NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Final appraisal determination

Infliximab for the treatment of adults with psoriasis

This guidance was developed using the single technology appraisal (STA) process.

1 Guidance

1.1 Infliximab, within its licensed indications, is recommended as a treatment option for adults with plaque psoriasis only when the following criteria are met.

- The disease is very severe as defined by a total Psoriasis Area Severity Index (PASI) of 20 or more **and** a Dermatology Life Quality Index (DLQI) of more than 18.
- The psoriasis has failed to respond to standard systemic therapies such as ciclosporin, methotrexate **or** PUVA (psoralen and long-wave ultraviolet radiation), **or** the person is intolerant to or has a contraindication to these treatments.

1.2 Infliximab treatment should be continued beyond 10 weeks only in people whose psoriasis has shown an adequate response to treatment within 10 weeks. 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 the DLQI from when treatment started.

1.3 When using the DLQI healthcare professionals should take care to ensure that they take account of a patient's disabilities (such as physical impairments) or linguistic or other communication difficulties, in reaching conclusions on the severity of plaque psoriasis. In such cases healthcare professionals should ensure that their use of the DLQI continues to be a sufficiently accurate measure. The same approach should apply in the context of a decision about whether to continue the use of the drug in accordance with section 1.2.

2 The technology

2.1 Infliximab (Remicade, Schering-Plough) is indicated for the treatment of moderate to severe plaque psoriasis in adults whose condition has failed to respond to, or who have a contraindication to, or who are intolerant of other systemic therapies including ciclosporin, methotrexate or PUVA.

2.2 The most common adverse events reported during infliximab therapy include acute infusion-related reactions, infections and delayed hypersensitivity reactions. Infliximab is contraindicated in people with moderate or severe heart failure and active infections. Before treatment is initiated, people must be screened for both active and inactive tuberculosis. The summary of product characteristics (SPC) lists a number of uncommon but serious adverse events related to the immunomodulatory activity of infliximab. For full details of side effects and contraindications, see the SPC.

2.3 Infliximab costs £419.62 per 100-mg vial ('British national formulary' [BNF] edition 53). It is given as a 5-mg/kg intravenous infusion over

a 2-hour period followed by additional 5-mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. The manufacturer estimates the average annual cost per patient to be approximately £11,750. Costs may vary in different settings because of negotiated procurement discounts.

3 The manufacturer's submission

The Appraisal Committee (appendix A) considered evidence submitted by the manufacturer of infliximab and a review of this submission by the Evidence Review Group (ERG; appendix B).

3.1 The manufacturer based its evidence submission on the assessment report and model from 'Etanercept and efalizumab for the treatment of adults with psoriasis', NICE technology appraisal guidance 103 (TA103). In this document these are referred to as the York report and the York model, respectively. The manufacturer stated that the population of interest should be people with a PASI score of 10 or more and a DLQI score of more than 10, in line with the recommendations in TA103. The PASI is a measure of severity of disease in terms of body surface area affected and the extent, scaliness, thickness and redness of plaques with scores ranging from 0 to 72. The DLQI is a disease-specific quality of life measure with scores ranging from 0 to 30. The manufacturer compared infliximab with etanercept, efalizumab and supportive care. In TA103, etanercept is recommended for intermittent use, in which treatment stops when remission is achieved. However, the manufacturer argued that in current clinical practice etanercept is used continuously, in which treatment is continued to maintain response, and therefore continuous etanercept was a more appropriate comparator than intermittent etanercept.

3.2 The manufacturer identified four randomised controlled trials (RCTs) that compared infliximab with placebo: Chaudhari et al. (n = 33, 10-week duration), a phase III, randomised, double-blind, placebo-controlled trial based in the USA; SPIRIT (n = 249, 10-week duration, 30-week follow-up), a phase II induction safety and efficacy study based in the USA; and EXPRESS (n = 378, 10-week duration, 50-week follow-up) and EXPRESS II (n = 835, 10-week duration, 36-week follow-up), which were both phase III multicentre, multinational, randomised, double-blind, placebo-controlled, parallel trials. The participants in the SPIRIT, EXPRESS and EXPRESS II trials had a PASI of at least 12. No trials were identified that compared infliximab with etanercept or efalizumab.

