

1.	<p><b>Treatment &amp; Condition</b></p> <p>Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome</p>																																				
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA615 (December 2019)</p> <p>Cannabidiol (Epidyolex<sup>®</sup>) with clobazam is recommended as an option for treating seizures associated with Lennox–Gastaut syndrome in people aged 2 years and older, only if:</p> <ul style="list-style-type: none"> <li>the frequency of drop seizures is checked every 6 months, and cannabidiol is stopped if the frequency has not fallen by at least 30% compared with the 6 months before starting treatment</li> <li>the company provides cannabidiol according to the commercial arrangement.</li> </ul>																																				
3.	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b></p> <p>The NICE Resource Impact Template that accompanies NICE TA615 estimates the patient numbers expected to take up the treatment as follows:</p> <table border="1" data-bbox="260 1144 1442 1458"> <thead> <tr> <th></th> <th>2020/21</th> <th>2021/22</th> <th>2022/23</th> <th>2023/24</th> <th>2024/25</th> </tr> </thead> <tbody> <tr> <td>Number of patients aged 2-17 years old (prevalent cases)</td> <td>6</td> <td>14</td> <td>17</td> <td>19</td> <td>20</td> </tr> <tr> <td>Number of patients aged 2-17 years old (new cases)</td> <td>1</td> <td>2</td> <td>3</td> <td>5</td> <td>6</td> </tr> <tr> <td>Total number of patients aged 2-17 years old (new and prevalent)</td> <td>7</td> <td>16</td> <td>20</td> <td>24</td> <td>26</td> </tr> <tr> <td>Number of adult patients</td> <td>11</td> <td>26</td> <td>32</td> <td>36</td> <td>37</td> </tr> <tr> <td><b>Total (children + adults)</b></td> <td><b>18</b></td> <td><b>42</b></td> <td><b>52</b></td> <td><b>60</b></td> <td><b>63</b></td> </tr> </tbody> </table>		2020/21	2021/22	2022/23	2023/24	2024/25	Number of patients aged 2-17 years old (prevalent cases)	6	14	17	19	20	Number of patients aged 2-17 years old (new cases)	1	2	3	5	6	Total number of patients aged 2-17 years old (new and prevalent)	7	16	20	24	26	Number of adult patients	11	26	32	36	37	<b>Total (children + adults)</b>	<b>18</b>	<b>42</b>	<b>52</b>	<b>60</b>	<b>63</b>
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4.	<p><b>Patient Access Scheme Availability</b></p> <p>(Yes/No)</p> <p>The company (GW Pharma) has a commercial arrangement. This makes cannabidiol available to the NHS with a discount. The size of the discount is commercial in confidence.</p>																																				
5.	<p><b>Infrastructure Requirements</b></p> <p>Any additional infrastructure costs associated will be managed with as part of the routine commissioning process.</p>																																				
6.	<p><b>Expected implementation period</b></p> <p>There is no impediment to immediate implementation for new patients.</p>																																				

7.	<p><b>Commissioning arrangements</b></p> <p>This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.</p>
8.	<p><b>Monitoring arrangements</b></p> <p>The HSCB cost per case process will generate quarterly reports on the number of applications.</p> <p>The HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist drugs.</p>
9.	<p><b>DoH (NI) Legislative/Policy Caveats</b></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> <p>The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the act.</p>