

Issue date: June 2008

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## **Adalimumab for the treatment of adults with psoriasis**

**This guidance was developed using the  
single technology appraisal process**

## **NICE technology appraisal guidance 146 Adalimumab for the treatment of adults with psoriasis**

### **Ordering information**

You can download the following documents from [www.nice.org.uk/TA146](http://www.nice.org.uk/TA146)

- The full guidance (this document).
- A quick reference guide for healthcare professionals.
- Information for people with psoriasis and their carers ('Understanding NICE guidance').
- Details of all the evidence that was looked at and other background information.

For printed copies of the quick reference guide or 'Understanding NICE guidance', phone NICE publications on 0845 003 7783 or email [publications@nice.org.uk](mailto:publications@nice.org.uk) and quote:

- N1610 (quick reference guide)
- N1611 ('Understanding NICE guidance').

### **This guidance is written in the following context**

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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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# 1 Guidance

1.1 Adalimumab is recommended as a treatment option for adults with plaque psoriasis for whom anti-tumour necrosis factor (TNF) treatment is being considered and when the following criteria are both 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 not responded to standard systemic therapies including ciclosporin, methotrexate **and** PUVA (psoralen and long-wave ultraviolet radiation); **or** the person is intolerant of, **or** has a contraindication to, these treatments.

1.2 Adalimumab should be discontinued in people whose psoriasis has not responded adequately at 16 weeks. An adequate response is defined as either:

- a 75% reduction in the PASI score (PASI 75) from when treatment started, **or**
- a 50% reduction in the PASI score (PASI 50) and a five-point reduction in DLQI from start of treatment.

1.3 When using the DLQI, healthcare professionals should ensure that when reaching conclusions on the severity of plaque psoriasis they take into account a person's disabilities (such as physical impairments) and linguistic or other communication difficulties. 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 adalimumab in accordance with section 1.2.

## 2 The technology

- 2.1 Adalimumab (Humira, Abbott Laboratories) is a recombinant human monoclonal antibody that binds specifically to tumour necrosis factor alpha (TNF- $\alpha$ ), blocking interaction with its cell-surface receptors and thereby limiting the promotion of inflammatory pathways. It has a marketing authorisation for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to, other systemic therapy including ciclosporin, methotrexate or PUVA. The recommended dosage for adalimumab is an initial 80 mg dose administered by subcutaneous injection, followed by 40 mg given subcutaneously every other week starting 1 week after the initial dose. Adalimumab is available in two presentations: a prefilled syringe and an autoinjection pen. For further information, see the summary of product characteristics (SPC).
- 2.2 Common adverse events associated with adalimumab, as reported in the SPC, include injection-site reactions, infections, dizziness, headache, diarrhoea, abdominal pain, stomatitis and mouth ulceration, nausea, increased hepatic enzymes, musculoskeletal pain and fatigue. Contraindications listed in the SPC include active tuberculosis or other severe infections such as sepsis, opportunistic infections and moderate to severe heart failure. For full details of side effects and contraindications, see the SPC.
- 2.3 Adalimumab costs £357.50 per 40 mg prefilled syringe or prefilled autoinjection pen (excluding VAT; 'British national formulary' [BNF] edition 55). The average annual cost per patient of adalimumab is estimated by the manufacturer to be £10,010 in the first year and £9295 in subsequent years. 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 adalimumab and a review of this submission by the Evidence Review Group (ERG; appendix B).

- 3.1 In its submission, the manufacturer compared adalimumab with etanercept, efalizumab, infliximab, methotrexate, ciclosporin and supportive care. Results are not presented below for comparisons with methotrexate or ciclosporin, to reflect the licensed use of adalimumab.
- 3.2 The major clinical outcome examined was improvement in PASI score – a measure of disease severity based on body surface area affected and the extent, scaliness, thickness and redness of plaques, with scores ranging from 0 to 72. The DLQI score was also used in the manufacturer's submission. This is a disease-specific quality-of-life measure with scores ranging from 0 to 30.
- 3.3 The main evidence on efficacy in the manufacturer's submission was derived from three randomised controlled trials (RCTs).
- M02-528 (n = 147, 12-week duration), a phase II, multicentre, randomised, double-blind, placebo-controlled, dose-ranging trial based in the USA and Canada.
  - REVEAL (n = 1212, 52-week duration), a phase III, multicentre, randomised trial based in the USA and Canada, consisting of a 16-week double-blind, placebo-controlled period, a 17-week open-label period and a 19-week double-blind, placebo-controlled period.
  - CHAMPION (n = 271, 16-week duration), a phase III, multicentre, randomised, double-blind, placebo-controlled trial based in Europe and Canada, which also compared adalimumab with methotrexate.