3.3 The results of all four RCTs showed statistically significant improvements in the percentage of people with a PASI 75 (a 75% improvement in the PASI score) after 10 weeks of infliximab compared with placebo (relative risk [RR] 4.5, 14.9, 31 and 39.2, respectively). In the SPIRIT and EXPRESS and EXPRESS II studies, statistically significant improvements were also observed in the percentage of people with PASI 50 and PASI 90. In the EXPRESS and EXPRESS II studies, after week 24 of follow-up the differences were no longer statistically significant, but the manufacturer attributed this to crossover.

3.4 In the absence of any direct trials comparing infliximab with etanercept or efalizumab, the manufacturer carried out an indirect comparison using a meta-analysis and Bayesian hierarchical model. The manufacturer used data from four infliximab trials, four efalizumab trials and three etanercept trials. The random-effects model used for combining 10-week data for infliximab resulted in an RR of 20.49 (95% confidence interval [CI] 16.28 to 25.37). The pooled RR calculated from the four trials of efalizumab was 7.41

(95% CI 5.96 to 9.09) and for 25-mg intermittent etanercept, the RR calculated using pooled data from the three trials was 9.06 (95% CI 7.03 to 11.53).

3.5 The manufacturer based its cost-effectiveness analysis on the York model. This was a two-state Markov model (the two states were on-treatment and off-treatment); alterations were made to include the new data from the infliximab studies. The rates of transitions between states in the model were informed by response and withdrawal rates from the RCTs. The economic analysis included comparisons with etanercept 25 mg, both intermittent and continuous, efalizumab and supportive care. There were no trials identified for continuous etanercept so the manufacturer used the RR for intermittent etanercept in subsequent analyses. The model had a 10-year time horizon and included a trial period after which treatment could be switched to efalizumab or supportive care if the patient's condition had not responded to initial therapy (defined as achieving PASI 75). For infliximab this trial period was 10 weeks (on the basis of RCT evidence), whereas for etanercept and efalizumab it was 12 weeks (corresponding to TA103). The cost and resource use data were obtained from the York report (inflated to present values), NHS reference costs and BNF 53, and were also supported by data that the manufacturer had on file and by clinical opinion.

3.6 The utility data were obtained from the York report. These utilities were based on values from etanercept trials that linked the DLQI with the PASI. A linear transformation was then used to calculate Euro Quality of Life Questionnaire (EQ-5D) scores. In the York report two populations were defined: the all-patient group and a 4th-quartile group, which corresponded to a subgroup with more severe psoriasis, defined as the 25% of people with the highest

scores on the DLQI. In both groups the participants had a PASI greater than 10. The manufacturer used the utilities from the 4th-quartile DLQI group for its base-case analysis to represent those with the worst quality of life at baseline.

3.7 The manufacturer's base-case analysis (using 4th-quartile DLQI utilities) against continuous etanercept resulted in a cost of £26,095 per quality-adjusted life year (QALY) gained. The incremental cost-effectiveness ratio (ICER) for infliximab compared with supportive care was £22,240 per QALY gained. The manufacturer carried out one-way sensitivity analyses. These demonstrated that changes in response rates and patients' weight (the dose of infliximab is dependent on a patient's weight, see section 2.3) had the greatest impact on the ICER. The probabilistic sensitivity analysis gives probabilities of being cost effective at £20,000 and £30,000 thresholds of 10% and 73%, respectively.

3.8 The manufacturer presented, in an appendix, an ICER for infliximab compared with supportive care, using the all-patient utilities, of £41,351 per QALY gained. The probabilistic sensitivity analysis gives a probability of being cost effective at the £30,000 threshold of 0%.

