**HSCB Service Notification for the managed entry of new medicines and technologies**

Health and Social Care Board

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| **1** | **Treatment & Condition**<br><br>Adalimumab for treating moderate to severe hidradenitis suppurativa |
| **2** | **Associated appraisal body *&* Summary of ruling**<br><br>NICE Technology Appraisal Guidance (TA392) June 2016<br><br>Adalimumab (Humira®) is recommended, within its marketing authorisation, as an option for treating active moderate to severe hidradenitis suppurativa in adults whose disease has not responded to conventional systemic therapy. The drug is recommended only if the company provides it at the price agreed in the patient access scheme.<br><br>Assess the response to adalimumab after 12 weeks of treatment, and only continue if there is clear evidence of response, defined as:<br>• a reduction of 25% or more in the total abscess and inflammatory nodule count and<br>• no increase in abscesses and draining fistulas. |
| **3** | **Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)*<br><br>According to the Resource Impact Template that accompanies TA392, the number of people whose condition does not respond to conventional treatments and may be eligible for adalimumab is 53. Of these, 5 patients are likely to be unsuitable for treatment with adalimumab and hence receive best supportive care. Thus, 48 patients will be eligible to be treated with adalimumab. |
| **4** | **Patient Access Scheme availability**<br><br>The company (AbbVie) has agreed a (non-confidential) patient access scheme with the Department of Health. The company will provide adalimumab at a fixed price of £284 for the 40mg prefilled pen or syringe for the hidradenitis suppurativa indication only. |
| **5** | **Costs** *(before PAS if applicable)* |
| **5.1** | **Drug cost per patient per annum (for new and prevalent cases)**<br><br>Adalimumab (Humira®) has a marketing authorisation in the UK for treating active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic hidradenitis suppurativa therapy.<br><br>Adalimumab costs £352.14 for a 40mg prefilled pen or syringe and for a 40mg/0.8ml vial. The recommended dose of adalimumab for people with hidradenitis suppurativa is 160mg on day 1 (given as 4 injections in 1 day or as 2 injections each day for 2 consecutive days), 80mg on day 15 (given as 2 injections in 1 day), and a single 40mg injection every week from week 4 onwards. |

<table>
<tr><td></td><td>The company (AbbVie) has agreed a (non-confidential) patient access scheme with the Department of Health. The company will provide adalimumab at a fixed price of £284 for the 40mg prefilled pen or syringe for the hidradenitis suppurativa indication only.<br><br>The annual cost of treatment with adalimumab is estimated at £15,336, based on the dosing regimen recommended in the summary of product characteristics.</td></tr>
<tr><td>5.2</td><td>Infrastructure costs per patient per annum<br><br>It is anticipated that infrastructure requirements will be minimal. The HSC Board will work with Trusts to confirm the requirements.</td></tr>
<tr><td>5.3</td><td>Current in year costs<br><br>The current in year costs will be covered via the cost per case arrangement.</td></tr>
<tr><td>5.4</td><td>Recurrent overall costs per annum (including additional costs)<br><br>The information from the Resource Impact Template that accompanies TA392, projects that the costs associated with the proposed number of patients on treatment over the next number of years is as follows:<br><br>
<table>
<tr><th>2016/17</th><th>2017/18</th><th>2018/19</th><th>2019/20</th><th>2020/21</th><th>2021/22</th></tr>
<tr><td>£125,983</td><td>£161,702</td><td>£210,434</td><td>£259,166</td><td>£282,702</td><td>£243,661</td></tr>
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<br>Steady state is assumed by 2021/22.</td></tr>
<tr><td>5.5</td><td>Opportunities for cost savings and how these will be secured<br><br>It is not anticipated that there will be any cost savings associated with the implementation of this technology appraisal.</td></tr>
<tr><td>6</td><td>Expected implementation period<br><br>There is no impediment to implementation of this guidance.</td></tr>
<tr><td>7</td><td>Commissioning arrangements<br><br>This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team.</td></tr>
<tr><td>8</td><td>Monitoring arrangements<br><br>The HSC Board will work with Trusts to ensure that information on the number of patients and associated drug costs is provided on a regular basis.</td></tr>
<tr><td>9</td><td>DHSSPS Legislative/Policy Caveats<br><br>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</td></tr>
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| | complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case. |