- 3.4 The results of the three RCTs showed that a statistically significantly greater proportion of people treated with adalimumab at its licensed dose experienced a 75% or greater reduction in PASI score (PASI 75; a primary endpoint in the trials) compared with those who received placebo. The proportions of people with at least a PASI 75 response, relative to baseline, for adalimumab compared with placebo were: 53% versus 4% (M02-528, 12 weeks); 71% versus 7% (REVEAL, 16 weeks); and 80% versus 19% (CHAMPION, 16 weeks); respectively ( $p < 0.001$  in all comparisons).
- 3.5 Longer-term data from the REVEAL trial showed that PASI response was maintained and continued to favour adalimumab over placebo. During the open-label period of the trial, 89% of people originally randomised to adalimumab, who achieved at least a PASI 75 response at week 16, had at least a PASI 75 response at week 33. In people originally randomly assigned to placebo, PASI 90 response rates increased from week 16 to weeks 24 and 33. During the re-randomisation period of the trial (week 33 to week 52), the proportion of people for whom an adequate response was lost (a primary outcome of the trial) was statistically significantly higher for people randomly reassigned to placebo (28%) compared with people re-randomised to adalimumab (5%) (between-group difference  $-23.5\%$ ; 95% confidence interval [CI]  $-16.9$  to  $-30.2$ ;  $p < 0.001$ ). Loss of adequate response was defined as less than a PASI 50 response relative to week 0 and at least a six-point increase in the PASI score relative to week 33.
- 3.6 For secondary outcomes recorded in the trials, such as the physician's global assessment (PGA) score, the DLQI score and other health-related quality of life scores, adalimumab showed statistically significant improvements compared with placebo.
- 3.7 Adalimumab was generally safe and well tolerated. Data from the placebo-controlled study set ( $n = 1469$ ) show that the incidence of

adverse events that might be related to the study drug was statistically significantly higher in the adalimumab treatment group than in the placebo treatment group. The most commonly reported adverse effects in people treated with adalimumab were nasopharyngitis, upper respiratory tract infection and headache. The incidence of severe adverse events was low and comparable in the adalimumab and placebo treatment groups.

3.8 The manufacturer carried out an indirect comparison of adalimumab with etanercept, efalizumab, infliximab, ciclosporin and methotrexate using a mixed-treatment comparison approach within a Bayesian evidence synthesis framework. The approach compared each treatment through common links to placebo, either by means of direct comparison or through comparison with any other active agent compared with placebo. The manufacturer included data from the three adalimumab RCTs described in section 3.3, four RCTs comparing etanercept with placebo, four comparing infliximab with placebo, five comparing efalizumab with placebo, one comparing ciclosporin with placebo and one comparing methotrexate with ciclosporin. The results from the evidence synthesis showed that the mean probability of achieving a PASI 75 response was 67% for adalimumab (95% CI 57 to 74), 81% for infliximab (95% CI 75 to 87), 38% for etanercept 25 mg (the dose recommended by NICE; 95% CI 29 to 47), 52% for etanercept 50 mg (not recommended by NICE, 95% CI 43 to 60), 29% for efalizumab (95% CI 24 to 35) and 5% for supportive care (95% CI 4 to 6).

3.9 The manufacturer based its cost-effectiveness analysis on the York model used in 'Etanercept and efalizumab for the treatment of adults with psoriasis' (NICE technology appraisal guidance 103 [TA 103]). The model was adapted by the manufacturer of adalimumab to incorporate additional evidence, including the results of the mixed-treatment comparison described in section 3.8.

The updated model also included new utility data derived from empirical estimates of the relationship between PASI response rates and changes in EQ-5D from the CHAMPION study and study M02-528.

