

**Guidance on
the use of
etanercept for
the treatment
of juvenile
idiopathic
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 N0070.

If you have access to the Internet and would like to find out more about JIA 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. N0073).

Mae'r daflen hon hefyd ar gael yn Gymraeg (rhif cyfeirnod N0073).

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**Further
information**

The doctor who prescribes etanercept or infliximab should, with the parents' and/or child's consent, register the child with the Biologics Registry, which has been set up by the BPRG. Every 3 months, the doctor will send information to the Registry on the dosage, the effects of the treatment and any side effects. This information will help researchers to find out about the long-term effectiveness and side effects of treatment with etanercept.

At the moment there is no evidence from clinical studies to show how effective etanercept for the treatment of JIA is beyond 2 years. Therefore the doctor should make a decision about whether to continue treatment with etanercept on the basis of how the child's condition is progressing and how well the drugs are working.

If you have, or a child you care for has, JIA then you can discuss this advice with the doctor at your next appointment.

Yes. The guidance will be reviewed in January 2005.

British Paediatric Rheumatology Group (BPRG). The BPRG protocol sets out the criteria for who should or should not be eligible for treatment and defines 'failure' of standard therapy. It also sets out the criteria for withdrawal of etanercept treatment, which include withdrawal of treatment if severe side effects occur, or if there is no response to treatment after 6 months.

Only a consultant who regularly sees children and young people with JIA and who runs specialised paediatric rheumatology clinics should prescribe etanercept. In addition, the clinic should have a nurse specialist or an appropriately trained nurse who is able to teach children and parents how to inject etanercept, and who does this regularly. Follow-up treatment will depend on local circumstances, and may be provided on a 'shared-care' basis, where GPs monitor patients' progress and any side effects.

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 provide guidance that would help the NHS in England and Wales decide where it should be used in the treatment of juvenile idiopathic arthritis.

What is juvenile idiopathic arthritis?

Juvenile idiopathic arthritis (JIA) is a term that covers a group of diseases that are characterised by persistent joint swelling, pain and limitation of movement. At its worst, JIA can affect growth, the muscles in joints and the eyes, and can cause permanent

disability. Many children and young people with JIA require replacement of joints damaged by JIA.

JIA affects children's personal and social development. Children often miss school and normal childhood activities, and as adults they may have a poorer chance of getting a well-paid job, or may not be able to work at all. JIA can also have a considerable impact on a child's family – not only emotionally but also financially because parents may restrict or give up their work so that they can care for their child.

JIA is a relatively rare disease: about 1 child in every 1000 has JIA, so about 10,000 children in the UK are affected.

A multidisciplinary approach is taken to the care and treatment of children with JIA. 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

What is etanercept?

disability and preventing loss of the use of the joint, and maintaining or improving quality of life.

Drug treatment for JIA involves non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and disease-modifying anti-rheumatic drugs (DMARDs). The most common DMARD used is methotrexate, which is given orally or by injection. However, neither methotrexate nor any other DMARD is currently licensed for use in children in the UK.

Children whose condition has not responded to methotrexate may benefit from treatment with etanercept.

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 JIA, too much TNF α is produced by the body and causes inflammation that damages the cartilage and bone.

Etanercept works by preventing TNF α attaching itself to the tissue in the joint. It is licensed

What has NICE recommended about the use of etanercept for JIA?

for the treatment of active JIA in children aged 4 to 17 years who have the disease in at least five joints and who have not responded to, or who have been unable to tolerate treatment with, methotrexate. Etanercept is administered twice weekly by injection.

Etanercept can be given for an indefinite period, but doctors usually stop treatment with etanercept once a child with JIA has had 2 years without any symptoms of the disease. However, 3 out of 10 children have a relapse after the treatment has been stopped.

NICE has made the following recommendations.

Etanercept is recommended for children aged 4 to 17 years who have active JIA in at least five joints and whose condition has not responded adequately to methotrexate or who have been unable to tolerate treatment with methotrexate.

Etanercept should be prescribed in accordance with relevant sections of the protocol that has been produced by the