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BRITISH LIVER TRUST

Pioneering liver health

9th December 2014

Please accept this as the British Liver Trust's response to the NICE appraisal of Sofosbuvir for treating chronic hepatitis C - Consideration of the case for extending the period before funding needs to be made available for a NICE technology appraisal

Liver Disease a Priority?

The NHS Outcomes Framework 2014/2015, Domain 1 – Preventing people from dying prematurely, prioritises liver disease as an improvement area and acknowledges that liver disease is a major cause of death. This is also reflected in the Public Health Outcomes Framework 2013- 2016 (4.6).[i]

Public Health England's Hepatitis C Annual Report[ii] highlighted that hospital admissions from hepatitis C-related end stage liver disease have risen from 608 in 1998 to 2,390 in 2012, while deaths have risen from 98 in 1996 to 428 in 2012. Liver transplants first registrations, where post-hepatitis C cirrhosis was an indication for transplant, have quadrupled from 45 in 1996 to 188 in 2013.

Therefore the British Liver Trust contends that if liver disease is a stated priority then all interventions that address this improvement area should be mandated for funding, especially when the 'cure' rates (sustained viral responses) as demonstrated with new hepatitis C treatments are high.

Justifiable Reasons for Funding Exemption?

The Secretary of State[iii] and the Health and Social Care Act 2013 set the deferred funding period for a NICE technology appraisal at 90 days from its issue.

This has been iterated in the Explanatory Memorandum to the National Institute for Health and Care Excellence (constitution and functions) and the health and social care information centre (functions) regulations 2013[iv]. Regulation 7 makes 'provision that requires the NHS Commissioning Board, clinical commissioning groups and, with respect to their public health functions, local authorities to comply with a NICE technology appraisal recommendation following a direction of the Secretary of State.'

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This regulation also underpins the NHS Constitution[v] right to "drugs and treatments that have been recommended by NICE technology appraisal guidance for use in the NHS, if your doctor says they are clinically appropriate for you."

A requirement to fund treatments recommended by NICE technology appraisal guidance previously applied to primary care trusts. This provision reflects the Government commitment to replicate the effect of the funding direction in the new NHS structures.

It is the position of the British Liver Trust having analysed NHS England's arguments that there are no viable reasons for an extension to this mandatory 90 days. We would emphasise that:

1. Sofosbuvir is both a clinically and cost-effective intervention for the treatment of hepatitis C[vi] and has met the NICE TAs affordability criteria.

2. The resources and arrangements for safe delivery of treatment are already in place as a result of the availability of telaprevir and boceprevir. Both these interventions have been funded by the NHS since they received NICE TA approvals in early 2012.

It is therefore not the case that 'Until last year the treatment of hepatitis C has depended on a combination of two relatively low cost drugs – interferon and ribavirin'.

3. There is considerable experience in the clinical trial use of sofosbuvir and other new hepatitis c treatments to ensure robust utilisation.

4. Sofosbuvir has been used in excess of 500 patients since the publication of the interim commissioning policy in April 2014[vii] by specialised centres that have effectively monitored sofosbuvir's availability.

Therefore the British Liver Trusts contends that NHS England's arguments do not satisfy the exemption criteria as defined in paragraph 2b and c of NICE's consultation document and that the mandatory funding of 90 days should be upheld. It is of great concern that lives will be lost if NHS England are allowed to delay treatment with sofosbuvir any longer.

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Yours faithfully

[redacted]
British Liver Trust

References:

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[iii] http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4075686.pdf

[iv] http://www.legislation.gov.uk/uksi/2013/259/pdfs/uksiem_20130259_en.pdf

[v] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf

[vi] http://www.nice.org.uk/guidance/indevelopment/gid-tag445/documents

[vii] http://www.england.nhs.uk/wp-content/uploads/2014/04/sofosbuvir-pol-stat.pdf