

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**GUIDANCE EXECUTIVE (GE)**

**Consideration of consultation responses on review proposal**

**Review of TA216; Bendamustine for the treatment of chronic lymphocytic leukaemia**

This guidance was issued in February 2011 with a review date of December 2013.

**Background**

At the GE meeting of 10 December 2013 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

<b>Proposal put to consultees:</b>	The guidance should be transferred to the 'static guidance list'.
<b>Rationale for selecting this proposal</b>	The guidance should be transferred to the 'static guidance' list. The new evidence identified for bendamustine is not likely to lead to a change in the recommendations of the original TA216 guidance. The 2 future treatments that may come to market will be assessed for appraisal via the usual topic selection process, if appropriate.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

<b>Recommendation post consultation:</b>	The guidance should be transferred to the 'static guidance list'.
--	---

<b>Respondent</b>	<b>Response to proposal</b>	<b>Details<sup>1</sup></b>	<b>Comment from Technology Appraisals</b>
Lymphoma Association	Agree	<p>We are happy to support the moving of Technology Appraisal Guidance No 216 to the static list, given the lack of any new evidence that might support a change to the current recommendations.</p> <p>It is our view that bendamustine will be increasingly used in combination with immunotherapy, however, having it available as monotherapy ensures that people who might not tolerate or want intravenous antibody therapy continue to have a better option available than chlorambucil therapy (the previous standard treatment in such cases).</p>	Comment noted.
Royal College of Nursing	No comment	<p>Feedback received from nurses caring for people with chronic lymphocytic leukaemia reviewed the documents on behalf of the Royal College of Nursing.</p> <p>They consider that there is no additional evidence to submit on behalf of the RCN at this stage.</p>	Comment noted.

---

<sup>1</sup> Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent	Response to proposal	Details <sup>1</sup>	Comment from Technology Appraisals
Royal College of Physicians National Cancer Research Institute		Our experts wish to flag that a large Phase III trial comparing BR with FCR which was recently presented at the American Society of Hematology meeting. NICE may therefore wish to take this into account and monitor the results as they are published.	Comment noted.

**No response received from:**

<u>Manufacturers/sponsors</u> <ul style="list-style-type: none"> <li>• Napp Pharmaceuticals</li> </ul> <u>Patient/carer groups</u> <ul style="list-style-type: none"> <li>• Action for Children</li> <li>• Action for Sick children</li> <li>• Afiya Trust</li> <li>• African Caribbean Leukaemia Trust</li> <li>• Anthony Nolan</li> <li>• Aplastic Anaemia Trust</li> <li>• Black Health Agency</li> <li>• Cancer Black Care</li> <li>• Cancer Equality</li> <li>• Cancer52</li> <li>• Childhood Cancer Parents Alliance</li> <li>• Children with Cancer</li> <li>• Chronic Lymphocytic Leukaemia Support Association</li> </ul>	<u>General</u> <ul style="list-style-type: none"> <li>• Allied Health Professionals Federation</li> <li>• Board of Community Health Councils in Wales</li> <li>• British National Formulary</li> <li>• Care Quality Commission</li> <li>• Commissioning Support Appraisals Service</li> <li>• Department of Health, Social Services and Public Safety for Northern Ireland</li> <li>• Healthcare Improvement Scotland</li> <li>• Medicines and Healthcare Products Regulatory Agency</li> <li>• National Association of Primary Care</li> <li>• National Pharmacy Association</li> <li>• NHS Alliance</li> <li>• NHS Commercial Medicines Unit</li> <li>• NHS Confederation</li> <li>• Scottish Medicines Consortium</li> </ul>
--	---

- Chronic Myeloid Leukaemia Support Group
- CLIC Sargent
- Equalities National Council
- Helen Rollason Cancer Charity
- Help Adolescents with Cancer
- Independent Cancer Patients Voice
- Leukaemia Cancer Society
- Leukaemia CARE
- Macmillan Cancer Support
- Maggie's Centres
- Marie Curie Cancer Care
- Muslim Council of Britain
- Muslim Health Network
- National Children's Bureau
- Rarer Cancers Foundation
- South Asian Health Foundation
- Specialised Healthcare Alliance
- Teenage Cancer Trust
- Tenovus
- United Kingdom Chronic Lymphocytic Leukaemia Forum
- WellChild

Professional groups

- Association of Cancer Physicians
- British Committee for Standards in Haematology
- British Geriatrics Society
- British Institute of Radiology
- British Psychosocial Oncology Society
- British Society for Haematology
- Cancer Network Pharmacists Forum

Comparator manufacturers

- AAH Pharmaceuticals (cyclophosphamide, fludarabine)
- Actavis (fludarabine)
- Aspen (chlorambucil)
- Baxter Healthcare (cyclophosphamide)
- Hospira (fludarabine)
- Pfizer (cyclophosphamide)
- Roche Products (rituximab)
- Sanofi (fludarabine)
- Teva (fludarabine)
- Wockhardt (fludarabine)

Relevant research groups

- Cochrane Haematological Malignancies Group
- Elimination of Leukaemia Fund
- Health Research Authority
- Institute of Cancer Research
- Leukaemia & Lymphoma Research
- Leukaemia Busters
- MRC Clinical Trials Unit
- National Cancer Programme
- National Cancer Research Institute
- National Cancer Research Network
- National Institute for Health Research
- Research Institute for the Care of Older People

Assessment Group

- Evidence Review Group tbc
- National Institute for Health Research Health Technology

<ul style="list-style-type: none"> <li>• Cancer Research UK</li> <li>• Royal College of General Practitioners</li> <li>• Royal College of Pathologists</li> <li>• Royal College of Radiologists</li> <li>• Royal Pharmaceutical Society</li> <li>• Royal Society of Medicine</li> <li>• Society and College of Radiographers</li> <li>• UK Health Forum</li> <li>• United Kingdom Clinical Pharmacy Association</li> <li>• United Kingdom Oncology Nursing Society</li> </ul> <p><u>Others</u></p> <ul style="list-style-type: none"> <li>• Department of Health</li> <li>• NHS Croydon CCG</li> <li>• NHS England</li> <li>• NHS Hounslow CCG</li> <li>• Welsh Government</li> </ul>	<p>Assessment Programme</p> <p><u>Associated Guideline Groups</u></p> <ul style="list-style-type: none"> <li>• National Collaborating Centre for Cancer</li> </ul> <p><u>Associated Public Health Groups</u></p> <ul style="list-style-type: none"> <li>• Public Health England</li> <li>• Public Health Wales NHS Trust</li> </ul>
---	---

**GE paper sign-off:** Frances Sutcliffe, Associate Director – Technology Appraisals Programme

**Contributors to this paper:**

Technical Lead: Helen Tucker

Project Manager: Andrew Kenyon

5 February 2014