further. In the context of HIV co-infection these patients would be at significant risk of disease progression in the next 6-9 months.
- We would welcome the development of a dashboard and database but do not accept that this should in any way delay access to sofosbuvir. Most clinics already have very robust monitoring and recall systems, particularly for patients with advanced liver disease (as evidence by the rapid and efficient uptake of sofosbuvir within the EAP). To put patients at risk of harm while insisting on systems to measure reduction in harm seems counter-intuitive at best. There are a significant number of patients who did not quite meet the criteria for the EAP who will progress rapidly.
- Since the sofosbuvir EAP closed in November 2014 we have no access to treatments outside of those already approved for use. This leaves non-genotype-1 patients and 1st generation protease inhibitor failures NO ALTERNATIVE TREATMENT OPTIONS. To delay access to sofosbuvir when there is simply no other option for many patients is unethical and unsafe. Whilst we applaud the NHSE for promising to re-institute expanded access to treatment for the sickest patients (de-compensated cirrhosis, Child-Pugh B/C), this still leaves many with advanced fibrosis 'at risk' whilst we delay therapy further and may require more to have access to IFN-free therapy when the programme gets underway after the delay because IFN would be contraindicated in those having progressed to CP-B/C disease or having had a de-compensation event.
- Boceprevir and telaprevir are associated with a high risk of adverse events resulting in extra visits, extra treatment, excess cost and suboptimal patient experience. In addition they are licensed only for genotype-1 infection leaving no available DAA for patients infected with other genotypes
- Patients are at risk of disease progression while access is delayed. Patient co-infected with HIV and hepatitis C experience a faster rate of disease progression and we believe that to condemn patients. Particularly those with already advanced liver disease, to further delay is simply unacceptable.
- Interactions between hepatitis C drugs and drugs used to treat HIV and HIV-related co-morbidities are complex and potentially dangerous. Sofosbuvir has minimal interaction potential including no interactions with HIV drugs so will reduce complexity, improve safety and increase access to hepatitis C therapy for co-infected individuals.

The group would also like to confirm its endorsement of the comments that are being submitted by Mr [redacted] on behalf of HIV i-Base.

We strongly urge NICE to reject the notion of delaying implementation of this very important guidance and stay with the time-lines promised so that we can prevent harm to vulnerable groups of patients, especially those with HCV/HIV co-infection.

Please contact the BHIVA Secretariat if you have any queries regarding these comments.

Yours sincerely

[redacted]

BHIVA Hepatitis Society Subcommittee

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BASHH [redacted]