NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Ceritinib for previously treated anaplastic lymphoma kinase-positive non-small-cell lung cancer [ID729]

Thank you for agreeing to give us a statement on your view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: Rachel Thomas

Name of your organisation Guy's and St Thomas' NHS Trust

Are you (tick all that apply):

- (-) a specialist in the treatment of people with the condition for which NICE is considering this technology? yes
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?
- (-) an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc.)? Yes
- other? (please specify)

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What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

Currently patients with an ALK translocation have first line platinum doublet chemotherapy followed by Crizotinib through the CDF.
ALK translocation is found in approx 5% of NSCLC patients diagnosed in the UK.
As far as I am aware there are no significant geographical variation to this practice in England however, in Wales as they do have access to the CDF patients may not be able to access Crizotinib via the CDF and so would not have access to this treatment.
Currently this patient group has very limited options when it comes to treatment. They can either have Crizotinib or Docetaxel.

Ceritinib would only be used for those small percent of patients who have a known ALK. It can be administered orally which will decrease the chair use in chemotherapy day units. Patients should only receive Ceritinib in a specialist cancer unit and not in the primary setting.

The Lung Cancer CNS will be an important component in the care of patients in particular in supporting the patient whilst on treatment and to monitor for any AE's.

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The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

The advantage of this treatment is that it provides a further level of treatment for a small group of patients who currently have very limited options.
Ceritinib should only be used in patients with a proven ALK.

I have experience of caring for two patients on Ceritinib, one patient had G2 vomiting and went on to have a dose reduction, then experienced altered ALT's so had a dose interruption of one week. Now recommenced Ceritinib and doing very well. The AE's did not lead to hospital admission or significantly altered the patient's quality of life. AE's appear to be easy for health professionals to manage and for patients to tolerate.
There have been no AE's in either of these patients that were unexpected.

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Equality and Diversity

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- Could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- Could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- Could lead to recommendations that have any adverse impact on people with a particular disability or disabilities

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts

It would be important to clarify that all Trusts have the ability to undertake ALK testing for all their NSCLC patients. The ALK testing needs to be undertaken in a timely and effective manner and not take weeks for a report to be produced. Their needs to be some guidance on when ALK testing should take place to ensure uniformity across the country and equity of service. Currently some Trusts will not even send samples for ALK testing until the patient has progressed on first line treatment, this could lead to patients not being able to have access to Ceritinib if the test is not performed in a timely manner.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

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Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

I think that extra education and training is usually well provided by individual pharmaceutical companies providing expert forums and educational meetings for staff to attend. Healthcare professionals can then disseminate this learning to their colleagues.
I cannot envisage that extra facilities or equipment would be needed.