Appendix G – patient/carer organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Obinutuzumab in combination with chlorambucil for previously untreated chronic lymphocytic leukaemia

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: Jacky Wilson

Name of your organisation: Lymphoma Association

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?

X 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)

Jacky Wilson – Medical Writer

- 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.

As CLL is an incurable condition, there is a need for repeated episodes of chemotherapy, which usually produce progressively shorter periods of remission. In those unable to tolerate regimens such as FCR, the likelihood of achieving a good remission is relatively low and the duration of that remission, even after the first course of treatment, can be very brief.

The treatment produces improved remission rates and longer progression-free survival.

People needing treatment for CLL typically have multiple symptoms, which may include enlarged lymph nodes, anaemia, low platelets, low neutrophils, recurrent infections, fever, sweats, poor appetite and weight loss.

The best way to relieve symptoms is to treat the disease effectively. This treatment produces better response rates, including a higher number of complete remissions, than is usually achieved in this group, so symptoms are more likely to be relieved.

Quality of life can be badly affected by ongoing symptoms and by concerns over imminent relapse, for example in those who have achieved only a partial remission. The technology produces improved response rates, with a higher number of complete remissions and some patients becoming minimal residual disease negative, meaning patients are likely to have improved quality of life after this treatment as their symptoms are relieved and they know they should remain well and in remission for a longer period of time.

Many effective treatments, including FCR, are not suitable for people who are older or less fit (the majority of people who need treatment for CLL). The treatment is suitable for people with comorbidities and offers them more effective treatment than has previously been available to them.

(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

A longer period of remission with a better level of health following this treatment.
Improved overall survival compared with chlorambucil alone.
Symptoms more likely to be resolved owing to the better depth of remission (ie more complete remissions and some minimal residual disease negativity).
Improved quality of life through resolution of symptoms and reduced anxiety as people feel well, can return to their usual lifestyle, and know it is likely to be longer until they become unwell again and need further treatment.

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)

Obinutuzumab is given intravenously, whereas chlorambucil alone is an oral therapy. Attendance is required at a hospital day-care unit for obinutuzumab to be administered.

Additional side effects can occur with the obinutuzumab administration (infusion reactions). Also there is a higher risk of other side effects such as anaemia, low platelets, and low neutrophils during the course of treatment than if chlorambucil only is given.

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

Some people, particularly those who are most frail, might not wish to consider treatment that includes an intravenous component and carries an increased risk of side effects, accepting that their time in remission, and ultimately their overall survival, might be shorter.

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?

This treatment offers those with CLL who need treatment but are unfit for FCR therapy the hope of achieving a lengthy period of good-quality remission for the first

time. Those who will benefit most are therefore people with comorbidities that make more intensive chemotherapy unsuitable.

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.

Chlorambucil
Chlorambucil + rituximab (not approved by NICE)
Bendamustine
Bendamustine + rituximab (not approved by NICE)

(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)

Based on the results of the CLL11 trial: Improved response rates compared with chlorambucil (both alone and with rituximab), translating into improved survival compared with chemotherapy alone. Not directly compared with bendamustine (with or without rituximab), but bendamustine is more intensive chemotherapy and therefore would be expected to have more side effects than chlorambucil alone.

(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).

The treatment requires attendance at a day unit for intravenous administration, unlike chlorambucil alone. This is not a disadvantage compared with the other regimens as they already require intravenous administration.

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Infusional side effects occur with obinutuzumab and these are additional to chlorambucil therapy alone. Differences in side effects are less marked than with rituximab-containing regimens, which also have a risk of infusional side effects. Bendamustine alone will have different side effects, eg short-term effects on bone marrow function and an increased risk of infection. These short-term side effects are also more likely with obinutuzumab and chlorambucil than with chlorambucil alone. The long-term side effects of obinutuzumab are net yet known.

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.

The technology is not yet in routine use as part of NHS care.

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

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?

For this group (those not fit for FCR), the technology represents a significantly more effective, yet still tolerable, treatment. It offers this group some of the benefits of

improved treatment that younger fitter people with CLL have been gaining from the availability of FCR therapy in recent years.

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

Those older less fit people needing treatment for CLL in England would not benefit from the potentially better quality of life and improved life-expectancy that the addition of this technology offers.

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

Some people with CLL may be too unfit to attend a day unit on a regular basis to receive this treatment.
A small number of patients experience severe infusional reactions, usually these problems lessen in later treatment cycles.

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.

Were this treatment not to be approved, it would impact most on the elderly, particularly those who are less fit for treatment (see answers above for additional explanation). Thus, they would potentially be discriminated against were this treatment not available.

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

The dosing regimen chosen in the CLL11 trial differed from that normally used in the UK.