Comments on the ACD Received from the Public through the NICE Website

Name	[redacted]
Role	other
Other role	Daughter of lung cancer patient
Location	England
Conflict	no
Notes	You should not stop the availability of this drug, it is and could help so many people. Look in your hearts if it was your dad, mum, daughter, son or anyone you cared about living with cancer wouldn't you want to give them every chance of spending more time with you?
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	No one conforms to set statistics! There are people without mutations doing well on these drugs. Why does the UK have to go backwards in medicine when all other countries advance!
Section 2 (Clinical need and practice)	Wouldn't you want to prolong your loved ones life if you knew that this drug could help! Cancer don't care who it strikes so don't think that just because you may not smoke you won't one day be hit with a lung cancer diagnosis! You may need this drug then!
Section 3 (The technologies)	Cancer affects 1 in 3 people. By taking away the chance of having accessibility to drugs that have proven positive effects is ridiculous. Whatever the percentage the fact is there is a percentage which means there's a chance! Â And every second we have in life cannot be measured in value!!!
Section 4 (Evidence and interpretation)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	Life is priceless- don't stop a drug that helps because of cost! You could be taking my Daddy away from me sooner
Section 8 (Proposed date for review of guidance)	Wouldn't you want to prolong your loved ones life if you knew that this drug could help! Cancer don't care who it strikes so don't think that just because you may not smoke you won't one day be hit with a lung cancer diagnosis! You may need this drug then!
Date	2/22/2014 9:35:00 PM

Name	[redacted]
Role	[redacted]
Other role	
Location	England
Conflict	no
Notes	GSTT Lung Cancer CNS Response To NICE Decision To Remove Erlotinib As Second Line Treatment For Patients With Non Small Cell Lung Cancer. The lung cancer clinical nurse specialists at [redacted] have a run a nurse led clinic for patients receiving TKI?s since March 2010. We consent the patients to treatment and then follow the patients through until they have disease progression. Six out of the ten in our current patient group are on second line erlotinib, with a range of treatment from 6 months up to 20 months. Our concerns regarding the removal of erlotinib as second line treatment are this: In the TAILOR Study it was found that 20% of the patients in the docetaxel arm suffered from grade 3-4 toxic effects with regards to their neutrophil count. Compared to the patients in the erlotinib arm who had no such events as erlotinib does not affect the bone marrow. This in itself would carry a potential cost to the NHS in the terms of visits to accident and emergency departments, IV antibiotics and potential inpatient stays. In the 5 years we have been caring for patients being treated with erlotinib we have admitted one patient due to toxicity and this was due to the patient being embarrassed about location of rash so not reporting it to the nurses. Also as nurses are able to effectively and safely care for these patients in a nurse led clinic this allows the clinicians to see more patients who have complex needs. We have seen patient waiting times reduce and patient satisfaction increase in the patients treated in the nurse led clinic. A nurse led clinic is also cost effective. With docetaxel the patients would need to see a clinician, have potentially more hospital visits due to toxicity management and have longer wait times in clinic. Patients who have had severe toxicities relating to first line chemotherapy in our experience are extremely reluctant to go on for second line chemotherapy. With some patients becoming very distressed in consultations where this is the next line of treatment suggested. Current practice has been that at the clinicians? discretion these patients have been offered erlotinib as second line. All of the patients are informed that this treatment may only offer a short term holding of their cancer, but they are still keen to try this over further chemotherapy. If NICE remove the option of erlotinib as second line then these patients will effectively be relegated to best supportive care only and a potential poor prognosis. We would suggest that ethically this does not sit right with the principle of beneficence and removes not only the patients? right to choice but also the clinicians? ability to use their expertise in deciding what the right treatment for the right individual is.

