NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Topotecan for the treatment of relapsed 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 manufacturer or sponsor of the technology, national professional organisations, national patient organisations, the Department of Health and the Welsh Assembly Government and relevant NHS organisations in England. Consultee organisations are invited to submit evidence and/or statements and respond to consultations. They are also have right to appeal against the Final Appraisal Determination (FAD). Consultee organisations representing patients/carers and professionals can nominate clinical specialists and patient experts to present their personal views to the Appraisal Committee.

Clinical specialists and patient experts – Nominated specialists/experts have the opportunity to make comments on the ACD separately from the organisations that nominated them. They do not have the right of appeal against the FAD other than through the nominating organisation.

Commentators – Organisations that engage in the appraisal process but that are not asked to prepare an evidence submission or statement. They are invited to respond to consultations but, unlike consultees, they do not have the right of appeal against the FAD. These organisations include manufacturers of comparator technologies, NHS Quality Improvement Scotland, the relevant National Collaborating Centre (a group commissioned by the Institute to develop clinical guidelines), other related research groups where appropriate (for example, the Medical Research Council and National Cancer Research Institute); other groups (for example, the NHS Confederation, NHS Information Authority and NHS Purchasing and Supplies Agency, and the *British National Formulary*).

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 may be summarised by the Institute secretariat – for example when many letters, emails and web site comments are received and recurring themes can be identified.

Comments received from consultees

Consultee	Comment	Response
GlaxoSmithKline	Thank you for the opportunity to comment on the Appraisal Consultation Document for topotecan. We welcome the Appraisal Committee's preliminary recommendation for oral topotecan within the NHS as monotherapy for the treatment of adult patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate and for whom treatment with CAV is contraindicated. We have identified one minor inaccuracy in the ACD document which refers to the presentation of oral topotecan which is currently dispensed in capsules (not tablets).	Comment noted. The FAD has been amended to reflect the reference to capsules (not tablets).
	Do you consider that all of the relevant evidence has been taken into account? The Appraisal Committee appears to have examined the relevant evidence thoroughly and has taken counsel from clinical specialists.	Comment noted. No action required.
	Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate? We believe that the ACD summaries of clinical and cost-effectiveness are reasonable interpretation of the evidence.	Comment noted. No action required.

Consultee	Comment	Response
	Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS? Oral topotecan provides a clinically and cost-effective treatment in patients with relapsed SCLC who are not considered as candidates for standard intravenous therapy with CAV, and for whom best supportive care is currently the only option. We therefore believe that the provisional recommendations are appropriate and constitute a suitable basis for the preparation of guidance to the NHS for this specific group of patients who otherwise have very limited treatment options in the last stages of their disease	Comment noted. No action required.
	Are there any equality related issues that may need special consideration? Availability of an oral formulation for the treatment of relapsed SCLC within the NHS will benefit patients in whom IV access is difficult and who otherwise might be prejudiced by the lack of alternative formulations. Therefore oral chemotherapy constitutes a convenient alternative for patients who otherwise would receive only best supportive care.	Comment noted. NICE are not aware of any equalities issues for this appraisal.
Welsh Assembly Government	Thank you for giving the Welsh Assembly Government the opportunity to comment on the above appraisal. We are content with the technical detail of the evidence supporting the appraisal and have no further comments to make at this stage.	Comment noted. No action required.
Department of Health	Thank you for the opportunity to comment on the appraisal consultation document and evaluation report for the above single technology appraisal. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Comment noted. No action required.
Roy Castle Lung Cancer Foundation	We have no additional comment and are pleased to note the Appraisal Committee's decision, to recommend oral Topotecan for relapsed small cell lung cancer, for whom iv CAV treatment is contraindicated. This will allow patients, who currently do not access treatment in second line, to now do so.	Comment noted. No action required.

Consultee	Comment	Response
Royal College of Nursing	*Has the relevant evidence has been taken into account?* The evidence considered seems comprehensive.	Comment noted. No action required.
	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence, and are the preliminary views on the resource impact and implications for the NHS appropriate? This seems appropriate.	Comment noted. No action required.
	Are the provisional recommendations of the Appraisal Committee sound and do they constitute a suitable basis for the preparation of guidance to the NHS? Nurses working in this area of health have reviewed the provisional recommendations of the Appraisal Committee and consider them sound and that they constitute a suitable basis for preparing guidance to the NHS. The RCN would welcome guidance to the NHS on the use of this health technology.	Comment noted. No action required.
	Are there any equality related issues that need special consideration that are not covered in the ACD? None that we are aware of at this stage. We would however, ask that any guidance issued should show that equality issues have been considered and that the guidance demonstrates an understanding of issues concerning patients' age, faith, race, gender, disability, cultural and sexuality where appropriate.	Comment noted. No action required.

Comments received from clinical specialists and patient experts

Nominating organisation	Comment	Response
NHS Quality Improvement Scotland	I would go along with the recommendation of the Appraisal Committee but suggest trying to define contraindications to CAV.	Comment noted. Guidance section 1.1 has been amended to include the following: 'For details of the contraindications to CAV see the summary of product characteristics for each of the component drugs'.

Comments received from commentators

Commentator	Comment	Response
NHS Quality Improvement Scotland	This NICE appraisal is identical to the previous SMC decision on oral topotecan and would not lead to any change in practice in Scotland. We already are using oral topotecan where appropriate in clinical practice. The advice on not using intravenous topotecan creates challenges for the ongoing clinical trial of IV topotecan versus IV amrubicin but that is an issue for the investigators of that trial.	Comment noted. No action required.

Comments received from members of the public

No comments were received from members of the public.