

1	<p><b>Treatment &amp; Condition</b></p> <p>Daclatasvir (Daklinza<sup>®</sup>) for treating chronic hepatitis C</p>																																																			
2	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal Guidance (TA364) November 2015</p> <p>Daclatasvir is recommended as an option for treating chronic hepatitis C in adults, as specified in the table below, only if the company provides daclatasvir at the same price or lower than that agreed with the Commercial Medicines Unit.</p> <table border="1" data-bbox="247 734 1444 2033"> <thead> <tr> <th colspan="6" data-bbox="247 734 1444 824">Daclatasvir for treating adults with chronic hepatitis C</th> </tr> <tr> <th data-bbox="247 824 443 952" rowspan="2">HCV genotype, liver disease stage</th> <th data-bbox="443 824 635 952" rowspan="2">Treatment</th> <th data-bbox="635 824 778 952" rowspan="2">Duration (weeks)</th> <th colspan="3" data-bbox="778 824 1444 862">Recommendation according to treatment history</th> </tr> <tr> <th data-bbox="778 862 1002 952">Untreated</th> <th data-bbox="1002 862 1225 952">Treated</th> <th data-bbox="1225 862 1444 952">Interferon-ineligible or intolerant</th> </tr> </thead> <tbody> <tr> <td data-bbox="247 952 443 1137">1, without cirrhosis</td> <td data-bbox="443 952 635 1137">Daclatasvir + sofosbuvir</td> <td data-bbox="635 952 778 1137">12</td> <td data-bbox="778 952 1002 1137">Recommended only if the person has significant fibrosis</td> <td data-bbox="1002 952 1225 1137">Recommended only if the person has significant fibrosis</td> <td data-bbox="1225 952 1444 1137">Recommended only if the person has significant fibrosis</td> </tr> <tr> <td data-bbox="247 1137 443 1323">4, without cirrhosis</td> <td data-bbox="443 1137 635 1323">Daclatasvir + sofosbuvir</td> <td data-bbox="635 1137 778 1323">12</td> <td data-bbox="778 1137 1002 1323">Not recommended</td> <td data-bbox="1002 1137 1225 1323">Recommended only if the person has significant fibrosis</td> <td data-bbox="1225 1137 1444 1323">Recommended only if the person has significant fibrosis</td> </tr> <tr> <td data-bbox="247 1323 443 1509">1 or 4, with compensated cirrhosis</td> <td data-bbox="443 1323 635 1509">Daclatasvir + sofosbuvir (with or without ribavirin)</td> <td data-bbox="635 1323 778 1509">24</td> <td data-bbox="778 1323 1002 1509">Not recommended</td> <td data-bbox="1002 1323 1225 1509">Not recommended</td> <td data-bbox="1225 1323 1444 1509">Recommended</td> </tr> <tr> <td data-bbox="247 1509 443 1695">3, without cirrhosis</td> <td data-bbox="443 1509 635 1695">Daclatasvir + sofosbuvir</td> <td data-bbox="635 1509 778 1695">12</td> <td data-bbox="778 1509 1002 1695">Not recommended</td> <td data-bbox="1002 1509 1225 1695">Not recommended</td> <td data-bbox="1225 1509 1444 1695">Recommended only if the person has significant fibrosis</td> </tr> <tr> <td data-bbox="247 1695 443 1881">3, with compensated cirrhosis</td> <td data-bbox="443 1695 635 1881">Daclatasvir + sofosbuvir + ribavirin</td> <td data-bbox="635 1695 778 1881">24</td> <td data-bbox="778 1695 1002 1881">Not recommended</td> <td data-bbox="1002 1695 1225 1881">Not recommended</td> <td data-bbox="1225 1695 1444 1881">Recommended</td> </tr> <tr> <td data-bbox="247 1881 443 2033">4</td> <td data-bbox="443 1881 635 2033">Daclatasvir + peginterferon alfa + ribavirin</td> <td data-bbox="635 1881 778 2033">24</td> <td data-bbox="778 1881 1002 2033">Recommended only if the person has significant fibrosis or compensated cirrhosis</td> <td data-bbox="1002 1881 1225 2033">Recommended only if the person has significant fibrosis or compensated cirrhosis</td> <td data-bbox="1225 1881 1444 2033">Not applicable</td> </tr> </tbody> </table>	Daclatasvir for treating adults with chronic hepatitis C						HCV genotype, liver disease stage	Treatment	Duration (weeks)	Recommendation according to treatment history			Untreated	Treated	Interferon-ineligible or intolerant	1, without cirrhosis	Daclatasvir + sofosbuvir	12	Recommended only if the person has significant fibrosis	Recommended only if the person has significant fibrosis	Recommended only if the person has significant fibrosis	4, without cirrhosis	Daclatasvir + sofosbuvir	12	Not recommended	Recommended only if the person has significant fibrosis	Recommended only if the person has significant fibrosis	1 or 4, with compensated cirrhosis	Daclatasvir + sofosbuvir (with or without ribavirin)	24	Not recommended	Not recommended	Recommended	3, without cirrhosis	Daclatasvir + sofosbuvir	12	Not recommended	Not recommended	Recommended only if the person has significant fibrosis	3, with compensated cirrhosis	Daclatasvir + sofosbuvir + ribavirin	24	Not recommended	Not recommended	Recommended	4	Daclatasvir + peginterferon alfa + ribavirin	24	Recommended only if the person has significant fibrosis or compensated cirrhosis	Recommended only if the person has significant fibrosis or compensated cirrhosis	Not applicable
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3	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b> <i>(including new cases per year)</i></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><b>Patient Access Scheme availability</b></p> <p>The company has agreed a nationally available price reduction for daclatasvir with the Commercial Medicines Unit. The contract prices agreed are commercial in confidence.</p>
5	<p><b>Costs</b> <i>(before PAS if applicable)</i></p>
5.1	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>The price of daclatasvir is £8,172.61 per 28-tablet pack of 60 mg daclatasvir. The average cost of daclatasvir plus sofosbuvir is £59,501 for a 12-week course and £119,002 for a 24-week course; when ribavirin is added these costs increase to £60,304 and £120,608 respectively. The average cost of a course of treatment with daclatasvir in combination with peginterferon alfa and ribavirin ranges from £53,628 to £58,221 (depending on whether peginterferon alfa and ribavirin are taken for 24 or 48 weeks; daclatasvir may only be taken for 24 weeks).</p>
5.2	<p><b>Infrastructure costs per patient per annum</b></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><b>Current in year costs</b></p> <p>Daclatasvir (Daklinza<sup>®</sup>) 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><b>Recurrent overall costs per annum</b> <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 of the DHSSPS 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><b>Opportunities for cost savings and how these will be secured</b></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><b>Expected implementation period</b></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><b>Commissioning arrangements</b></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><b>Monitoring arrangements</b></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><b>DHSSPS Legislative/Policy Caveats</b> <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>