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PRESS RELEASE

Kidney transplant patients to benefit from latest NICE guidance on immunosuppressive therapy

The National Institute for Clinical Excellence (NICE or the 'Institute') has issued guidance to the NHS in England and Wales on the use of immunosuppressive therapy for renal (kidney) transplantation in adults. The guidance recommends:

- 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 (a calcineurin inhibitor) 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.
- 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.
- Sirolimus as one of a combination of immunosuppressive drugs, but only for people who cannot use calcineurin inhibitors because of their side effects.

Andrew Dillon, NICE Chief Executive and Executive Lead said: "Renal transplantation is a well established procedure but approaches to the use of drugs designed to help the body to accept the new organ vary considerably. This guidance, developed in conjunction with transplantation specialists, will guide doctors and patients to get the best results."

He continued, "Unusually for NICE guidance, these recommendations contain advice that may result in some medicines being prescribed outside the terms of their marketing authorisation. Because of the way these drugs are used in combination with each other, this already happens extensively. Our guidance will help manage such use and of course, clinicians prescribing these drugs should ensure that patients are aware of when this is happening, and that they consent to their use in such circumstances."

Most people who have a kidney transplant need to take at least one immunosuppressive drug for the rest of their lives to prevent rejection of the new kidney. These drugs weaken the body's immune system, making it less likely to attack the new kidney. 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.

Ends

For more information call Fraser Woodward on 020 7067 5905.

Notes to Editors

About the NICE guidance on immunosuppressive therapy

1. A quick reference version of the guidance is available on the NICE website at www.nice.org.uk/TA085quickrefguide. The full guidance is also available on the NICE website at www.nice.org.uk/TA085guidance

About NICE

2. NICE is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care for those using the NHS in England and Wales. Its guidance is for healthcare professionals and patients and their carers to help them make decisions about treatment and healthcare. For further information about NICE you can visit www.nice.org.uk.
3. NICE produces guidance in three areas of health:
 - a. the use of new and existing medicines and treatments within the NHS in England and Wales technology appraisals.
 - b. the appropriate treatment and care of patients with specific diseases and conditions within the NHS in England and Wales – clinical guidelines.
 - c. whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use – interventional procedures.
4. NICE also funds three enquiries that undertake research into the way patients are treated to identify ways of improving the quality of care (the investigations are known as confidential enquiries).
5. NICE guidance and recommendations are prepared by independent groups that include professionals working in the NHS and people who are familiar with the issues affecting patients and carers.