NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 44a draft remits and draft scopes and summary of comments and discussions at scoping workshops

Item	ID	Topic
5.1	867	Ramucirumab in combination with FOLFIRI for treating metastatic colorectal cancer after progression with bevacizumab, oxaliplatin and fluoropyrimidine
5.2	876	Trifluridine in combination with tipiracil hydrochloride for previously treated metastatic colorectal cancer
5.3	874	AZD9291 for previously treated locally advanced or metastatic, EGFR and T790M mutation positive non-small-cell lung cancer

Provisional Title	Ramucirumab in combination with FOLFIRI for treating metastatic colorectal cancer after progression with bevacizumab, oxaliplatin and fluoropyrimidine		
Topic Selection ID Number	7650	**Wave / Round**	R130
TA ID Number	ID867		
Manufacturer	Eli Lilly		
Anticipated licensing information	***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of ramucirumab in combination with FOLFIRI within its marketing authorisation for treating metastatic colorectal cancer after progression with bevacizumab, oxaliplatin and fluoropyrimidine.		
Main points from consultation	Following the consultation exercise, the Institute is of the opinion that an appraisal of ramucirumab in combination with FOLFIRI for treating metastatic colorectal cancer after progression with bevacizumab, oxaliplatin and fluoropyrimidine is <u>not appropriate</u>. The scoping workshop for this topic was cancelled because of comments received in response to the draft scope. Three consultees responded stating that the topic should not progress and that there would not be any eligible patients. This is due to the technology being proposed to be used after specific drugs, some of which have not been recommended by NICE and have now been taken off the Cancer Drug Fund list therefore this technology does not currently have a place in the pathway for use in the NHS.		
Population size	Approximately 0 people would be eligible for treatment by the NHS with ramucirumab.		
Process (MTA/STA/HST)	Not applicable – referral not sought		
Proposed changes to remit (in bold)	Not applicable – referral not sought		
Costing implications of remit change	No cost impact because 0 people would be eligible for treatment by the NHS with ramucirumab.		
Timeliness statement	Not applicable – referral not sought		

Provisional Title	Trifluridine in combination with tipiracil hydrochloride for previously treated metastatic colorectal cancer		
Topic Selection ID Number	7786	**Wave / Round**	R142
TA ID Number	876		
Manufacturer	Servier		
Anticipated licensing information	***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of trifluridine in combination with tipiracil hydrochloride within its marketing authorisation for treating metastatic colorectal cancer after at least 2 prior chemotherapy regimens.		
Main points from consultation	Following the consultation exercise and a scoping teleconference, the Institute is of the opinion that an appraisal of trifluridine in combination with tipiracil hydrochloride for previously treated metastatic colorectal cancer is appropriate. The proposed remit is not appropriate and should be amended as follows: *To appraise the clinical and cost effectiveness of trifluridine in combination with tipiracil hydrochloride within its marketing authorisation for treating metastatic colorectal cancer after* ***standard therapy*** The wording of the proposed draft remit does not reflect the anticipated indication for trifluridine in combination with tipiracil. In particular the section of the remit which states “after at least 2 prior chemotherapy regimens”. Comments were only received on the draft scope from the company and the Royal College of Radiologists. It was decided not to hold a workshop for this topic. Instead a teleconference was held and two company representatives and a clinician attended. During the teleconference the company explained where their technology was likely to be placed in the treatment pathway and its likely marketing authorisation. Given the anticipated wording this technology would be expected to be used 3rd line or later. In response to this information, it was agreed that the only comparator is best supportive care. The issue of subgroups was also discussed and it was agreed that there were no biologically plausible subgroups that this treatment would have a differential effect on, so no subgroups have been included in the scope.		
Population size	The number of people in England that would be eligible for treatment with this technology is unknown. Approximately 34,322 patients diagnosed with colorectal cancer. 10-25% will have metastatic disease at diagnosis, and approximately 50% will develop metastatic disease. Unsure how many patients will be fit enough for treatment after all standard therapies have been used.		
Process (MTA/STA/HST)	STA		

Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of trifluridine in combination with tipiracil hydrochloride within its marketing authorisation for treating metastatic colorectal cancer after ~~at least 2 prior chemotherapy regimens~~ **standard therapy**
Costing implications of remit change	There are around 35,000 new cases of colorectal cancer registered each year. Around 28,750 of these are metastatic at diagnosis or advance to become metastatic, usually within 2 years of early stage diagnosis. The proportion of people who require second line treatment after standard therapy is not known. The cost of trifluridine in combination with tipiracil hydrochloride is not yet known.
Timeliness statement	Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

Provisional Title	AZD9291 for previously treated locally advanced or metastatic, EGFR and T790M mutation positive non-small-cell lung cancer		
Topic Selection ID Number	7766	**Wave / Round**	R140
TA ID Number	874		
Manufacturer	AstraZeneca		
Anticipated licensing information	***CONFIDENTIAL INFORMATION REMOVED***		
Draft remit	To appraise the clinical and cost effectiveness of AZD9291 within its marketing authorisation for previously treated locally advanced or metastatic, EGFR and T790M mutation positive 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 AZD9291 for treating locally advanced or metastatic EGFR and T790M mutation positive non-small-cell lung cancer is appropriate. The proposed remit is appropriate. No changes are required. There have been no significant changes made to the PICO table, although the comparator treatments have been split to clarify that there are two possible positions for this treatment: after one TKI therapy; and after two prior treatments (a TKI and one other therapy). A brief discussion took place regarding diagnostic testing, however it was clarified that there is no companion diagnostic involved. The T790M mutation usually develops as a result of TKI therapy. Current methods of testing for the EGFR mutation can also be used for testing for T790M mutation, usually at the point of progression.		
Population size	Approximately 215 people in England would be eligible for treatment with AZD9291. Approximately 430 people a year in England are eligible to receive first-line treatment with an EGFR-TKI therapy (taken from costing statement for TA258, 'Erlotinib for the first-line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small-cell lung cancer'). Of these approximately 50% have the T790M mutation. If all of these fail treatment then approximately 215 people would be eligible for AZD9291.		
Process (MTA/STA/HST)	STA		
Proposed changes to remit (in bold)	None		
Costing implications of remit change	The incidence of lung cancer in England was around 35,900 in 2012. Of these people 31,400 have non-small cell lung cancer (85%-90%); around 21,700 (69%) present with locally or regionally advanced or with metastases, of whom 4,990 (23%)		

	receive first line chemotherapy. Around 430 of these people are expected to have a positive EGFR-TK mutation status, and so be eligible for treatment with an EGFR-TKI therapy. Of these approximately 50% have the T790M mutation. If all of these fail treatment then approximately 215 people would be eligible for AZD9291. The cost of AZD9291 is not yet known. It is an additional treatment option for this group so there may be offsetting savings where used in place of alternative options. The comparators, erlotinib, gefitinib and afatinib are available with patient access schemes, which makes them available at a discount to the NHS. Additional costs would be incurred testing eligibility for treatment - people with cancer aren't currently routinely tested for the T790M mutation, and additional biopsies may be required to establish eligibility for treatment with AZD9291.
Timeliness statement	Assuming that the anticipated date of the marketing authorisation is the latest date that we are aware of and the expected referral date of this topic, issuing timely guidance for this technology will be possible