- 3.10 Within the model, each person underwent a preliminary period of treatment after which initial response was assessed (this was referred to as the trial period). Continuation of therapy into the next phase (referred to as the treatment period) only occurred if a PASI 75 response was achieved in the trial period. The relevant European marketing authorisations defined the time at which response was measured. These time points were 12 weeks (etanercept, efalizumab), 14 weeks (infliximab) and 16 weeks (adalimumab). The treatment period for each therapy (following a response) was taken from the York model, estimated using an annual drop-out rate of 20% for all patients. The cost and resource use data were taken from the York model, NHS Reference Costs and National Tariff and the BNF edition 53. The Personal Social Services Research Unit (PSSRU) inflation index was used to update costs to 2005–6 if current costs were not available.
- 3.11 In the manufacturer's base-case analysis, the incremental cost per quality-adjusted life year (QALY) gained for adalimumab compared with supportive care was £30,500. Etanercept given continuously was dominated by adalimumab (that is, adalimumab had greater effectiveness and lower costs than etanercept), and etanercept given intermittently (assumed to be 88% of the cost of continuous etanercept) and efalizumab were ruled out on the grounds of extended domination (that is, the incremental costs per QALY gained were higher than for adalimumab even though either the cost or effectiveness was more favourable).
- 3.12 The manufacturer's base-case analysis included only people whose psoriasis had a substantial effect on their quality of life, as indicated by a baseline DLQI score greater than 10. The

manufacturer conducted a sensitivity analysis for people with milder forms of psoriasis (baseline DLQI less than or equal to 10) and this increased the incremental cost per QALY gained for adalimumab compared with supportive care from £30,500 (baseline DLQI greater than 10) to £80,100 (baseline DLQI less than or equal to 10).

- 3.13 The manufacturer carried out further sensitivity analyses to test key assumptions in the model. Changing the number of hospital inpatient days assumed to be avoided by using a biological therapy instead of supportive care had a large impact on the results. Changing the assumption used in the base-case analysis (21 hospital inpatient days avoided per year) to 0 days and 39 days was associated with incremental costs per QALY gained of £60,600 and £4800, respectively, compared with supportive care.
- 3.14 Changing the assumption regarding the cost of intermittent etanercept from 88% of the cost of continuous etanercept to 74% (the figure used in the York model) reduced the incremental cost per QALY gained for intermittent etanercept compared with supportive care from £37,300 to £27,600.
- 3.15 The manufacturer also carried out a probabilistic sensitivity analysis. This estimated that adalimumab had a 46% probability of being cost effective at a threshold of £30,000 per QALY gained.
- 3.16 The ERG considered there to be a number of limitations with the evidence in the manufacturer's submission. It noted that very limited descriptions of the comparator trials and the methodological assumptions used in the mixed-treatment comparison were provided by the manufacturer. It was also uncertain about the appropriateness of the mixed-treatment comparison because the manufacturer did not discuss the issue of possible heterogeneity across the trials. The ERG did, however, state that the results for most of the included treatments were broadly similar to those

published by the York Assessment Group in their analysis of etanercept and efalizumab (TA 103).

- 3.17 The ERG also commented that it is uncertain to what extent the trial populations included in the adalimumab and comparator trials match the population specified in the decision problem, in terms of prior treatment with systemic therapy.
- 3.18 The ERG identified a number of limitations with the manufacturer's model. Because of the limited information provided, the ERG was unclear about the appropriateness of the approach used by the manufacturer to relate changes in PASI scores to EQ-5D data.
- 3.19 The ERG pointed out the lack of information available on the number of hospital inpatient days that are avoided by use of biological therapy instead of supportive care and that changes to the assumption used in the manufacturer's model (21 days per year) had a large impact on the results for all the biological drugs. The ERG also commented that the baseline DLQI was important in determining the cost-effectiveness results (see section 3.12).
- 3.20 The ERG was concerned that the manufacturer's base-case assumptions for intermittent etanercept did not seem appropriate and that the dose of intermittent therapy used in the model (88% of continuous therapy) to calculate costs was inconsistent with the dose used to calculate utility gains (68%).
- 3.21 The ERG ran the manufacturer's model, changing the assumption for the cost of intermittent etanercept to the value used in the York model (74% of the continuous etanercept cost); this resulted in £27,300 per QALY gained for intermittent etanercept compared with supportive care and £36,700 per QALY gained for adalimumab compared with intermittent etanercept. Changing the assumption for the cost of intermittent etanercept did not alter the cost effectiveness results for adalimumab compared with continuous

etanercept; adalimumab continued to have greater effectiveness and lower costs than etanercept.

3.22 The ERG performed a probabilistic sensitivity analysis, re-running the manufacturer's model using different assumptions for treatment with intermittent etanercept (74% of the continuous etanercept dose used to calculate costs rather than 88%) and infliximab (three infusions in the trial period rather than four). The ERG found that adalimumab had a 16% probability of being cost effective at a threshold of £30,000 per QALY, compared with 46% estimated by the manufacturer (see section 3.15).

