NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosis

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: Michael J. Tidman

Name of your organisation: British Association of Dermatologists

Are you (tick all that apply):

- ✓ a specialist in the treatment of people with the condition for which NICE is considering this technology?

  As a dermatologist, I do see and treat patients with lupus erythematosus, but usually those with cutaneous disease.

- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?

  No.

- ✓ 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.)?

  As chair of the Therapy & Guidelines subcommittee, I represent the British Association of Dermatologists

- other? (please specify)

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

How the condition is currently treated in the NHS?

As indicated in Appendix A.

Is there significant geographical variation in current practice?

Not as far as we are aware.

Are there differences of opinion between professionals as to what current practice should be?

Not as far as we are aware.

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

As indicated in Appendix A.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient?

Gender and racial differences, as indicated in Appendix A.

Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

Not as far as we are aware.

In what setting should/could the technology be used ï for example, primary or secondary care, specialist clinics?

Secondary care.

Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

As belimumab is administered intravenously, specialist nursing care will be required.

If the technology is already available, is there variation in how it is being used in the NHS?

Not to our knowledge.

Is it always used within its licensed indications? If not, under what circumstances does this occur?

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We are not aware that belimumab is currently used for conditions other than lupus erythematosus.

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

We are not aware of any relevant clinical guidelines.

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK.

Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

We suspect that the practical implications for the use of belimumab will be similar to the other biological agents in current use.

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

We have no comment to make.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

We are not sufficiently familiar with the evidence base to comment.

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

We do not have sufficient experience in the use of belimumab to comment.

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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.

We are not aware of any further relevant evidence.

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

We assume that the delivery of this technology would be similar to the delivery of other biological agents, and, as such, would not require additional NHS resources.

Equality

Are there any issues that require special attention in light of the NICEôs duties to have due regard to the need to eliminate unlawful discrimination and promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others?

We are not aware of any.