

1	<p>Treatment & Condition</p> <p>Sofosbuvir for treating chronic hepatitis C.</p>																																													
2	<p>Associated appraisal body & Summary of</p> <p>NICE technology appraisal guidance 330 (February 2015)</p> <p>Sofosbuvir is recommended as an option for treating chronic hepatitis C in adults, as specified in Table 1.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="5" style="text-align: center;">Table 1: Sofosbuvir for treating adults with chronic hepatitis C</th> </tr> <tr> <th></th> <th colspan="2" style="text-align: center;">Sofosbuvir in combination with peginterferon alfa and ribavirin</th> <th colspan="2" style="text-align: center;">Sofosbuvir in combination with ribavirin</th> </tr> <tr> <th style="text-align: center;">HCV Genotype</th> <th style="text-align: center;">Treatment history</th> <th style="text-align: center;">Recommendation</th> <th style="text-align: center;">Treatment history</th> <th style="text-align: center;">Recommendation</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Adults with genotype 1</td> <td style="text-align: center;">All</td> <td style="text-align: center;">Recommended</td> <td style="text-align: center;">All</td> <td style="text-align: center;">Not recommended</td> </tr> <tr> <td rowspan="2" style="text-align: center;">Adults with genotype 2</td> <td rowspan="2" style="text-align: center;">All</td> <td rowspan="2" style="text-align: center;">Not licensed for this population</td> <td style="text-align: center;">Treatment-naive</td> <td style="text-align: center;">Only recommended for people who are intolerant to or ineligible for interferon</td> </tr> <tr> <td style="text-align: center;">Treatment-experienced</td> <td style="text-align: center;">Recommended</td> </tr> <tr> <td rowspan="2" style="text-align: center;">Adults with genotype 3</td> <td style="text-align: center;">Treatment-naive</td> <td style="text-align: center;">Only recommended for people with cirrhosis</td> <td style="text-align: center;">Treatment-naive</td> <td style="text-align: center;">Only recommended for people with cirrhosis who are intolerant to or ineligible for interferon</td> </tr> <tr> <td style="text-align: center;">Treatment-experienced</td> <td style="text-align: center;">Recommended</td> <td style="text-align: center;">Treatment-experienced</td> <td style="text-align: center;">Only recommended for people with cirrhosis who are intolerant to or ineligible for interferon</td> </tr> <tr> <td style="text-align: center;">Adults with genotype 4, 5 or 6</td> <td style="text-align: center;">All</td> <td style="text-align: center;">Only recommended for people with cirrhosis</td> <td style="text-align: center;">All</td> <td style="text-align: center;">Not recommended</td> </tr> </tbody> </table> <p>HCV – hepatitis C virus</p> <p>Treatment-naive – the person has not had treatment for chronic hepatitis C</p> <p>Treatment-experienced – the person's hepatitis C has not adequately responded to interferon-based treatment</p>					Table 1: Sofosbuvir for treating adults with chronic hepatitis C						Sofosbuvir in combination with peginterferon alfa and ribavirin		Sofosbuvir in combination with ribavirin		HCV Genotype	Treatment history	Recommendation	Treatment history	Recommendation	Adults with genotype 1	All	Recommended	All	Not recommended	Adults with genotype 2	All	Not licensed for this population	Treatment-naive	Only recommended for people who are intolerant to or ineligible for interferon	Treatment-experienced	Recommended	Adults with genotype 3	Treatment-naive	Only recommended for people with cirrhosis	Treatment-naive	Only recommended for people with cirrhosis who are intolerant to or ineligible for interferon	Treatment-experienced	Recommended	Treatment-experienced	Only recommended for people with cirrhosis who are intolerant to or ineligible for interferon	Adults with genotype 4, 5 or 6	All	Only recommended for people with cirrhosis	All	Not recommended
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3	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>Based on a pro rata calculation extrapolated from the Costing Statement that accompanies NICE TA330, the population eligible for treatment with Sofosbuvir is approximately 971 people per year in Northern Ireland. Hepatology clinicians have indicated that the number of patients in Northern Ireland that would potentially benefit from this therapy would be significantly lower.</p> <p>Furthermore, treatment for patients with hepatitis C is evolving rapidly and additional therapies with increased sustained virological responses (SVR) are currently under consideration by NICE. Subject to a positive outcome from NICE, clinicians have indicated that these new therapies would be preferential for patients. As a result, it is anticipated that the use of this therapy will be minimal.</p>
4	<p>Patient Access Scheme availability</p> <p>Not applicable</p>
5	<p>Costs (before PAS if applicable)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Dose = 1 x 400mg tablet daily for 12 or 24 weeks</p> <p>The cost of sofosbuvir is £11,660.98 per 28 tablet pack of 400 mg tablets. The cost of a 12 week course of treatment is £34,982.94 and a 24 week course is £69,965.88, not including the cost for ribavirin and peginterferon alfa. Costs may vary in different settings because of negotiated procurement discounts</p> <p>These costs need to be offset against the cost of existing patient treatments.</p>
5.2	<p>Infrastructure costs per patient per annum</p> <p>It is recognised from the NICE guidance that there may be 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>
5.3	<p>Current in year costs</p> <p>Clinicians have indicated that the use of this therapy in 2015/16 will be minimal. For the small number of patients commenced on this therapy in 2015/16, this will be an alternative treatment to those therapies currently available. Any additional costs over and above the costs of existing therapies will be funded from 2014/15 specialist drug monies earmarked for hepatitis C.</p>
5.4	<p>Recurrent overall costs per annum</p> <p>Based on a pro rata calculation extrapolated from the NICE costing statement that accompanies TA330, the cost of introducing this therapy in Northern Ireland is estimated at £3.6m.</p> <p>However as outlined, treatment for patients with hepatitis C is evolving rapidly and</p>

	<p>additional therapies with increased sustained virological responses (SVR) are currently under consideration by NICE. Subject to a positive outcome from NICE, clinicians have indicated that these new therapies would be preferential for patients. As a result, it is anticipated that the use of this therapy will be minimal. For the small number of patients accessing this therapy, this will be alternative treatment to those currently available and the costs of the existing treatment will offset the recurrent requirements. Any additional requirements will be funded from 2014/15 specialist drug funding for hepatitis C.</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>It is not anticipated that there will be cost savings associated with the introduction of this treatment. The costs of current therapies for those patients with hepatitis C will offset the total requirements of introducing sofosbuvir.</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 the third quarter of 2015/16. 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.</p>
7	<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>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.</p> <p>An investment proposal template will be completed by the BHSCT and the final profile of resources and monitoring arrangements agreed.</p>
8	<p>Monitoring arrangements</p> <p>The Trust will be required to provide a quarterly report to the Specialist Services Commissioning Team on the number of patients receiving treatment including the cost of the drugs per patient.</p>
9	<p>DHSSPS 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>