ITEM 4

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION

Consultation on Batch 11 draft remits and draft scopes

Summary of comments and discussions at scoping workshops

Batch 11 topics	
Acute hypertension - clevidipine	
Bipolar 1 disorder - risperidone	
Chronic Iron overload - defasirox and deferiprone	
COPD - Roflumilast	
Cystic fibrosis - colistimethate sodium powder	
Depression - agomelatine	Originally batch 10
Depression - quetiapine	Originally batch 10
Generalised anxiety disorder – quetiapine	Originally batch 10
Idiopathic pulmonary fibrosis - pirfenidone	Originally batch 10
Macular oedema (retinal vein occlusion) - dexamethasone	
Macular oedema with central retinal vein occulsion - ranibizumab	
Myocardial Infarction - bivalirudin	
Obesity - lorcaserin	
Venom anaphylaxis - immunotherapy pharmalgen	

Provisional Title	Clevidipine butyrate for the control of blood pressure in the peri-operative setting
Topic Selection ID Number	4231
Wave	24
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of clevidipine butyrate within its licensed indication for the treatment of acute hypertension.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of clevidipine butyrate for the treatment of acute hypertension is not appropriate at this time. During consultation the manufacturer explained that the licensed indication will specify that clevidipine butyrate will only be used for the reduction of blood pressure in the peri-operative setting, and therefore the current draft remit is too broad. The Institute recommends that the topic should not be referred to the appraisals programme pending further investigation of the clinical area.
Process (MTA/STA)	Referral is not sought at this time. Results of further investigation will be presented and discussed at the Decision Point 4 meeting on 16 June 2010.
Proposed changes to remit (in bold)	There are no changes to the proposed remit – referral is not sought at this time.
Costing implications of remit change	Given that a referral is not sought at this time the cost impact is considered to be neutral.
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	Risperidone long-acting injection for the maintenance treatment of bipolar I disorder
Topic Selection ID Number	4487
Wave	24
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of risperidone long-acting injection within its licensed indication for the maintenance treatment of 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 risperidone long-acting injection for the maintenance treatment of bipolar I disorder is not appropriate. Consultees commented that long acting injections are usually only considered for people who have poor adherence, or have risk of poor adherence to oral antipsychotics. However, there is a lack of consensus regarding the place of long-acting injections of anti-psychotics in the treatment of bipolar disorder. Consultees agreed that a technology appraisal would not answer this clinical question and that it would be better suited to a clinical guideline. They discussed the NICE Clinical Guideline No. 38 'The management of bipolar disorder in adults, children and adolescents, in primary and secondary care', which was published in July 2006 and is expected to be considered for review in July 2011. The guideline states that "long-acting intramuscular injections of antipsychotics ('depots') are not recommended for routine use in bipolar disorder. They may be considered for people who were treated successfully for mania with oral antipsychotics, but have had a relapse because of poor adherence". The consultees thought that because more anti-psychotic long-acting injections have become available since the publication of this guideline (and more are becoming available), it would be logical to update the guideline to include recommendations relating to specific long-acting injections.
Process (MTA/STA)	Not applicable – referral is not sought.
Proposed changes to remit (in bold)	There are no changes to the proposed remit – referral is not sought.
Costing implications of remit change	Not appraising this is considered to be cost neutral.
Timeliness statement	Given that marketing authorisation is expected in March 2010, issuing timely guidance for this technology will **not** be possible.

Provisional Title	Roflumilast for the management of chronic obstructive pulmonary disease.
Topic Selection ID Number	4489
Wave	24
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of roflumilast for the management of chronic obstructive pulmonary disorder (COPD).
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of roflumilast for the management of chronic obstructive pulmonary disease is appropriate. The Institute recommends that the proposed remit is changed to more specifically reflect the licensed indication for roflumilast in terms of maintenance treatment and severity of disease.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of roflumilast **within its licensed indication** for the **maintenance** treatment of **severe** chronic obstructive pulmonary disease (COPD).
Costing implications of remit change	No impact on original cost estimate.
Timeliness statement	Given the anticipated date of the marketing authorisation and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

Provisional Title	Deferasirox and deferiprone for the treatment of chronic iron overload
Topic Selection ID Number	3110
Wave	22
Anticipated licensing information	Deferasirox and deferiprone are already licensed for the treatment of chronic iron overload. Deferasirox was licensed for this indication on 28 August 2006. Deferiprone was licensed for this indication on 25 August 1999.
Draft remit	To appraise the clinical and cost effectiveness of deferasirox and deferiprone, within their licensed indications, for the treatment of chronic iron overload.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that receipt of a formal referral for an appraisal of deferasirox and deferiprone for the treatment of chronic iron overload is not appropriate at this time. However it is expected that this topic may be referred to the appraisals programme at a future date once consideration has been given to re-developing the draft scope focussing on chronic iron overload in people with thalassaemia. It is proposed that an additional draft scope consultation will be completed to inform a final remit and possible formal referral. The key points arising from consultation were as follows: 1. Chronic iron overload is caused by a number of diverse anaemias. These affect different age groups, have differential iron loading effects with different natural histories. In addition, there is no data available on the treatment of chronic iron overload caused by rarer anaemias. It was considered that these issues would make an MTA too complicated and large. Some consultees considered that a clinical guideline on the treatment of chronic iron overload would be more appropriate than an appraisal. 2. The available data is limited; there is a paucity of quality of life and mortality data. In addition, the outcomes measured vary internationally and it may be difficult to use trial data in an economic model. Also there is no long-term data available, making extrapolation to an appropriate time horizon difficult. 3. The drugs are being used off-license as part of combination therapy; there are ongoing trials of combination therapy, but it is unclear if the marketing authorisations will be changed and the earliest expected reporting from relevant trials is late 2011.

