

# Drugs to prevent the rejection of kidney transplants in adults

**Understanding NICE guidance – information for people undergoing kidney transplants, their families and carers, and the public**

September 2004



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**Understanding NICE guidance – information for people**  
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**public**

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Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0543. A version in Welsh and English is also available, reference number N0544. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0544. The NICE technology appraisal on which this information is based, 'Immunosuppressive therapy for renal transplantation in adults', is available from the NICE website ([www.nice.org.uk/TA085guidance](http://www.nice.org.uk/TA085guidance)). A short version of the guidance (a 'quick reference guide') is available from the website ([www.nice.org.uk/TA085quickrefguide](http://www.nice.org.uk/TA085quickrefguide)) or from the NHS Response Line, reference number N0542.

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## Contents

What is NICE guidance?	4
When is kidney transplantation needed?	5
What are immunosuppressive drugs?	5
What has NICE recommended?	7
What should I do next?	9
Will NICE review its guidance?	10
Further information	10

## What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS in England and Wales.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance.

NICE was asked to look at the available evidence on the use, in adults, of medicines called basiliximab, daclizumab, tacrolimus, mycophenolate mofetil and sirolimus. These belong to a group of medicines known as immunosuppressive drugs, which are given to people who have had a kidney transplant, to prevent the new kidney being rejected. NICE was asked to provide guidance that will help the NHS in England and Wales decide when to give these medicines to adults having a kidney transplant.

## When is kidney transplantation needed?

The kidneys remove waste products and excess water from the blood. Kidney failure occurs when the kidneys are not working properly. When kidney failure is extremely severe (end-stage kidney failure), the work of the kidneys must be done either by dialysis, or by giving the person a replacement kidney. Replacing a kidney with one from someone who has recently died or from a relative (the donor) is known as kidney transplantation.

## What are immunosuppressive drugs?

One problem with kidney transplantation is that the person's immune defence system (which protects the body from infection) attacks the transplanted kidney. This attack is known as rejection, and it prevents the kidney from working properly. Rejection can be prevented by taking medicines known as immunosuppressive drugs (also called immunosuppressive therapy or immunosuppressants). These drugs weaken the body's immune system, making it less likely to attack the new kidney.

Most people who have a kidney transplant need to take at least one immunosuppressive drug for the rest of their lives.

Immunosuppressive drugs often have side effects, which are more severe for some people than for others. The side effects of the different drugs vary. Some immunosuppressive drugs may damage the transplanted kidney in some people.

Rejection of a kidney is most likely to happen in the first 3 months after a transplant. During this time, people often take a combination of three different drugs:

- one of a type known as calcineurin inhibitors (such as one called ciclosporin)
- one of a type known as antiproliferative agents (such as one called azathioprine)
- and another of a type known as corticosteroids.

This is usually called initial treatment. The person may then stay on these drugs, but at lower doses, for the rest of his or her life, or until the new kidney fails. This is usually called maintenance treatment.

Doctors may sometimes decide to use even more intensive immunosuppressive drugs for the first 2 weeks after a transplant, and this is usually called induction treatment.

Basiliximab, daclizumab, tacrolimus, mycophenolate mofetil and sirolimus are newer immunosuppressant drugs than ciclosporin and azathioprine. NICE has looked at the evidence on them and recommended when they should be used to prevent the rejection of transplanted kidneys.

## **What has NICE recommended on the use of immunosuppressive drugs to prevent the rejection of kidney transplants in adults?**

During the appraisal, NICE's Appraisal Committee read and heard evidence from:

- good-quality studies, in adults, of basiliximab, daclizumab, tacrolimus, mycophenolate mofetil and sirolimus
- doctors with specialist knowledge of immunosuppressive drugs to prevent the rejection of kidney transplants
- individuals with specialist knowledge of the issues affecting people undergoing kidney transplantation
- organisations representing the views of people who will be affected by the guidance (because they have, or care for someone with,

kidney disease or because they work in the NHS and are involved in providing care for people undergoing a kidney transplant)

- the manufacturers of the immunosuppressive drugs.

The evidence is summarised in the full guidance (see end for details). More information about the studies is provided in the Assessment Report for this appraisal (see end for details).

NICE has made the following recommendations about the use of immunosuppressive drugs in adults receiving kidney transplants within the NHS in England and Wales.

Doctors should consider using basiliximab or daclizumab for induction treatment (immediately after the kidney transplant). These drugs should be used with a combination of other drugs including a calcineurin inhibitor such as ciclosporin. The cheapest one of the two (basiliximab or daclizumab) should be used.

Tacrolimus is a calcineurin inhibitor and can be used instead of ciclosporin when a person needs a calcineurin inhibitor as part of their initial or maintenance immunosuppressive treatment after a kidney transplant. The drug (tacrolimus or ciclosporin) that is least likely to have serious side effects in that particular person should be used.

Doctors should consider using mycophenolate mofetil as part of immunosuppressive treatment after kidney transplant only when a person has to stop taking a calcineurin inhibitor, or has to take a lower dose. This could be needed because the calcineurin inhibitor has already damaged the transplanted kidney. It might also be needed for a few weeks or months when there is a high risk that the calcineurin inhibitor would damage the kidney.

Sirolimus should be considered as one of a combination of immunosuppressive drugs, but only for people who cannot use calcineurin inhibitors because of their side effects.

By following these recommendations, doctors would sometimes be using medicines in ways that are not covered by their licences. NICE has reminded doctors that, when this happens, they should explain this to the person involved, and make sure he or she consents to taking the drug.

## **What should I do next?**

If you or someone you care for is about to have or has had a kidney transplant, you should discuss this guidance with your specialist.

## Will NICE review its guidance?

Yes. The guidance will be reviewed in August 2007.

## Further information

The NICE website ([www.nice.org.uk](http://www.nice.org.uk)) has further information about NICE and the full guidance on immunosuppressive therapy for renal transplantation that has been issued to the NHS. The assessment report, which contains details of the studies that were looked at, is also available from the NICE website. A short version of the guidance (a 'quick reference guide') is available on the website and from the NHS response line (reference number N0542).

An appraisal of immunosuppressive therapy for renal transplantation in children and adolescents is ongoing.

If you have access to the Internet, you can find more information about kidney failure and kidney transplants on the NHS Direct website ([www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)). You can also phone NHS Direct on 0845 46 47.





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