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: [redacted]

Name of your organisation Cancer Network Pharmacists Forum

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)

Representative of the Cancer Network Pharmacists Forum. I am employed as Associate Director, Pharmacy at the Greater Midlands Cancer Network

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

How is the condition currently treated in the NHS?

Network guidelines state the following:
Treatment is continued until best response and then the patient is regularly followed up for evidence of progressive disease

Is there significant geographical variation in current practice?

No information is currently available to assess this aspect

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

No information is currently available to assess this aspect

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

The patient will currently be monitored, without active therapy. The advantage of this approach is that the patient will not need infusional drug treatment during this period.

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

No comment

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

No comment

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

There is potential for different setting of drug delivery to be explored as part of a service improvement

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

Yes as the drug needs to be administered and monitored. There will also be potential for adverse events to arise and then there will be a requirement for these to be managed

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

Yes, currently it is used in several settings including 'near label' usage.

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

No, we have guidelines recommending the drug's use in 'near label' settings. The Network has produced guidance for these other haematological settings to enable budgeting for commissioners.

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.

The Network has its own clinical guidelines and also where appropriate will adopt international consensus guidelines (e.g. Recommendations from the Fourth International Workshop on Waldenstroms Macroglobulinaemia). Guidelines are produced by the 'Haematology Network Site Specific group'.

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?

The new intervention will require an infusion which will require reconstitution and some 'chair time'. However the infusion if be given in line with the licence for patients who have not received Rituximab in an earlier stage will only need to be given every three months. In other setting the drug will be given more frequently. Administration of any medicine will involve an element of weighing the risks and benefits. Infusion reactions and other adverse events are a consideration and may affect the patient adversely. The SPC states, for example:

MabThera infusions should be administered under the close supervision of an experienced physician, and in an environment where full resuscitation facilities are immediately available

and

Localised candida infections as well as Herpes zoster was reported at a higher incidence in the MabThera-containing arm of randomised studies. Severe infections were reported in about 4 % of patients treated with MabThera monotherapy. Higher frequencies of infections overall, including grade 3 or 4 infections, were observed during MabThera maintenance treatment up to 2 years when compared to observation

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.

No comment

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?

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?

I am not familiar enough with the whole evidence body for treatment of this specific patient group to give a detailed commentary. However data from the EMEA assessment report appear to reflect current practice. The most important outcome would be overall survival. Progression free survival time to progression are also suitable end points but of lesser importance than overall survival. Quality of life data would also be welcome if available.
Adverse events are significant but may be outweighed by the significant demonstration of benefit.

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 comment

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)?

Additional resource will be needed for the reconstitution of Rituximab – some centres may wish to use the pharmacy aseptic suite for this purpose. Both chemotherapy suites and pharmacy currently work towards the limit of their capacity hence there may be ain impact on these services.