3.23 Full details of all the evidence are in the manufacturer's submission and the ERG report, which are available from [www.nice.org.uk](http://www.nice.org.uk)

## **4 Consideration of the evidence**

4.1 The Appraisal Committee reviewed the data available on the clinical and cost effectiveness of adalimumab for the treatment of psoriasis in adults, having considered evidence on the nature of the condition and the value placed on the benefits of adalimumab 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 considered that the RCTs identified in the manufacturer's submission showed the clinical effectiveness of adalimumab compared with placebo in people with moderate to severe plaque psoriasis. The Committee, however, also noted that the inclusion criteria for the studies did not fully reflect the population for which this technology is licensed because the psoriasis of the participants in the trials had not necessarily failed to respond to systemic therapies. However, the Committee was reassured by the views of the clinical experts that adalimumab is as effective for people who have not responded to other available treatments as for those who are otherwise treatment naive.

- 4.3 The Committee noted that there are no head-to-head studies comparing adalimumab with the current standard treatment for people who have not responded to systemic therapies, in particular other biological treatments that are used in UK clinical practice as recommended in TA 103. The Committee heard from the clinical experts that, from clinical experience, when anti-TNF is considered an appropriate treatment for a person with severe psoriasis, adalimumab could provide greater clinical benefit than etanercept. The Committee also noted the results of the mixed-treatment comparison conducted by the manufacturer, which suggested a higher probability of response after treatment with adalimumab than with etanercept. It was aware, however, that the ERG had expressed concerns about this analysis and that the robustness of the results was uncertain. For example, very limited descriptions of the comparator trials and the methodological assumptions used in the mixed-treatment comparison were provided by the manufacturer, and the issue of possible heterogeneity across the trials was not discussed. Therefore the Committee was persuaded that, although there is some evidence to suggest that adalimumab may be more effective than etanercept in some circumstances, clinical superiority of adalimumab over etanercept has not been firmly established in the treatment of severe psoriasis.
- 4.4 The Committee heard from the clinical experts and patient representatives that adalimumab is generally easier to use than etanercept because of the self-injection dosing regimen every other week.
- 4.5 The Committee discussed the results of the economic analysis conducted by the manufacturer. It considered that the overall approach adopted by the manufacturer was appropriate but that there was uncertainty in the estimates of cost effectiveness. A crucial assumption in the model is that 21 hospital inpatient days are avoided by using a biological therapy compared with using

supportive care without biological therapy. The Committee noted the lack of data available to inform this assumption. It heard from the clinical experts that 21 days of inpatient treatment is an appropriate estimate for people in this group with severe psoriasis who do not receive biological treatment, and that this view is supported by recently published, multicentre audit data. The Committee was also aware that this assumption had been accepted in TA 103 and, in the absence of any strong evidence to the contrary, agreed that this represented the most appropriate estimate.

- 4.6 The Committee noted that in the manufacturer's base-case analysis using indirect comparisons, etanercept given continuously was dominated by adalimumab (that is, adalimumab had greater effectiveness and lower costs) and etanercept given intermittently (assumed to be 88% of the cost of continuous etanercept) was ruled out on the grounds of extended domination (that is, the incremental cost per QALY gained was higher even though either the cost or effectiveness was more favourable).
- 4.7 The Committee noted that the manufacturer's base-case analysis included an estimate of utility for the use of intermittent etanercept that assumed a disutility related to the associated 'gaps' in therapy. The Committee was concerned, however, that the dose of intermittent therapy used to calculate costs (88% of the continuous etanercept dose) was estimated from US data and was inconsistent with the dose assumed in TA103 (74%). The Committee noted that assumptions regarding the yearly dose for etanercept based on an intermittent dosing schedule had a large impact on the results, and it agreed that the assumptions used should be consistent with those applied in TA103. It also noted the manufacturer's sensitivity analysis, where the assumption regarding the cost of intermittent etanercept was changed to 74% of the cost of continuous etanercept (as in TA103); the resulting incremental cost per QALY

gained for intermittent etanercept compared with supportive care (£27,600) was consistent with the value calculated by the ERG (£27,300) in its re-analysis of the manufacturer's model. In addition, the Committee noted that the ERG had also estimated the incremental cost per QALY gained for adalimumab compared with intermittent etanercept, which was £36,700.

