

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA29; Guidance on the use of fludarabine for B-cell chronic lymphocytic leukaemia

This guidance was issued in September 2001.

Background

At the GE meeting of 8 October 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.

Proposal put to consultees:	The guidance should be transferred to the 'static guidance list'.
Rationale for selecting this proposal	No new evidence has been identified that would impact on the current recommendations in technology appraisal guidance 29. It is therefore appropriate for the guidance to be to be transferred to the 'static guidance list'.

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.

Recommendation post consultation:	The guidance should be transferred to the 'static guidance list'.
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Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Nursing	No comment	There are no comments to submit on behalf of the Royal College of Nursing to inform on the review proposal for the above appraisal.	Response noted.
Chronic Lymphocytic Leukaemia Support Association	Agree	We have looked at the Guidance and as Fludarabine would not currently be used as a monotherapy and as cost calculations are well out of date we would be supportive of NICE moving this to the static list.	Response noted. In 2001, the cost of a 6-cycle course of fludarabine was £3900. In 2013, it was £2419. Because the Committee considered that fludarabine was cost effective at the original cost of £3900, the reduced cost would not affect the recommendations in TA29.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Physicians		<p>In part, our experts found the proposal document somewhat ambiguous. It appears to suggest changing the fludarabine guidance to avoid using it in Stage C CLL whereas within the "current Indication (for this appraisal)" section it states that it:</p> <ul style="list-style-type: none"> • should be used in patients with good bone marrow reserve • can be used in Stage C CLL (ie those with a failing marrow) with progressive disease <p>Regardless of whether we have interpreted the document correctly our experts do not believe that fludarabine monotherapy is ever indicated in CLL. The evidence suggests that fludarabine+cyclophosphamide is better and further NICE Guidance indicates (correctly) that FCR should be used.</p>	<p>Response noted.</p> <p>The 'Current Indication (for this appraisal)' entry refers to the licensed indications for fludarabine as in the Summary of Product Characteristics. In TA29, which is the subject of this review, fludarabine is recommended as second-line therapy for B-cell chronic lymphocytic leukaemia for patients who have either failed, or are intolerant of, first-line chemotherapy, and who would otherwise have received certain combination chemotherapy. This review concluded that the current recommendations in TA29 should be transferred to the 'static guidance list' because no new evidence has been identified that would impact on the current recommendations. The review proposal did not suggest any change to the current guidance.</p>

No response received from:

<p><u>Manufacturers/sponsors</u></p> <ul style="list-style-type: none"> • Actavis UK (fludarabine) • Fresenius Kabi (fludarabine) • Hospira UK (fludarabine) 	<p><u>General</u></p> <ul style="list-style-type: none"> • Allied Health Professionals Federation • Board of Community Health Councils in Wales • British National Formulary
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- Sanofi (fludarabine)
- Teva UK (fludarabine)

Patient/carer groups

- Afiya Trust
- African Caribbean Leukaemia Trust (ACLT)
- Anthony Nolan
- Aplastic Anaemia Trust
- Black Health Agency
- Cancer Black Care
- Cancer Equality
- Cancer52
- Chronic Myeloid Leukaemia Support Group
- Equalities National Council
- Help Adolescents with Cancer
- Helen Rollason Cancer Charity
- Independent Cancer Patients Voice
- Leukaemia Cancer Society
- Leukaemia CARE
- Lymphoma Association
- Macmillan Cancer Support
- Maggie's Centres
- Marie Curie Cancer Care
- Muslim Council of Britain
- Muslim Health Network
- Rarer Cancers Foundation
- South Asian Health Foundation
- Specialised Healthcare Alliance
- Tenovus
- United Kingdom Chronic Lymphocytic Leukaemia Forum

- Care Quality Commission
- Commissioning Support Appraisals Service
- Department of Health, Social Services and Public Safety for Northern Ireland
- Healthcare Improvement Scotland
- Medicines and Healthcare Products Regulatory Agency
- National Association of Primary Care
- National Pharmacy Association
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Scottish Medicines Consortium

Comparator manufacturers

- Actavis (doxorubicin, prednisolone)
- Alliance Pharmaceuticals (prednisolone)
- Amdipharm (prednisolone)
- Baxter Healthcare (cyclophosphamide)
- Eli Lilly and Company (vincristine)
- Genus Pharmaceuticals (vincristine)
- Hameln Pharms (doxorubicin)
- Hospira (doxorubicin, vincristine)
- Medac (doxorubicin)
- Pfizer (cyclophosphamide, doxorubicin, prednisolone)
- Teva UK (doxorubicin, vincristine)
- Wockhardt (doxorubicin, prednisolone)
- Zentiva UK (prednisolone)

Relevant research groups

- Cochrane Haematological Malignancies Group

Professional groups

- Association of Cancer Physicians
- British Association for Services to the Elderly
- British Committee for Standards in Haematology (BCSH)
- British Geriatrics Society
- British Psychosocial Oncology Society (BPOS)
- British Society for Haematology
- Cancer Network Pharmacists Forum
- Cancer Research UK
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal Pharmaceutical Society
- Royal Society of Medicine
- UK Health Forum
- United Kingdom Clinical Pharmacy Association
- United Kingdom Oncology Nursing Society

Others

- Department of Health
- NHS England
- NHS Hambleton, Richmondshire and Whitby CCG
- NHS Vale of York CCG
- Welsh Government

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

Assessment Group

- National Institute for Health Research Health Technology Assessment Programme

Associated Guideline Groups

- National Collaborating Centre For Cancer

Associated Public Health Groups

- Public Health England
- Public Health Wales NHS Trust

GE paper sign-off: Helen Knight, Associate Director – Technology Appraisals Programme

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