NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 15 draft remits and draft scopes

Summary of comments and discussions at scoping workshops

ITEM	Batch 15 topics
5.1	Bevacizumab in combination with paclitaxel and carboplatin for the first-line treatment of advanced and/or metastatic ovarian cancer
5.2	Asenapine for the treatment of moderate to severe manic episodes associated with bipolar I disorder
5.3	Rivaroxaban for the treatment and secondary prevention of venous thromboembolism
5.4	S1 for the treatment of advanced gastric cancer
5.5	Bendamustine in combination with rituximab for the first-line treatment of low-grade non-Hodgkin's lymphoma
5.6	Tapentadol for the treatment of severe chronic pain

Provisional Title	Bevacizumab in combination with paclitaxel and carboplatin for the first-line treatment of advanced and/or metastatic ovarian cancer
Topic Selection ID Number	4534
Wave	25
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of bevacizumab within its licensed indication in combination with paclitaxel and carboplatin for the first-line treatment of advanced and/or metastatic ovarian 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 the first-line treatment of ovarian cancer is appropriate. The proposed remit is not appropriate. It should be amended to reflect that the proposed marketing authorisation for the technology does not specify that ovarian cancer need be advanced or metastatic. In addition, the population in the appraisal may have previously received surgery as a treatment. Therefore the remit should be amended to reflect that the population in the appraisal is people who have not previously had chemotherapy treatment for ovarian cancer.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of bevacizumab within its licensed indication in combination with paclitaxel and carboplatin for the first-line **chemotherapy** treatment of ovarian cancer.
Costing implications of remit change	Clarifying that the scope includes patients with stage I or II ovarian cancer will increase the patient group and increase potential cost.
Timeliness statement	Assuming 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	Asenapine for the treatment of moderate to severe manic episodes associated with bipolar I disorder
Topic Selection ID Number	4604
Wave	25
Anticipated licensing information	Marketing authorisation: granted September 2010 Launch date: Confidential
Draft remit	To appraise the clinical and cost effectiveness of asenapine within its licensed indication for the treatment of moderate to severe manic episodes associated with bipolar I disorder.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of asenapine for the treatment of moderate to severe manic episodes associated with bipolar I disorder is not appropriate. Asenapine is a type of antipsychotic medication. The Institute has provided guidance on the use of antipsychotic medications (olanzapine, quetiapine and risperidone) for the treatment of manic episodes in Clinical Guideline No.36. 'The management of bipolar disorder in adults, children and adolescents, in primary and secondary care'. Consultees considered that a comparison of the kind undertaken in a clinical guideline would be the most useful route for an evaluation of this product.. In light of comments from consultees about the importance of considering asenapine in the context of the treatment pathway, it is not considered that a technology appraisal of asenapine will provide value to the NHS.
Process (MTA/STA)	No referral requested
Proposed changes to remit (in bold)	No referral requested
Costing implications of remit change	N/A
Timeliness statement	No referral requested

Provisional Title	Rivaroxaban for the treatment and secondary prevention of venous thromboembolism
Topic Selection ID Number	4547
Wave	25
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of rivaroxaban within its licensed indication for the treatment and secondary prevention of venous thromboembolism
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of rivaroxaban for the treatment and secondary prevention of venous thromboembolism is appropriate. The manufacturer explained during the scoping workshop that at present there is insufficient data on which to base a submission for marketing approval for rivaroxaban for the treatment of pulmonary embolism. The manufacturer explained that it expected to submit a separate application for marketing approval for rivaroxaban for the treatment of pulmonary embolism. The manufacturer confirmed that there would be two separate licence indications: • the treatment of symptomatic deep vein thrombosis and the prevention of recurrent deep vein thrombosis and pulmonary embolism • the treatment of acute symptomatic pulmonary embolism with or without symptomatic deep vein thrombosis and the prevention of recurrent venous thromboembolic events. The Institute considers that separate appraisals reflecting each of these indications would be appropriate. It is recommended that a single remit is developed, worded to cover both potential indications. If necessary, two separate appraisals can be developed from this remit. The wording of the draft remit is appropriate for this purpose.
Process (MTA/STA)	Two STAs, each reflecting one of the proposed marketing authorisations
Proposed changes to remit (in bold)	No changes requested.
Costing implications of remit change	We have reviewed the original costing comments and feel our initial estimate of cost neutral due to preventing adverse events is optimistic. There is a potential maximum population of around 400,000, which at a cost per patient of £3,300 could lead to

