Appendix G – Patient/carer organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Bevacizumab in combination with paclitaxel and carboplatin for the first-line treatment of advanced ovarian 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

[redacted]

Name of your organisation: *Ovarian Cancer Action*

Are you (tick all that apply):

- *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)*

  My Position: Healthcare Project Manager

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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.

The specific areas that the technology will help with are:

*1. **Improvement in Progression Free Survival-** Research has suggested that first line treatment of advanced staged ovarian cancer with bevacizumab in combination with paclitaxel and carboplatin increases progression free survival compared to the standard treatment of paclitaxel and carboplatin. Studies have shown that the increase in progression free survival is modest with a 3.8 month improvement seen in progression free survival.*

NB: Progression free survival –the length of time during and after the treatment of a disease that a patient lives with the disease but it does not get worse.

*2**. Improvement in overall length of survival -** when looking at overall survival this new treatment regimen is expected to increase overall survival with patients in early studies shown to live almost 8 months longer than those on standard chemotherapy treatment.*

NB: Overall survival (in this context)- the length of time a patient is expected to live following treatment

*3. **Improved patient response to chemotherapy** - Research suggests that the use of bevacizumab enhances sensitivity to chemotherapy resulting in a better response rate to treatment (tumour shrinkage, improved survival).*

(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

The benefits of bevacizumab would be as listed above i.e. patients would benefit from a slight increase in progression free survival and an improvement in overall survival. It is also possible that the increased progression free and overall survival may have a positive impact on the mental state of patients and their families. These extra months of progression free and overall survival can be very significant to patients.

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2. Disadvantages
Please list any problems with or concerns you have about the technology. Disadvantages might include:

The concern we have about the bevacizumab treatment is the relatively small improvement in survival relative to the side effects that patients may experience. The improvement in survival may come at a cost to the patient's quality of life. The side effects of bevacizumab may include high blood pressure and heart, stomach and gut problems but we do appreciate that patients do value any improvement in survival thus any increase in overall survival this treatment enables despite the side effects may be worth it from a patient's point of view.

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

It is possible that media coverage has led patients to misunderstand the extent of the significance of the effect of bevacizumab with paclitaxel and carboplatin. Patients need to be provided with accurate and balanced information so that they are well informed about the effectiveness of bevacizumab. This will ensure that they can make an informed decision about their healthcare and if bevacizumab is appropriate for them.

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?

Research would suggest that patients at a high risk of disease progression (high grade tumours) would benefit most from bevacizumab as well as those with the most advanced cancers.

Patients with high blood pressure may benefit less from this technology as they may be at a greater risk of developing heart complications as a side effect.

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.

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Generally the standard treatment for ovarian cancer is surgery followed by 3-6 rounds of chemotherapy (paclitaxel and carboplatin). Sometimes carboplatin alone is given to patients.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them.

The advantages that this new technology has over standard practice are:

1. A ~3 month increase in progression free survival and an ~8 month improvement in overall survival. This has been reported in patients treated with bevacizumab with paclitaxel and carboplatin compared to the standard treatment (paclitaxel and carboplatin) for ovarian cancer. Although this may seem modest patients with advanced disease may find this increase in survival to be significant.

2. An increase in the treatment options available to advanced stage ovarian cancer patients. There are very limited options for patients with advanced ovarian cancer and if for whatever reason the existing treatment is not deemed suitable for patients this leaves patients with no alternative which can create a lot of distress to patients. Including bevacizumab with paclitaxel and carboplatin as a treatment option provides an alternative which may be more effective.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them.

There may be some additional side effects apart from those caused by paclitaxel and carboplatin that are associated with bevacizumab. These side effects may include moderate to serious high blood pressure, moderate to severe bleeding and perforated intestines.

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.

Bevacizumab in combination with standard chemotherapy has been used in the treatment of advanced stage breast cancer. Follow-up studies and routine treatment found that the actual improvement in progression free-survival was less than that in the initial clinical trials and there was a high rate of side effects. These side effects included severe high blood pressure, bleeding, heart attack or heart failure and damage to various parts of the body including the nose, stomach and intestines.

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Bevacizumab in combination with paclitaxel and carboplatin is also used as first line treatment for advanced non-squamous non-small cell lung cancer. Clinical trials showed a 2 month improvement in progression free survival in lung cancer patients and a 2 month improvement in overall survival compared to the standard treatment. Follow-up studies and routine treatments involving bevacizumab with paclitaxel and carboplatin continued to show a modest improvement in survival compared to standard treatment of just paclitaxel and carboplatin with a small but significant number of patients experiencing some additional symptoms due to the presence of Bevacizumab.

Finally, bevacizumab in combination with paclitaxel and carboplatin is used as first line treatment for advanced stage colorectal cancer. Initial clinical trials showed that this treatment improved survival by 2 and 4.5 months and this survival still persists in follow up studies and routine use of this treatment; some patients do experience additional side effects due to the presence of Bevacizumab.

For lung and colorectal cancer the effects of bevacizumab in routine care reflect what was seen in clinical trials but for breast cancer the effects seen in routine care did not reflect that in clinical trials – treatment was found not to be as effective and there were high rates of side effects.

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

It is too early to say for ovarian cancer but for the treatment of advanced stage breast cancer using bevacizumab in combination with paclitaxel and carboplatin follow-up studies to the initial clinical trials found that the actual improvement in progression free-survival was less than three months and there was a high rate of side effects. These side effects included severe high blood pressure, bleeding, heart attack or heart failure and damage to various parts of the body including the nose, stomach and intestines. This should be noted as with breast cancer the early data was similar to that of the current ovarian cancer data.

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.

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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?

Including bevacizumab with paclitaxel and carboplatin as a treatment option provides an alternative which may be more effective. Currently there are limited options for patients with advanced stage ovarian cancer, having an additional first line treatment that clinicians can choose from which may also be more effective would be beneficial to patient's health and state of mind.

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

By not making this technology available to patients on the NHS patients would be denied a treatment that might extend their overall survival by 8 months and their progression free survival by almost 4 months.

Are there groups of patients that have difficulties using the technology?

Those with high blood pressure may have difficulties with this treatment as they may be at a greater risk of developing heart complications as a side effect.

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.

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Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts. **Other Issues** Please consider here any other issues you would like the Appraisal Committee to consider when appraising this technology.