	We have recently had a case where a patient was diagnosed with an EGFR WT adenocarcinoma, she struggled to cope with the effects of chemotherapy but managed to complete her treatment. However, this left her fatigued and very adverse to further chemotherapy in the future. Sadly this lady?s cancer progressed soon after chemotherapy had finished and the clinician on examining her CT scans felt that the tumour was behaving in the pattern of an EGFR +ve tumour. The only way to disprove the original EGFR test undertaken in another Trust would be to take a new biopsy and repeat the test in GSTT. The lady was not really fit enough to undergo another biopsy and so in discussion with the patient, family and clinician erltonib was prescribed. So far although we acknowledge it is early days this lady is doing well and has now been able to have a repeat biopsy and we await the result. If erlotinib had been removed by NICE at this point this lady would have been denied treatment that has so far improved her condition. Whilst we acknowledge the findings of the TAILOR study and the fact that docetaxel is a much cheaper drug we would request that NICE think very carefully before making any decisions. Treatment options for lung cancer patients are still very limited when compared to treatment options for other cancers. These patients continue to have a poor prognosis and face the stigma of having a cancer that the majority of the general public only associate with heavy smokers. Whilst clinical trials are vital for the future treatment of patients with lung cancer we should never lose sight of the patient and their families who have to deal with a cancer that is debilitating and has a devastating effect on both the patient and their families. As nurses it is our duty to speak out for our patients and this is acknowledged in the government white paper which highlighted those patients who had access to a clinical nurse specialist had better access to treatment and tended to cope better with that treatment. It is with all of the above in mind that we feel that erlotinib should to be offered as second line treatment to patients with non small cell lung cancer.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	GSTT Lung Cancer CNS Response To NICE Decision To Remove Erlotinib As Second Line Treatment For Patients With Non Small Cell Lung Cancer. The lung cancer clinical nurse specialists at [redacted] have a run a nurse led clinic for patients receiving TKI?s since March 2010. We consent the patients to treatment and then follow the patients through until they have disease progression. Six out of the ten in our current patient group are on second line erlotinib, with a range of treatment from 6 months up to 20 months. Our concerns regarding the removal of erlotinib as second line treatment are this: In the TAILOR Study it was found that 20% of the patients in the docetaxel arm suffered from grade 3-4 toxic effects with regards to their neutrophil count. Compared to the patients in the erlotinib arm who had no such events as erlotinib does not affect the bone marrow.

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	general public only associate with heavy smokers. Whilst clinical trials are vital for the future treatment of patients with lung cancer we should never lose sight of the patient and their families who have to deal with a cancer that is debilitating and has a devastating effect on both the patient and their families. As nurses it is our duty to speak out for our patients and this is acknowledged in the government white paper which highlighted those patients who had access to a clinical nurse specialist had better access to treatment and tended to cope better with that treatment. It is with all of the above in mind that we feel that erlotinib should to be offered as second line treatment to patients with non small cell lung cancer.
Section 2 (Clinical need and practice)	
Section 3 (The technologies)	
Section 4 (Evidence and interpretation)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date for review of guidance)	
Date	2/24/2014 11:51:00 AM

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There are patients who are EGFR negative who have responded to erlotinib/tarceva
Section 2 (Clinical need and practice)	
Section 3 (The technologies)	
Section 4 (Evidence and interpretation)	Cost comparisons between docetaxel & erlotinib not robust. Docetaxel more costly to administer due to need to attend hospital, erlotinib taken at home. Patients needing 2nd line treatment are often not strong enough to tolerate chemo. Erlotinib works quickly, so efficacy can be established early on.Lung cancer research pitifully underfunded. Critically ill patients should not be deprived of a drug which can extend quality of life, give time for them and family etc to come to terms with situation.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date for review of guidance)	
Date	2/23/2014 2:47:00 PM

Admin PA - [redacted]
Clinical PA - [redacted]
Fax - [redacted]
Mob – [redacted]

Friday 21st February 2014

Meindert Boysen
Programme Director, Technology Appraisals
National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester
M1 4BT

Ref: erlotinib in non-small cell lung cancer (TA162, TA175)

I write in response to the recent appraisal consultation document regarding the use of erlotinib and gefitinib in lung cancer (non-small cell) rev TA162, TA175. The outcome of the ACD is to recommend that access to erlotinib is denied to those patients that have a negative EGFR test. This outcome follows publication of the results of recent international clinical trials.

