

NICE TA 308 – Rituximab in combination with glucocorticoids for treating anti-neutrophil cytoplasmic antibody-associated vasculitis

1	<p>Summary of NICE TA 308</p> <p>Rituximab, in combination with glucocorticoids, is recommended as an option for inducing remission in adults with anti-neutrophil cytoplasmic antibody [ANCA]-associated vasculitis (severely active granulomatosis with polyangiitis [Wegener's] and microscopic polyangiitis), only if:</p> <ul style="list-style-type: none"> • further cyclophosphamide treatment would exceed the maximum cumulative cyclophosphamide dose or • cyclophosphamide is contraindicated or not tolerated or • the person has not completed their family and treatment with cyclophosphamide may materially affect their fertility or • the disease has remained active or progressed despite a course of cyclophosphamide lasting 3–6 months or • the person has had uroepithelial malignancy.
2	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>The costing statement that accompanies NICE TA308 refers to an annual cost of £1.1m associated with the implementation of the TA in England. This equates to around 225 patients at an average cost of £4,890 per patient.</p> <p>Proportionally this would equate to between 8 – 10 patients in NI. However, information from the HSC Board Extra Contractual Referral (ECR) database would indicate between 10 and 15 referrals per annum.</p>
3	<p>Costs</p>
3.1	<p>Drug cost per patient per annum</p> <p>Rituximab is priced at £174.63 per 10 ml vial and £873.15 per 50 ml vial (excluding VAT; BNF edition 66). The recommended dosage for treating granulomatosis with polyangiitis and microscopic polyangiitis (2 types of anti-neutrophil cytoplasmic antibody [ANCA]-associated vasculitis) is 375 mg/m² body surface area, administered intravenously once weekly for 4 weeks (4 infusions in total). The manufacturer's estimate of the average cost of a course of treatment is £4,890 (based on 1.79 m² body surface area and no vial sharing).</p>
3.2	<p>In year costs</p> <p>The average cost per patient during 2014/15 will be £2,445.</p>
3.3	<p>Infrastructure Costs per annum</p> <p>It is not anticipated that additional infrastructure will be required given the low number of patients expected to access this therapy.</p>

3.4	<p>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.</p>
3.5	<p>Recurrent overall cost</p> <p>The annual cost associated with implementing the guidance is estimated as £1.1 million for the total population of England. Information from the HSC Board ECR database would indicate between 10 and 15 referrals per annum in Northern Ireland which would equate to an estimated annual cost between £49,000 and £73,000.</p>
4	<p>Expected implementation period</p> <p>It is expected that subject to submission and agreement of investment proposals by Trusts, that this therapy will be introduced in the second quarter of 2014/15 on a cost per case basis.</p>
5	<p>Commissioning arrangements</p> <p>This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team.</p>
6	<p>Monitoring arrangements</p> <p>Trusts will be required to provide Specialist Services Commissioning Team on a quarterly basis with the following information:</p> <ul style="list-style-type: none"> • the number of patients that have been given the drug and the cost of the drug per patient; • confirmation that each patient complies with the NICE requirements for this treatment.
7	<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>