

<p>1</p>	<p>Treatment & Condition</p> <p>Ombitasvir–paritaprevir–ritonavir (Viekirax[®]) with or without dasabuvir (Exviera[®]) for treating chronic hepatitis C.</p>																																									
<p>2</p>	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA365 (November 2015)</p> <p>Ombitasvir–paritaprevir–ritonavir with or without dasabuvir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, as specified in the table below, only if the company provides ombitasvir–paritaprevir–ritonavir and dasabuvir at the same price or lower than that agreed with the Commercial Medicines Unit.</p> <table border="1" data-bbox="245 808 1445 1765"> <tr> <th colspan="4" data-bbox="245 808 1445 913">Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating adults with chronic hepatitis C</th> </tr> <tr> <th data-bbox="245 913 544 1048" rowspan="2">HCV genotype, liver disease stage</th> <th data-bbox="544 913 943 1048" rowspan="2">Treatment</th> <th data-bbox="943 913 1102 1048" rowspan="2">Duration (weeks)</th> <th colspan="2" data-bbox="1102 913 1445 1014">Recommendation according to treatment history</th> </tr> <tr> <th data-bbox="1102 1014 1262 1048">Untreated</th> <th data-bbox="1262 1014 1445 1048">Treated</th> </tr> <tr> <td data-bbox="245 1048 544 1182">1a, without cirrhosis</td> <td data-bbox="544 1048 943 1182">Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin</td> <td data-bbox="943 1048 1102 1182">12</td> <td colspan="2" data-bbox="1102 1048 1445 1182">Recommended</td> </tr> <tr> <td data-bbox="245 1182 544 1317">1a, with compensated cirrhosis</td> <td data-bbox="544 1182 943 1317">Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin</td> <td data-bbox="943 1182 1102 1317">24</td> <td colspan="2" data-bbox="1102 1182 1445 1317">Recommended</td> </tr> <tr> <td data-bbox="245 1317 544 1429">1b, without cirrhosis</td> <td data-bbox="544 1317 943 1429">Ombitasvir–paritaprevir–ritonavir with dasabuvir</td> <td data-bbox="943 1317 1102 1429">12</td> <td colspan="2" data-bbox="1102 1317 1445 1429">Recommended</td> </tr> <tr> <td data-bbox="245 1429 544 1563">1b, with compensated cirrhosis</td> <td data-bbox="544 1429 943 1563">Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin</td> <td data-bbox="943 1429 1102 1563">12</td> <td colspan="2" data-bbox="1102 1429 1445 1563">Recommended</td> </tr> <tr> <td data-bbox="245 1563 544 1675">4, without cirrhosis</td> <td data-bbox="544 1563 943 1675">Ombitasvir–paritaprevir–ritonavir with ribavirin</td> <td data-bbox="943 1563 1102 1675">12</td> <td colspan="2" data-bbox="1102 1563 1445 1675">Recommended</td> </tr> <tr> <td data-bbox="245 1675 544 1765">4, with compensated cirrhosis</td> <td data-bbox="544 1675 943 1765">Ombitasvir–paritaprevir–ritonavir with ribavirin</td> <td data-bbox="943 1675 1102 1765">24</td> <td colspan="2" data-bbox="1102 1675 1445 1765">Recommended</td> </tr> </table>	Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating adults with chronic hepatitis C				HCV genotype, liver disease stage	Treatment	Duration (weeks)	Recommendation according to treatment history		Untreated	Treated	1a, without cirrhosis	Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin	12	Recommended		1a, with compensated cirrhosis	Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin	24	Recommended		1b, without cirrhosis	Ombitasvir–paritaprevir–ritonavir with dasabuvir	12	Recommended		1b, with compensated cirrhosis	Ombitasvir–paritaprevir–ritonavir with dasabuvir and ribavirin	12	Recommended		4, without cirrhosis	Ombitasvir–paritaprevir–ritonavir with ribavirin	12	Recommended		4, with compensated cirrhosis	Ombitasvir–paritaprevir–ritonavir with ribavirin	24	Recommended	
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<p>3</p>	<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 ombitasvir–paritaprevir–ritonavir and dasabuvir with the Commercial Medicines Unit. The contract prices agreed are commercial in confidence.</p>
5	<p>Costs</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Ombitasvir–paritaprevir–ritonavir (Viekirax[®]) is a fixed-dose combination of 2 direct-acting anti-hepatitis C virus drugs (ombitasvir and paritaprevir) and ritonavir. Each tablet contains 12.5 mg ombitasvir, 75 mg paritaprevir, and 50 mg ritonavir. The recommended dose is 2 tablets once daily. It is taken orally for 12 or 24 weeks with or without dasabuvir, with or without ribavirin.</p> <p>Dasabuvir (Exviera[®]) is a direct-acting anti-hepatitis C virus drug which inhibits a viral enzyme (NS5B) that has a role in viral genome replication. The recommended dose is 1 tablet (250 mg) twice daily. It is taken orally for 12 or 24 weeks with ombitasvir–paritaprevir–ritonavir and with or without ribavirin. The recommended treatment duration and whether ribavirin is co-administered depends on the subtype of genotype 1 hepatitis C virus (HCV) and the presence of cirrhosis.</p> <p>Ombitasvir–paritaprevir–ritonavir costs £10,733.33 excluding VAT for 28 days supply. The total costs of a 12-week and a 24-week course of ombitasvir–paritaprevir–ritonavir are £32,200 and £64,400 respectively (both excluding VAT). Dasabuvir costs £933.33 excluding VAT for 28 days' supply. The total costs of a 12-week and a 24-week course of dasabuvir are £2,800 and £5,600 respectively (both excluding VAT)</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>Ombitasvir–paritaprevir–ritonavir (Viekirax[®]) 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 (including additional costs)</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</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>