	4. An STA of deferasirox for treating chronic iron overload in people with thalassaemia was considered possible, but it was noted that there is a published HTA monograph (deferasirox for the treatment of iron overload associated with regular blood transfusions (transfusional haemosiderosis) in patients suffering with chronic anaemia: a systematic review and economic evaluation) and Cochrane reviews for this expected soon.
Process (MTA/STA)	MTA
Proposed changes to remit (in bold)	Referral is not sought at this time. An additional draft scope consultation will be held to determine a proposed final remit and formal referral.
Costing implications of remit change	Given that a referral is not sought the cost impact is considered to be neutral.
Timeliness statement	Given that marketing authorisations have already been received, issuing timely guidance for these technologies will not be possible.

Provisional Title	Colistimethate sodium powder for inhaler device for the treatment of pseudomonas aeruginosa lung infection in cystic fibrosis.
Topic Selection ID Number	4249
Wave	24
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of colistimethate sodium powder for inhaler device within its licensed indication for the treatment of pseudomonas aeroginosa lung infection in cystic fibrosis.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of colistimethate sodium powder for inhalation for the treatment of pseudomonas aeruginosa lung infection in cystic fibrosis is appropriate. The Institute recommends that tobramycin powder for inhalation is appraised alongside colistimethate sodium powder for inhalation. During the consultation exercise and the scoping workshop, consultees highlighted that other pseudomonal antibiotics are in development for use in cystic fibrosis. Consultees considered that the MTA process would be more appropriate if the timings of the marketing authorisations for dry powder tobramycin and colistimethate sodium allowed.
Process (MTA/STA)	MTA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of colistimethate sodium powder **and tobramycin powder for inhalation** within their licensed indications for the treatment of pseudomonas lung infection in cystic fibrosis.
Costing implications of remit change	The original cost estimate was uncertain due to the price of the drug being unknown, but estimated to be in the region of £7 million. The addition of a second therapy may not affect costs if it is for use in the same patient population and at a similar cost. However, the cost of both products are still unknown.
Timeliness statement	As this has been requested to be an MTA, producing timely guidance will **not** be possible.

Provisional Title	Agomelatine for the treatment of major depressive episodes.
Topic Selection ID Number	4243
Wave	23
Anticipated licensing information	Agomelatine is licensed for the treatment of major depressive episodes in adults.
	Agomelatine gained a marketing authorisation in February 2009.
	This was a new licence.
Draft remit	To appraise the clinical and cost effectiveness of agomelatine within its licensed indication for the treatment of major depressive episodes (MDE) in adults.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of agomelatine for the treatment of major depressive episodes is appropriate. The Institute recommends that the proposed remit is appropriate. In their response to the consultation and confirmed at the scoping workshop, the manufacturer of agomelatine (Servier) did not consider it appropriate for NICE to appraise agomelatine. Agomelatine gained a marketing authorisation in February 2009 and was previously not considered a priority by NICE at topic selection stage, a decision that was later reversed. Servier consider that an appraisal at this stage means that guidance would be issued after the product has already been licensed for a time, and after local bodies have already put in place decision making tools. Other consultees generally considered an appraisal to be appropriate as it was not included in the update of the NICE clinical guideline (CG90) and is now licensed for depression.
Process (MTA/STA)	STA.
Proposed changes to remit (in bold)	No changes are proposed.
Costing implications of remit change	No impact on cost estimate.
Timeliness statement	Given that marketing authorisation has already been received, issuing timely guidance for this technology will not be possible.

Provisional Title	Quetiapine for the treatment of major depressive disorder.
Topic Selection ID Number	4325
Wave	23
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of quetiapine within its licensed indication for the treatment of major depressive disorder (MDD).
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of quetiapine for the treatment of major depressive disorder is not appropriate. The recently updated NICE clinical guideline for depression (CG90) includes a recommendation for the use of atypical antipsychotics including quetiapine (off label) as an add-on therapy in this population. In light of the clinical guideline recommendations, it is not considered that there would be additional value to the NHS in appraising quetiapine as add-on therapy.
Process (MTA/STA)	Not applicable – referral is not sought
Proposed changes to remit (in bold)	There are no changes to the proposed remit – referral is not sought.
Costing implications of remit change	Given that a referral is not sought the cost impact is considered to be neutral.
Timeliness statement	If marketing authorisation is received by the date indicated, issuing timely guidance for this technology will not be possible.