3.9 The ERG had three main areas of concern over the modelling.

- The ERG expressed concern regarding the reasoning behind the exclusive use of the 4th-quartile DLQI utility values. This does not correspond to the total population in the decision problem (that is those with a PASI score of at least 10 and a DLQI score greater than 10) or the data used for the indirect clinical effectiveness estimation. The ERG was unclear as to which severity of psoriasis the results of this analysis would apply.

- The assumed annual drop-out rate in the model was considered by the ERG to be an underestimate because it was based on 6-month rather than annual data. The ERG postulated that the drop-out rate might be as high as 50%. This would result in the ICER against continuous etanercept increasing to approximately £37,000 per QALY gained.
- The ERG considered that the cost of an inpatient stay might have been overestimated because it was based on an elective inpatient code rather than elective and non-elective codes with excess bed days incorporated. The cost of an inpatient day would be reduced from £6189 to £5091 using elective codes and to £5488 using a combination of codes for elective and non-elective admissions. Using a cost of £5091 would increase the ICER against continuous etanercept to approximately £30,000 per QALY gained.

3.10 The ERG produced a cumulative scenario analysis in which all of the changes arising from the assumptions described in section 3.9 were combined. This increased the ICER of infliximab compared with continuous etanercept from £26,095 to approximately £41,000 per QALY gained when the alternative drop-out rate and inpatient costs assumptions were combined. When the all-patient utility was included, the ICER increased to approximately £77,000.

3.11 The ERG also extended the manufacturer's probabilistic sensitivity analysis to include the extra variables of annual drop-out rate, cost of infliximab, length of inpatient stay and number of outpatient visits. The combined result of these changes gave an ICER of £33,200 using 4th quartile utilities and a 38% probability of being cost effective at a £30,000 threshold.

3.12 At the request of the Committee the manufacturer undertook additional analyses which are described in sections 3.13 to 3.15.

3.13 The manufacturer presented an analysis using utilities derived from the EXPRESS trial. It converted SF-36 (36-item Short Form Health Survey) quality of life data into EQ-5D utilities by using an algorithm that was based on unpublished research. However, the manufacturer argued that the utilities from the York report are more appropriate on the grounds that: a) they are more generalisable to the wider patient population because they are based on data that reflect clinical practice; b) SF-36 displays a floor effect and as such can underestimate the impact of some chronic conditions on health-related quality of life. The manufacturer produced utilities for the whole trial population corresponding to the all-patient group defined in the York report, and a 4th-quartile group defined as those with a PASI greater than 12 and a DLQI greater than 18. In addition, the manufacturer combined the utilities from the York report and those from EXPRESS to obtain a pooled mean estimate.

3.14 The manufacturer presented analyses using three different values for the cost of infusions. It used its base case of £65.02 per infusion from national reference costs for dermatology outpatient visits, £78.20 derived from TA103 and £124 described as the cost per administration in the assessment report for rheumatoid arthritis (a systematic review of the effectiveness of adalimumab , etanercept and infliximab for the treatment of rheumatoid arthritis in adults and an economic evaluation of their cost effectiveness, West Midlands Health Technology Assessment Collaboration, October 2005).

3.15 For the all-patient population the ICER against etanercept varied from £44,000 to £49,000 per QALY gained, and in comparison with efalizumab the ICER varied from £42,000 to £47,000 per QALY gained depending on the utilities and costs used. For the

population defined as being in the 4th quartile of DLQI values, the ICER against continuous etanercept varied from £26,000 in the base case to a maximum of £35,000 and when compared with efalizumab the ICER varied from £25,000 in the base case to a maximum of £34,000. Combining the use of EXPRESS utilities and a cost of £124 per infusion resulted in the highest ICERs.

