

<p>1.</p>	<p>Treatment & Condition</p> <p>Immunosuppressive therapy for kidney transplant in children and young people</p>
<p>2.</p>	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA482 (October 2017)</p> <p>This guidance replaces NICE TA99.</p> <p><u>Basiliximab</u>, when used as part of an immunosuppressive regimen that includes a calcineurin inhibitor, is recommended as an initial option to prevent organ rejection in children and young people having a kidney transplant.</p> <p><u>Immediate-release tacrolimus</u>, when used as part of an immunosuppressive regimen, is recommended as an initial option to prevent organ rejection in children and young people having a kidney transplant. Treatment should normally be started with the least expensive product.</p> <p>However, treatment can be started with an alternative dosage form if the least expensive product is not suitable (for example, if the child or young person is not able to swallow capsules or they are unable to have a particular ingredient because of allergy or religious reasons). Tacrolimus granules for oral suspension (Modigraf[®]) should be used only if the company provides it at the same price or lower than that agreed with the Commercial Medicines Unit.</p> <p><u>Mycophenolate mofetil</u>, when used as part of an immunosuppressive regimen, is recommended as an initial option to prevent organ rejection in children and young people having a kidney transplant. Treatment should normally be started with the least expensive product.</p> <p>However, treatment can be started with an alternative dosage form if the least expensive product is not suitable (for example, if the child or young person is not able to swallow capsules or they are unable to have a particular ingredient because of allergy or religious reasons).</p> <p><u>Rabbit anti-human thymocyte immunoglobulin</u>, <u>prolonged-release tacrolimus</u>, <u>mycophenolate sodium</u>, <u>sirolimus</u>, <u>everolimus</u> and <u>belatacept</u> are not recommended as initial treatments to prevent organ rejection in children and young people having a kidney transplant.</p>
<p>3.</p>	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>Based on local clinical advice 2 children and young people are expected to take up this therapy treatment every year.</p> <p>All children receive tacrolimus and mycophenolate mofetil and basiliximab</p>

4.	<p>Patient Access Scheme Availability</p> <p>(Yes/<u>No</u>)</p> <p>A Patient Access Scheme is not available.</p>
5.	<p>Costs (<i>before PAS if applicable</i>)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p><u>Basiliximab</u> (Simulect[®]) is administered intravenously. In children and young people weighing less than 35kg, the recommended total dose is 20mg given in 2 doses of 10mg each. In children and young people weighing 35kg or more, the recommended dose is 40mg given in 2 doses of 20 mg each. Basiliximab is available in 10mg and 20mg vials at a price of £758.69 and £842.38 respectively (excluding VAT), equating to £1,517 per course of treatment for a patient weighing under 35kg and £1,685 for a patient weighing 35kg or more.</p> <p>For all brands of <u>immediate-release tacrolimus</u>, the summary of product characteristics recommends an initial dose for children (age range not specified) of 0.3mg/kg/day orally or 0.075 to 0.100mg/kg/day intravenously and states that the dosage is usually reduced in the period after the transplant. Tacrolimus immediate-release capsules are available as 0.5mg, 0.75mg, 1mg, 2mg and 5mg capsules, the price of which varies by brand. The NICE assessment group estimated that the weekly cost of maintenance therapy with immediate-release tacrolimus capsules for a 10-year-old boy is £34.</p> <p><u>Mycophenolate mofetil</u> can be administered orally (capsules or an oral suspension) or intravenously. The summary of product characteristics states that the recommended daily dose for children and young people (aged 2 to 18 years) is 1,200 mg/m² up to a maximum of 2g per day.</p> <p>The price of mycophenolate mofetil varies by brand. The oral suspension (CellCept[®]) is available in 175ml containers of 1g/5 ml suspension at a price of £3.29 per g (excluding VAT). At the time of the initial NICE committee discussion (July 2015), the average cost paid by the NHS for mycophenolate mofetil capsules was £0.38 per g (excluding VAT). The NICE assessment group estimated that the weekly cost of maintenance therapy with mycophenolate mofetil capsules for a 10-year-old boy is between £1.74 and £3.48.</p>
5.2	<p>Infrastructure costs Per annum</p> <p>It is not anticipated that there will be a requirement to fund infrastructure as no significant change in practice is anticipated as a result of implementation of this guidance. The recommended immunosuppressive therapy treatments are already available through the NHS for patients having a kidney transplant.</p>
6.	<p>Expected implementation period</p> <p>The recommended immunosuppressive therapy treatments are already available on the NHS for patients having a kidney transplant.</p>

7.	Commissioning arrangements The recommended immunosuppressive therapy treatments are already available through the NHS for patients having a kidney transplant.
8.	Monitoring arrangements No specific monitoring required because as current best practice should not substantially change.
9.	DoH (NI) 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.