

1	<p>Treatment & Condition</p> <p>Belimumab for treating active autoantibody-positive systemic lupus erythematosus</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA397 (June 2016)</p> <p>Belimumab is recommended as an option as add-on treatment for active autoantibody-positive systemic lupus erythematosus in adults only if all of the following apply:</p> <ul style="list-style-type: none"> • There is evidence for serological disease activity (defined as positive anti-double-stranded DNA and low complement) and a Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of greater than or equal to 10 despite standard treatment. • Treatment with belimumab is continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more. • The company provides belimumab with the discount agreed in the patient access scheme. • Under the conditions for data collection, monitoring, patient eligibility and consent, ongoing treatment, cost to the NHS, and review by NICE as laid out in sections 5 and 6 of the full NICE guidance document which can be found at: (https://www.nice.org.uk/guidance/ta397/resources/belimumab-for-treating-active-autoantibodypositive-systemic-lupus-erythematosus-82602915211717)
3	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>The NICE Resource Impact Statement that accompanies this guidance states that ‘it is unlikely that the guidance will result in a significant change in resource use in the NHS because the population eligible for treatment is low.’</p> <p>Trust will be required to submit cost per case requests for this therapy to allow the HSC Board to monitor the number of patients accessing this therapy locally.</p>
4	<p>Patient Access Scheme availability</p> <p>The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of belimumab. The level of the discount is commercial in confidence.</p>
5	<p>Costs (before PAS if applicable)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Belimumab (Benlysta[®]) is available as a 120mg or 400mg powder for intravenous</p>

	<p>infusion in solution. The recommended dose regimen is 10 mg/kg belimumab on days 0, 14 and 28 and at 4-week intervals thereafter. The list price of belimumab is £121 for a 120-mg vial and £405 for a 400-mg vial. Assuming vial wastage, the drug cost per administration for a person weighing 65–76 kg is £769</p> <p>Thus the annual cost per patient is as follows:</p> <ul style="list-style-type: none"> • Year 1 = 15 doses = £11,500 • Year 2 and subsequent years = 13 doses = £10,000
5.2	<p>Infrastructure costs per patient per annum</p> <p>It is anticipated that infrastructure requirements will be minimal.</p> <p>Infrastructure requirements for the delivery of all biologics are reviewed annually as part of the routine commissioning arrangements for supporting growth in the provision of these therapies.</p>
5.3	<p>Current in year costs</p> <p>The NICE Resource Impact Statement that accompanies this guidance states that it is unlikely that the guidance will result in a significant change in resource use in the NHS because the population eligible for treatment is low.</p> <p>The HSC Board will assess any in year requirements on the basis of cost per case requests received. Any recurrent costs will be included in the HSC Board financial planning assumptions for predicted growth in this area in 2017/18.</p>
5.4	<p>Recurrent overall costs per annum (<i>including additional costs</i>)</p> <p>The NICE Resource Impact Statement that accompanies this guidance states that it is unlikely that the guidance will result in a significant change in resource use in the NHS because the population eligible for treatment is low.</p> <p>The HSC Board will assess any recurrent requirements on the basis of cost per case requests received. Any recurrent costs will be included in the HSC Board financial planning assumptions for predicted growth in this area in 2017/18.</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>It is not anticipated that there will be any cost savings associated with the implementation of this technology appraisal.</p>
6	<p>Expected implementation period</p> <p>There is no impediment to implementation of this guidance.</p>
7	<p>Commissioning arrangements</p> <p>This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team.</p>

8	Monitoring arrangements Initially the number of patients accessing this treatment will be monitored via the cost per case requests received by the Board. The HSC Board has robust arrangements in place for the monthly monitoring of other biologic therapies use (activity/cost and waiting times) and this regime will be included within the routinely provided return from 2017/18. All monitoring returns for biologics are reviewed by the specialist services commissioning team monthly.
9	DHSSPS Legislative/Policy Caveats 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.