3.16 Full details of all the evidence are in the manufacturer's submission, the ERG report and responses to clarification requests, which are available from www.nice.org.uk/TAxxx

4 Consideration of the evidence

4.1 The Appraisal Committee reviewed the data on the clinical and cost effectiveness of infliximab for the treatment of adults with psoriasis, having considered evidence on the nature of the condition and the value placed on the benefits of infliximab by people with psoriasis, those who represent them, and clinical specialists. It was also mindful of the need to take account of the effective use of NHS resources.

4.2 The Committee discussed the nature of moderate to severe psoriasis and how it affects patients, including the variability in the extent and nature of skin manifestations over time. In particular, the Committee understood that the effect of psoriasis on patients' quality of life is related both to the degree of skin involvement and to the body sites affected. It understood that the PASI is primarily a measure of severity estimated on clinical examination and that the DLQI is a patient estimated measure of quality of life.

4.3 The Committee considered the cost-effectiveness estimates for the all-patient group (PASI of 10 or more and DLQI of more than 10). The Committee was persuaded that under all scenarios presented the ICERs compared with best supportive care, etanercept and

efalizumab were greater than £35,000. Therefore the Committee concluded that in this all-patient group infliximab could not be considered a cost-effective use of NHS resources.

4.4 The Committee understood that in the pathway of care, infliximab may have a particular role in the treatment of patients in whom the disease is very severe or potentially life threatening, and who need a rapid response to treatment. It noted from the British Association of Dermatologists and the Royal College of Physicians, that patients with very severe psoriasis could be defined as those with a PASI score of 20 or more and a DLQI score higher than 10.

4.5 The Committee considered how the population with very severe psoriasis could be defined. The Committee observed that the manufacturer's submission for this appraisal had focused on a subgroup of patients with psoriasis with a particularly poor quality of life, as defined by the highest 25% of DLQI scores at baseline in the EXPRESS trial (DLQI greater than 18), that is those in the 4th quartile. Taking this into account, as well as the considerations in section 4.4, the Committee considered that the combination of a PASI of 20 or more and a DLQI of more than 18 would be an appropriate definition for very severe psoriasis, which could reasonably be expected to represent those whose psoriasis requires a rapid response or is so severe in some circumstances as to be potentially life threatening.

4.6 The Committee considered what the appropriate comparator technologies were for infliximab in the treatment of severe psoriasis. The Committee thought that the principal comparator should be etanercept, given intermittently in line with NICE guidance (TA103). The Committee also accepted that in very severe psoriasis etanercept given continuously would probably be considered by clinicians as a treatment option, because recurrence

of very severe psoriasis between cycles of intermittent etanercept would be likely to significantly affect quality of life. The Committee was therefore persuaded that continuous etanercept was also an appropriate comparator in the subgroup of patients with very severe disease even though it was not currently NICE guidance. The Committee also accepted that in the absence of RCT evidence demonstrating any clinical difference between intermittent and continuous etanercept, it was reasonable to assume for the purposes of cost-effectiveness analysis, that there was no difference in clinical outcomes between continuous and intermittent treatment.

4.7 The Committee discussed the RCT evidence for infliximab compared with placebo in the treatment of psoriasis and concluded that the evidence supported a clinically important effect on both the extent and severity of skin disease (reduction in PASI score) and the quality of life of patients with moderate to severe psoriasis in comparison with best supportive care. The Committee considered that, given the evidence presented by the manufacturer, the clinical benefit of infliximab in the 4th-quartile DLQI group could be assumed to be equivalent to its benefit, measured by improvement in PASI score, in the all-patient group defined on the basis of a PASI of 10 or more and a DLQI greater than 10.

4.8 The Committee discussed the clinical effectiveness of infliximab compared with etanercept or efalizumab taking into account the indirect comparison presented by the manufacturer and the information presented by the clinical specialists and patient experts. The Committee considered that the heterogeneity among the trials included in the indirect comparison could result in uncertainty around the conclusions. Therefore, the Committee could not conclude definitely that infliximab had a statistically significantly

greater clinical effectiveness than intermittent etanercept and efalizumab. However, it heard from clinical specialists and patient experts that in clinical practice infliximab is associated with a higher response rate and a more rapid and longer-lasting response than other therapies with a comparable adverse effect profile, particularly in patients with very severe disease.

