Appendix D – Clinical specialist statement template

**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 : North Wales Adolescent Service**
**Betsi Cadwaladr Ubiversity Health Board. North Wales.**

**Are you (tick all that apply):**

- ✓ a specialist in the treatment of people with the condition for which NICE is considering this technology? Yes
- 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.)? No
- 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?
With a combination of psychological, family and social interventions alongside antipsychotic medication.

Is there significant geographical variation in current practice? There is significan variation in which antipsychotics are used.

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

What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?
Alternatives to Aripiprazole include Quetiapine, Risperidone, Olanzapine and 1st generation antipsychotics such as Haloperidol. Clozapine may also be used.
The advantages and disadvantages of the use of these agents is mostly linked to side effect profile. Evidence generally less available in under 18 year old group.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient?
Very early onset psychosis generally has worse prognosis. Younger patients tend to be more sensitive to side effects of the different ant psychotic agents.

Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?
The younger child is generally more likely to be put at risk.

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)?
Technology should be used in secondary care in specialist CAMHS or Early onset Psychosis teams.

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

Is it always used within its licensed indications? If not, under what circumstances does this occur? It is prescribed off licence in under 18 year olds.

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 NICE Bipolar Guideline has relevance re recommendations for treatment & management of psychotic symptoms.

The Schizophrenia NICE Guideline is highly relevant but applies only to over 18 year olds.

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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?
The way Aripiprazole will be used will not significantly alter current practice in UK or the use of comcomitant treatments.

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?
A better evidence base is required in this age group.

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?

In clinical practice agitation is seen more often in the younger age group on commencement of Aripiprazole and on increase of dose.

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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.
No

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**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)?
No significant extra resources would be required to prescribe Aripiprazole.