NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

SINGLE TECHNOLOGY APPRAISAL

Necitumumab for untreated advanced or metastatic, squamous non-small-cell lung cancer [ID835]

The following documents are made available to the consultees and commentators:

1. **Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD)**

2. **Consultee and commentator comments on the Appraisal Consultation Document** from:
   - Eli Lilly

'No comments' responses were received from the British Thoracic Oncology Group and the department of Health. There were no responses to the appraisal consultation document from clinical or patient experts or through the NICE website.

Any information supplied to NICE which has been marked as confidential, has been redacted. All personal information has also been redacted.

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Single Technology Appraisal

Necitumumab for untreated advanced or metastatic, squamous non-small-cell lung cancer

Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD)

Definitions:

Consultees – Organisations that accept an invitation to participate in the appraisal including the companies, national professional organisations, national patient organisations, the Department of Health and the Welsh Government and relevant NHS organisations in England. Consultees can make a submission and participate in the consultation on the appraisal consultation document (ACD; if produced). All non-company consultees can nominate clinical experts and/or patient experts to verbally present their personal views to the Appraisal Committee. Company consultees can also nominate clinical experts. Representatives from NHS England and clinical commissioning groups invited to participate in the appraisal may also attend the Appraisal Committee as NHS commissioning experts. All consultees have the opportunity to consider an appeal against the final recommendations, or report any factual errors, within the final appraisal determination (FAD).

Clinical and patient experts and NHS commissioning experts – The Chair of the Appraisal Committee and the NICE project team select clinical experts and patient experts from nominations by consultees and commentators. They attend the Appraisal Committee meeting as individuals to answer questions to help clarify issues about the submitted evidence and to provide their views and experiences of the technology and/or condition. Before they attend the meeting, all experts must either submit a written statement (using a template) or indicate they agree with the submission made by their nominating organisation..

Commentators – Commentators can participate in the consultation on the ACD (if produced), but NICE does not ask them to make any submission for the appraisal. Non-company commentator organisations can nominate clinical experts and patient experts to verbally present their personal views to the Appraisal Committee. Commentator organisations representing relevant comparator technology companies can also nominate clinical experts. These organisations receive the FAD and have opportunity to report any factual errors. These organisations include comparator technology companies, Healthcare Improvement Scotland any relevant National Collaborating Centre (a group commissioned by NICE to develop clinical guidelines), other related research groups where appropriate (for example, the Medical Research Council and National Cancer Research Institute); other groups such as the NHS Confederation, the NHS Commercial Medicines Unit, the Scottish Medicines Consortium, the Medicines and Healthcare Products Regulatory Agency, the Department of Health, Social Services and Public Safety for Northern Ireland).

Public – Members of the public have the opportunity to comment on the ACD when it is posted on the Institute's web site 5 days after it is sent to consultees and commentators. These comments are usually presented to the appraisal committee in full, but NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

Please note: 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.

Comments received from consultees

Consultee	Comment [sic]	Response
Eli Lilly	Lilly is disappointed that NICE has not recommended necitumumab, in combination with gemcitabine and cisplatin, within its marketing authorisation for treating locally advanced or metastatic epidermal growth factor receptor (EGFR)-expressing squamous non-small-cell lung cancer that has not been previously treated with chemotherapy in adults. Lilly is proud to have developed the first licensed first-line therapy for advanced squamous non-small cell lung cancer in over 20 years. The addition of necitumumab as a treatment option for this relatively small patient population is helping to address a high unmet medical need and it is disappointing that patients in England will not be able to access it through the NHS. The outcome of this appraisal has once again highlighted the limitations of using the cost per quality adjusted life year (QALY) to determine the value of technologies that manage conditions with short life expectancies and with no new treatment introductions in many years. However we are pleased that the committee acknowledged that the SQUIRE trial was of good quality and concluded that current evidence suggests that necitumumab is an effective treatment option which offers a clinically important improvement in overall survival compared with gemcitabine and cisplatin.	Thank you for your comments. No further action required.

The British Thoracic Oncology Group and the Department of Health stated that they had no comments on the appraisal consultation document.

Comments received from clinical experts and patient experts

None

Comments received from commentators

None

Comments received from members of the public

None

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RE: Lilly response to appraisal consultation document (ACD): necitumumab for untreated advanced, metastatic squamous non-small-cell lung cancer [ID835]

Dear Helen,

Lilly is disappointed that NICE has not recommended necitumumab, in combination with gemcitabine and cisplatin, within its marketing authorisation for treating locally advanced or metastatic epidermal growth factor receptor (EGFR)-expressing squamous non-small-cell lung cancer that has not been previously treated with chemotherapy in adults.

Lilly is proud to have developed the first licensed first-line therapy for advanced squamous non-small cell lung cancer in over 20 years. The addition of necitumumab as a treatment option for this relatively small patient population is helping to address a high unmet medical need and it is disappointing that patients in England will not be able to access it through the NHS.

The outcome of this appraisal has once again highlighted the limitations of using the cost per quality adjusted life year (QALY) to determine the value of technologies that manage conditions with short life expectancies and with no new treatment introductions in many years.

However we are pleased that the committee acknowledged that the SQUIRE trial was of good quality and concluded that current evidence suggests that necitumumab is an effective treatment option which offers a clinically important improvement in overall survival compared with gemcitabine and cisplatin.

Please contact me if you have any further queries.

Yours sincerely,

[redacted]