

<p>1.</p>	<p>Treatment & Condition</p> <p>Mepolizumab for treating severe refractory eosinophilic asthma.</p>
<p>2.</p>	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA431 (25 January 2017)</p> <p>Mepolizumab, as an add-on to optimised standard therapy, is recommended as an option for treating severe refractory eosinophilic asthma in adults, only if:</p> <ul style="list-style-type: none"> • the blood eosinophil count is 300 cells/microlitre or more in the previous 12 months • the person has agreed to and followed the optimised standard treatment plan and <ul style="list-style-type: none"> ➢ has had 4 or more asthma exacerbations needing systemic corticosteroids in the previous 12 months or ➢ has had continuous oral corticosteroids of at least the equivalent of prednisolone 5 mg per day over the previous 6 months • the company provides the drug with the discount agreed in the patient access scheme. <p>At 12 months of treatment:</p> <ul style="list-style-type: none"> • stop mepolizumab if the asthma has not responded adequately¹ or • continue treatment if the asthma has responded adequately and assess response each year. <p>¹An adequate response is defined as:</p> <ul style="list-style-type: none"> • at least 50% fewer asthma exacerbations needing systemic corticosteroids in those people with 4 or more exacerbations in the previous 12 months or • a clinically significant reduction in continuous oral corticosteroid use while maintaining or improving asthma control.
<p>3.</p>	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>From the NICE Resource Impact Template that accompanies TA431, it is estimated that 100 people in Northern Ireland will have treatment with mepolizumab each year. The Resource Impact Template assumes that the number will increase to 100 over the next 4 years.</p>
<p>4.</p>	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The manufacturer of mepolizumab (GlaxoSmithKline) has agreed a patient access scheme (PAS) with the Department of Health. This makes mepolizumab available at a discounted price. The size of this discount is commercial in confidence.</p>

5.	Costs (<i>before PAS if applicable</i>)
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The recommended dose of mepolizumab is 100 mg administered subcutaneously once every 4 weeks. It is intended for long-term treatment, but the summary of product characteristics states that 'the need for continued therapy should be considered at least on an annual basis as determined by physician assessment of the patient's disease severity and level of control of exacerbations'.</p> <p>The list price of mepolizumab is £840 per dose (excluding VAT). Therefore the annual cost per patient = £10,920 (assuming 13 doses are given annually)</p>
5.2	<p>Total Drug Costs Per Annum</p> <p>As per the NICE Resource Impact Template the estimated recurrent costs after four years (at a steady state) are £465,000 which includes expected savings of £16k for reductions in corticosteroid bursts.</p>
5.3	<p>Infrastructure Costs Per Annum</p> <p>Uptake of this treatment will be monitored on a cost per case basis and the HSC Board will work with clinicians to identify any additional infrastructure requirements to support the implementation of this treatment regime.</p>
6.	<p>Expected implementation period</p> <p>This therapy is currently available in Northern Ireland on a cost per case basis. It is expected that this therapy will be formally commissioned during 2017/18.</p>
7.	<p>Commissioning arrangements</p> <p>This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis.</p>
8.	<p>Monitoring arrangements</p> <p>The Belfast Trust will be required to provide regular updates to the Specialist Services Commissioning Team on the number of patients receiving treatment with mepolizumab and the associated drug costs.</p>
9.	<p>DoH (NI) 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>