Appendix D– Clinical statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Intrabeam targeted intraoperative radiotherapy for the treatment of early or locally advanced breast cancer

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

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

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. Please do not exceed the 8-page limit.

About you

Your name: Mr Michael Douek

Name of your organisation: Association of Breast Surgeons

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)
- other? (please specify)

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What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. Advantages

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

Delivery of adjuvant radiotherapy for breast cancer treatment:

- as a single treatment rather than 3-5 week course
- at the time of surgery
- specifically to the tumour bed (avoiding missing target volume)

Avoidance of side-effects of radiotherapy:

- improved cosmetic outcome
-

Avoidance of mastectomy as only option for breast recurrence:
- ability to re-excise recurrent disease and proceed with external beam radiotherapy

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:
- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above

Quality of life

– shorter treatment course
– improved cosmesis

Other people

- less time off work

Pain / level of disability
- localised treatment with avoidance of side effects to remaining breast tissue

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2. Disadvantages
Please list any problems with or concerns you have about the technology. Disadvantages might include:
- aspects of the condition that the technology cannot help with or might make worse
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or thier family (for example cost of travel needed to access the technology, or the cost of paying a carer)

Lack of access to the technology at a national level – only 6 NHS sites and only 1 currently active

Level 1 evidence: lack of 5 year follow-up data on all cohort in TARGIT A Trial

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

In general patients support this and are grateful for the reduction in treatment duration and avoidance of whole breast radiotherapy.

There are mixed views about this technology amongst clinical and medical oncologists

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4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

The patients who benefit more are:

1. those not suitable for external bream radiotherapy and who would avoid mastectomy by opting for IORT
2. Those who meet the TARGIT A trial criteria for pre-pathology randomisation
3. Patients who meet the ASTRO and ESTRO criteria for the 'low risk' group

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

External beam whole breast radiotherapy

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:
- improvement of the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc)

The Intrabeam technique has advantages over external beam radiotherapy – as described above. Single fraction, delivered to the tumour bed etc But also no need for lead lined operating theatres and no radiation whilst the machine is switched off.

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(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:
- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

Increase in local recurrence rate in data so far.

Research evidence on patient or carer views of the technology
If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

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Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

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Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

-

Availability of this technology to patients in the NHS
What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

Most important impact would be the avoidance of mastectomy for patients who are not suitable for external beam radiotherapy (EBRT). Also, avoidance of EBRT to those patients who meet the low risk group of ASTRO / ESTRO guidelines.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

Lack of access to IORT within the UK – whilst it is widely available in the USA, Eurpe and elsewhere.

Are there groups of patients that have difficulties using the technology? No

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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.

No

Other Issues
Please consider here any other issues you would like the Appraisal Committee to consider when appraising this technology.

Availability of other IORT techniques – particularly ELIOT which does have level 1 published evidence with longer (5 year) follow-up date