

<p>1.</p>	<p>Treatment & Condition</p> <p>Immunosuppressive therapy for kidney transplant in adults</p>
<p>2.</p>	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA481 (October 2017).</p> <p>This guidance replaces NICE TA85.</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 adults having a kidney transplant.</p> <p>Immediate-release <u>tacrolimus</u>, when used as part of an immunosuppressive regimen, is recommended as an initial option to prevent organ rejection in adults having a kidney transplant. Treatment should normally be started with the least expensive product. However, treatment can be started with an alternative dosage form if the least expensive product is not suitable (for example, if the person is not able to swallow capsules as a result of a disability 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 adults having a kidney transplant. Treatment should normally be started with the least expensive product. However, treatment can be started with an alternative dosage form if the least expensive product is not suitable (for example, if the person is not able to swallow capsules as a result of a disability 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 adults 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 110 adults are expected to take up this therapy every year as follows:</p> <ul style="list-style-type: none"> • All new transplant patients receive immunosuppression which includes: <ul style="list-style-type: none"> ➢ Tacrolimus ➢ Mycophenolate mofetil • For a subset of new transplant patients basiliximab is added to the two drugs

	<p>listed above</p> <ul style="list-style-type: none"> • On average there are 110 adults transplanted every year: <ul style="list-style-type: none"> ➤ 60 on average receive Tacrolimus and Mycophenolate mofetil ➤ 50 (based on 2017) receive Tacrolimus and Mycophenolate mofetil and basiliximab
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 2 doses of 20mg each (one 2 hours before the surgery and the second 4 days after). Basiliximab is available in 10mg and 20mg vials, at a price of £758.69 and £842.38 respectively (excluding VAT) equating to £1,685 per course of treatment (2 doses of 20mg).</p> <p>For all brands of <u>immediate-release tacrolimus</u>, the summary of product characteristics recommends an initial dose of 0.2 to 0.3mg/kg/day orally or 0.05 to 0.1mg/kg/day intravenously, and states that the dosage is usually reduced in the period after the transplant. Tacrolimus immediate-release capsules are available as 0.5-mg, 0.75-mg, 1-mg, 2-mg and 5-mg capsules (depending on the brand), the price of which varies by brand.</p> <p>The NICE assessment group calculated that the average cost paid by the NHS for immediate release tacrolimus capsules is £0.52 per mg (excluding VAT), This equates to £50.96 to £76.44 per week for an initial dose of 0.2 to 0.3 mg/kg/day in a 70kg person.</p> <p><u>Mycophenolate mofetil</u> can be administered orally (capsules or an oral suspension) or intravenously, at a recommended dose of 2g/day. 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), equating to £5.28 per week.</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 on the NHS for patients having a kidney transplant.</p>

6.	Expected implementation period The recommended immunosuppressive therapy treatments are already available on the NHS for patients having a kidney transplant.
7.	Commissioning arrangements No specific action is required as current best practice will not substantially change.
8.	Monitoring arrangements No specific monitoring is required as current best practice will 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.