

1.	<p>Treatment & Condition</p> <p>Sofosbuvir–velpatasvir (Epclusa®) for treating chronic hepatitis C.</p>																																																												
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance (TA430) January 2017</p> <p>Sofosbuvir–velpatasvir is recommended as an option for treating chronic hepatitis C in adults, as specified in table 1, only if the company provides the drug with the discount agreed in the simple discount agreement.</p> <table border="1" data-bbox="260 678 1439 1733"> <thead> <tr> <th colspan="5" data-bbox="260 678 1439 757">Table 1: Sofosbuvir–velpatasvir for treating chronic hepatitis C in adults</th> </tr> <tr> <th data-bbox="260 757 408 864" rowspan="2">HCV genotype</th> <th data-bbox="408 757 659 864" rowspan="2">Liver disease stage</th> <th data-bbox="659 757 963 864" rowspan="2">Treatment</th> <th colspan="2" data-bbox="963 757 1439 819">Recommendation according to treatment history</th> </tr> <tr> <th data-bbox="963 819 1224 864">Untreated</th> <th data-bbox="1224 819 1439 864">Treated</th> </tr> </thead> <tbody> <tr> <td data-bbox="260 864 408 958">1</td> <td data-bbox="408 864 659 958">With or without compensated cirrhosis</td> <td data-bbox="659 864 963 958">Sofosbuvir–velpatasvir</td> <td colspan="2" data-bbox="963 864 1439 958">Recommended</td> </tr> <tr> <td data-bbox="260 958 408 1205" rowspan="2">2</td> <td data-bbox="408 958 659 1140">Without cirrhosis</td> <td data-bbox="659 958 963 1140">Sofosbuvir–velpatasvir</td> <td data-bbox="963 958 1224 1140">Recommended only for people who cannot tolerate interferon or it is not suitable for them</td> <td data-bbox="1224 958 1439 1140">Recommended</td> </tr> <tr> <td data-bbox="408 1140 659 1205">Compensated cirrhosis</td> <td data-bbox="659 1140 963 1205">Sofosbuvir–velpatasvir</td> <td colspan="2" data-bbox="963 1140 1439 1205">Recommended</td> </tr> <tr> <td data-bbox="260 1205 408 1330" rowspan="2">3</td> <td data-bbox="408 1205 659 1238">Without cirrhosis</td> <td data-bbox="659 1205 963 1238">Sofosbuvir–velpatasvir</td> <td colspan="2" data-bbox="963 1205 1439 1238">Recommended</td> </tr> <tr> <td data-bbox="408 1238 659 1330">Compensated cirrhosis</td> <td data-bbox="659 1238 963 1330">Sofosbuvir–velpatasvir (with or without ribavirin)</td> <td colspan="2" data-bbox="963 1238 1439 1330">Recommended</td> </tr> <tr> <td data-bbox="260 1330 408 1424">4</td> <td data-bbox="408 1330 659 1424">With or without compensated cirrhosis</td> <td data-bbox="659 1330 963 1424">Sofosbuvir–velpatasvir</td> <td colspan="2" data-bbox="963 1330 1439 1424">Recommended</td> </tr> <tr> <td data-bbox="260 1424 408 1518">5</td> <td data-bbox="408 1424 659 1518">With or without compensated cirrhosis</td> <td data-bbox="659 1424 963 1518">Sofosbuvir–velpatasvir</td> <td colspan="2" data-bbox="963 1424 1439 1518">Recommended</td> </tr> <tr> <td data-bbox="260 1518 408 1612">6</td> <td data-bbox="408 1518 659 1612">With or without compensated cirrhosis</td> <td data-bbox="659 1518 963 1612">Sofosbuvir–velpatasvir</td> <td colspan="2" data-bbox="963 1518 1439 1612">Recommended</td> </tr> <tr> <td data-bbox="260 1612 408 1671">1-6</td> <td data-bbox="408 1612 659 1671">Decompensated cirrhosis</td> <td data-bbox="659 1612 963 1671">Sofosbuvir–velpatasvir (with ribavirin)</td> <td colspan="2" data-bbox="963 1612 1439 1671">Recommended</td> </tr> <tr> <td colspan="5" data-bbox="260 1671 1439 1733"> HCV = hepatitis C virus. Treated = the person's hepatitis C has not adequately responded to interferon-based treatment. </td> </tr> </tbody> </table>	Table 1: Sofosbuvir–velpatasvir for treating chronic hepatitis C in adults					HCV genotype	Liver disease stage	Treatment	Recommendation according to treatment history		Untreated	Treated	1	With or without compensated cirrhosis	Sofosbuvir–velpatasvir	Recommended		2	Without cirrhosis	Sofosbuvir–velpatasvir	Recommended only for people who cannot tolerate interferon or it is not suitable for them	Recommended	Compensated cirrhosis	Sofosbuvir–velpatasvir	Recommended		3	Without cirrhosis	Sofosbuvir–velpatasvir	Recommended		Compensated cirrhosis	Sofosbuvir–velpatasvir (with or without ribavirin)	Recommended		4	With or without compensated cirrhosis	Sofosbuvir–velpatasvir	Recommended		5	With or without compensated cirrhosis	Sofosbuvir–velpatasvir	Recommended		6	With or without compensated cirrhosis	Sofosbuvir–velpatasvir	Recommended		1-6	Decompensated cirrhosis	Sofosbuvir–velpatasvir (with ribavirin)	Recommended		HCV = hepatitis C virus. Treated = the person's hepatitis C has not adequately responded to interferon-based treatment.				
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3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>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.</p> <p>Actual use of this therapy will be included as part of the monitoring arrangements in place.</p>																																																												

4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The company (Gilead) has a simple discount agreement which provides a discount to the list price of sofosbuvir–velpatasvir at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
5.	<p>Costs (<i>before PAS if applicable</i>)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Sofosbuvir–velpatasvir (Epclusa®) is a fixed-dose combination drug. It is taken orally. The recommended dose is 1 tablet once daily, for 12 weeks. Each tablet contains 400 mg sofosbuvir and 100 mg velpatasvir. The marketing authorisation states that decompensated cirrhosis should be treated with sofosbuvir–velpatasvir in combination with ribavirin, for 12 weeks. Ribavirin plus sofosbuvir–velpatasvir may also be considered for people with genotype 3 HCV who have compensated cirrhosis.</p> <p>Sofosbuvir–velpatasvir costs £12,993.33 per 28 day pack at the list price. The total cost of a 12week treatment course is £38,980 per person. Ribavirin costs £246.65 per 56-tablet pack. The total cost of a 12week treatment course of sofosbuvir–velpatasvir with ribavirin is £40,089.93.</p> <p>The company has a simple discount agreement which provides a discount to the list price of sofosbuvir–velpatasvir at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
5.2	<p>Total Drug Costs Per Annum</p> <p>It is not anticipated that the use of this therapy will generate additional costs. The Resource Impact Statement from NICE that accompanies TA413 indicates that no resource impact is anticipated from this technology appraisal. Sofosbuvir–velpatasvir is a further option for treating chronic hepatitis C in adults with the relevant genotypes.</p>
5.3	<p>Infrastructure costs Per annum</p> <p>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.</p>
6.	<p>Expected implementation period</p> <p>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 one of 2017/18. 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.</p>

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 HSC Board will assess any recurrent requirements on the basis of cost per case requests received. Any recurrent costs will be included in the HSC Board financial planning assumptions for predicted growth in this area in 2018/19.
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 specialist drug treatment for Hepatitis C 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.