

1.	<p>Treatment & Condition</p> <p>Etelcalcetide for treating secondary hyperparathyroidism</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal Guidance (TA448) June 2017</p> <p>Etelcalcetide (Parsabiv[®]) is recommended as an option for treating secondary hyperparathyroidism in adults with chronic kidney disease on haemodialysis, only if:</p> <ul style="list-style-type: none"> • treatment with a calcimimetic is indicated but cinacalcet is not suitable and • the company provides etelcalcetide with the discount agreed in the patient access scheme
3.	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>Based on a <i>pro rata</i> calculation from the estimates for England given in the NICE Resource Impact Statement, the population treated with etelcalcetide is estimated to be around 54 for Northern Ireland.</p> <p>However, local clinical advice indicates that circa 5 patients will be treated with this therapy.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The company (Amgen) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of etelcalcetide, with the discount applied at the point of purchase or invoice. 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>Etelcalcetide is indicated for the treatment of secondary hyperparathyroidism in adults with chronic kidney disease on haemodialysis.</p> <p>The recommended initial dose of etelcalcetide is 5mg administered by bolus injection 3 times per week. Corrected serum calcium should be at or above the lower limit of the normal range before administration of the first dose of etelcalcetide. Etelcalcetide should be titrated so that doses are individualised between 2.5mg and 15mg.</p> <p>NHS list prices (excluding VAT):</p> <ul style="list-style-type: none"> • £136.87 per pack of 6 vials of 2.5 mg in 0.5 ml solution (£9.12 per mg)

	<ul style="list-style-type: none"> • £163.92 per pack of 6 vials of 5 mg in 1 ml solution (£5.46 per mg) • £327.84 per pack of 6 vials of 10 mg in 1 ml solution (£5.46 per mg) <p>At the list price, the cost per patient per annum, at a dose of between 2.5mg to 15mg three times per week, will be £3,559 to £12,786.</p>
5.2	<p>Infrastructure costs Per annum</p> <p>It is anticipated that infrastructure requirements will be minimal.</p> <p>Any additional infrastructure costs associated with the introduction of this therapy will be dealt with as part of the routine commissioning process.</p>
6.	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p>Commissioning arrangements</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 for a period of 12 months. After this time, numbers of patients who received or are receiving treatment and the associated costs will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.</p>
8.	<p>Monitoring arrangements</p> <p>Trusts will be required to provide regular updates to the Specialist Services Commissioning Team on the number of patients receiving treatment with etelcalcetide 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>