

From the Chief Medical Officer
Dr Michael McBride



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

www.dhsspsni.gov.uk

POLICY CIRCULAR

AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

Subject: NICE Guidance update

Circular Reference: HSC (SQSD) (NICE) 21/09

Date of Issue: 13 March 2009

Chief Executives of HSS Boards – **for distribution to:**
Directors of Public Health
Directors of Nursing
Directors of Pharmaceutical Services
Directors of Primary Care – for cascade to prescribing and
GP Advisors

Related documents
HSS (MD) 7/2009

Chief Executives of HSC Trusts – **for distribution to:**
Medical Directors – for cascade to relevant staff
Directors of Nursing – for cascade to relevant staff
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relevant staff

Superseded documents
HSC (SQSD) (NICE) 11/07

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, NICPPET
Chief Executive, NIPEC
Chief Executive, RMSC

Summary of Contents:

**Revised circular to advise HSC organisations of the withdrawal
of NICE guidance on the use of Efavirumab for the treatment of
Psoriasis in light of the EMEA safety alert**

Implementation: immediate

Enquiries:

Any enquiries about the content of this Circular should be addressed
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<http://www.dhsspsni.gov.uk/>

DH1/09/37129

Dear Colleague

This circular supersedes circular HSC (SQSD) (NICE) 11/07 - NICE Technology Appraisal Guidance No TA 103 – Psoriasis – Efalizumab and Etanercept

NICE has suspended the use of Efalizumab for the treatment of psoriasis due to a safety alert from the European Medicines Agency (EMA).

The EMA, the European Union (EU) body which is responsible for monitoring the safety of medicines, has recommended that marketing authorisation be suspended for Serono's psoriasis drug efalizumab (raptiva) over possible links between the drug and a rare but deadly brain infection.

The Department of Health, Social Services and Public Safety has issued an Urgent Communication letter HSS (MD) 7/2009 to HSC organisations which can be accessed at: <http://www.dhsspsni.gov.uk/hss-md-7-2009.pdf>

As a result of the EMA's decision, NICE has temporarily withdrawn its guidance on the use of efalizumab for the treatment of adults with psoriasis. Guidance on the use of etanercept for the treatment of adults with psoriasis remains the same and in force. NICE will continue to review the status of its guidance in light of any further changes to efalizumab's marketing authorisation.

Further information on the EMA's decision is available from its website at <http://www.ema.europa.eu/>

Circular HSC (SQSD) (NICE) 11/07 TA 103/07 recommended etanercept and efalizumab within their licensed indications for the treatment of adults with severe plaque psoriasis when the psoriasis has failed to respond to standard systemic therapies, or where the person is intolerant to, or has a contraindication to, these treatments. As a result of EMA's safety alert the Department of Health, Social Services and Public Safety is also withdrawing the use of efalizumab for the treatment of psoriasis.

The appraisal guidance and other related documents are available for download at <http://www.nice.org.uk/guidance/TA103>

Etanercept for the treatment of adults with severe plaque psoriasis

HSC organisations should note that:

1. DHSSPS advises that this NICE appraisal, in relation to etanercept, is valid for Northern Ireland and endorses it for implementation in the HSC sector.

2. Etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately to treatment at 12 weeks – further treatment cycles are not recommended in these patients.
3. Use of etanercept for psoriasis should be initiated and supervised only by specialist physicians experienced in the diagnosis and treatment of psoriasis.
4. The Department expects HSC organisations to implement this guidance with immediate effect.
5. NICE provides a range of implementation tools such as costing templates and audit advice which HSC organisations may find helpful in assessing the likely impact of the appraisal locally. Additionally, an easy to read summary of the guidance, called "Understanding NICE Guidance" is published on the NICE website to provide information for patients and the public.
6. 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.

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) 01/06 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://dhsspsni.gov.uk/nice_guidance_01-06.pdf



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