BMJ 2016;355:i6499 doi: 10.1136/bmj.i6499 (Published 1 December 2016)

NEWS

Wales approves new hepatitis C drug while England deliberates

Piotr Ozieranski [1], Lawrence King [2]

[1]Bath; [2]Cambridge

A new drug for hepatitis C has been approved for use in Wales ahead of its appraisal by the National Institute for Health and Care Excellence (NICE) for use in England and is being made available to patients in line with the Welsh strategy to prevent the transmission of the virus.

The All Wales Medicines Strategy Group recommended Epclusa (sofosbuvir with velpatasvir) for use in the NHS in Wales after concluding that the treatment would be cost effective for most patients.[1] The treatment will be funded under the Welsh patient access scheme. The price proposed by its manufacturer, Gilead, is confidential but likely to involve a discount from the UK list price of about £40 000 (€47 000; $50 000) for a 12 week course of treatment.

Epclusa is the first single tablet regimen approved to treat all hepatitis C genotypes, with clinical trial cure rates typically over 89%.[2] It is especially welcome for treating genotype 3, which affects about half of all people infected with hepatitis C in Wales. Currently patients with genotype 3 hepatitis C who haven't developed cirrhosis or advanced fibrosis are treated with regimens that include interferon, which are associated with considerable side effects.

Epclusa has been undergoing appraisal by NICE since March 2016, with final guidance scheduled for January 2017. The All Wales Medicines Strategy Group would not normally assess a drug that was being appraised by NICE, but in June this year the Welsh government asked the group to provide accelerated advice on Epclusa because of the unmet patient need, *The BMJ* has learnt.

Pervious NICE appraisals of new hepatitis C drugs Sovaldi (sofosbuvir) and Harvoni (ledipasvir with sofosbuvir) each took 21 months to complete. An investigation this year by *The BMJ* found that the delay was primarily due to unprecedented tactics on the part of NHS England, including trying to alter the outcome of the appraisal process.[3]

The urgent appraisal of Epclusa in Wales is consistent with the government's liver disease delivery plan, which emphasises the role of new treatments in tackling hepatitis C as a public health problem. The plan recognises that "targeting injecting drug users represents the biggest opportunity to prevent onward transmission of hepatitis C."[4]

As part of its strategy the Welsh government aims to increase the number of treated patients to 900 in 2016-17, with £12m for new hepatitis C drugs in 2015-16.[5]

Rather than adopting the treatment as a way to prevent hepatitis C infection, NHS England prioritises treating patients with cirrhosis and advanced fibrosis and has imposed strict treatment quotas.[6] In 2016-17 it allocated funding for 10 011 patients to be treated, out of 160 000 people in England with hepatitis C.

In its submission to NICE's appraisal of Epclusa, the charity Hepatitis C Trust has said that the quotas were in "direct contravention of NICE technology guidance [on Sovaldi and Harvoni]."

Commenting on the Welsh decision, Steve Ryder, consultant in hepatology and gastroenterology at Nottingham University Hospitals NHS Trust, said, "The Welsh plan is logical: we will not eliminate HCV until we stop new infections which are in people who inject drugs."

NHS England has emphasised that its ability to provide the revolutionary treatments depends on the industry's readiness to negotiate affordable pricing arrangements.[7]

In 2015 Gilead's worldwide revenue from hepatitis C drugs exceeded $19bn.

thebmj.com **Feature** A pill too hard to swallow: how the NHS is limiting access to high priced drugs doi:10.1136/bmj.i4117; **Analysis** Betting on hepatitis C: how financial speculation in drug development influences access to medicines doi:10.1136/bmj.i3718

1 All Wales Medicines Strategy Group. AWMSG Secretariat Assessment Report. Sofosbuvir/velpatasvir (Epclusa®) 400 mg/100 mg film-coated tablets. Reference number: 2417. Full submission 2016. www.awmsg.org/awmsgonline/app/appraisalinfo/2417.
2 NICE. NICE says yes to another hepatitis C drug 2016. Sep 2016. https://www.nice.org.uk/news/article/nice-says-yes-to-another-hepatitis-c-drug.
3 Gornall J, Hoey A, Ozieranski P. A pill too hard to swallow: how the NHS is limiting access to high priced drugs. *BMJ* 2016;354:i4117. doi:10.1136/bmj.i4117 pmid:27469086.
4 Welsh Government. Together for health: liver disease delivery plan. http://gov.wales/docs/dhss/publications/150505liveren.pdf.
5 All Wales Medicines Strategy Group. Clinical expert summary: sofosbuvir/velpatasvir (Epclusa®) 400 mg/100 mg film-coated tablets 2016. www.awmsg.org/awmsgonline/app/appraisalinfo/2417.
6 Hawkes N. NICE approval of new hepatitis drug could result in £700m bill for NHS. *BMJ* 2015;351:h5554. doi:10.1136/bmj.h5554 pmid:26491096.
7 England NHS. World hepatitis day: a chance to reflect on achievements to date and redouble efforts 2016. Nov 2016. www.england.nhs.uk/2016/07/peter-huskinson/ accessed 28 November 2016.