

1	Treatment & Condition		
	Ledipasvir–sofosbuvir (Harvoni®) for treating chronic hepatitis C		
2	Associated appraisal body & Summary of ruling		
	NICE Technology Appraisal guidance (TA363) November 2015		
	Ledipasvir–sofosbuvir is recommended as an option for treating chronic hepatitis C in adults, as specified in the following table:		
	Ledipasvir–sofosbuvir for treating adults with chronic hepatitis C		
	HCV genotype, liver disease stage	Duration (weeks)	Recommendation according to treatment history
		Untreated	Treated
	Ledipasvir–sofosbuvir		
	Genotype 1, without cirrhosis	8	Recommended
		12	Not recommended
		24	Not recommended
	Genotype 1, with compensated cirrhosis	12	Recommended
			Not recommended
			Not recommended
	Genotype 4, without cirrhosis	12	Not recommended
		24	Not recommended
	Genotype 4, with compensated cirrhosis	12	Recommended
			Not recommended
			Not recommended
	Ledipasvir–sofosbuvir plus ribavirin		
	Genotype 1	Not the licensed regimen for this population	
	Genotype 3	24	Not recommended
	Genotype 4	Not the licensed regimen for this population	

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.</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>The company has agreed a nationally available price reduction for ledipasvir sofosbuvir with the Commercial Medicines Unit. The contract prices agreed are 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>The cost of ledipasvir–sofosbuvir is £12,993.33 per 28-tablet pack. The cost of a 8-week course of treatment is £25,986.66 per patient and a 12-week course is £38,979.99 per patient.</p>
5.2	<p>Infrastructure costs per patient 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>
5.3	<p>Current in year costs</p> <p>Ledipasvir–sofosbuvir (Harvoni[®]) is an additional option for the treatment of patients with hepatitis C. Any 2015/16 costs will be addressed by the funding made available to Belfast Trust for the treatment of patients with hepatitis C.</p>
5.4	<p>Recurrent overall costs per annum (<i>including additional costs</i>)</p> <p>The recurrent costs of implementing this TA have been included in the HSC Board financial planning assumptions for predicted growth in this area from 2016/17. The position for 2016/17 is subject to confirmation by DHSSPS of the funding position for specialist drug therapies.</p> <p>Recurrent funding of £1.7m has been provided to the BHSCT to treat approximately 45 to 60 patients per annum. The costs of treating patients will be closely monitored by the HSCB.</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 recurrent funding available for current therapies for those patients with hepatitis C will offset the total requirements of introducing this regimen.</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 from the beginning of 2016/17. 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>
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>
8	<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>
9	<p>DHSSPS Legislative/Policy Caveats <i>(NICE guidance only)</i></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>