

1.	<p>Treatment & Condition</p> <p>Sofosbuvir–velpatasvir–voxilaprevir for treating chronic hepatitis C.</p>															
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA507 (February 2018)</p> <p>Sofosbuvir–velpatasvir–voxilaprevir (Vosevi®) is recommended as an option for treating chronic hepatitis C in adults, only if it is used as specified in the table below and the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.</p> <table border="1" data-bbox="261 775 1445 1088"> <thead> <tr> <th colspan="4">Sofosbuvir–velpatasvir–voxilaprevir for treating chronic hepatitis C</th> </tr> <tr> <th>Treatment history</th> <th>Hepatitis C genotype</th> <th>Liver disease stage</th> <th>Recommendation</th> </tr> </thead> <tbody> <tr> <td>Previous direct-acting antivirals</td> <td>1-6</td> <td rowspan="2">With or without compensated cirrhosis</td> <td>Recommended for 12 weeks</td> </tr> <tr> <td>No direct-acting antivirals</td> <td>3</td> <td>Recommended for 8 weeks</td> </tr> </tbody> </table>	Sofosbuvir–velpatasvir–voxilaprevir for treating chronic hepatitis C				Treatment history	Hepatitis C genotype	Liver disease stage	Recommendation	Previous direct-acting antivirals	1-6	With or without compensated cirrhosis	Recommended for 12 weeks	No direct-acting antivirals	3	Recommended for 8 weeks
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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 80 – 100 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>(<u>Yes</u>/No)</p> <p>The company (Gilead Sciences) has agreed a nationally available price reduction for sofosbuvir–velpatasvir–voxilaprevir with the Commercial Medicines Unit. The contract prices agreed through the framework are commercial in confidence.</p>															
5.	<p>Infrastructure Requirements</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>															

<p>6.</p>	<p>Expected implementation period</p> <p>This therapy is currently available in Northern Ireland on a cost per case basis.</p> <p>It is expected that this therapy will be formally commissioned during 2018/19. The introduction will be subject to confirmation of the level of funding available and submission of an IPT by Belfast Trust for the overall drug cost 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>
<p>7.</p>	<p>Commissioning arrangements</p> <p>This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis.</p>
<p>8.</p>	<p>Monitoring arrangements</p> <p>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.</p>
<p>9.</p>	<p>DoH (NI) Legislative/Policy Caveats</p> <p>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.</p>