NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA243; Rituximab for the first-line treatment of stage III-IV follicular lymphoma, and TA226; Rituximab for first line maintenance treatment of follicular non-Hodgkin's lymphoma

TA243 was issued in January 2012. TA226 was issued in June 2011.

The review date for this guidance is May 2014.

Background

At the GE meeting of 3 June 2014 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	New evidence available since TA243 and TA226 were published includes a license extension for a subcutaneous (s.c) formulation (granted April 2014), with the same drug acquisition cost as the current intravenous (i.v) formulation and clinical efficacy and safety trial data showing that the s.c formulation was non-inferior to the i.v formulation. In addition, rituximab biosimilars may be available in future, which may affect drug acquisition costs, but it is not expected that cost would increase. Therefore, none of the new evidence available since the publication of TA243 and TA226 is expected to have an impact on the clinical and cost-effectiveness positive recommendations for rituximab for first line treatment or maintenance of follicular non-Hodgkin's lymphoma. A clinical guideline for non-Hodgkin's lymphoma is on-going. This guideline will cross-refer to the recommendations of both technology appraisals TA243 and TA226, however, if during development of the

	guideline it is decided that the recommendations should be incorporated, then this would be permitted as the guidance would be on the static 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'.

Respondent	**Response to proposal**	**Details**[1]	**Comment from Technology Appraisals**
Boehringer Ingelheim	Agree	Boehringer Ingelheim agrees to the proposal to move this to the static list.	Comment noted. The guidance will be transferred to the 'static guidance list'.
Department of Health	No comment	The Department of Health has no comments to make regarding NICE's proposal to move the existing guidance to the static list.	Comment noted. The guidance will be transferred to the 'static guidance list'.

[1] 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[1]	Comment from Technology Appraisals
Sandoz	Agree	Sandoz support the proposal to move both TA243 and TA226 to the static list of technology appraisals. Sandoz are currently conducting a Phase III trial to Compare the Efficacy, Safety and Pharmacokinetics of GP2013 vs. MabThera® in Patients With Previously Untreated, Advanced Stage Follicular Lymphoma (ASSIST_FL). Details of the study can be found on the clinical trials.gov site and accessed via the following link; http://www.clinicaltrials.gov/ct2/show/NCT01419665?term=novartis+and+GP2013&rank=3. This trial is on the critical path for EU approval and we ask for consideration of this to be included in your decision to move these TA's to the static list.	Comment noted. The guidance will be transferred to the 'static guidance list'. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be identified for review by the Guidance Executive. NICE will consider all the relevant evidence in its decision. See section 6 'Guide to the single technology appraisal process'.
Roche Products	Agree	We are happy with the proposal to move the above guidance to the static list	Comment noted. The guidance will be transferred to the 'static guidance list'.
Royal College of Nursing	No comment	There are no comments to submit on behalf of the Royal college of Nursing to inform on the above review proposal	Comment noted. The guidance will be transferred to the 'static guidance list'.
British Society for Haematology Royal College of Pathologists	No comment	The Royal College of Pathologists and BSH has no comments to make on the review of the above technology appraisal guidance. Our advisor feels there is no need to change this guidance.	Comment noted. The guidance will be transferred to the 'static guidance list'.

No response received from:

<u>Patient/carer groups</u> • Afiya Trust • Black Health Agency • Cancer Black Care • Cancer Equality • Cancer52 • Equalities National Council • HAWC • 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 <u>Professional groups</u> • Association of Cancer Physicians • British Committee for Standards in Haematology • British Geriatrics Society • British Psychosocial Oncology Society	<u>General</u> • Allied Health Professionals Federation • Board of Community Health Councils in Wales • British National Formulary • Care Quality Commission • 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 <u>Comparator manufacturers</u> • None <u>Relevant research groups</u> • 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 Research Institute

• Cancer Network Pharmacists Forum • Cancer Research UK • Royal College of General Practitioners • Royal College of Physicians • Royal Society of Medicine • UK Health Forum • United Kingdom Clinical Pharmacy Association • United Kingdom Oncology Nursing Society <u>Others</u> • NHS Bassetlaw CCG • NHS Doncaster CCG • NHS England • Welsh Government	• National Cancer Research Network • National Institute for Health Research <u>Assessment Group</u> • National Institute for Health Research Health Technology Assessment Programme <u>Associated Guideline Groups</u> • National Collaborating Centre for Cancer (NCC-C) <u>Associated Public Health Groups</u> • Public Health England • Public Health Wales NHS Trust

GE paper sign-off: Elisabeth George, Associate Director – Technology Appraisals Programme

Contributors to this paper:

Technical Lead: Pilar Pinilla-Dominguez

Project Manager: Andrew Kenyon

01 08 2014