HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

<table>
<tr><td>1</td><td>Treatment & Condition

Elbasvir–grazoprevir for treating chronic hepatitis C.</td></tr>
<tr><td>2</td><td>Associated appraisal body & Summary of ruling

NICE Technology Appraisal Guidance (TA413) October 2016

Elbasvir–grazoprevir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, as specified in the table below, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.

<table>
<tr><th colspan="2">Elbasvir–grazoprevir for treating chronic hepatitis C in adults</th></tr>
<tr><th>Genotype</th><th>Treatment and duration</th></tr>
<tr><td>1a</td><td>Elbasvir–grazoprevir for 12 weeks.</td></tr>
<tr><td></td><td>Consider elbasvir–grazoprevir plus ribavirin for 16 weeks in people with a baseline hepatitis C virus RNA level of more than 800,000 IU/ml or specific NS5A polymorphisms causing at least a 5‑fold reduction in activity of elbasvir.</td></tr>
<tr><td>1b</td><td>Elbasvir–grazoprevir for 12 weeks.</td></tr>
<tr><td>4</td><td>Elbasvir–grazoprevir for 12 weeks.</td></tr>
<tr><td></td><td>Consider elbasvir‑grazoprevir plus ribavirin for 16 weeks in people with a baseline hepatitis C virus RNA level of more than 800,000 IU/ml.</td></tr>
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</td></tr>
<tr><td>3</td><td>Number of people in Northern Ireland expected to take up service/therapy

Hepatology clinicians have indicated that between 45 – 60 new cases of patients with hepatitis C requiring treatment with specialist therapies will present each year. Use of this therapy will be a further option for treatment for patients with the relevant genotype.

Actual use of this therapy will be included as part of the monitoring arrangements in place.</td></tr>
<tr><td>4.</td><td>Patient Access Scheme Availability

The company has agreed a nationally available price reduction for elbasvir–grazoprevir with the Commercial Medicines Unit. The contract prices agreed through the framework are commercial in confidence.</td></tr>
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5.	**Costs**
5.1	**Drug cost per patient per annum (for new and prevalent cases)** Elbasvir–grazoprevir (Zepatier®) is a fixed-dose combination drug. Elbasvir inhibits hepatitis C virus non‑structural viral protein NS5A and grazoprevir inhibits HCV NS3/4A protease. Elbasvir–grazoprevir has a marketing authorisation in the UK for treating chronic hepatitis C in adults. The recommendations in the marketing authorisation for the specific genotypes are listed below: • genotype 1a: 12 weeks (16 weeks plus ribavirin should be considered in patients with baseline HCV RNA level >800,000 IU/ml or the presence of specific NS5A polymorphisms causing at least a 5‑fold reduction in activity of elbasvir to minimise the risk of treatment failure) • genotype 1b: 12 weeks • genotype 4: 12 weeks (16 weeks plus ribavirin should be considered in patients with baseline HCV RNA level >800,000 IU/ml to minimise the risk of treatment failure). Elbasvir–grazoprevir is taken orally. The recommended dose of elbasvir–grazoprevir is 1 tablet once daily. Each tablet contains 50 mg elbasvir and 100 mg grazoprevir. Elbasvir–grazoprevir costs £12,166.67 per 28‑day pack. The total cost of a 12‑week treatment course is £36,500 per patient (list price).
5.2	**Total Drug Costs Per annum** The Resource Impact Statement from NICE that accompanies TA413 indicates that no resource impact is anticipated from this technology appraisal. Elbasvir–grazoprevir is a further option for treating genotype 1 or 4 chronic hepatitis C in adults.
5.3	**Infrastructure costs Per annum** It is recognised from the NICE guidance that there may be some infrastructure requirements associated with the introduction of this therapy. The HSC Board does not anticipate that this will be a significant resource and will work with clinicians to identify how the requirements compare to current infrastructure needs.
6.	**Expected implementation period** This therapy is currently available in Northern Ireland on a cost per case basis. It is expected that this therapy will be formally commissioned during quarter four of 2016/17. The introduction will be subject to confirmation of the level of funding available for the overall drug requirements for treating patients with hepatitis C. For patients being considered for drug treatment for chronic hepatitis C, it is expected that this regimen be considered as an option for treatment alongside the currently available therapies.

7.	**Commissioning arrangements** This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. The treatment will be commissioned through the existing Investment Proposal Templates and subsequent negotiation process as part of the overall commissioning arrangements for hepatitis drugs.
8.	**Monitoring arrangements** The Belfast Trust will be required to continue to provide regular updates to the Specialist Services Commissioning Team on the number of patients receiving treatment including the cost by drug therapy.
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.