NHS organisation statement template

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Primary Care Trusts (PCTs) provide a unique perspective on the technology, which is not typically available from the published literature. NICE believes it is important to involve NHS organisations that are responsible for commissioning and delivering care in the NHS in the process of making decisions about how technologies should be used in the NHS.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Short, focused answers, giving a PCT perspective on the issues you think the committee needs to consider, are what we need.

About you

Your name: **Debbie Morrison**

Name of your organisation **NHS Cambridgeshire acting as nominated expert on behalf of NHS Havering**

Please indicate your position in the organisation:

- **commissioning services for the PCT specific to the condition for which NICE is considering this technology?**

- **other (please specify): pharmaceutical specialist with experience of collaborative development of pathways for drug use for this condition**

What is the expected place of the technology in current practice?

As an alternative to existing AntiTNFs. The addition of golimumab, as it is to be injected at longer intervals (once a month) may increase the number of patients for whom antiTNFs may be considered an appropriate treatment option. This could have a significant impact on the NHS as prevalence is quoted by NICE as in the range 0.1% to 1%; there is therefore substantial variation for an individual PCT in the number of patients who may present to treatment with a cost impact on an average PCT of 300,000 population of up to 25 extra patients over 0.3% prevalence rate we have used to calculate likely patient numbers who may meet the criteria for use of golimumab. If golimumab were priced similarly to etanercept and adalimumab and assuming the majority of patients self administer, then the average PCT could see a cost pressure of up to £250,000 pa recurrent if golimumab led to 25 extra patients being identified for antiTNF treatment.

It is not expected that golimumab would be suitable for use as a follow-on treatment after failure of another antiTNF: the one published RCT that we have been able to identify excluded patients who has received prior therapy with antiTNF, Rituximab or natalizumab; it appears that in the case of other agents failure to respond to one predicts failure to respond to a second agent.

It is not expected that golimumab would completely replace any of the existing agents. Its place in therapy compared to Ustekinumab[1] is not clear.

[1] We are advised by clinical colleagues that Ustekinumab is to be licensed for PsA. In addition it is used for patient with PsA who have presented first with, or who have concurrent, psoriasis

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences in opinion between professionals as to what current practice should be?

Standard treatment of the condition currently is with DMARDs before antiTNF. No particular variations in the DMARDs stage of the treatment are known to the respondent.

We would expect only about 2.4% of patients with this condition to be offered an antiTNF as a treatment option. There are currently three AntiTNFs in use for Psoriatic Arthritis (PsA) all of which have been assessed individually by NICE. Golimumab is also indicated for psoriatic arthritis in patients who have not responded to DMARDs and is therefore in direct competition with existing treatments.

There appear to be differences of opinion between professionals as to what current practice should be in relation to the use of AntiTNFs in PsA, as demonstrated in the charges made to PCTs for PsA treatment.

The picture is further complicated by the fact that treatment decisions on AntiTNFs in PsA may be made either by rheumatologists (who use AntiTNFs widely in other diseases they manage e.g. RA) or by dermatologists (whose use of AntiTNFs is more limited and whose approach to use of antiTNF appears more cautious).

What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

- Etanercept is suitable for self-administration by patients, or by carers and is given twice a week. Local opinion appears to favour this apparently shorter-acting preparation in patients where there are concerns about adverse effects including infections.
- Adalimumab is suitable for self-administration by patients, or by carers and is given every other week. Local opinion appears to favour this preparation in patients who have reasonable compliance. Preliminary data from PbR excluded drugs charges locally appears to suggest that adverse effects may be experienced at a higher rate than with etanercept and drop outs may be higher.
- Infliximab is given as an infusion and is generally used for patients unable to self administer. It appears to be used more frequently in some centres than others; it is not clear whether this reflects case mix or local clinical preference. The cost to the NHS of Infliximab given at 8-week intervals is significantly increased by the administration costs charged to PCTs though PbR tariffs for admitted patient care (day case units) or specialist OP clinics. Based on NICE calculation of dose and frequency and latest cost of Infliximab (BNF 59) the cost of infliximab is almost £5,000 (50%) more than etanercept or adalimimab (£9,295 pa)
- The availability of golimumab as an alternative with a longer interval between injections may offer the NHS reduced costs compared with Infliximab in patients who are unable to self-inject.
- All the antiTNF have the potential for significant adverse effects and there appears to be little clinical consensus on which drug to use first line from amongst currently available therapies.

