Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Omalizumab for previously treated chronic spontaneous urticaria [ID707]

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: [redacted], Lead for Policy Development, Dermatology Clinical Reference Group (CRG) for Specialised Commissioning, NHS England.

Name of your organisation: Dermatology Clinical Reference Group (CRG) for Specialised Commissioning, NHS England
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? Clinical lead for Policy Development, Dermatology CRG for Specialised Commissioning, NHS England

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

How is the condition currently treated in the NHS?
The current mainstay of treatment is with H1 antihistamines at standard doses. Those unresponsive may be treated with increased doses of HI antihistamines, leukotriene antagonists, dapsone and immunosuppressives (all off-licence)

Is there significant geographical variation in current practice?
Most patients are managed in primary care. Those with severe disease are referred to Dermatology clinics. Some will also be referred to Allergy/Immunology clinics if these exist locally.

Are there differences of opinion between professionals as to what current practice should be?
Dermatologists do not regard the condition as a 'true' allergy. Management is similar between the specialty groups although Dermatologists are more likely to try immunosuppressive treatment for chronic urticaria and allergist/Immunologists more likely to use treatments for 'angioedema'.

What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?
The current alternatives to Omalizumab include up-dosed H1 antihistamines, H2 antihistamines, doxepin, leukotriene antagonists. Some patients will require dapsone, sulphasalazine or immunosuppressive drugs such as ciclosporin, methotrexate and mycophenolate mofetil. These are 'off licence' and all have potential side effects which will require regular clinical and blood monitoring.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient?
A small proportion of patients will have severe urticaria with a considerable effect on quality of life. This group may also exhibit angioedema. There are no clinically available tests to predict severity or response to medication.

Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?
No

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics?
Secondary and tertiary care with a small number of specialised tertiary centres.

Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?
Subcutaneous injections can be given by trained nurses. The risks are low but facilities for resuscitation will need to be available.

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If the technology is already available, is there variation in how it is being used in the NHS?
Yes. Prior to 'Specialised Commissioning' Omalizumab was available to patients with severe urticaria seen in specialist clinics following an IFR application. These are now suspended so patient access to the drug is currently being denied.

Is it always used within its licensed indications? If not, under what circumstances does this occur?
Some patients with 'physical urticarias' may respond according to small case series.

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.
Omalizumab recommended as third line treatment by European guidelines and 4th line treatment by American guidance.

The advantages and disadvantages of the technology
About 50% of patients with CSU will respond to the licensed doses of non-sedating H1 antihistamines with up to 70% responding to up-dosing to fourfold. Others are treated with a other off-licence therapies, including short courses of oral (rescue) corticosteroids, immunosuppressive drugs such as ciclosporin. Other treatments that may benefit severe chronic urticaria, when taken in conjunction with H1 antihistamines, include leukotriene receptor antagonists, dapsone and H2 antihistamines. Immunosuppressive drugs require blood monitoring for myelosuppression, renal or liver dysfunction and are contraindicated by prior malignancy (except non-melanoma skin cancer) and chronic viral infection (including hepatitis and HIV).
The main advantage of omalizumab over unlicensed therapies is the level of effectiveness (complete symptom relief in about 40% and good symptom control in about 60% of patients in the phase III licensing studies), its apparent safety and lack of requirement for routine blood monitoring. The main disadvantage is the need for post treatment monitoring for adverse reactions, including anaphylaxis, and the implication that the treatments would generally be given in secondary care.

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?
Omalizumab is given by subcutaneous injection so it can be administered by suitably trained healthcare professionals provided facilities for ambulant monitoring and resuscitation are available.
Currently used immunosuppressive drugs for these patients are 'off licence' and all have potential side effects which require regular clinical and blood monitoring.

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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.
There are no tests routinely available to predict which patients might benefit from treatment and so eligibility will be based on severity of disease and lack of response to conventional treatments. Starting and stopping criteria might include;-

Starting Criteria –
-failure to respond to licensed dose antihistamines(1st line), high dose antihistamines (2nd Line) and 3rd line agent (eg ciclosporin)
-baseline UAS7 score and DLQI score

Stopping criteria-
-Inadequate response at week 8
-end 6 month course with retreatment considered if relapse

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?
No 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?
The treatment modality seems to be safe in clinical practice reported to date.

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.
No

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.
No comment

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)?
The main providers of omalizumab for chronic spontaneous urticaria will be Dermatologists, Allergists and Immunologists in secondary and tertiary care. Education in completing urticarial activity scores (UAS7) and Dermatology Life Quality Index (DLQI) scores to assess the pre-treatment severity of CSU and monitor progress may be required but is easy to achieve and the documentation to create the score sheets is straightforward with no additional cost. Medical and nursing staff might need additional training in administration of subcutaneous injections and resuscitation skills. The latter are usually compulsory modules of mandatory training in secondary care and should not provide a burden on health care resource utilization.

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Equality
NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:
- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.
None needed