Complete Summary

GUIDELINE TITLE

Etanercept and efalizumab for the treatment of adults with psoriasis.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Etanercept and efalizumab for the treatment of adults with psoriasis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jul. 35 p. (Technology appraisal guidance; no. 103).

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references drug(s) for which important revised regulatory and/or warning information has been released.

- October 17, 2008, Raptiva (efalizumab): The U.S. Food and Drug Administration (FDA) notified healthcare professionals of extensive labeling changes, including a Boxed Warning, to highlight the risks of life-threatening infections, including bacterial sepsis, viral meningitis, invasive fungal disease, progressive multifocal leukoencephalopathy and other opportunistic infections with the use of Raptiva. In addition, the prescribing information will be updated to describe a potential risk for the permanent suppression of the immune system with repeat administration of Raptiva in children. Raptiva is not approved for children under 18 years of age.
- May 1, 2008, Enbrel (etanercept): Amgen and Wyeth Pharmaceuticals informed healthcare professionals of changes to the BOXED WARNING section of the prescribing information for Enbrel regarding the risk of serious infections, including bacterial sepsis and tuberculosis, leading to hospitalization or death. The ADVERSE REACTIONS section of the label was updated to include information regarding global clinical studies and the rate of occurrence of tuberculosis in patients treated with Enbrel.

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SCOPE

DISEASE/CONDITION(S)

Psoriasis

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness Management Treatment

CLINICAL SPECIALTY

Dermatology Family Practice

INTENDED USERS

Advanced Practice Nurses Nurses Pharmacists Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness, safety, tolerability and cost-effectiveness of etanercept and efalizumab for the treatment of moderate to severe chronic plaque psoriasis

TARGET POPULATION

Adults with moderate to severe chronic plaque psoriasis

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Etanercept
- 2. Efalizumab

MAJOR OUTCOMES CONSIDERED

Clinical effectiveness

Outcomes of primary interest were derived from the Psoriasis Area and Severity Index (PASI). Data on the following outcomes were also eligible in the review of efficacy:

- Physician's Global Assessment (PGA)
- Patient-centred outcome measures
- Self Administered Psoriasis Area and Severity Index (SAPASI)
- Psoriasis Disability Index (PDI)
- Total Severity Score (TSS)
- Investigator's Assessment of Global Improvement (IAGI)
- Quality of life (QoL)
- Dermatology Life Quality Index (DLQI)
- Duration of remission
- Cost effectiveness of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Centre for Reviews and Dissemination/ Centre for Health Economics (CRD/CHE) Technology Assessment Group, University of York (see the "Availability of Companion Documents" field.)

Search Strategy

Searches were undertaken on the following databases to identify relevant clinical and cost-effectiveness literature. Full details of the search strategies are reported in Appendix 10.1 of the Assessment Report (see "Availability of Companion Documents" field). Searches took place over a period of time from April to July 2004

- Medline and In-Process Citations (OVID Online)
- Embase (OVID Online)
- National Research Register (NRR) (cd-rom)
- Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Library via the internet)

- CenterWatch (internet http://www.centerwatch.com/index.html)
- Current Controlled Trials (internet http://controlled-trials.com/)
- ClinicalTrials.gov (internet http://clinicaltrials.gov/)
- National Health Service Economic Evaluation Database (NHS EED) (CRD administration database)
- Health Economic Evaluation Database (HEED) (CD-ROM)
- EconLit (SilverPlatter on the web)
- ISI Science and Technology Proceedings (Web of Knowledge http://wos.mimas.ac.uk)
- Social Science Citation Index (Web of Science http://wos.mimas.ac.uk/)
- Science Citation Index (Web of Science http://wos.mimas.ac.uk/)

All databases were searched from their inception to the date of the search. Searches were also undertaken on several Internet resources, which are documented in Appendix 10.1 of the Assessment Report (see "Availability of Companion Documents" field).

