NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 20 draft remits and draft scopes

Summary of comments and discussions at scoping workshops

	Batch 20 topics
5.1	Abiraterone acetate for the treatment of chemotherapy naïve metastatic castrate-resistant prostate cancer
5.2	Apixaban for the prevention of stroke and systemic embolism in people with atrial fibrillation
5.3	Bosutinib for the first-line treatment of Philadelphia chromosome positive chronic myeloid leukaemia in the chronic phase
5.4	Crizotinib for the treatment of non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene
5.5	Denosumab for prolonging bone metastasis-free survival in castrate-resistant prostate cancer
5.6	Lapatinib in combination with paclitaxel for the first-line treatment of HER2 positive metastatic breast cancer
5.7	Rifaximin for the maintenance treatment of hepatic encephalopathy
5.8	Romidepsin for the treatment of relapsed or refractory peripheral T-cell lymphoma
5.9	Vorinostat in combination with bortezomib for the treatment of multiple myeloma in people who have received at least one prior therapy

Provisional Title	Abiraterone acetate for the treatment of chemotherapy naïve metastatic castrate-resistant prostate cancer
Topic Selection ID Number	4935
Wave	27
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of abiraterone in combination with prednisolone within its licensed indication for the treatment of metastatic, castration-resistant prostate cancer in men who have not been previously treated with chemotherapy.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of abiraterone acetate for the treatment of chemotherapy naïve metastatic castrate-resistant prostate cancer is appropriate. The draft remit is not appropriate. Consultees at the scoping workshop indicated that both 'castration-resistant' and 'castrate-resistant' are used in clinical practice. 'Castration-resistant' is considered clinically to be the most accurate term. However, there are sensitivities around the use of the term castration. It was considered that castrate-resistant as is being used in other appraisals would be more appropriate. Consultees further indicated that people who have undergone a male-to-female gender reassignment may be able to develop prostate cancer. This population identifies as female. It was therefore considered appropriate to use the term people in the remit. The technology is called abiraterone acetate. It was recommended to include the full name of the technology in the remit.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of abiraterone **acetate** in combination with prednisolone within its licensed indication for the treatment of metastatic, **castrate-**resistant prostate cancer in **people** who have not been previously treated with chemotherapy
Costing implications of remit change	No change to cost impact
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	Apixaban for the prevention of stroke and systemic embolism in people with atrial fibrillation
Topic Selection ID Number	4943
Wave	27
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of apixaban within its licensed indication for the prevention of stroke and systemic embolism in people with atrial fibrillation.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of apixaban for the prevention of stroke and systemic embolism in people with atrial fibrillation is appropriate. The proposed remit is not appropriate. The remit should be changed to specify people with non-valvular atrial fibrillation with one or more risk factors for stroke to reflect the population included in the clinical trials.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of apixaban within its licensed indication for the prevention of stroke and systemic embolism in people with **non-valvular** atrial fibrillation **with one or more risk factors for stroke or systemic embolism**.
Costing implications of remit change	The proposed change in remit to be those people with non-valvular atrial fibrillation will reduce the eligible population and also the cost impact. The original cost impact comments identified a population of around 700,000; this was people with atrial fibrillation. This will be reduced. It is not known how significant this reduction will be at this point. The cost of the technology is not yet known. This topic is still considered to be a low cost topic.
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	Bosutinib for the first-line treatment of Philadelphia chromosome positive chronic myeloid leukaemia in the chronic phase
Topic Selection ID Number	4725
Wave	26
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of bosutinib within its licensed indication for the first-line treatment of chronic myeloid leukaemia.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of bosutinib for the first-line treatment of chronic myeloid leukaemia is appropriate. The proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes proposed
Costing implications of remit change	No change to cost impact
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	Crizotinib for the treatment of non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene
Topic Selection ID Number	5116
Wave	28
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of crizotinib within its licensed indication for the treatment of non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene, after previous 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 crizotinib for the treatment of non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene is appropriate. The draft remit is not appropriate. Consultees stated that some people may not receive first-line treatment with platinum-based chemotherapy, but these people may still be appropriate for treatment with crizotinib. The manufacturer stated that there was some uncertainty around the wording of the marketing authorisation. However, it may state previously treated or it may state more specifically after previous platinum therapy.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of crizotinib within its licensed indication for the treatment of **previously treated** non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene.
Costing implications of remit change	No change to cost impact
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	Denosumab for prolonging bone metastasis-free survival in castrate resistant prostate cancer
Topic Selection ID Number	3761
Wave	22
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost-effectiveness of denosumab within its licensed indication for prolonging bone metastasis-free survival in hormone-refractory prostate cancer.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of denosumab for prolonging bone metastasis free survival in hormone-refractory prostate cancer is appropriate. The draft remit is not appropriate. Consultees stated that the term 'hormone refractory prostate cancer' is technically incorrect because although people may achieve an inadequate response to 1st line hormone therapy, this does not mean that they will not respond to 2nd or subsequent lines of hormone therapy and therefore few people with prostate cancer have truly hormone-refractory disease. Consultees explained that the remit should refer to 'castrate-resistant prostate cancer' which is the medical term currently preferred in clinical practice.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost-effectiveness of denosumab within its licensed indication for prolonging bone metastasis-free survival in **castrate-resistant** prostate cancer
Costing implications of remit change	The original cost impact comments identified a population of around 14,000; this is the population who are non metastatic. When the proportion who is castrate-resistant is considered, the eligible population for this technology will be lower. The cost of the technology is now known. It is estimated that the cost impact if treatment of all the non-metastatic population was assumed could be around £66 million. The cost impact will be less taking into account the restriction to those that are castrate-resistant. Limited trial data currently exists and the cost estimate assumes a full twelve months usage. The cost impact would be reduced if patients use the technology for less time. Even if both these factors that may reduce the cost impact are considered, the topic is still estimated to be high cost.
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	Lapatinib in combination with paclitaxel for the first-line treatment of HER2 positive metastatic breast cancer.
Topic Selection ID Number	4587
Wave	25
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of lapatinib in combination with paclitaxel within its licensed indication for the first-line treatment of metastatic breast cancer which over-expresses ErbB2 (HER2) receptor.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of lapatinib in combination with paclitaxel for the first-line treatment of HER2 positive metastatic breast cancer is appropriate. The proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes proposed.
Costing implications of remit change	No change to cost impact
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	Rifaximin for the maintenance treatment of hepatic encephalopathy
Topic Selection ID Number	5017
Wave	27
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of rifaximin within its licensed indication for the maintenance treatment of hepatic encephalopathy.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of rifaximin for the maintenance treatment of hepatic encephalopathy is appropriate. The proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes proposed
Costing implications of remit change	No change to cost impact
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	Romidepsin for the treatment of relapsed or refractory peripheral T-cell lymphoma
Topic Selection ID Number	5204
Wave	28
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of romidepsin within its licensed indication for the treatment of relapsed or refractory peripheral T-cell lymphoma.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of romidepsin for the treatment of relapsed or refractory peripheral T-cell lymphoma is appropriate. The proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes proposed
Costing implications of remit change	No change to cost impact
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	Vorinostat in combination with bortezomib for the treatment of multiple myeloma in people who have received at least one prior therapy
Topic Selection ID Number	4247
Wave	28
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of vorinostat in combination with bortezomib within its licensed indication for the treatment of multiple myeloma in people who have received at least one prior therapy.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of vorinostat in combination with bortezomib for the treatment of multiple myeloma in people who have received at least one prior therapy is appropriate. The proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes proposed
Costing implications of remit change	No change to cost impact
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.