To what extent and in which population(s) is the technology being used in your local health economy?

Golimumab is not currently being used; other AntiTNFs are being used to treat PsA

- is there variation in how it is being used in your local health economy?

- is it always used within its licensed indications? If not, under what circumstances does this occur? Other antiTNFs are not always used within licensed indications or in line with NICE cost-effectiveness thresholds e.g. use earlier in disease or when contra-indications or cautions exist e.g. respiratory disease

- what is the impact of the current use of the technology on resources?

- what is the outcome of any evaluations or audits of the use of the technology?

- Drugs that are licensed for psoriasis or Rheumatoid Arthritis (RA) are used in patients who also have PsA. Evaluation of the use and effectiveness and cost effectiveness of AntiTNFs in PsA is complicated by the management of concurrent RA and psoriasis.
what is your opinion on the appropriate use of the technology?

Potential impact on the NHS if NICE recommends the technology

What impact would the guidance have on the delivery of care for patients with this condition?

- If recommended for use in the NHS it is unclear what the implementation issues might be in ensuring access to this drug. The manufacturer's submission is expected to contain further information that may clarify some of these issues. This drug has marketing approval for self-administration by patients and if it is suitable, the training arrangements for etanercept self injection should be relevant to golimumab. Increasing variance between drugs in their presentation as to syringes, vials and administration schedules may increase risks to patients and the burden on the NHS.
- The use of biologics in psoriatic arthritis has an impact on the progression of the psoriasis also – as many patients have both conditions an evaluation of this drug should also evaluate the impact on the psoriasis compared to other agents as this will substantially affect the cost effectiveness of the drug to the NHS.
- The reduced frequency of golimumab injections, compared with alternatives, may be preferred by patients, however in the single published RCT that we have been able to find the drug has not been shown to have better outcomes (it is not more effective or less harmful) than alternatives in an indirect comparison. The NHS would benefit from a full assessment of the place in therapy of golimumab in relation to other agents and an ongoing, national, structured programme of assessment of relative benefit, adverse effects and drop out rates in actual clinical practice (for all AntiTNFs)
- The treatment pathway for psoriasis, as suggested by NICE, allows for a wider variety of treatment approaches than that for psoriatic arthritis – patients may then move between rheumatologists and dermatologists. The patient pathway needs to be clear in any guidance if the guidance is to be cost-effective.
- The NHS would benefit from guidance in which NICE evaluated which clinicians assume treatment responsibility for patients with Psoriasis and PsA, as they may be managed by either rheumatologists or dermatologists. Local experience indicates that this could affect what NICE accepts as current practice, what treatment options are decided upon and therefore the overall cost-effectiveness.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional resources (for example, staff, support services, facilities or equipment)?
Currently antiTNFs are prescribed and used only by teams with experience of the technology. This means hospital prescribing only. In the case of etanercept and adalimumab self-administration by patients remains the clinical responsibility of the clinician who may only see the patient once or twice a year. Infliximab is given by infusion and nurses experienced in the use of this drug may therefore assess the patient more frequently, at the time of administration in a hospital clinic

The NICE would benefit from advice from NICE on the impact of specialist community clinics as golimumab could have on costs.

The potential adverse-effects of all AntiTNFs present a challenge to the primary care physician as they have few patients on these technologies (av for all indications ca 3 to 5 patients per average

GP practice and therefore 1 to 4 patients per average GP at any one time). Further support for GPs to monitor patients receiving AntiTNFs would improve patient safety and could improve patient outcomes. NHS Cambridgeshire is implementing a structured programme to address these issues and has identified that this, whilst important, is resource intensive in both the PCT and primary care.
The addition of a further agent where substantially less is inevitably known about adverse effects and their management in a drug given less frequently would increase the burden on the NHS.

Can you estimate the likely budget impact? If this is not possible, please comment on what factors should be considered (for example, costs, and epidemiological and clinical assumptions).
The submission to the EMEA for monthly use may mean that a number of patients come forward for treatment who would not have found adalimumab (fortnightly) or etanerceot (twice weekly) acceptable. This could significantly increase overall use of antTNFs in people with PsA.

