

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

Abatacept for the treatment of rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs

The impact on equality has been assessed during this appraisal according to the principles of the NICE Equality scheme.

Consultation

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| 1. Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how? |
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No potential equality issues were identified during the scoping process.
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| 2. Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the Committee addressed these? |
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<p>The Committee was aware that the manufacturer suggested that abatacept is suitable for people who might otherwise fall outside or through the current net of treatment, specifically those who require or reasonably request intravenous infusion. The Committee heard from the clinical specialists that the devices used to self-administer subcutaneous injections had improved considerably and were adapted for patients with significant hand deformities. The Committee heard that subcutaneous interventions could be administered at home by a nurse or a family member, subject to local decision making, or in hospitals (as with intravenous infusions), where clinicians could monitor patients more closely if required. The Committee was aware that the manufacturer proposed that the population for whom subcutaneous therapy was not appropriate would include patients with needle phobia. However, the Committee concluded that people with needle phobia would have the same problem with intravenous therapy. The Committee agreed that there was no</p>
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clinically plausible reason related to route of administration that supports limiting the decision problem to this population.

The Committee was also aware that the manufacturer's submission noted that treatment of rheumatoid arthritis with anti-TNF agents is associated with an increased risk of reactivation of latent tuberculosis, whereas treatment with abatacept may have a lower propensity to reactivate latent tuberculosis. It also noted that the manufacturer stated that there is a raised prevalence of tuberculosis among ethnic subgroups, and that a person from an ethnic minority group may therefore not receive the full benefit of current treatment options, and that because abatacept is associated with a reduced risk of reactivation of latent tuberculosis, it may reduce inequity in access to treatment for that subgroup of people. The Committee was aware that abatacept has a different mechanism of action to TNF inhibitors, as it affects the costimulation of T cells. The Committee was mindful that for people who have one or more contraindications to treatment with a TNF inhibitor the appropriate comparator for this population of people would be conventional DMARDs. The Committee was also aware that in practice these patients may receive rituximab. The Committee therefore agreed that there are alternative treatment options for people who have one or more contraindications to treatment with a TNF inhibitor.

3. Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?

No additional potential equality issues were identified by the Committee.

4. Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to access for the specific group?

No

5. Are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to access identified in question 4, or otherwise fulfil NICE's obligations to promote equality?

No

6. Have the Committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?

The summary table in the ACD describe the Committee's considerations of any potential equality issues.

Approved by Associate Director (name): Elisabeth George

Date: 23 03 11

Final appraisal determination

1. Have any additional potential equality issues been raised during the consultation, and, if so, how has the Committee addressed these?

One stakeholder stated that whilst NICE may not be discriminating against the group of patients for whom anti-TNF is contra-indicated [in legal terms], that patients would suffer discrimination on grounds of health which the stakeholder felt was equally unfair. It was not possible for the Committee to address this point because of lack of clarity.

Another consultee considered it to be essential to offer the choice of an alternative biologic to those patients in whom infliximab has been shown to be ineffective, or in whom conventional TNF inhibitor agents are contraindicated, as these patients really do not have any other treatment option. This potential equality issue was discussed by the Committee, and is described in section 4.20 and the summary table in the ACD.

The Committee considered that this group of patients would be likely to be regarded as having a separate, additional disability alongside their disabilities caused by rheumatoid arthritis. The Committee noted that if the clinical effectiveness in this group of people was assumed to be the same as in the overall trial population, the ICER was several times higher than what is normally considered to be an appropriate use of NHS resources (see section

4.18). The Committee agreed that a more important consideration was that there was no evidence how much clinical benefit abatacept may provide in this population. The Committee noted that these patients have very complex medical needs and that any decision on the use of biological treatments in this group would require a careful balance of the potential benefits and harms for the individual patient.

For these reasons the Committee concluded that a general positive recommendation for abatacept for this group of people could not be justified. The Committee considered that this group of people has very complex medical needs which require careful assessment by clinicians on an individual basis.

2. If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to access for the specific group?

The recommendations have not changed after consultation.

3. If the recommendations have changed after consultation, are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to access identified in question 2, or otherwise fulfil NICE's obligations to promote equality?

n/a

4. Have the Committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?

Sections 4.19 and 4.20 of the FAD.

Approved by Centre or Programme Director (name): Meindert Boysen

Date: 14 07 11