Appendix G – NHS organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Axitinib for the treatment of advanced renal cell carcinoma after failure of prior systematic treatment

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Primary Care Trusts (PCTs) provide a unique perspective on the technology, which is not typically available from the published literature. NICE believes it is important to involve NHS organisations that are responsible for commissioning and delivering care in the NHS in the process of making decisions about how technologies should be used in the NHS.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Short, focused answers, giving a PCT perspective on the issues you think the committee needs to consider, are what we need.

About you

Your name: [redacted]

Name of your organisation NHS Norfolk

Please indicate your position in the organisation:

- commissioning services for the PCT in general?
- commissioning services for the PCT specific to the condition for which NICE is considering this technology? Yes
- responsible for quality of service delivery in the PCT (e.g. medical director, public health director, director of nursing)?
- 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. participation in clinical trials for the technology)?
- 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 in 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?

First line treatment in line with NICE approved Sunitinb or Pazopanib. There are currently no treatments approved for this second line indication within the NHS however sunitinib and everolimus are occasionally prescribed as second-line treatments through the Cancer Drugs Fund. In the absence of a cost effective treatment, best supportive care was considered the most appropriate comparator for this technology appraisal

To what extent and in which population(s) is the technology being used in your local health economy?

- is there variation in how it is being used in your local health economy?
- is it always used within its licensed indications? If not, under what circumstances does this occur?
- what is the impact of the current use of the technology on resources?
- what is the outcome of any evaluations or audits of the use of the technology?
- what is your opinion on the appropriate use of the technology?

The technology is currently not used as it has it is not yet licensed.

Potential impact on the NHS if NICE recommends the technology

What impact would the guidance have on the delivery of care for patients with this condition?

For patients within the proposed EMA marketing authorisation, it would represent a possible extra line in therapy, provided the effectiveness has been adequately demonstrated. Harms need to be taken into consideration, and the limitations of the trials.

It is estimated that around 4 people per 100,000 could have advanced or metastatic RCC that is suitable for first-line treatment with immunotherapy, but it is not possible to estimate the number of people who would not respond to prior systemic therapy and so be eligible to receive axitinib in-line with the marketing authorisation (this appraisal does not specify the number of prior regimens or treatment cycles)

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In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional resources (for example, staff, support services, facilities or equipment)?

Secondary care. Possible Homecare use if approved – but prescribing by specialist. However, other considerations need to be taken into account. If side effects are limiting quality of life, compliance may be an issue – clinicians will need to be clear about the place of this treatment in the pathway

Can you estimate the likely budget impact? If this is not possible, please comment on what factors should be considered (for example, costs, and epidemiological and clinical assumptions).

No trials of axitinib compared with best supportive care were identified and BSC is the most usual intervention at this stage locally if other treatments not used as above

We have not found any economic evaluations of axitinib for advanced or metastatic RCC that has failed to respond to prior systemic treatment – so it's not possible to comment on this.

No trials of axitinib compared with best supportive care have been identified and no costs have been made known.

The AXIS study was not powered to assess overall survival which will be reported later when survival data is mature – so this adds to the difficulty of estimating budget impact

Would implementing this technology have resource implications for other services (for example, the trade-off between using funds to buy more diabetes nurses versus more insulin pumps, or the loss of funds to other programmes)?

Most likely yes, but depends on costs. Likely extra costs compared to BSC need to be identified. Likely harms need to be identified.

Prescribing information for axitinib cautions that hypertension, including hypertensive crisis, has been observed and blood pressure should be well controlled prior to starting treatment and monitored. The AXIS trial excluded people with uncontrolled hypertension and did not increase the dose above 5mg twice daily in people with hypertension. Prescribing information from Pfizer also cautions that arterial and venous thrombotic events have been observed and caution use in people who are at increased risk for these events. The AXIS trial excluded people who had deep vein thrombosis or pulmonary embolism within the past 6 months. Axitinib has also been associated with haemorrhagic events, and Pfizer advise against use in people with untreated brain metastasis or recent active gastrointestinal bleeding

Other costs to add are managing costs of PAS – these costs are much higher than those anticipated by NICE for previous schemes, in terms of Trusts and

Commissioners, and history has shown that tracking reimbursements to the NHS is complicated and costly – without tracing the NHS loses much of the value of any PAS

Would there be any need for education and training of NHS staff?

Yes – mainly in Trusts. Patient education is important also – patients need to be told the risks/benefits of potential therapies at these difficult times, and not given misleading information about therapies.

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.

AXIS was not powered to assess overall survival, which the researchers say will be reported later when survival data is mature – when will this be?

Cost needs to be known

It is estimated that about 4 people per 100,000 could have advanced or metastatic RCC that is suitable for first-line treatment with immunotherapy, but it is not possible to estimate the number of people who would not respond to prior systemic therapy and so be eligible to receive axitinib in-line with the marketing authorisation (the scope does not specify the number of prior regimens or treatment cycles). Can this be obtained?

The scope does not specify consideration of axitinib for people who are unsuitable for first-line immunotherapy and it is not expected that the final marketing authorisation for axitinib would cover this population group.

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Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology?

Please refer to our earlier response regarding the scope – the final scope should consider the licensed drug indication as NICE has approved two prior treatments for first line therapy, and the EMA advised that the marketing authorisation was for patients with advances RCC after failure of suntinib or cytokine – not as stated in scope.

ECOG status needs to be clearly identified.

PAS needs clarity about actual benefit to NHS – after all costs taken into consideration.