It is estimated that for an average PCT of 300,000 patients about 11 patients would meet the criteria for treatment of their PsA with an antiTNF (any). If all these individuals received golimumab only 8 of them would achieve a response sufficient to justify ongoing treatment after an initial 14-week trial period.

Price information on golimumab is not available and therefore the epidemiology and natural history of the disease, including spontaneous remissions and arrangements for 'drug holidays' should be considered when NICE makes its recommendations to the NHS.

The impact on cost of the frequency of injections and the proportion of patients who may be able to be trained to self administer or who may attend their GP for administration (if suitable training and information for professionals was available) should be taken into account to guide the NHS.

Patient Access schemes are difficult to manage and rarely lead to recovery of the intended price reduction/refund for the NHS therefore it would be far simpler if no PAS were to be used in the case of golimumab.

Would implementing this technology have resource implications for other services (for example, the trade-off between using funds to buy more diabetes nurses versus more insulin pumps, or the loss of funds to other programmes)?
Previous experience suggests that the introduction of an additional agent into the market is likely to expand the number of patients treated. Therefore the additional cost would inevitably affect money available for these and other patients to receive other types of intervention and support for their condition and its impact on their activities of daily living/QOL.

Would there be any need for education and training of NHS staff?
Yes
The European assessment report published by the EMEA (April 2010) states that golimumab is given as a once monthly injection, given on the same day each month.
This will require additional resources and potentially new skills compared with etanercept or adalimumab in pre-filled syringes. The cost of golimumab to the NHS should therefore include education and training costs.

The NHS would encourage NICE to consider if possible the potential for golimumab to be given closer to home, under a shared care agreement between the patient's GP practice and a dermatologist or rheumatologist from the perspective of safety, patient convenience and overall health system cost.

The EMEA goes on to say that patients may be taught to self inject if their doctor agrees. This would have implications for training of staff and time and skills to train patients or their carers. If self-injecting patients would have less contact with health care professionals than if the injection is given by a doctor or nurse. Effective criteria for monitoring for response, adverse effects and reporting systems to ensure these are captured would help patients and the NHS to ensure better outcomes as well as value for money but would require resources for education and training of a wider cohort of staff than is currently the case in our locality and in most others.

The side effects of all AntiTNFs are potentially very serious and may be insidious in their onset. Therefore to match most PCTs processes for safe and appropriate implementation of NICE guidance relating to drugs it is suggested that pharmacists and local area prescribing committees should be involved in approving such guidance on use in ways that make it appropriate for local resources and skills. Area prescribing committees should also be responsible for disseminating that local implementation guidance as a basis for training needs assessment and training programmes with competence assessment

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

- We understand that Ustekinumb is also being put forward for licensing for PsA . It has a different mechanism of action to the other biologics. It also has head to head studies against another anti-TNF. Local clinician feedback is that this is a highly effective agent.
- Therefore we ask NICE to consider in its deliberations whether there is then a place for golimumab at all on the current level of evidence; the results of the one RCT could still be a statistical anomaly. Moreover, this trial evidence does not show major advancement on the 3 biological agents already NICE-approved for this indication.
- The NHS would wish to see that consideration is given by NICE in this STA to the longer-term cost of dealing with malignancies and antibody formation – treatment period in the RCT for golimumab was very short for a drug which is likely to be used long-term.
- Re: Technology Appraisal in preparation, 'Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (review of TA104 and TA125)'. Expected date of issue: July 2010.

  Whilst it is helpful for the NHS (PCT and GP commissioners) to receive guidance from NICE that rings TA104 and TA125 together, the delivery by NICE of this appraisal means that for the NHS it is essential that the golimumab review considers and gives explicit guidance to the NHS on the relative place in treatment of each of the agents that are available and in use at the present time to treat PsA: adalimumab, etanercept, infliximab, golimumab and ustekinumab.

- Guidance to the NHS on the place in therapy should aim to set out if/where in the range of options available golimumab sits in relation to other treatments and of used what proportion of treatments might be with each agent

  The chart in CG 87 (newer drugs in diabetes) in the costing template that sets out % of each type of drug expected to be used supports audit to secure overall cost effective use of these agents is extremely useful in assessing compliance with NICE guidance. We would ask that NICE considers publishing a similar tool for PCTs and clinicians in relation to guidance on drugs in PsA