Professional organisation statement template

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: Professor Robert John Moots

Name of your organisation: British Society of Rheumatology

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? √
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? √
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc.)?
- other? (please specify) √
  Trustee British Society of Rheumatology
  Representative for British Society of Rheumatology in this appraisal

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

Rheumatoid Arthritis (RA) is treated in the NHS with a focus on attempting to identify and diagnose the condition as early as possible and institute therapy to induce and maintain remission – but where remission is not achievable, the lowest disease activity state practical.

At present, treatment of RA is determined by NICE guidance, with treatment by disease modifying anti rheumatic drugs (DMARDs) at diagnosis and then tumour necrosis factor (TNF) alpha inhibitors (TNFIs) in situations of intolerance to or inefficacy of DMARDS. There should not be significant geographical variation in current practice with this. Patients who fail to respond to a TNFI are able, following NICE guidance, to swap to the CD20 depletor, rituximab. There is currently no formal guidance for biologic therapy in situations where rituximab has failed. Other biologic agents including abatacept and tocilizumab have not been approved by NICE. The publication of most recent NICE guidance on biologic drugs in RA (which addresses issues of swapping biologics etc) is due later this week. As not yet public domain, this cannot be discussed here.

There are currently four other biologic TNFIs approved by NICE for treatment of RA (infliximab, adalimumab, certrolizumab and etanercept). These agents are all approved for use in patients who have failed on DMARDS within appropriate guidelines. Infliximab is administered by intravenous infusions at 0, 2, 6 and then 8 weekly intervals. Etanercept is administered by subcutaneous injection at weekly intervals and adalimumab and certrolizumab by subcutaneous injections at fortnightly intervals. Certrolizumab is currently provided without charge to the NHS for the first three months with a patent access programme.

There are no current biomarkers available to predict response to a TNFi in an individual patient. It is generally accepted that approximately 70% of patients will respond to any one TNFi, with some responding to one but not another, unpredictably. The efficacy of current TNFi's is broadly comparable, as is adverse event profile. At present, NICE does not recommend swapping TNFI's if inefficacy, but further guidance will follow this week.

Golimumab will be used within a secondary care setting in specialist clinics run by Rheumatologists. Golimumab is administered subcutaneously but also with a potential for intravenous infusion. If the latter, then there will need to be appropriate access to, for example, day case infusion units. These are, however, readily available for other infused biologic drugs in a rheumatological setting and this is not likely to add to this significantly.

Golimumab is not currently available outside of clinical trials.

It is anticipated that Golimumab will be used within the same guideline as for other TNFα inhibitors as in previous NICE appraisals. In other words, for patients with Rheumatoid Arthritis who have failed on at least two DMARDS (including Methotrexate) at appropriate dosage for a relevant period of time and with an appropriate measure of disease activity (DAS 28 greater than 5.1 at present).

The advantages and disadvantages of the technology

Golimumab is a humanised monoclonal antibody. It differs significantly from other available TNFα inhibitors because it can be injected at monthly intervals subcutaneously (compared to weekly or fortnightly for the other agents). Golimumab is also unique at present because it can also be administered intravenously instead of subcutaneously. It is therefore theoretically possible that the dual mode of administration could be effective in patients who start the drug subcutaneously but find the response limited and therefore have an option to have intravenous dosing where a bolus injection may be more effective. Evidence supporting this is currently being gathered in clinical trials. I am not aware of formal reports around this yet.

Clinical trials show that Golimumab is an effective agent in Rheumatoid Arthritis when used after other TNFi agents. There are no formal clinical trials addressing this for other TNFi.

Clinical Trials show the adverse effect profile of Golimumab to be comparable of other TNFα inhibitors currently used in the NHS.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

Not Applicable

Implementation issues

It is likely that Golimumab will be used as one of the choices for patients starting a TNFα inhibitor. There are some appropriate differences between this technology and other drugs to suggest that access to Golimumab will provide additional choice for patients. It is not likely that there will be any significant issues in implementing this new technology in the NHS.