Terminology

The terms for the search strategies were identified through discussion between an Information Officer and the research team, by scanning the background literature, and by browsing the Medline Thesaurus (MeSH). No language or other restrictions were applied.

Management of References

As several databases were searched, some degree of duplication resulted. In order to manage this issue, the titles and abstracts of bibliographic records were downloaded and imported into Endnote bibliographic management software to remove duplicate records.

Handsearching

The bibliographies of all included studies and industry submissions made to NICE were reviewed to identify further relevant studies. Handsearching continued throughout the project.

Inclusion and Exclusion of Studies

Study Selection

Two reviewers selected the studies for the review. Discrepancies were resolved by consensus and a third reviewer was consulted when necessary.

All titles and abstracts identified by the search were screened and any references that were considered relevant by either reviewer were obtained.

No language restrictions were applied to study selection. Trials reported as full publications or unpublished full reports were included in the review. Trials reported as abstracts only were to be included if adequate information was

provided. All of the data submitted by Wyeth and Serono were considered in the review.

Inclusion/Exclusion Criteria

Efficacy of Interventions

The review addressed the following questions about the efficacy of etanercept and efalizumab in the treatment of moderate to severe psoriasis:

- Is the drug effective at all?
- How effective is it?
- Can the drugs be used long-term?
- How long is remission and is there any rebound if active treatment is replaced with passive treatment?
- How effective is retreatment in patients who have relapsed following an earlier treatment period?

Studies were included in the review according to the inclusion criteria described in the following paragraphs.

Intervention

Etanercept and efalizumab administered by subcutaneous injection were the interventions of interest. Comparisons with either placebo or any other active agent were eligible for inclusion.

Participants

Studies of adults with moderate to severe psoriasis were included. These patients are usually defined as having an inadequate response to topical treatments alone and to have either received prior systemic therapy or phototherapy or are candidates for such therapy.

Study Design

Only randomised controlled trials were included in the evaluation of efficacy.

Outcomes

The outcomes of primary interest were those derived from the Psoriasis Area and Severity Index (PASI). Data on the following outcomes were also eligible in the review of efficacy: Physician's Global assessment (PGA); patient-centred outcome measures; Self Administered Psoriasis Area and Severity Index (SAPASI); Psoriasis Disability Index (PDI); Total Severity Score (TSS); Investigator's Assessment of Global Improvement (IAGI); quality of life (QoL); Dermatology Life Quality Index (DLQI); duration of remission.

Adverse Effects of Interventions

Adverse events data was summarised from key sources and existing reviews. This was supplemented by a systematic review of adverse events data from clinical studies. See section 3.2.2.2 of the Assessment Report (see "Availability of Companion Documents" field) for a description of the inclusion criteria. The reference details and reasons for exclusion of studies are presented in Appendix 10.3 of the Assessment Report (see "Availability of Companion Documents" field).

Other Treatments for Moderate to Severe Psoriasis

In an attempt to put into context the evidence base for the efficacy of etanercept and efalizumab we investigated the evidence available for other treatments for moderate to severe psoriasis. See section 3.2.2.3 of the Assessment Report (see "Availability of Companion Documents" field) for a description of the inclusion criteria.

Economic Evaluations – Systematic Review

Studies were eligible for inclusion if they assessed both the costs and benefits of either efalizumab or etanercept and compared findings with an appropriate comparator treatment.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

- Three randomized controlled trials (RCTs) related to the efficacy of etanercept were included in the review.
- Five randomised controlled trials related to the efficacy of efalizumab were included in the review.

Cost Effectiveness

- One study of etanercept met the inclusion criteria.
- No economic evaluation of efalizumab was found.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Centre for Reviews and Dissemination/ Centre for Health Economics (CRD/CHE) Technology Assessment Group, University of York (see the "Availability of Companion Documents" field.)

