NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 42b draft remits and draft scopes and summary of comments and discussions at scoping workshops

Item number	ID	Topic
5.8	838	Paclitaxel formulated as albumin-bound nanoparticles in combination with carboplatin for untreated non-small-cell lung cancer
5.9	553	Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer

Provisional Title	Paclitaxel formulated as albumin-bound nanoparticles in combination with carboplatin for untreated non-small-cell lung cancer		
Topic Selection ID Number	5722	**Wave / Round**	R20
TA ID Number	ID553		
Company	Celgene		
Anticipated licensing information	Paclitaxel formulated as albumin-bound nanoparticles in combination with carboplatin already has a marketing authorisation in the UK for the first-line treatment of non-small-cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.		
Draft remit	To appraise the clinical and cost effectiveness of paclitaxel formulated as albumin-bound nanoparticles in combination with carboplatin within its marketing authorisation for untreated non-small-cell lung cancer.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of paclitaxel formulated as albumin-bound nanoparticles in combination with carboplatin within its marketing authorisation for untreated non-small-cell lung cancer is appropriate. No changes to the remit or scope are required. The company informed NICE in May 2012 that they were not seeking a licence for this indication, but subsequently applied for regulatory approval and did not update NICE about revised licencing dates. The company has indicated that they are not pursuing a commercial launch for this indication, but it is already included in the SmPC and therefore is available in the UK. The clinical experts at the scoping workshop explained that paclitaxel is rarely used in clinical practice as a first-line treatment and the clinical trials for paclitaxel formulated as albumin-bound nanoparticles have demonstrated little efficacy over standard paclitaxel. Therefore, they were of the opinion that an appraisal would be of limited value to the NHS. The company (Celgene) did not attend the scoping workshop and did not provide any comments during consultation on the draft scope. Decision-makers at the decision point 4 meeting considered that NICE has a duty to appraise all new significant indications for cancer therapies, therefore referral for an appraisal for this topic should be sought.		
Population size	Expected population size: 34,889 diagnosed with lung cancer per year 85% have incurable NSCLC (n=29,655) 69% with advanced disease (n=23,130) 30% receive 1st line treatment (n=6,939)		
Process (MTA/STA/HST)	STA		

Proposed changes to remit (in bold)	None
Costing implications of remit change	Not applicable, no changes to remit
Timeliness statement	As the technology has received a marketing authorisation, issuing timely guidance will **not** be possible.

Provisional Title	Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer		
Topic Selection ID Number	7549	**Wave / Round**	R125
TA ID Number	838		
Company	Eli Lilly		
Anticipated licensing information	*****CONFIDENTIAL INFORMATION REMOVED*****		
Draft remit	To appraise the clinical and cost effectiveness of ramucirumab within its marketing authorisation for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after platinum-based chemotherapy.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer is appropriate. No changes to the remit are required. Consultees agreed that best supportive care is not a suitable comparator because it is only considered for patients who are unlikely to tolerate chemotherapy (docetaxel), and who would consequently be ineligible for ramucirumab in combination with docetaxel. It was agreed that best supportive care should be removed as a comparator and the following comparators should be added to the scope (in addition to the existing comparators of docetaxel, erlotinib (subject to ongoing NICE appraisal) and nintedanib in combination with docetaxel (for people with adenocarcinoma tumour histology only): • nivolumab for people with squamous tumour histology only (subject to ongoing NICE appraisal) • crizotinib (for people with ALK-positive non-small-cell lung cancer only)		
Population size	Approximately 4600 patients in England are estimated to be eligible for treatment.		
Process (MTA/STA/HST)	STA		
Proposed changes to remit (in bold)	None		
Costing implications of remit change	Not applicable, no changes to remit		
Timeliness statement	Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the requested early referral date of this topic as part of Batch 42, issuing timely guidance for this technology will be possible.		