

**Guidance on
the use of
etanercept and
for infliximab
for the
treatment of
rheumatoid
arthritis**

Further information on NICE, and the full guidance issued to the NHS is available on the NICE website (www.nice.org.uk).

The guidance can also be requested from 0870 555 455, quoting reference N0074.

If you have access to the Internet and would like to find out more about RA visit the NHS Direct website: www.nhsdirect.nhs.uk. If you would like to speak to NHS Direct, please phone 0845 46 47.

This leaflet is also available in Welsh, (Ref no. N0077).

Mae'r daflen hon hefyd ar gael yn Gymraeg (rhif cyfeirnod N0077).

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**Further
information**

to the Registry on the drug you are receiving, the effects of the treatment and any side effects you have experienced. This information will help researchers to find out about the long-term effectiveness and side effects of treatment with etanercept and infliximab.

There is currently no evidence to support treatment with etanercept or infliximab for more than 4 years. A decision to continue therapy should therefore be based on how your condition is progressing and how well the drugs are working for you.

There is no evidence to suggest that these drugs should be used one after the other, and so this is not recommended.

If you, or someone you care for, have RA then you can discuss this advice with the doctor at your next appointment.

Yes. The guidance will be reviewed in March 2005.

**What has NICE
recommended
about the use
of etanercept
and infliximab?**

NICE has made the following recommendations.

Etanercept or infliximab (infliximab only in combination with methotrexate) are recommended as treatment options for adults with active RA who have not responded well to treatment with at least two DMARDs, including methotrexate.

Both etanercept and infliximab should be prescribed in accordance with the relevant sections of the guidelines that have been produced by the British Society for Rheumatology.

Only a consultant rheumatologist should prescribe etanercept or infliximab and provide follow-up treatment and monitoring. Your consultant rheumatologist should discuss with you which drug to prescribe and take into account your preferences.

The doctor who prescribes etanercept or infliximab for you should, with your consent, register you with the Biologics Registry, which has been set up by the British Society for Rheumatology. Every 6 months, the doctor will send information

**What should I
do?**

**Will NICE
review its
guidance?**

What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is a part of the NHS. It produces guidance for both the NHS and patients on medicines, medical equipment, diagnostic tests and clinical and surgical procedures and where they should be used.

When the Institute evaluates these things, it is called an appraisal. Each appraisal takes around 12 months to complete and involves the manufacturers of the drug or device, the professional organisations and the groups who represent patients.

NICE was asked to look at the available evidence on etanercept and infliximab and provide guidance that would help the NHS in England and Wales decide where it should be used in the treatment of rheumatoid arthritis.

Rheumatoid arthritis (RA) is a chronic (long-term), progressive, destructive and disabling condition that impacts severely on a person's quality of life. RA affects all aspects of life from education and employment through to family and social life. It is estimated that 40 out of 100 people with RA stop working

within 5 years of being diagnosed with the condition. RA affects up to 1 in 100 people, and it is estimated that over 420,000 people in England and Wales have RA.

RA is caused by the inflammation of tissue in the joints, which causes pain, swelling and stiffness and can destroy the joint. Approximately 15 out of 100 people with RA have a particularly severe form of the disease that causes constant pain and swelling, which results in severe disability and loss of the use of the joints.

A multidisciplinary approach is taken to the care and treatment of people with RA. This includes physical therapy (for example exercises to help keep the joints working), surgery and treatment with drugs. The main aims of treatment include controlling joint pain and inflammation, reducing joint damage and disability and preventing loss of the use of the joint, and maintaining or improving quality of life.

Traditional drug therapy for RA relies on various combinations of non-steroidal anti-inflammatory drugs (NSAIDs), analgesics (pain-

relieving drugs), corticosteroids and disease-modifying anti-rheumatic drugs (DMARDs). Evidence suggests that patients with RA should be treated with DMARDs soon after diagnosis. If treatment with DMARDs is delayed then it is likely that the patient's condition will get worse more quickly.

DMARDs act to improve symptoms and slow down damage to the joints. These drugs are usually used in sequence, starting with methotrexate.

If treatment with DMARDs does not work, the only option available to doctors and patients is to try to relieve the symptoms of RA rather than delay the course of the disease. This means that people with RA who do not respond to DMARDs are not having their medical needs met, and it is this group that may benefit from treatment with etanercept or infliximab.

Tumour necrosis factor alpha (TNF α) is a substance produced by the body. It is involved in the process of inflammation. In people who have RA, too much TNF α is produced by the body and causes inflammation that damages the cartilage and bone.

What are etanercept and infliximab?

Etanercept works by preventing TNF α attaching itself to the tissue in the joint. It is licensed for the treatment of active RA in adults when treatment with DMARDs, including methotrexate, has not worked. It is given by injection at a dose of 25 mg twice a week and may be given for an indefinite period. A dose of 25 mg given once a week gives a slower response and may be less effective in some patients.

Infliximab works by attaching itself to TNF α and making it inactive. It is currently licensed for use only in combination with methotrexate:

- for the reduction of the signs and symptoms of RA in patients with active disease
- to improve the physical ability of patients with RA and reduce the rate of progression of joint damage

when treatment with DMARDs, including methotrexate, has not worked.

Infliximab is given through a drip at 0, 2 and 6 weeks and then at 8-weekly intervals. Methotrexate is given once a week during this treatment.

What is rheumatoid arthritis?