	additional cost, not all of which will be offset by events avoided.
Timeliness statement	Assuming 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	S1 for the treatment of advanced gastric cancer
Topic Selection ID Number	3039
Wave	20
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of S-1 within its licensed indication for the treatment of advanced gastric cancer.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of S1 for the treatment of advanced gastric cancer is not appropriate. S1 is an oral fluoropyrimidine chemotherapy. Capecitabine is also oral fluoropyrimidine and is widely used in the NHS and recommended for such use by NICE. Consultees at the workshop indicated that they considered that the efficacy profiles of the two technologies were comparable, and although S1 may offer some benefits in terms of its side effect profile, clinicians did not consider that this had been robustly shown. Therefore clinicians did not consider that S1 had clearly demonstrated benefits over the use of capecitabine. If S1 were to be used in the NHS, it would be used as an alternative to capecitabine. This would be as part of a triple regimen of a fluoropyrimidine in combination with epirubicin and a platinum compound (cisplatin or oxaliplatin). However, the marketing authorisation for S1 will be for double therapy: S1 plus cisplatin. In accordance with the marketing authorisation NICE would only be able to make recommendations for the use of S1 plus cisplatin and not as part of the triple regimen. Clinicians at the workshop confirmed that double regimens of capecitabine and platinum compounds are used only where there is a specific contraindication to epirubicin. In light of current NHS best practice, it is not considered that there would be additional value to the NHS in appraising S1 within the terms of its marketing authorisation.
Process (MTA/STA)	No referral requested
Proposed changes to remit (in bold)	No referral requested
Costing implications of remit change	N/A
Timeliness statement	No referral requested

Provisional Title	Bendamustine in combination with rituximab for the first-line treatment of low-grade non-Hodgkin's lymphoma
Topic Selection ID Number	4900
Wave	26
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of bendamustine in combination with rituximab within its licensed indication for the first-line treatment of people with advanced low-grade non-hodgkin's lymphoma
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of bendamustine in combination with rituximab for the first-line treatment of low-grade non-Hodgkin's lymphoma is appropriate. The proposed remit is not appropriate. Attendees at the scoping workshop preferred the term 'indolent' to 'low-grade'. The manufacturer stated that the indication is expected to include mantle cell lymphoma in addition to advanced indolent non-Hodgkin's lymphoma. Consultees considered that an appraisals in mantle cell lymphoma should be considered if mantle cell lymphoma is included in the license. Non-Hodgkin's lymphoma and mantle cell lymphoma have different clinical courses and comparators. Therefore it is recommended that these are considered as separate appraisals. The decision to refer an appraisal for mantle cell lymphoma is to be deferred while further clarification on the specific intention of the marketing authorisation is requested from the manufacturer.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of bendamustine in combination with rituximab within its licensed indication for the first-line treatment of advanced **indolent** non-Hodgkin's lymphoma.
Costing implications of remit change	The cost is still unknown, it is anticipated that the change will only add a small number of additional patients affected by guidance to the estimated 9,000 patients. Therefore, we still consider this has the potential to be high cost (> £15 million) but cannot quantify it at this stage.
Timeliness statement	Assuming 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	Tapentadol for the treatment of severe chronic pain
Topic Selection ID Number	4412
Wave	25
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of tapentadol within its licensed indication for the treatment of severe chronic pain.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of tapentadol for the treatment of severe chronic pain in adults is not appropriate. The proposed marketing authorisation for tapendatol includes a range of different types of chronic pain conditions. At the scoping workshop consultees expressed their concern that many opioid analgesics (alone or in combination with other analgesics and non-analgesics) may have to be considered and that an approach that considers pain management holistically would be optimal. Thus there would be benefits to the consideration of this topic as part of a clinical guideline. It is not considered that a technology appraisal of tapendatol considered in isolation from other aspects of the management of chronic pain will provide value to the NHS.
Process (MTA/STA)	No referral requested
Proposed changes to remit (in bold)	No referral requested
Costing implications of remit change	N/A
Timeliness statement	No referral requested