

## Patient/carer organisation statement template

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:** Jacquelyn Williams Durkin

**Name of your organisation:** Chronic Lymphocytic Leukaemia Support Association (CLLSA)

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

- a patient with the condition for which NICE is considering this technology? **X**
- 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) **X Trustee**
- other? (please specify)

### 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.

*I would expect the technology(Rituximab) to reduce the level of leukaemic B cells in the blood, and specifically to reduce the size of lymph nodes. There will also be a*

## Patient/carer organisation statement template

*reduction in the so called 'b cell' symptoms, eg sweating profusely, tiredness . Initially this will contribute to the patient feeling better in general.*

*The elimination of the cancerous B cells enables the production of healthy B cells which results in the opportunity for a functioning immune system once treatment has finished. When speaking with CLL patients and their carers, the constant nature of repeated infections, sweating and tiredness becomes increasingly insidious and impacts directly on quality of life.*

(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.

*Short term benefits: would include response to technology that may result in quick reduction in lymph node size (in my own case within 28 hours nodes were not palpable). This had a huge impact on confidence that the disease can be tackled and that technology is working. Large lymph nodes (in excess of 6cm) create discomfort especially in the armpit (axial) and in the groin (inguinal) – reducing the size of nodes obviously reduces the discomfort. Enlarged lymph nodes in the neck (cervical) create a 'mumps' look and can be quite distressing.*

*Long term benefits: CLL patients look for outcomes that extend time to next relapse and need for further treatment. In combination with other chemotherapy drugs this technology provides an opportunity to impact positively on the amount of time a patient remains in remission.*

*Please be aware that the longer someone stays well ie CLL all but eliminated and not in treatment, overall level of health and well being improves. Recovery from chemotherapy takes 6 months and in some cases 12 months. The longer the duration of remission the better the chance that there is a real and tangible period of feeling well and functioning normally. This means being able to undertake tasks, journeys and work on consecutive days without needing a 'day to recover'. It would also enable planning of holidays (and access to health insurance cover) and looking forward to future events eg wedding anniversaries. The world of the CLL patient becomes very small; every action, trip, event has to be planned in order to minimise exhaustion. In addition, exposure to 'bugs' needs to be constantly assessed. If the body has a longer period of wellness and recovery then the patient is better placed for the next round of treatment.*

*The impact on family and close carers is profound as their lives also become dependent on the ability of the sick member to function in a given situation.*

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

**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 their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

*Side effects of technology: the main drawback is a possible initial reaction to the infusion – known as ‘shake and bake’ – a type of allergic reaction. As this is well documented, staff in chemotherapy units are well versed in the appropriate actions to take – use of antihistamine and steroids, and reducing the rate of infusion. Some individuals may never be able to tolerate the technology but my understanding is that for most patients further infusions are well tolerated.*

*If this technology is added to other chemotherapy that is usually taken at home in tablet form (Fludarabine and Cyclophosphamide), then a trip to hospital/or chemotherapy centre for infusion will be necessary; particularly the first time (see above). This may result in an additional unwanted trip by patients and hospitals will need to ensure there are enough beds in day units to accommodate extra patients. However when in treatment for FC monthly visits for patients are necessary in any event. The introduction of delivering chemotherapy infusions at home are under discussion at the moment and may be introduced in the future.*

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

*Most opinion expressed has related to whether the technology does in fact improve the efficacy of other drugs. At a recent conference there was much interest in forthcoming publication of research that will report on the technology and its impact on inhibiting CLL disease.*

*It would be fair to say that there is a difference in perception in those who have undergone chemotherapy for CLL and those in ‘watch and wait’. Those who have had chemotherapy already (and perhaps had more than one course of treatment) are concerned about toxicity and side-effects of additional technologies being added to existing drugs.*

*Some patients are aware that in the USA the technology is used as a maintenance drug to keep the CLL under control. They are also aware that it is possible to become refractory to the technology ie the technology stops being effective*

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?

*Our understanding is that the technology is better at clearing out the CLL from lymph nodes than in the bone marrow or peripheral blood. It may be that a subset of CLL patients respond better to the technology than others. This would require cytogenetic testing for specific abnormalities and access to trial data..*

*A recent paper in the British Journal of Haematology by Keating et al (BJH 141 Apr 2008) suggested that CLL patients with a chromosomal abnormality - trisomy 12 - showed a larger number of CD20 antigenetic sites than patients with other abnormalities. CD20 is targeted by the technology. These patients showed a high response rate when given the technology*

*In the future it may be possible to match patients to therapies. However currently this technology provides a significant addition for medical personnel to consider as a treatment with existing drugs.*

### **Comparing the technology with alternative available treatments or technologies**

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

(i) Please list any current standard practice (alternatives if any) used in the UK.  
*Chlorambucil; Fludarabine ,Cyclophosphamide; Prednisolone (steriods); Campath (alemtuzumab); CHOP; PBSCT*

(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 in 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.)

*As stated above our view is that the technology will improve the condition overall by providing longer periods between relapses. Long term side effects tend to be less than other technologies eg Campath is highly toxic with long term t cell depletion.*

*Taking current chemotherapy tablets at home is very isolating for patients as there is very little contact with, or support from, the Haematology team or community cancer teams, that is 'built in' when receiving treatment as a day patient. There is also no*

## Patient/carer organisation statement template

*possibility to gain contact with other patients 'in the same boat' when taking tablets at home. Taking the treatment at home places huge strain on carers who do not want to leave the patient whilst tablets are taken.*

(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 main disadvantage as stated above is the possible initial infusion reaction. The technology would need to be administered in a clinical setting via infusion. Current therapy is tablet based taken in the home which may be preferable for some patients reducing visits to hospital and having some control of the time the tablets are taken. However Campath (currently given when FC is not working, or if p53 deleted), requires 3 x hospital visits per week for up to 12 weeks..*

### **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.

*As this technology is rarely used for treatment of CLL it is difficult to comment. One CLLSA patient received the technology after previous treatments with other drugs and reported that they achieved a response. I received the technology as part of treatment for NHL and responded extremely well (see above)*

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

*None that we are aware of.*

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.

*No specific research re the technology per se that we are aware of.*

### **Availability of this technology to patients in the NHS**

## Patient/carer organisation statement template

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

*It would create additional options for clinicians in the treatment of CLL. As stated above extending the period of wellness for CLL patients and their families is crucial.*

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

*It is completely debilitating to know that there is a technology available for some years in the western world that can improve the CLL condition but is not available in this country.*

*Shorter remissions lead to more frequent treatments (and associated infections and side effects) which impact on health and well being and make life miserable. It is also costly in terms of numbers of drugs taken. Going from one round of treatment to another, does not lead to a good quality of life.*

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

*People who have to travel a long distance to hospital or have transport difficulties.*

### **Other Issues**

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

None