4.8 The Committee considered whether the appropriate comparator for adalimumab should be etanercept given continuously or given intermittently, in line with TA103 and as indicated in the marketing authorisation for etanercept. It heard from the clinical experts that people with severe disease are either not treated with intermittent therapy or have a very small gap (often no more than 1 week) between courses of treatment if the disease flares up very quickly. The Committee was therefore persuaded that, for some people with severe psoriasis, the periods of time between courses of intermittent treatment with etanercept could often be very short. The Committee therefore agreed that, for people with severe psoriasis, the incremental cost per QALY gained for adalimumab compared with etanercept that reflected clinical practice should take into account the results calculated by the ERG for both intermittent etanercept and continuous etanercept (that is, £36,700 per QALY gained and dominating [greater effectiveness and lower costs for adalimumab], respectively). Although the precise value was not known and would depend on the assumptions regarding the length of time between courses of etanercept, the Committee accepted that it would be likely to be within a range consistent with that which it had previously considered to be a cost-effective use of NHS resources.

4.9 The Committee was aware that the manufacturer's base-case analysis (and the ERG's re-analysis of this described in section 4.6) only included people whose psoriasis had a substantial effect on their quality of life, as indicated by a baseline DLQI score greater

than 10. The Committee noted that the manufacturer had conducted a sensitivity analysis on the base case for people with milder forms of psoriasis (baseline DLQI less than or equal to 10) and that this increased the incremental cost per QALY gained for adalimumab compared with supportive care from £30,500 (baseline DLQI greater than 10) to £80,100 (baseline DLQI less than or equal to 10). The Committee therefore agreed that the use of adalimumab for people who have moderate disease with a DLQI less than or equal to 10 would not be a cost-effective use of NHS resources.

4.10 The Committee considered how the population with severe psoriasis could be defined. It heard from the clinical experts that a combination of DLQI and PASI is routinely used in clinical practice and agreed that it would be appropriate to define severe disease as a PASI of 10 or more and a DLQI of more than 10 in line with TA 103.

4.11 The Committee concluded that adalimumab should be recommended as a treatment option only for people with severe plaque psoriasis when standard systemic therapies have failed. Owing to the limitations of the clinical effectiveness data and the uncertainty around the cost-effectiveness results, the Committee further concluded that it could not recommend adalimumab in preference to etanercept and that clinicians would need to exercise their clinical judgement in choosing between the two treatments.

4.12 The Committee considered the appropriate duration of treatment. It noted that the principal endpoint in the phase III adalimumab trials was a PASI 75 response at 16 weeks and that this was the time-point at which response to treatment was assessed in the cost-effectiveness analysis. Therefore, the Committee concluded that it would be appropriate for treatment to be continued beyond 16 weeks only in people whose psoriasis had shown a PASI 75 response to treatment within 16 weeks. In addition, the Committee

agreed that the response criteria should be defined in a similar way to TA 103 and should include an additional alternative criterion of a PASI 50 response and a five-point reduction in the DLQI from start of treatment.

- 4.13 The Committee was aware that there may be some circumstances when the DLQI is not a clinically appropriate tool to inform a clinician's conclusion on the severity of plaque psoriasis, for example, because of a person'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 adalimumab.

## **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 that requires local health boards and NHS trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.

- 5.3 NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website ([www.nice.org.uk/TA146](http://www.nice.org.uk/TA146)).
- Costing report and costing template to estimate the savings and costs associated with implementation.
  - Audit support for monitoring local practice.

## **6 Recommendations for further research**

- 6.1 The Committee recommends that further research should be conducted comparing available anti-TNF agents (such as adalimumab, etanercept and infliximab) with each other.

## **7 Related NICE guidance**

- Infliximab for the treatment of adults with psoriasis. NICE technology appraisal guidance 134 (2008). Available from [www.nice.org.uk/TA134](http://www.nice.org.uk/TA134)
- Adalimumab for the treatment of psoriatic arthritis. NICE technology appraisal guidance 125 (2007). Available from: [www.nice.org.uk/TA125](http://www.nice.org.uk/TA125)
- Etanercept and infliximab for the treatment of adults with psoriatic arthritis. NICE technology appraisal guidance 104 (2006). Available from [www.nice.org.uk/TA104](http://www.nice.org.uk/TA104)
- Etanercept and efalizumab for the treatment of adults with psoriasis. NICE technology appraisal guidance 103 (2006). Available from [www.nice.org.uk/TA103](http://www.nice.org.uk/TA103)

## **8 Review of guidance**

- 8.1 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.
- 8.2 The guidance on this technology will be considered for review in July 2008 at the same time that 'Etanercept and efalizumab for the treatment of adults with psoriasis' (NICE technology appraisal guidance 103) and 'Infliximab for the treatment of adults with psoriasis' (NICE technology appraisal guidance 134) are considered for review.

