

1	<p>Treatment & Condition</p> <p>Simeprevir in combination with peginterferon alfa and ribavirin for treating genotypes 1 and 4 chronic hepatitis C.</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE technology appraisal guidance 331.</p> <p>Simeprevir, in combination with peginterferon alfa and ribavirin, is recommended within its marketing authorisation as an option for treating genotype 1 and 4 chronic hepatitis C in adults.</p>
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 TA331, the population eligible for treatment with simeprevir is 448 people annually 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 <i>(before PAS if applicable)</i></p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Simeprevir costs £1866.50 per pack of 7x150 mg tablets. A course of simeprevir (for 12 weeks) plus peginterferon alfa and ribavirin (both for 24 weeks) costs £27,220. A course of simeprevir (for 12 weeks) plus peginterferon alfa and ribavirin (both for 48 weeks) costs £32,155. 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 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>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 for 2014/15 specialist drug monies earmarked for hepatitis C.</p>
5.4	<p>Recurrent overall costs per annum (including additional costs)</p> <p>Based on a pro rata calculation extrapolated from the NICE costing statement that accompanies TA331, the cost of introducing this therapy in Northern Ireland is estimated at £140k.</p> <p>However as outlined, 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. 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 Simeprevir.</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. For patients being considered for drug treatment for chronic hepatitis C (genotypes 1 and 4), it is expected that Simeprevir in combination with peginterferon alfa and ribavirin 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> <p>An investment proposal template will be completed by the BHSCT and the final profile of resources and monitoring arrangements agreed</p>

8	Monitoring arrangements 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.
9	DHSSPS 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.