

From the Chief Medical Officer
Dr Michael McBride



Department of
**Health, Social Services
and Public Safety**

www.dhsspsni.gov.uk

Circular HSC (SQSD) (NICE) 29/08 TA 130

AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydënter Heisin
an Fowk Siccar**

Chief Executives of HSS Boards – **for distribution to:**
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Directors of Nursing
Directors of Pharmaceutical Services
Directors of Primary Care – for cascade to prescribing and GP
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Chief Executives of HSC Trusts – **for distribution to:**
Medical Directors – for cascade to relevant staff
Directors of Nursing – for cascade to relevant staff
Directors of Pharmaceutical Services – for cascade to relevant
staff

Date: 9 July 2008

General Practitioners

HSC Clinical and Social Governance Leads

Chief Executives of HSC Special Agencies and NDPBs

For Information

Chairs of HSS Boards
Chairs of HSC Trusts
Chief Executive, Regulation & Quality Improvement Authority
Chief Officers HSC Councils
Chief Executive/Postgraduate Dean, NIMDTA
Chief Executive, NIPPET
Chief Executive, NIPEC
Chief Executive, RMSC

Dear Colleagues

Technology Appraisal 130 – Adalimumab, Etanercept and Infliximab for the Treatment of Rheumatoid Arthritis

The tumour necrosis factor alpha (TNF- α) inhibitors adalimumab, etanercept and infliximab are recommended as options for the treatment of adults who have both of the following characteristics:

- Active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions 1 month apart.
- Have undergone trials of two disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated). A trial of a DMARD is defined as being normally of 6 months, within 2 months at standard dose, unless significant toxicity has limited the dose or duration of treatment.

TNF- α inhibitors should normally be used in combination with methotrexate. Where a patient is intolerant of methotrexate or where methotrexate treatment is considered to be inappropriate, adalimumab and etanercept may be given as monotherapy.

Treatment with TNF- α inhibitors should be continued only if there is an adequate response at 6 months following initiation of therapy. An adequate response is defined as an improvement in DAS28 of 1.2 points or more.

After initial response, treatment should be monitored no less frequently than 6-monthly intervals with assessment of DAS28. Treatment should be withdrawn if an adequate response (as defined above) is not maintained.

An alternative TNF- α inhibitor may be considered for patients in whom treatment is withdrawn due to an adverse event before the initial 6-month assessment of efficacy, provided the risks and benefits have been fully discussed with the patient and documented.

Escalation of dose of the TNF- α inhibitors above their licensed starting dose is not recommended.

Treatment should normally be initiated with the least expensive drug (taking into account administration costs, required dose and product price per dose). This may need to be varied in individual cases due to difference in the mode of administration and treatment schedules.

Use of the TNF- α inhibitors for the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate or other DMARDs is not recommended.

Initiation of TNF- α inhibitors and follow-up of treatment response and adverse events should be undertaken only by a specialist rheumatological team with experience in the use of these agents.

DHSSPS advises that this appraisal guidance is valid for Northern Ireland and endorses it for implementation in HSC.

The full NICE technology appraisal is available for download at:
<http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11867>

NICE has published related guidance on the treatment of rheumatoid arthritis (NICE TA126, TA72 & TA35) available for download at:
<http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11821>

<http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11522>

<http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11446>

The HSC sector also should note that;

1. The Department expects HSC organisations to put plans in place within 3 months of the date of issue of this e-mail alert to facilitate the implementation of this guidance, taking account of previous Departmental guidance and targets on the introduction of antiTNFs for severe arthritis.
2. This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.
3. NICE has developed tools to help organisations implement this guidance. These are available at <http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11892> and include costing tools, implementation advice and audit criteria to monitor local practice.

All NICE guidance endorsed by the Department to date can be accessed on the DHSSPS website at <http://www.dhsspsni.gov.uk/sqsd-guidance-nice-guidance>

Circular HSS (PPMD) (NICE)01/006 issued on 30 June 2006 provides further information on the Northern Ireland process for reviewing NICE guidance and further details on the local status of the Institute's guidance. This circular can be accessed at: http://www.dhsspsni.gov.uk/nice_guidance_01-06.pdf



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