Provisional Title	Quetiapine for the treatment of generalised anxiety disorder.
Topic Selection ID Number	4333
Wave	23
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of quetiapine within its licensed indication for the treatment of generalised anxiety disorder.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of quetiapine for the treatment of generalised anxiety disorder is appropriate. The Institute recommends that the proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes are proposed.
Costing implications of remit change	The original cost estimate of a maximum of £6 million remains appropriate.
Timeliness statement	If marketing authorisation is received by the date indicated, issuing timely guidance for this technology will not be possible.

Provisional Title	Pirfenidone for the treatment of idiopathic pulmonary fibrosis.
Topic Selection ID Number	4219
Wave	23
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of pirfenidone within its licensed indication for the treatment of idiopathic pulmonary fibrosis.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of pirfenidone for the treatment of idiopathic pulmonary fibrosis is appropriate. The Institute recommends that the proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes are proposed.
Costing implications of remit change	No impact on original cost estimate.
Timeliness statement	Given the anticipated date of the marketing authorisation and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

Provisional Title	Dexamethasone intravitreal implant for the treatment of macular oedema caused by retinal vein occlusion (RVO)
Topic Selection ID Number	4272
Wave	24
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of dexamethasone intravitreal implant within its licensed indication for the treatment of macular oedema caused by retinal vein occlusion (RVO).
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of dexamethasone intravitreal implant for macular oedema caused by retinal vein occlusion is appropriate. The Institute recommends that the proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes are proposed.
Costing implications of remit change	No impact on original cost estimate
Timeliness statement	Given the anticipated date of the marketing authorisation and the expected referral date of this topic, issuing timely guidance for this technology will **not** be possible.

Provisional Title	Ranibizumab for the treatment of macular oedema caused by central retinal vein occlusion (CRVO).
Topic Selection ID Number	4326
Wave	23
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of ranibizumab within its licensed indication for the treatment of macular oedema caused by central retinal vein occlusion (CRVO).
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of ranibizumab for macular oedema caused by central retinal vein occlusion is appropriate. The Institute recommends that the proposed remit is not appropriate and that the cause of macular oedema should be broadened from CRVO to RVO. The manufacturer informed attendees at the scoping workshop that it would be appropriate to appraise both central and branch retinal vein occlusion in the same appraisal, because the likely licence for both indications is expected at the same time.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of ranibizumab within its licensed indication for the treatment of macular oedema caused by **retinal vein occlusion (RVO)**.
Costing implications of remit change	Any widening of the patient group (from CRVO to RVO) could potentially increase the eligible population and affect the cost impact, however, it is unclear whether the patient population was specific to CRVO. If not then the original cost estimate of 38,700 patients and £227 million will stand.
Timeliness statement	Given the anticipated date of the marketing authorisation and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

Provisional Title	Bivalirudin for the treatment of ST-segment elevation myocardial infarction (STEMI)
Topic Selection ID Number	4230
Wave	23
Anticipated licensing information	Bivalirudin is licensed as an anticoagulant for adult patients undergoing PCI including patients with STEMI undergoing primary PCI.
	Bivalirudin was licensed for this indication on 20/09/2009.
	This was an extension to the licence.
Draft remit	To appraise the clinical and cost effectiveness of bivalirudin within its licensed indication for the treatment of ST-segment elevation myocardial infarction (STEMI).
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of bivalirudin for the treatment of STEMI is appropriate. The Institute recommends that the proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes are proposed.
Costing implications of remit change	No impact on original cost estimate.
Timeliness statement	Given that marketing authorisation has already been received, issuing timely guidance for this technology will not be possible.

Provisional Title	Lorcaserin hydrochloride for the treatment of obesity and overweight
Topic Selection ID Number	3420
Wave	21
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of lorcaserin hydrochloride within its licensed indication for the treatment of adults who are obese and the treatment of adults who are overweight who have at least one obesity related co-morbidity.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of lorcaserin hydrochloride for the treatment of obesity and overweight is appropriate. The Institute recommends that the proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes are proposed.
Costing implications of remit change	No impact on original cost estimate.
Timeliness statement	Given the anticipated date of the marketing authorisation and the expected referral date of this topic, issuing timely guidance for this technology will be possible.

Provisional Title	Pharmalgen for the treatment of venom allergy
Topic Selection ID Number	3317
Wave	23
Anticipated licensing information	Pharmalgen Bee Venom is licensed in the UK for the diagnosis and treatment of IgE-mediated allergy to bee venom. Pharmalgen Wasp Venom is licensed in the UK for the diagnosis and treatment of IgE-mediated allergy to wasp venom.
	Marketing authorisation was granted in 1982.
Draft remit	To appraise the clinical and cost effectiveness of pharmalgen for the treatment of bee and wasp venom allergy within its licensed indication.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of pharmalgen for the treatment of venom allergy is appropriate. The Institute recommends that the draft remit is appropriate.
Process (MTA/STA)	MTA.
Proposed changes to remit (in bold)	No changes are proposed.
Costing implications of remit change	No impact on original cost estimates
Timeliness statement	Given that marketing authorisations have already been received, issuing timely guidance for these technologies will **not** be possible.