4.9 The Committee considered that the approach adopted by the manufacturer for the economic modelling was appropriate since it captured the main aspects of the presentation and course of the disease. However, the Committee expressed concerns over the validity of main input parameters in the model and subsequent analyses.

4.10 Particularly, the Committee considered that the manufacturer's approach to the mapping of SF-36 quality of life data to EQ-5D scores using an un-validated and unpublished algorithm was not appropriate. The Committee would have preferred it if the SF-36 data had been converted to values appropriate to calculate QALYs with a validated instrument, such as SF-6D (short form 6 dimensions, a utility instrument). The Committee did not accept the manufacturer's reasons for using an unvalidated instrument. However, the Committee considered that the utilities presented by the manufacturer along with those from the York report could be accepted as a plausible range for estimating the cost effectiveness of infliximab.

4.11 The Committee also discussed the range of alternatives presented by the manufacturer for the costs of administering infliximab. The Committee considered that it would be difficult to estimate with any certainty the precise infusion costs given the variations within the NHS in clinical practice, local circumstances and interpretation of costing codes. The Committee therefore concluded that, given the

methods behind the calculation of reference costs, the base-case figure of £65.02 and the figure of £124 used in sensitivity analysis represented a plausible range for these costs.

4.12 The Committee finally discussed the ERG's concerns over the drop-out rate for patients being given infliximab and the various inpatient costs. The Committee noted that the ERG's analysis had assumed a 50% drop-out rate over 12 months whereas the rate suggested by the manufacturer was 20% based on the York report. The Committee considered that the appropriate drop-out rate was likely to lie between these two estimates, particularly because the majority of drop-outs would occur in the first 6 months. Therefore it accepted that the values adopted by the manufacturer were appropriate.

4.13 The Committee next considered the cost-effective use of infliximab in the subgroup of patients identified by the manufacturer as those in the 4th quartile of baseline DLQI values among those with a PASI of 12 or more. The Committee noted that these patients would be treated with intermittent etanercept according to NICE guidance (TA103). The ICERs provided by the manufacturer of infliximab compared with intermittent etanercept in this group ranged from £33,000 to £44,000, whereas the ICERs compared with continuous etanercept ranged from £26,000 to £35,000 for the various utilities and costs presented. The Committee was persuaded by the clinical experts' view, as explained in section 4.6, that for people with very severe disease the appropriate alternative to infliximab is more likely to be etanercept given continuously, even though this is not recommended by TA103. The Committee was therefore persuaded that the use of infliximab in the subgroup of patients with very severe disease was a cost-effective use of NHS resources. The Committee further concluded that the

definition of very severe psoriasis, as discussed in section 4.5, of a PASI of 20 or more combined with a DLQI of more than 18 would ensure that infliximab was appropriately targeted at those patients who were most likely to benefit from this treatment.

4.14 The Committee considered the appropriate duration of treatment. It noted that the principal endpoint in the infliximab trials was a PASI 75 response at 10 weeks, and that in the manufacturer's economic modelling it had been assumed that treatment would be discontinued if this response were not achieved at 10 weeks. The Committee thought it appropriate for treatment to be continued beyond 10 weeks only in people whose psoriasis has shown a PASI 75 response to treatment within 10 weeks. In addition the Committee were persuaded that for consistency the response criteria should be defined in a similar way to TA103 (including a 50% reduction in the PASI score and a five-point reduction in the DLQI) except that the assessment should made at 10 weeks after initiation of therapy.