As a specialist in lung cancer treatment I wish to inform you that your appraisal is flawed with respect to the assumptions made in item 4.1.13.

Our own data was recently reported as an audit of almost 100 patients with EGFR negative non-small cell lung cancer treated with erlotinib post-chemotherapy. This audit shows that judicious, use of erlotinib results in a two-fold improvement in clinical benefit compared to the results of recent clinical trials.

Docetaxel chemotherapy in England is not administered in the same dosing schedule as reported by the TAILOR study. In addition, the high frequency of intolerable side-effects associated with docetaxel mean that this is an unacceptable treatment. Given that this is a patient group with limited survival, there is no data to support symptom improvement or favourable quality of life with docetaxel.

The implication of the ACD outcome will be that a high proportion of lung cancer patients will be denied access to life extending second-line treatment, which is a backward step in the treatment of this disease.

It is my opinion that clinicians, who are very experienced in treating this complex and ultimately deadly disease, should be given the opportunity to select the right treatments for each patient.

I request the appraisal group reconsider its recommendation.

[redacted]

Name	[redacted]
Role	[redacted]
Other role	[redacted], [redacted]
Location	England
Conflict	yes
Notes	Have had conference funding from Roche and spoken at promotional events for them on the use of Tarceva. Have conducted trials using a number of different TKIs including tarceva in Topical trial, was an author on that paper.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Feel that you will be denying a very useful treatment i.e second line erlotinib to a vulnerable patient group where they would not otherwise access 2nd line treatment. Assume you will include stable disease as response and not require RECIST criteria.
Section 2 (Clinical need and practice)	Feel that you have failed to recognise that the lung cancer community has offered tarceva 2nd line to a wider group of people that we would offer docetaxel to based on clinical experience. the trials have generally younger patients in than my population many of whom are over 70 , even 75 for whom docetaxel would simply be inappropriate and hence the excellent option of erlotinib has been used with good clinical benefit.
Section 3 (The technologies)	TKIs are very well tolerated and manageable with flexible dosing such that treatment very rarely needs to be stopped completely
Section 4 (Evidence and interpretation)	The rates of neutropaenic sepsis seen in these Docetaxel studies are not representative of UK experience where almost 20% pts are admitted as we cannot use PEG GCSF for palliative pts. The Tailor study did not use erlotinib as intended as it it mandated stopping for grade 3 rash, this in my opinion may have biased the rests as TKIs should be dose reduced in this setting . Erlotinib can be used successfully in pts who do not wish to lose their hair, do not wish to accept the dreadful toxicity we see in the real world with docetaxel for a small clinical response. The grade 1 and 2 toxicity with docetaxel should not be underestimated. Having treated over 100 pts with 2nd line TKI for wild type disease, they fall into 2 groups- those who derive no clinical benefit which you can generally see by 4 weeks and therefore stop and those who have ver durable responses and improvement in quality of life. I have a number of patients for whom this has been several years. You need to look at the audit experience of the lung cancer community in the UK as they are a different population to those shown in these studies. (with the exception of BR21)
Section 5 (Implementation)	Entirely agree with 1st line usage
Section 6 (Proposed recommendations for further research)	SACT data should show the drop in patients accessing 2nd line therapy if the CRG do not recumbent erlotinib or other single agents e.g gemcitabine , vinorelbine or taxol as beyond1st line treatment.
Section 7 (Related NICE guidance)	within one year to look at impact on lung cancer survival in UK
Section 8 (Proposed date for review of guidance)	Feel that you have failed to recognise that the lung cancer community has offered tarceva 2nd line to a wider group of people that we would offer docetaxel to based on clinical

	experience. the trials have generally younger patients in than my population many of whom are over 70 , even 75 for whom docetaxel would simply be inappropriate and hence the excellent option of erlotinib has been used with good clinical benefit.
Date	2/23/2014 9:41:00 AM