National Institute for Health and Clinical Excellence

Pemetrexed for the maintenance treatment of first line non-small cell lung cancer

Comment 1: the draft remit

Section	Consultees	Comments	Action
Appropriateness	British Thoracic Society Lung Cancer and mesothelioma Specialist Advisory Group	I don't think the drug is licensed for this indication and there is little published evidence apart from a paper presented as an abstract at ASCO 2008 (T. E. Ciuleanu et al).	Comment noted. The technology currently has a positive opinion from the CHMP, has been selected as a topic for consideration by NICE and will therefore be subject to a technology appraisal.
	Royal College of Nursing	Yes.	Comment noted.
Wording	Eli Lilly and Company	Please note that the licence for this indication is likely to be for "the maintenance treatment of non-small cell lung cancer of other than predominantly squamous histology".	Pemetrexed will be appraised within its expected licensed indications.

Section	Consultees	Comments	Action
	British Thoracic Society Lung Cancer and mesothelioma Specialist Advisory Group	Title should be: Pemetrexed for the maintenance treatment of non-small cell lung cancer after first-line chemotherapy	It was agreed at the scoping workshop to amend the remit to: "To appraise the clinical and cost effectiveness of pemetrexed, within its licensed indications, for maintenance treatment immediately after first line chemotherapy of non-small cell lung cancer."
	Royal College of Nursing	Yes	Comment noted.
Timing Issues	Eli Lilly and Company	The licence is anticipated [redacted].	Comment noted.
	British Thoracic Society Lung Cancer and mesothelioma Specialist Advisory Group	Not urgent.	Comment noted.

Section	Consultees	Comments	Action
Additional comments on the draft remit	British Thoracic Society Lung Cancer and mesothelioma Specialist Advisory Group	It would be useful to know why and by whom this drug/indication has been referred for assessment.	As outlined in the Cancer Reform Strategy, it is the default position of the Department of Health to refer to NICE all new cancer drugs and significant new licensed indications, providing that the Institute agrees that there is a sufficient patient population and evidence base on which to carry out an appraisal and that there is not a more appropriate alternative mechanism for appraisal.

Comment 2: the draft scope

Section	Consultees	Comments	Action
Background information	Eli Lilly and Company	We have recent data that suggests the proportion of patients receiving second line therapy is 20%.	Comment noted. Scope amended accordingly.
	Royal College of Nursing	Yes.	Comment noted.
The technology/ intervention	Eli Lilly and Company Limited	Please note; the licence for first line use of pemetrexed in patients who are chemonaive is in combination with cisplatin and only in patients of 'other than predominantly squamous histology'. The licence for second line NSCLC is for use of pemetrexed as monotherapy but is also only for use in patients of other than predominantly squamous histology.	Scope amended accordingly.
	British Thoracic Society Lung Cancer and mesothelioma Specialist Advisory Group	Presumably the drug is given continuously until disease progression.	Pemetrexed is given until disease progression or until unacceptable toxicity is observed. For more information, please see the SPC.
	Royal College of Nursing	Yes.	Comment noted.
Population	Eli Lilly and Company	Add 'other than predominantly squamous histology'.	Scope amended accordingly.
	Royal College of Nursing	Should include all patients who are not eligible for surgery/radical RT.	The marketing authorisation specifies those patients with locally advanced or metastatic non-small-cell lung cancer. Therefore, this group will not be covered.
Comparators	Eli Lilly and Company	In the trial, BSC exluded anti tumour therapies being used for maintenance and palliative radiotherapy.	Comment noted.
	Royal College of Nursing	Yes	Comment noted.

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Outcomes	British Thoracic Society Lung Cancer and mesothelioma Specialist Advisory Group	Is there actually any data on overall survival?	The Institute has not begun to review the availability of evidence at this stage. It is noted that data from phase III clinical trials reporting overall survival were submitted to the EMEA as evidence of clinical efficacy, as reported on the EMEA website.
Questions for consultation	Eli Lilly and Company	See above.	Comment noted.
	British Thoracic Society Lung Cancer and mesothelioma Specialist Advisory Group	Does this treatment become "second-line therapy"? How would it influence existing guidance on second-line treatment?	Maintenance therapy with pemetrexed is considered to be an intermediary between the end of first-line treatment with platinum-based chemotherapy and the progression of disease. It is not anticipated to influence current guidance on treatment initiated as second-line therapy at progression.
Additional comments on the draft scope.	Eli Lilly and Company	TA124 now refers of out of licence use of pemetrexed.	The Institute has begun consultation on its review of this guidance.

Comment 4: Regulatory issues

Section	Consultees	Comments	Action
Remit	Eli Lilly and Company	Please note that the licence for this indication is likely to be for "the maintenance treatment of non-small cell lung cancer of other than predominantly squamous histology".	Scope amended accordingly.

Section	Consultees	Comments	Action
Current or proposed marketing authorisation	Eli Lilly and Company	*What are the current indications for the technology?* 1st & 2nd line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology, Malignant Pleural Mesothelioma *What are the planned indications for the technology* Maintenance treatment of non-small cell lung cancer of other than predominantly squamous histology *FOR EACH PLANNED INDICATION* Maintenance treatment of non-small cell lung cancer of other than predominantly squamous histology *What is the target date for regulatory submission?* [redacted] *Which regulatory process are you following* Centralised Procedure *What is the anticipated date of CHMP positive opinion and regulatory approval?* [redacted]	No action required.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

NHS Quality Improvement Scotland
NPHS Wales
Royal College of Pathologists
RICE - The Research Institute for the Care of Older People
Welsh Assembly Government