4.15 The Committee was aware that there may be some circumstances in which DLQI is not a clinically appropriate tool to inform a clinician's conclusion on the severity of plaque psoriasis, for example, because of a patient's disabilities (such as physical impairments) or linguistic or other communication difficulties. The Committee concluded that in such cases healthcare professionals should ensure that their use of the DLQI continues to be a sufficiently accurate measure. The same approach should apply in the context of a decision about whether to continue the use of the infliximab.

5 Implementation

5.1 The Healthcare Commission assesses the performance of 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 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.

5.2 '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. [Note: check for each appraisal on relevance for Wales]

5.3 NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/TAXXX). [NICE to amend list as needed at time of publication]

- Slides highlighting key messages for local discussion.
- Costing report and costing template to estimate the savings and costs associated with implementation.

- Implementation advice on how to put the guidance into practice and national initiatives that support this locally.

- Audit criteria to monitor local practice.

6 Related NICE guidance

6.1 Etanercept and efalizumab for the treatment of adults with psoriasis. NICE technology appraisal guidance 103 (2006). Available from: www.nice.org.uk/TA103

6.2 Etanercept and infliximab for the treatment of psoriatic arthritis. NICE technology appraisal guidance 104 (2006). Available from: www.nice.org.uk/TA104

7 Review of guidance

7.1 The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider whether the technology should be reviewed. This decision will be taken in the light of information gathered by the Institute, and in consultation with consultees and commentators.

7.2 The guidance on this technology will be considered for review at the same time that "Etanercept and efalizumab for the treatment of adults with psoriasis" NICE technology appraisal guidance 103 (2006) is considered for review in 2008.

David Barnett
Chair, Appraisal Committee
November, 2007

Appendix A: Appraisal Committee members and NICE project team

A Appraisal Committee members

The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets three times a month except in December, when there are no meetings. The Committee membership is split into three branches, each with a chair and vice chair. Each branch considers its own list of technologies, and ongoing topics are not moved between the branches.

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.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Keith Abrams
Professor of Medical Statistics, University of Leicester

Dr Jeff Aronson
Reader in Clinical Pharmacology, Radcliffe Infirmary

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, Leicester Royal Infirmary

Professor Stirling Bryan

Director of the Health Economics Facility, University of Birmingham

Professor John Cairns

Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Mark Charkravarty

Head of Government Affairs and NHS Policy, Procter and Gamble Pharmaceuticals (UK)

Professor Jack Dowie

Health Economist, London School of Hygiene and Tropical Medicine

Ms Lynn Field

Nurse Director, Pan Birmingham Cancer Network

Professor Christopher Fowler

Professor of Surgical Education, University of London

Dr Fergus Gleeson

Consultant Radiologist, Churchill Hospital

Ms Sally Gooch

Former Director of Nursing and Workforce Development, Mid Essex Hospital Services NHS Trust

Mrs Barbara Greggains

Lay Member

Mr Sanjay Gupta

Former Service Manager in Stroke, Gastroenterology, Diabetes and Endocrinology, Basildon and Thurrock University Hospitals Foundation NHS Trust

Dr Mike Laker

Medical Director, Newcastle Hospitals NHS Trust

Mr Terence Lewis

Mental Health Consultant, National Institute for Mental Health in England

Professor Gary McVeigh

Professor of Cardiovascular Medicine, Queens University, Belfast

Dr Ruairidh Milne

Senior Lecturer in Health Technology Assessment, National Coordinating Centre for Health Technology

Dr Neil Milner

General Medical Practitioner, Tramways Medical Centre, Sheffield

Dr Rubin Minhas

General Practitioner, CHD Clinical Lead, Medway PCT

Dr John Pounsford

Consultant Physician, North Bristol NHS Trust

Dr Rosalind Ramsay

Consultant Psychiatrist, Adult Mental Health Services, Maudsley Hospital

Dr Christa Roberts

UK Country Manager, Abbott Vascular

Dr Stephen Saltissi

Consultant Cardiologist, Royal Liverpool University Hospital

Dr Lindsay Smith

General Practitioner, East Somerset Research Consortium

Mr Roderick Smith

Director of Finance, West Kent Primary Care Trust

Mr Cliff Snelling

Lay Member

Professor Ken Stein

Professor of Public Health, Peninsula Technology Assessment Group (PenTAG), University of Exeter

Professor Andrew Stevens

Professor of Public Health, University of Birmingham

Dr Rod Taylor

Associate Professor in Health Services Research, Peninsula Medical School, Universities of Exeter and Plymouth.

