NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION

Technology Appraisals

Consultation on Batch 14 draft remits and draft scopes

Summary of comments and discussions at scoping workshops

Batch 14 topics
Diabetic macular oedema - flucinolone acetonide intravitreal insert
Lymphoma (relapsed or refractory follicular non-Hodgkin's) – bortezomib
Non Hodgkin's lymphoma (relapsed refractory, 3rd/4th line) - pixantrone dimaleate
Osteoarthritis (2nd line) - naproxcinod
Stroke prevention in atrial fibrillation - rivaroxaban
Systemic lupus erythematosus (active seropositive) - belimumab

Provisional Title	Fluocinolone acetonide intravitreal insert for the treatment of diabetic macular oedema
Topic Selection ID Number	4384
Wave	25
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of fluocinolone acetonide intravitreal insert within its licensed indication for the treatment of diabetic macular oedema.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of flucinolone acetonide intravitreal insert for the treatment of diabetic macular oedema is appropriate. The proposed remit is not appropriate. It was recommended at the scoping workshop that the name of the technology should be amended in line with the anticipated marketing authorisation (that is, the word 'insert' should be changed to 'implant').
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of fluocinolone acetonide intravitreal **implant** within its licensed indication for the treatment of diabetic macular oedema.
Costing implications of remit change	No impact on original cost impact assessment.
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	Bortezomib for the treatment of relapsed or refractory follicular non-Hodgkin's lymphoma
Topic Selection ID Number	3381
Wave	22
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of bortezomib within its licensed indication for the treatment of relapsed or refractory follicular 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 bortezomib for the treatment of relapsed or refractory follicular non-Hodgkin's lymphoma is appropriate. The proposed remit is considered appropriate and no changes have been requested during consultation. It is possible that the population and comparators in the scope may need to be amended once more information on the marketing authorisation and trial populations are known (trial data expected in December 2010). The remit may also need to be amended to specify the line of relapse where this technology is to be used (e.g. adults with relapsed or refractory follicular non-Hodgkin's lymphoma for whom single-agent chemotherapy is being considered). If the marketing authorisation and trial population is broad (that is, all patients with relapsed or refractory follicular NHL), then no changes to the remit will be required.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes currently proposed. At the DP4 meeting it was agreed that the remit should remain broad at present in order for this appraisal to remain timely, however it was acknowledged that a further update to the remit may be required once more information on the marketing authorisation is available form the manufacturer.
Costing implications of remit change	No impact on original cost impact assessment.
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	Pixantrone dimaleate monotherapy for the treatment of relapsed or refractory aggressive non-Hodgkin's lymphoma
Topic Selection ID Number	4541
Wave	25
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of pixantrone dimaleate monotherapy within its licensed indication for the treatment of relapsed or refractory aggressive non-Hodgkin's lymphoma in people who have had at least two prior therapies.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of pixantrone dimaleate monotherapy for the treatment of relapsed or refractory aggressive non-Hodgkin's lymphoma is appropriate. The proposed remit is not appropriate. It should be amended to reflect the position in the care pathway where pixantrone dimaleate will be licensed and where it is expected to be used in the NHS, that is, as a second or subsequent line of treatment when single-agent chemotherapy is being considered. During the scoping workshop, consultees indicated that while most patients receive single-agent chemotherapy as a 3rd-line treatment, some patients with low performance status or who are unable to be treated with combination chemotherapy currently receive single-agent chemotherapy as a 2nd-line treatment. Consultees were concerned that the draft remit restricts use to 3rd or subsequent line use and may deny some patients access to the technology. They proposed that the remit should be changed to: "To appraise the clinical and cost effectiveness of pixantrone dimaleate monotherapy within its licensed indication for the treatment of relapsed or refractory aggressive non-Hodgkin's lymphoma in people **for whom treatment with single agent chemotherapy is being considered".**
Process (MTA/STA)	STA Consultees expressed concern that up to 6 comparators may have to be considered which would increase the complexity of the STA.
Proposed changes to remit (in bold)	The remit should be updated in line with comments from consultees to: To appraise the clinical and cost effectiveness of pixantrone dimaleate monotherapy within its licensed indication for the treatment of relapsed or refractory aggressive non-Hodgkin's lymphoma **in people for whom treatment with single agent chemotherapy is being considered**.
Costing implications of remit change	The original costing work indicated that the number of patients is in the region of 1,300 – 2,800. If the treatment is considered as 2nd as well as 3rd line then the number of patients will be more towards the top end of this estimate.
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	Naproxcinod for the treatment of osteoarthritis
Topic Selection ID Number	4271
Wave	25
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of naproxcinod within its licensed indication for the treatment of primary osteoarthritis.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of naproxcinod for the treatment of osteoarthritis is appropriate. The proposed remit is considered appropriate. No changes are required.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes proposed.
Costing implications of remit change	No impact on original cost impact assessment.
Timeliness statement	Assuming the anticipated launch date for naproxcinod 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	Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation
Topic Selection ID Number	4485
Wave	24
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of rivaroxaban 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 rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation is appropriate. The proposed remit is not appropriate. It was recommended at the scoping workshop that it should be amended to reflect the patient population in the pivotal trials and in the anticipated marketing authorisation.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of rivaroxaban within its licensed indication for the prevention of stroke and **non-central nervous system (CNS)** systemic embolism in people with **non-valvular** atrial fibrillation.
Costing implications of remit change	No impact on original cost impact assessment.
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	Belimumab for the treatment of active seropositive systemic lupus erythematosus
Topic Selection ID Number	4560
Wave	25
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of belimumab within its licensed indication for the treatment of active seropositive systemic lupus erythematosus.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of belimumab for the treatment of active seropositive systemic lupus erythematosus is appropriate. The proposed remit is not appropriate. It was recommended at the scoping workshop that it should be amended to reflect the patient population in the pivotal trials and in the anticipated marketing authorisation.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of belimumab within its licensed indication for the treatment of active **autoantibody-positive** systemic lupus erythematosus.
Costing implications of remit change	No impact on original cost impact assessment.
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.