Methods

A systematic review evaluated the clinical efficacy and adverse effects of etanercept and efalizumab. The efficacy of other treatments for moderate to severe psoriasis was also reviewed and, where data allowed, all treatments were compared in an evidence synthesis utilising a mixed treatment comparison implemented as a Bayesian hierarchical model. Following evaluation of existing economic evaluations of etanercept and efalizumab in moderate to severe psoriasis, a new economic model was developed (the York Model), which directly utilised the results from the evidence synthesis.

Evidence Synthesis

To enable indirect comparisons between all treatments for moderate to severe psoriasis, a meta-analysis of the Psoriasis Area and Severity Index (PASI) 50, 75 and 90 response rates from the randomised trials was performed. The endpoints were jointly modelled using an ordered probit model. The available data permitted the inclusion of etanercept (25 mg and 50 mg), efalizumab, infliximab, ciclosporin, methotrexate, Fumaderm and placebo in this mixed-treatment comparison which was implemented as a Bayesian hierarchical model.

For a full discussion of the methods used to analyze the evidence, see sections 3.2.3, 3.2.4, and 3.2.5 in the Assessment Report (see "Availability of Companions Documents" field).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under

review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Published Economic Evaluations

The Assessment Group did not identify any published economic evaluations that considered efalizumab. The Assessment Group identified only one published economic evaluation of etanercept that met its inclusion criteria. The base-case

analysis found ultraviolet B (UVB) phototherapy to be the most cost-effective option, followed by methotrexate. Of the three biological therapies examined (infliximab, etanercept and alefacept), infliximab was found to be the most cost effective, although it was still less cost effective than non-biological treatments. The analysis, however, had limited usefulness for decision making primarily because it was United States (US)-based and the results were not expressed as incremental costs per quality-adjusted life year (QALY).

See sections 4.2.2 and 4.2.3 in the original guideline document for information about manufacturers' models of cost-effectiveness for etanercept and efalizumab.

The Assessment Group Model

The Assessment Group developed its own model for assessing the cost effectiveness of etanercept and efalizumab. The main analysis compared etanercept (intermittent 25 mg and 50 mg, and continuous 25 mg), efalizumab (continuous) and supportive care without disease-modifying anti-rheumatic drugs (DMARDs) or biological therapies. Utilities were estimated by mapping the mean change in Dermatology Life Quality Index (DLQI) score (conditional on Psoriasis Area and Severity Index [PASI] response) to changes in EuroQol-5D (EQ-5D) (a non-disease specific instrument for describing and valuing health-related quality of life [HRQoL]). When modelling intermittent etanercept treatment, it was assumed that the time between 12 week treatment cycles would be 29 days, resulting in 3.2 treatment cycles per year. This was based on the median duration of PASI 75 response as reported in an unpublished etanercept re-treatment study. Annual discount rates of 6% on costs and 1.5% on outcomes were applied in the analyses. Adverse events were not directly modelled. Decision uncertainty was examined using probabilistic sensitivity analysis.

The base-case analysis showed that supportive care is the only cost-effective strategy until the threshold reaches 70,000 pounds sterling per QALY. The ICER for intermittent low-dose (25 mg) etanercept was found to be £65,320 per QALY gained. The incremental cost-effectiveness ratio (ICER) for intermittent high-dose (50 mg) etanercept treatment was substantially higher. Efalizumab was dominated in the analysis by intermittent etanercept 25 mg. The results of several alternative scenarios presented indicated that the cost effectiveness of efalizumab and etanercept varied considerably according to baseline DLQI and whether it was assumed that all non-responders were hospitalised for 21 days annually. In all cases, the ICERs of the biological agents were found to be lower than in the base-case; but efalizumab was less cost-effective than intermittent etanercept 25 mg. In the scenario that considered both poor baseline quality of life and hospitalisation for non-responders, the ICER for intermittent etanercept 25 mg was £14,460 per QALY gained.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document

(ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- 1. Etanercept, within its licensed indications, administered at a dose not exceeding 25 mg twice weekly is recommended for the treatment of adults with plaque psoriasis only when the following criteria are met.
 - The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10.
 - The psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate, and psoralen and long-wave ultraviolet radiation (PUVA); or the person is intolerant to, or has a contraindication to, these treatments.
- 2. Etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. Further treatment cycles are not recommended in these patients. An adequate response is defined as either:
 - A 75% reduction in the PASI score from when treatment started (PASI 75), or
 - A 50% reduction in the PASI score (PASI 50) and a five-point reduction in DLQI from when treatment started
- 3. Efalizumab, within its licensed indications, is recommended for the treatment of adults with plaque psoriasis under the circumstances detailed in section 1 (above) only if their psoriasis has failed to respond to etanercept or they are shown to be intolerant of, or have contraindications to, treatment with etanercept.
- 4. Further treatment with efalizumab is not recommended in patients unless their psoriasis has responded adequately at 12 weeks as defined in section 2 (above).
- 5. It is recommended that the use of etanercept and efalizumab for psoriasis should be initiated and supervised only by specialist physicians experienced in the diagnosis and treatment of psoriasis. If a person has both psoriasis and psoriatic arthritis their treatment should be managed by collaboration between a rheumatologist and a dermatologist.
- 6. Patients who have begun a course of treatment with efalizumab at the date of publication of this guidance should have the option of continuing to receive treatment until the patients and their clinicians consider it is appropriate to stop.

CLINICAL ALGORITHM(S)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of efalizumab and etanercept in the treatment of adults with psoriasis

POTENTIAL HARMS

Etanercept

The most frequent adverse events reported during etanercept therapy include injection site reactions, infections, and allergic reactions. The Summary of Product Characteristics (SPC) specifies a number of uncommon but serious adverse events that may be related to the immunomodulatory activity. There are no monitoring requirements.

Efalizumab

The most frequent adverse drug reactions reported during efalizumab therapy are mild to moderate dose-related acute flu-like symptoms (associated with the first few doses), leukocytosis, and lymphocytosis. Owing to the risk of thrombocytopenia, monthly platelet counts are recommended on initiation of therapy, but the frequency can be decreased to every 3 months with continued treatment.

For full details of side effects and contraindications, see the Summary of Product Characteristics for each drug, available at http://emc.medicines.org.uk/.

CONTRAINDICATIONS

CONTRAINDICATIONS

The United Kingdom (UK) marketing authorisation for efalizumab specifies that the psoriasis should be chronic, and it is contraindicated in patients with specific forms of psoriasis like guttate, erythrodermic, or pustular psoriasis as the sole or predominant form.

For full details of side effects and contraindications, see the Summary of Product Characteristics for each drug, available at http://emc.medicines.org.uk/.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Notes on the Generalisability of the Findings

For both etanercept and efalizumab, the trial populations may not truly reflect the difficult-to-treat patients for whom these two biologics are licensed. In addition, the results of both the clinical and economic evaluations relate to induction of remission rather than long-term effectiveness in the treatment of psoriasis.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- 'Healthcare Standards for Wales' was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (<u>www.nice.org.uk/TA103</u> [see also the "Availability of Companion Documents" field]).
 - Costing report and costing template to estimate the savings and costs associated with implementation.
 - Audit criteria to monitor local practice (see appendix C of the original quideline document).