B NICE project team

Each technology appraisal is assigned to a team consisting of one or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

Prashanth Kandaswamy and Nicola Hay

Technical Leads

Helen Chung

Technical Adviser

Natalie Bemrose

Project Manager

Appendix B: Sources of evidence considered by the Committee

A The Evidence Review Group (ERG) report for this appraisal was prepared by Southampton Health Technology Assessment Centre, University of Southampton:

- Loveman, E, Turner, D, Hartwell, D, et al. Infliximab for the treatment of adults with psoriasis, July 2007

B The following organisations accepted the invitation to participate in this appraisal. They were invited to comment on the draft scope, the ERG report and the appraisal consultation document (ACD). Organisations listed in I were also invited to make written submissions. Organisations listed in II gave their expert views on infliximab by providing a written statement to the Committee. Organisations listed in I and II have the opportunity to appeal against the final appraisal determination.

I Manufacturer/sponsor:

- Schering-Plough

II Professional/specialist and patient/carer groups:

- Arthritis and Musculoskeletal Alliance
- Changing Faces
- Psoriasis Association
- Psoriatic Arthropathy Alliance
- Skin Care Campaign
- Skinship (UK)
- Specialised Healthcare Alliance
- British Association of Dermatologists
- British Dermatological Nursing Group
- British Skin Foundation
- British Society for Rheumatology
- Community Practitioners' and Health Visitors Association
- Primary Care Dermatology Society
- Primary Care Rheumatology Society
- Royal College of General Practitioners
- Royal College of Nursing

- Royal College of Paediatrics and Child Health
- Royal College of Physicians
- Royal Pharmaceutical Society

III Commentator organisations (did not provide written evidence and without the right of appeal):

- Board of Community Health Councils in Wales
- British National Formulary
- Department of Health, Social Services and Public Safety for Northern Ireland
- Medicines and Healthcare products Regulatory Agency (MHRA)
- National Public Health Service for Wales
- NHS Confederation
- NHS Purchasing and Supply Agency
- NHS Quality Improvement Scotland
- Scottish Medicines Consortium
- Serono (efalizumab)
- Wyeth (etanercept, methotrexate)
- Roche (acitretin)
- Novartis (ciclosporin)
- Wockhardt UK (methotrexate)
- Mayne Pharma (methotrexate)
- Bristol Myers Squibb (hydroxycarbamide)
- Medac (hydroxycarbamide)
- Cochrane Skin Group (Centre of Evidence-based Dermatology, University of Nottingham)
- Skin Research Centre, University of Leeds
- Skin Treatment and Research Trust (START)
- MRC Clinical Trials Unit
- National Coordinating Centre for Health Technology Assessment
- Southampton Health Technology Assessment Centre, University of Southampton

C The following individuals were selected from clinical specialist and patient advocate nominations from the non-manufacturer/sponsor consultees and commentators. They gave their expert personal view on infliximab by attending the initial Committee discussion and providing written evidence to the Committee. They are invited to comment on the ACD.

- Dr Chris Griffiths, nominated by Royal College of Physicians – clinical specialist
- Professor Jonathan Barker, nominated by the British Association of Dermatologists – clinical specialist
- Mrs Karina Jackson, nominated by the British Dermatological Nursing Group – clinical specialist
- Ms Gladys Edwards, nominated by Psoriasis Association – patient expert
- Mr Ray Jobling, nominated by Psoriasis Association – patient expert