**Appendix D – clinical specialist statement template**

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Single Technology Appraisal (STA)

### Alemtuzumab for the treatment of relapsing-remitting multiple sclerosis

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 Queen Elizabeth Hospital Birmingham**

**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)

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

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

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.

***There are currently 1st and 2nd line treatments for MS within the NHS. The decision as to which treatment should be used is based on the clinical and radiological presentation of individuals with MS. The technology provides an alternative to current treatments particularly those that patients that have failed on current treatments or cannot receive for reasons such as PML risks.***

***There is a sub group of patients who are highly active relapsing remitting, who experience a high number of relapses and accumulate disability.***

***The technology should be used in specialist clinics (within secondary care). This would ensure that the appropriate people with MS receive the appropriate treatments. There maybe increased demands on hospital beds due to patients requiring a bed for 5 days as an inpatient.***

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

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**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?

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.

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?

***Those patients who have highly active relapsing remitting MS, will experience a reduction in relapse rates and therefore will accumulate less disability, lessening the demands on health and social care in the long term.***

***Although the concept of less frequent injections and infusions appeals to patients, many have not considered the monitoring that would be involved. I have concerns regarding compliance for monitoring inbetween infusions particularly as the side effect profile is more significant than some of the other treatments available.***

***The disadvantages will be the side effect profile including graves disease and ITP. Monitoring is also quite extensive, with uncertainty as to who will undertake the role.***

***Ongoing monitoring of the therapy will require specialist nursing input. This will put demands on resources. There would need to be a great deal of liaising between those at the clinical centres and MS nurses within the community areas who provide local monitoring of the patients.***

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Single Technology Appraisal (STA)

**Equality and Diversity**

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

***There would be no issues regarding equality as the technology would be used for specific MS types with specific criteria. However, there may be issues with distance patients may need to travel to centres of excellence to access the technology.***

**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.***

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Single Technology Appraisal (STA)

**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)?

***There maybe implementation issues due to lack of resources and capacity, including the safe administration and monitoring of the technology. There are concerns that patients treatments would be cancelled for more acute admissions or winter pressures. There may also be issues if funding is capped for this treatment, which has been seen in some areas.***