



News

NICE Recommends Abbott's Adalimumab (HUMIRA®) for the Treatment of Severe Active Ankylosing Spondylitis

MAIDENHEAD, UK, 28 MAY 2008 — The National Institute for Health and Clinical Excellence (NICE) has today recommended adalimumab (HUMIRA) as one of the treatment options for people with severe active ankylosing spondylitis (AS),¹ a painful and progressive rheumatic disease.

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This is the first time that NICE has reviewed anti-tumour necrosis factor (anti-TNF) therapies for AS. Today's decision is also the third positive opinion from NICE for adalimumab for rheumatological conditions, having been recommended for the treatment of active and progressive psoriatic arthritis and moderate-to-severe active rheumatoid arthritis in 2007.^{2,3}

In Britain, AS is estimated to affect 1 in 200 men and 1 in 500 women.⁴ AS is an incurable disease, which primarily affects the joints of the spine, causing inflammatory back pain, stiffness, pain in the ligaments and the tendons. In its most severe form, AS can result in complete spinal fusion, leading to severe functional limitation and deformity over time. The exact cause of AS is unknown but it is believed that certain genetic, immune and environmental factors may be involved.

Until recently, treatment of AS has been limited to non-steroidal anti-inflammatory drugs (NSAIDs) and physiotherapy. Adalimumab works by blocking a protein known to cause inflammation and is indicated for the treatment of severe active AS in adults who have had an inadequate response to conventional therapy.

"Today's recommendations by NICE mark an important step forward for the management of patients with ankylosing spondylitis," commented Dr Bruce Kirkham, Consultant Rheumatologist, Guy's Hospital, London, "People living with AS will welcome today's recommendation. The use of the anti-TNF class of treatments significantly improves the quality of life of those receiving them."

Further information on the recommendation from NICE can be found in the notes to editors below.

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Notes to Editors

About the NICE Guidance

Adalimumab is recommended by NICE as a treatment option for adults with severe active AS only if all of the following criteria are fulfilled:

- The patient's disease satisfies the modified New York criteria for diagnosis of ankylosing spondylitis.
- There is confirmation of sustained active spinal disease, demonstrated by:
 - a score of at least 4 units on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) **and**
 - at least 4 cm on the 0 to 10 cm spinal pain visual analogue scale (VAS).These should both be demonstrated on two occasions at least 12 weeks apart without any change of treatment.
- Conventional treatment with two or more non-steroidal anti-inflammatory drugs taken sequentially at maximum tolerated or recommended dosage for 4 weeks has failed to control symptoms.

Primary Care Trusts have a statutory duty to fund NICE technology appraisals within three months of publication. Further information on the NICE guidance can be found at www.nice.org.uk.

About AS

The course of AS is variable, but the majority of patients have continuous disease activity with episodes of acute pain, known as 'flare ups', against a background of persistent symptoms. There is a need for joint replacement surgery in some patients. In its most severe form, AS can result in complete spinal fusion, which can cause severe functional limitation and the potential for deformity over time. Disease damage is progressive and irreversible and in later life there is an increased risk of spinal fracture and/or mortality due to cardiac valvular disease, amyloidosis and fractures.

Although symptoms can occur at any stage of life, onset of AS is typically in the late teenage years and twenties. AS is nearly three times as common in men as it is in women, and men are also more likely to develop severe spinal disease. About a third of people with AS may be unable to work altogether, with a further 15 per cent reporting some changes to their working lives.

The prevalence of AS is unknown, although according to the British Society for Rheumatology (BSR) guidelines it has been estimated to range from 0.05 per cent to 0.23 per cent. Population figures for England and Wales, in 2004, suggest that there are approximately 2,300 new cases each year.

The disease is associated with other inflammatory diseases of the skin, eyes and intestines including psoriasis, ulcerative colitis and Crohn's disease.

About Adalimumab (HUMIRA®)⁵

Adalimumab (pronounced ā-da-lim-you-mab) is an anti-TNF (tumour necrosis factor) and was developed by Abbott as a treatment for use in a number of chronic inflammatory diseases not adequately controlled by traditional therapies.

Adalimumab is licensed in the UK for the following five immunological conditions:

Ankylosing Spondylitis

Adalimumab is indicated for the treatment of adults with severe active AS who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis

Adalimumab in combination with methotrexate (MTX) is indicated for:

- the treatment of moderate-to-severe, active rheumatoid arthritis (RA) in adult patients when the response to disease-modifying anti-rheumatic drugs including MTX has been inadequate.
- the treatment of severe, active and progressive RA in adults not previously treated with MTX.

Adalimumab has been shown to reduce the rate of joint damage in RA as measured by X-ray and improve physical function, when given in combination with MTX. Adalimumab can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

Psoriatic Arthritis

Adalimumab is indicated for the treatment of active and progressive psoriatic arthritis (PsA) in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate.

Psoriasis⁵

Adalimumab is indicated for the treatment of adults with moderate-to-severe chronic plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to, other systemic therapy including cyclosporine, methotrexate or PUVA (psoralen and long-wave ultraviolet radiation).

Crohn's Disease

Adalimumab is indicated for treatment of severe, active Crohn's disease (CD), in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.

For induction treatment, adalimumab should be given in combination with corticosteroids. Adalimumab can be given as monotherapy in case of intolerance to corticosteroids or when continued treatment with corticosteroids is inappropriate.

Dosing

Adalimumab is administered as a subcutaneous injection either as a pre-filled pen or pre-filled syringe. For the AS, RA and PsA indications, adalimumab is usually administered as 40mg every other week as a single dose. For CD the recommended dosing is 80mg at week 0 followed by 40mg at week 2 and 40 mg every other week thereafter. For psoriasis the recommended dosing is an initial dose of 80mg, followed by 40 mg given every other week starting one week after the initial dose.

It is essential to be screened for tuberculosis before starting treatment with adalimumab. Patients who have suffered from Hepatitis B, from chronic lung disease or who are heavy smokers should discuss the risk of taking adalimumab with their doctor. As adalimumab impacts on the immune system, patients may become more susceptible to infections and should contact their doctor if they develop signs of infection. Patients are advised to avoid becoming pregnant.

It is very important to read the Patient Information leaflet or read the Summary of product characteristics for more information on adalimumab.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 68,000 people and markets its products in more than 130 countries.

References:

1. National Institute for Clinical Excellence. Adalimumab, etanercept and infliximab for ankylosing spondylitis – Guidance. May 2008 www.nice.org.uk
2. National Institute for Clinical Excellence. Adalimumab for the treatment of moderate-to severe psoriatic arthritis – Guidance. August 2007 www.nice.org.uk
3. National Institute for Clinical Excellence. Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis – Guidance. October 2007 www.nice.org.uk
4. Rogers F.J. The National Ankylosing Spondylitis Society, Guidebook for Patients, A Positive Response to Ankylosing Spondylitis, NASS, June 2004; 3
5. Electronics Medicines Compendium HUMIRA (adalimumab) Summary of Product Characteristics <http://emc.medicines.org.uk/>