

Dr Amanda Adler Chair, NICE Appraisal Committee National Institute for Health and Clinical Excellence MidCity Place 71 High Holborn London WC1V 6NA

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Dear Dr Adler,

Cancer Research UK welcomes the opportunity to respond to this consultation. However, we are very disappointed that NICE do not feel able to recommend gefitinib (Iressa) for patients with non-small cell lung cancer.

Gefitinib as a targeted treatment

Gefitinib provides a good example of how advances in medical research have led to a more individualised approach to cancer treatment. We know that this drug only works in patients with a specific genetic mutation.

Treating only the patients that will respond to this drug will not only mean that many patients won't have to undergo unnecessary treatments, but should save the NHS money in the long term. The ability to classify individuals into sub-populations that differ in their response to a specific treatment means that patients will get more effective treatments, with fewer side effects, and the NHS will improve prescription cost-effectiveness.

However, we are concerned that NICE hasn't taken the benefits of this stratified approach adequately into consideration when conducting their appraisal.

Potential cost-savings of targeting treatment

EGFR testing is an excellent way of targeting treatment to a minority of patients with mutEGFR non-small cell lung cancer. There is no mention anywhere in Section 1 of the potential for substantial savings by preventing usage of EGFR antagonists in patients with mutRAS or wtEGFR.

Targeted use of gefitinib in the first line setting will largely eliminate the use of erlotinib in the second line setting. This shift in clinical practice carries with it a significant potential cost-saving. It isn't clear how NICE have taken this into consideration in their evaluation.

The document also repeatedly mentions the cost related to biopsy and suggests that repeated biopsies may be needed. However, our understanding is that, in actual clinical practice, the biopsy used to make the first diagnosis is usually suitable for EGFR analysis.

The role of NICE in appraising stratified medicines

In this and in future appraisals we feel it is crucial that NICE exploits the best science available.

We recognise that in the Appraisal Consultation Document, NICE has asked the manufacturers to address some clarifying questions. We also ask that NICE seek additional oncological expertise in answering some of these questions. For example, we believe that the establishment of an EGFR-TK mutation testing service would not be as complex as suggested in the appraisal (point 3.27) and that this is something the manufacturers would likely be inclined to support. Furthermore we are concerned that NICE has overestimated the likely lifetime for patients with locally advanced or metastatic disease (point 3.32) in this appraisal.

We hope that NICE will work quickly to resolve these issues. It is already nearly six months since gefitinib was launched for use as a first line treatment for non-small cell lung cancer in the UK, and many patients who could benefit from this treatment are being left in limbo while this decision is being made.

We urge NICE not to miss this golden opportunity to support the development of stratified medicines and recommend the use of targeted treatments for cancer patients in the NHS.

Yours Sincerely,

