NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 39 draft remits and draft scopes and summary of comments and discussions at scoping workshops

Batch 39
Ruxolitinib for treating polycythaemia vera that is resistant or intolerant to hydroxycarbamide
Bevacizumab for treating relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer

Provisional Title	**Ruxolitinib for treating polycythaemia vera that is resistant or intolerant to hydroxycarbamide**		
Topic Selection ID Number	6480	**Wave / Round**	R52
TA ID Number	734		
Company	Novartis		
Anticipated licensing information	*****CONFIDENTIAL INFORAMTION REMOVED*****		
Draft remit	To appraise the clinical and cost effectiveness of ruxolitinib within its licensed indication for treating polycythaemia vera that is resistant or intolerant to hydroxycarbamide.		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of ruxolitinib for treating polycythaemia vera that is resistant or intolerant to hydroxycarbamide is appropriate The proposed remit is appropriate. No changes are required <u>Intervention and comparators</u> Clinical experts at the scoping workshop explained that everyone with PV would have phlebotomy and aspirin (including those receiving ruxolitinib). The wording of the intervention and comparators has therefore been amended to include 'established clinical practice' throughout. Melphalan has been removed as a comparator as it is not often used in clinical practice <u>Outcomes</u> Complete haematological remission has been added, as this is widely used in clinical practice Thrombosis has been added as an outcome because it is a particular concern for this population.		
Population size	The incidence of PV in England is 2 to 2.8 per 100,000 (which equates to a population of approximately 1000 to 1500 people in England). The expected MA limits this treatment to people who are HC intolerant or resistant. Clinical experts at the scoping workshop indicated this would be approximately 5%-10% of the PV population, which equates to an expected population size between 50 and 150 people in England.		
Process (MTA/STA/HST)	STA		
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of ruxolitinib within its **marketing authorisation** for treating polycythaemia vera that is resistant or intolerant to hydroxycarbamide.		
Costing implications of remit change	Original topic selection costing comments have been updated to include the proportion of people who are HC intolerant or resistant as this information was not available at the time the original comments were completed.		

	The incidence of polycythemia vera (PV) is around 2.4 (range 2.0-2.8) per 100,000 people in the UK, which equates to around 1,250 (range 1000-1500) people in England. Ruxolitinib is only being considered for people with PV who are resistant to, or intolerant of, hydroxyurea. Clinical opinion indicates that this would be approximately 5%-10% of the PV population, equating to between 50 and 150 people in England. The average cost of treatment with ruxolitinib is £3,600 or £5,400 (average £4,500) per 30-day cycle depending on doseage, and because it represents an additional treatment option this cost is expected to be incremental. This would equate to an annual cost of approximately £43,200 - £64,800 per patient. The active treatment period is not known but each 30-day cycle may cost up to around £700,000 if all eligible people received ruxolitinib. However expert opinion suggests there may be savings from a reduction in other treatment costs if ruxolitinib reduces the risk of PV transforming into myelofibrosis or acute myeloid leukaemia or if ruxolitinib replaces the need for phlebotomy.
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	Bevacizumab for treating relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer		
Topic Selection ID Number	6635	**Wave / Round**	R62
TA ID Number	684		
Company	Roche		
Anticipated licensing information	Bevacizumab has a marketing authorisation in the UK (granted August 2014). Bevacizumab in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin is indicated for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents.		
Draft remit	To appraise the clinical and cost effectiveness of bevacizumab within its licensed indication for treating relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer		
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of bevacizumab for relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer is appropriate The proposed remit is appropriate. No changes are required <u>Comparators</u> Updated to include platinum-based chemotherapy • The population states platinum-resistant, which is defined as a relapse within 6 months. However, some people can still have a good response to subsequent platinum-based chemotherapy. And, therefore, it is used in clinical practice. <u>Outcomes</u> • Updated to include symptom control • Bowel perforation specified in adverse effects of treatment <u>Subgroups</u> • To consider subgroups based on the drug with which bevacizumab is combined		
Population size	Approx. 1600–2600 patients per year in England (6500 cases per year, 50–80% relapse rate; attendees at the workshop noted that all relapsed ovarian cancers will become platinum-resistant at some point, but less than 50% will be resistant after 1–2 lines of therapy, as specified in the MA)		
Process (MTA/STA/HST)	STA		

Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of bevacizumab within its **marketing authorisation** for treating relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer
Costing implications of remit change	Original costing comments have been updated to reflect new information regarding patient numbers and treatment regimen. There are around 6000 diagnoses of ovarian cancer in England each year (ONS, 2014). Based on information in the horizon scanning briefing note, it is estimated that 70-80% of women relapse after first line platinum sensitive chemotherapy. Expert opinion suggests that less than 50% will be resistant after 1-2 lines of therapy. Therefore around 2250 women each year are estimated to be platinum-resistant and would be eligible for treatment with bevacizumab. Bevacizumab would be a new treatment option alongside chemotherapy for this indication and therefore would be an additional cost to the NHS. Based on information in the horizon scanning briefing note, it is estimated that an average of 7 cycles of treatment with bevacizumab would be given. The cost of a 3 week cycle with bevacizumab at 15mg/kg is £2,773; the cost for 7 cycles is £19,411. If all eligible women received bevacizumab the annual cost may be around £44 million.
Timeliness statement	Considering that this technology has been granted a marketing authorisation for this indication and the expected referral date of this topic, issuing timely guidance for this technology will not be possible.