Andrew Dillon  
Chief Executive  
June 2008

## **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 Ray Armstrong**

Consultant Rheumatologist, Southampton General Hospital

#### **Dr Jeff Aronson**

Reader in Clinical Pharmacology, University Department of Primary Health Care, University of Oxford

#### **Dr Darren Ashcroft**

Reader in Medicines Usage and Safety, School of Pharmacy and Pharmaceutical Sciences, University of Manchester

#### **Professor David Barnett (Chair)**

Professor of Clinical Pharmacology, University of Leicester

**Professor Stirling Bryan**

Head, Department of Health Economics, University of Birmingham

**Professor John Cairns**

Professor of Health Economics, Department of Public Health and Policy,  
London School of Hygiene and Tropical Medicine

**Dr Mark Charkravarty**

Director, External Relations, Procter and Gamble Health Care, Europe

**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, Barts and The London School of Medicine  
and Dentistry, Queen Mary, University of London

**Dr Fergus Gleeson**

Consultant Radiologist, Churchill Hospital, Oxford

**Ms Sally Gooch**

Independent Nursing and Healthcare Consultant

**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

**Mr Terence Lewis**

Lay member

**Professor Gary McVeigh**

Professor of Cardiovascular Medicine, Queens University, Belfast

**Dr Ruairidh Milne**

Senior Lecturer in Public Health, National Coordinating Centre for Health Technology, University of Southampton

**Dr Neil Milner**

General Medical Practitioner, Tramways Medical Centre, Sheffield

**Dr Rubin Minhas**

General Practitioner, Coronary Heart Disease Clinical Lead, Medway PCT

**Dr John Pounsford**

Consultant Physician, Frenchay Hospital, Bristol

**Dr Rosalind Ramsay**

Consultant Psychiatrist, Adult Mental Health Services, Maudsley Hospital, London

**Dr Stephen Saltissi**

Consultant Cardiologist, Royal Liverpool University Hospital

**Dr Lindsay Smith**

General Practitioner, East Somerset Research Consortium

**Mr Roderick Smith**

Finance Director, West Kent PCT

**Mr Cliff Snelling**

Lay member

**Professor Ken Stein**

Professor of Public Health, Peninsula College of Medicine and Dentistry, University of Exeter

**Professor Andrew Stevens**

Professor of Public Health, Department of Public Health and Epidemiology, 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.

**Helen Knight**

Technical Lead

**Zoe Charles**

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 Assessments Centre (SHTAC), University of Southampton:

- Turner D, Picot J, Cooper K et al. Adalimumab for the treatment of psoriasis, November 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 and III had the opportunity to give their expert views on adalimumab by providing a written statement to the Committee. Organisations listed in I, II and III have the opportunity to appeal against the final appraisal determination.

I Manufacturer/sponsor:

- Abbott Laboratories Limited

II Professional/specialist, patient/carer groups:

- Psoriasis and Psoriatic Arthritis Alliance
- Psoriasis Association
- British Association of Dermatologists
- Royal College of Nursing
- Royal College of Physicians

III Other consultees:

- Nottinghamshire PCT
- Department of Health
- Welsh Assembly Government

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

- Department of Health, Social Services and Public Safety for Northern Ireland
- NHS Quality Improvement Scotland
- Novartis Pharmaceuticals UK Limited
- Pfizer
- MerckSerono Limited
- Wyeth Pharmaceuticals

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 adalimumab by attending the initial Committee discussion and providing written evidence to the Committee. They were also invited to comment on the ACD.

- Professor Christopher Griffiths, Professor of Dermatology, Head of The Dermatology Centre and Division of Medicine and Neurosciences, University of Manchester. Nominated by Royal College of Physicians – clinical specialist
- Professor Jonathan Barker Professor of Consultant Dermatologist, Head of Psoriasis Unit, St John's Institute of Dermatology. Nominated by the British Association of Dermatologists – clinical specialist
- Mr Ray Jobling, Chairman of the Psoriasis Association. Nominated by the Psoriasis Association – patient expert
- Mr David Chandler. Nominated by the Psoriasis and Psoriatic Arthritis Alliance – patient expert