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Etanercept and efalizumab for the treatment of adults with psoriasis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jul. 35 p. (Technology appraisal guidance; no. 103).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Jul

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Ms Julie Acred, Chief Executive Officer, Derby Hospitals; Dr Darren Ashcroft, Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical Sciences, University of Manchester; Professor David Barnett (Chair) Professor of Clinical Pharmacology, University of Leicester; Dr Peter Barry, Consultant in Paediatric Intensive Care and Honorary Senior Lecturer, Department of Child Health, Leicester Royal Infirmary; Mr Brian Buckley, Vice Chairman, InContact; Professor Mike Campbell, Statistician, Institute of General Practice & Primary Care, Sheffield: Dr Mark Chakravarty, Head of Government Affairs and NHS Policy, Procter and Gamble Pharmaceuticals (UK) Ltd, Egham, Surrey; Dr Peter I Clark, Consultant Medical Oncologist, Clatterbridge Centre for Oncology, Wirral, Merseyside; Ms Donna Covey, Chief Executive, Asthma UK; Dr Mike Davies, Consultant Physician, University Department of Medicine & Metabolism, Manchester Royal Infirmary: Mr Richard Devereaux-Phillips, Public Affairs Manager, Medtronic Ltd; Professor Jack Dowie, Health Economist, London School of Hygiene; Professor Gary A Ford (Vice Chair) Professor of Pharmacology of Old Age/Consultant Physician, Newcastle upon Tyne Hospitals NHS Trust; Dr Fergus Gleeson, Consultant Radiologist, The Churchill Hospital, Oxford; Ms Sally Gooch, Former Director of Nursing, Mid-Essex Hospital Services NHS Trust, Chelmsford; Professor Trisha Greenhalgh, Professor of Primary Health Care, University College London; Miss Linda Hands, Clinical Reader in Surgery, University of Oxford; Professor Peter Jones, Professor of Statistics & Dean Faculty of Natural Sciences, Keele University; Professor Robert Kerwin, Professor of Psychiatry and Clinical Pharmacology, Institute of Psychiatry, London; Ms Rachel Lewis, Nurse Advisor to the Department of Health; Professor Jonathan Michaels, Professor of Vascular Surgery, University of Sheffield; Dr Ruairidh Milne, Senior Lecturer in Public Health, National Coordinating Centre for Health Technology Assessment, University of Southampton; Dr Neil Milner, General Medical Practitioner, Sheffield; Dr Rubin Minhas, General Practitioner with a Special Interest in Coronary Heart Disease, Primary Care CHD Lead, Medway PCT & Swale PCT; Mr Miles Scott, Chief Executive, Harrogate Health Care NHS Trust; Professor Mark Sculpher, Professor of Health Economics, University of York; Dr Ken Stein, Senior Lecturer, Peninsula Technology Assessment Group (PenTAG), University of Exeter; Professor Andrew Stevens, Professor of Public Health, University of Birmingham; Ms Jayne Wilson, Systematic Reviewer, WMHTAC, Department of Public Health and Epidemiology

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Etanercept and efalizumab for the treatment of adults with psoriasis. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jul. 2 p. (Technology appraisal 103). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Costing template and report. Psoriasis -etanercept and efalizumab. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006.
 Various p. (Technology appraisal 103). Available in Portable Document Format (PDF) from the NICE Web site.
- Efalizumab and etanercept for the treatment of psoriasis. Assessment report.
 Centre for Reviews and Dissemination/Centre for Health Economics
 Technology Assessment Group, University of York. 2005 Feb 4. Electronic copies: Available from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1090. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix C of the <u>original guideline</u> document.

PATIENT RESOURCES

The following is available:

Etanercept and efalizumab for the treatment of psoriasis. Understanding NICE guidance. Information for people who use NHS services. London (UK):
 National Institute for Health and Clinical Excellence (NICE); 2006 Jul. 4 p. (Technology appraisal 103).

Electronic copies: Available in Portable Document Format (PDF) from the <u>National Institute for Health and Clinical Excellence (NICE) Web site</u>.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1091. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on February 26, 2007. This summary was updated by ECRI Institute on May 15, 2008 following the U.S. Food and Drug

Administration advisory on Enbrel (etanercept). This summary was updated by ECRI Institute on October 30, 2008 following the U.S. Food and Drug Administration advisory on Raptiva (efalizumab).

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