

1	<p><b>Treatment &amp; Condition</b></p> <p>Vedolizumab for treating moderately to severely active ulcerative colitis.</p>																					
2	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance 342 (June 2015)</p> <p>Vedolizumab is recommended, within its marketing authorisation, as an option for treating moderately to severely active ulcerative colitis in adults only if the company provides vedolizumab with the discount agreed in the patient access scheme.</p> <p>The marketing authorisation for vedolizumab states that vedolizumab is indicated - 'for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, or lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha antagonist'.</p> <p>Vedolizumab should be given until it stops working or surgery is needed. At 12 months after the start of treatment, people should be reassessed to see whether treatment should continue. Treatment should only continue if there is clear evidence of ongoing clinical benefit. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. People who continue vedolizumab should be reassessed at least every 12 months to see whether continued treatment is justified.</p>																					
3	<p><b>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</b></p> <p>Implementation of this guidance offers an additional treatment option for treating moderately to severely active ulcerative colitis in adults. Infliximab, adalimumab and golimumab are already licensed and NICE-approved for the management of this condition.</p> <p>The following table is extrapolated from the Costing Statement that accompanies TA342. It shows that 85 people in Northern Ireland could potentially be treated with vedolizumab:</p> <table border="1" data-bbox="247 1646 1437 2038"> <thead> <tr> <th colspan="3">No. per 100,000 population potentially eligible for treatment with vedolizumab</th> </tr> <tr> <th>Population</th> <th>Percentage</th> <th>Number of people in NI</th> </tr> </thead> <tbody> <tr> <td>Number of adults</td> <td></td> <td>1,400,000</td> </tr> <tr> <td>Prevalence of UC</td> <td>0.24%</td> <td>3,360</td> </tr> <tr> <td>Prevalence of moderate to severe disease</td> <td>52.33%</td> <td>1,758</td> </tr> <tr> <td>Proportion of people whose condition fails conventional therapy and who are treated with a biologic</td> <td>16.20%</td> <td>285</td> </tr> <tr> <td>Estimated uptake for treatment with vedolizumab</td> <td>30%</td> <td>85</td> </tr> </tbody> </table>	No. per 100,000 population potentially eligible for treatment with vedolizumab			Population	Percentage	Number of people in NI	Number of adults		1,400,000	Prevalence of UC	0.24%	3,360	Prevalence of moderate to severe disease	52.33%	1,758	Proportion of people whose condition fails conventional therapy and who are treated with a biologic	16.20%	285	Estimated uptake for treatment with vedolizumab	30%	85
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4	<p><b>Patient Access Scheme availability</b></p> <p>The company that makes vedolizumab has agreed a patient access scheme (PAS) with the Department of Health. The level of the discount is commercial in confidence.</p>
5	<p><b>Costs</b></p>
5.1	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>The recommended dose regimen of vedolizumab is 300 mg administered by intravenous infusion at zero, two and six weeks and then every eight weeks thereafter.</p> <p>Continued therapy for patients with ulcerative colitis should be carefully reconsidered if no evidence of therapeutic benefit is observed by Week 10. Some patients who have experienced a decrease in their response may benefit from an increase in dosing frequency to vedolizumab 300 mg every four weeks.</p> <p>The NHS list price is £2,050 per 300 mg vial of vedolizumab. This gives an annual cost per patient of £16,913 in the first year and £13,325 in subsequent years (before PAS discount is applied).</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 with work with Trusts to identify how the requirements compare to current infrastructure needs.</p>
5.3	<p><b>Current in year costs</b></p> <p>Vedolizumab is an additional treatment option alongside current standard treatment options for ulcerative colitis. It is projected that around 40 patients may benefit from this treatment in 2015/16 at a cost of £338k before the PAS discount is applied.</p>
5.4	<p><b>Recurrent overall costs per annum (including additional costs)</b></p> <p>The recurrent costs of implementing this TA for 85 patients would be £1.1m before taking account of the agreed patient access scheme. The recurrent costs will be included in the HSC Board financial planning assumptions for predicted growth in this area in 2016/17.</p>
5.5	<p><b>Opportunities for cost savings and how these will be secured</b></p> <p>The manufacturer of vedolizumab suggests that there could be a reduction in the number of drug-related adverse events compared with other biologic drugs. Based on the estimates in the manufacturer's submission, there could be 189 less adverse events such as skin reactions and serious infections. With a weighted average adverse event cost of £1,581, this gives potential savings of around £300k in England per year. This extrapolates to 8 fewer adverse events in Northern Ireland and potential savings of £12k in Northern Ireland per year.</p>

	<p>The HSC Board will work with Trusts to ensure that opportunities to achieve any savings are maximised.</p>
<b>6</b>	<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 the therapy will be formally commissioned during the fourth quarter of 2015/16. The introduction will be subject to confirmation of the level of funding available and submission of IPTs by Trusts for the drug costs and any infrastructure requirements.</p>
<b>7</b>	<p><b>Commissioning arrangements</b></p> <p>This therapy will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis.</p> <p>Investment Proposal Templates will be completed by each Trust and the final profile of resources and revised monitoring arrangements agreed.</p> <p>Each Trust should submit an operational protocol specific to this regime setting out the arrangements for the reassessment intervals as set out in the NICE guidance.</p>
<b>8</b>	<p><b>Monitoring arrangements</b></p> <p>HSCB currently receives monthly monitoring information in relation to the usage of biologic drugs in inflammatory bowel disease.</p> <p>The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.</p>
<b>9</b>	<p><b>DHSSPS 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>