ITEM 4

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION

Consultation on Batch 12 draft remits and draft scopes

Summary of comments and discussions at scoping workshops

Batch 12 topics
Diabetic macular oedema - ranibizumab
Leukaemia (acute myeloid) – decitabine (1st line)
Leukaemia (chronic myeloid) - dasatinib (1st line)
Lung cancer (non-small cell) – BIBW 2992
Rheumatoid Arthritis - abatacept (2nd line)
Chronic iron overload - deferasirox and deferiprone

Provisional Title	Ranibizumab for the treatment of diabetic macular oedema
Topic Selection ID Number	4327
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 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 ranibizumab for the treatment of diabetic macular oedema is appropriate. The Institute is of the opinion that the proposed remit is not appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	The Institute proposes that the remit should be made more specific and changed to: "To appraise the clinical and cost effectiveness of ranibizumab within its licensed indication for the treatment of **visual impairment secondary to** diabetic macular oedema".
Costing implications of remit change	No change to original cost 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. In order to achieve this, we request that a formal referral is received quickly to allow an appraisal to begin as soon as possible.

Provisional Title	Decitabine for the treatment of acute myeloid leukaemia
Topic Selection ID Number	3382
Wave	22
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of decitabine within its licensed indication for the treatment of acute myeloid leukaemia
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of decitabine for the treatment of acute myeloid leukaemia is appropriate. The Institute is of the opinion that the proposed remit is not appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	The Institute proposes that the remit should be made more specific and changed to: "To appraise the clinical and cost effectiveness of decitabine within its licensed indication for the treatment of **newly diagnosed** acute myeloid leukaemia **for whom intensive chemotherapy is considered inappropriate**"
Costing implications of remit change	No change to original cost 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	Dasatinib for the first line treatment of chronic myeloid leukaemia
Topic Selection ID Number	3014
Wave	24
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of dasatinib 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 dasatinib for the treatment of chronic myeloid leukaemia is appropriate. However, consultees felt that dasatinib should be referred as an MTA and combined with a new appraisal of nilotinib and a review of TA70 (imatinib for first-line treatment of CML). Consultees noted the similarity of the patient populations for all of these interventions and the fact that there will be a need for clinicians to decide between which of the 3 technologies should be used in practice. The Institute is of the opinion that the proposed remit is not appropriate
Process (MTA/STA)	Scoped as an STA. MTA with nilotinib and imatinib preferred option for consultees.
Proposed changes to remit (in bold)	The Institute proposes that the remit should be changed to: 'To appraise the clinical and cost effectiveness of dasatinib, **nilotinib and standard-dose imatinib** within **their** licensed indication**s** for the first-line treatment of chronic myeloid leukaemia (**including part-review of TA70).** Note niltonib and standard-dose imatinib as first-line treatments for chronic myeloid leukaemia have already been referred to the Institute (niltonib has been referred as an STA and imatinib was appraised in TA 70 and a review of this guidance was proposed)
Costing implications of remit change	No change to original cost estimate, if referred as an STA. If this becomes an MTA then costs could depend on relative costs of dasatinib compared with nilotinib and imatinib.
Timeliness statement	If referred as an STA: 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 not be possible. If referred as an MTA: As this is recommended to be an MTA, issuing timely guidance for this technology will not be possible.

Provisional Title	BIBW 2992 for the treatment of non-small cell lung cancer
Topic Selection ID Number	3380
Wave	22
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of BIBW 2992 within its licensed indication for the treatment of non-small cell lung cancer after previous platinum containing chemotherapy and gefitinib or erlotinib.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of BIBW 2992 for the treatment of non-small cell lung cancer is appropriate. The Institute is of the opinion that the proposed remit is not appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	The Institute proposes that the remit should be made more specific and changed to: "To appraise the clinical and cost effectiveness of BIBW 2992 within its licensed indication for the treatment of **locally advanced or metastatic** non-small cell lung cancer after previous platinum containing chemotherapy and gefitinib or erlotinib."
Costing implications of remit change	No change to original cost 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	Abatacept for the treatment of rheumatoid arthritis after the failure of disease-modifying anti-rheumatic drugs
Topic Selection ID Number	4488
Wave	24
Anticipated licensing information	Confidential
Draft remit	To appraise the clinical and cost effectiveness of abatacept within its licensed indication for the treatment of rheumatoid arthritis after the failure of disease-modifying anti-rheumatic drugs
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of abatacept for the treatment of rheumatoid arthritis after the failure of disease modifying anti-rheumatic drugs is appropriate. However, the Institute is of the opinion that the proposed remit is not appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	The institute suggests that the remit should be changed to: 'To appraise the clinical and cost effectiveness of abatacept within its licensed indication for the treatment of rheumatoid arthritis **only** after the failure of **conventional** disease-modifying anti-rheumatic drugs'. This is to reflect the fact that biological treatments are also disease modifying anti-rheumatic drugs (DMARDs) but this appraisal will specifically consider the use of abatacept after the failure of conventional but not biological DMARDs. Consideration of the use of abatacept after the failure of biological DMARDs has been addressed in existing NICE guidance. In addition, this will be clearly stated within the appraisal scope.
Costing implications of remit change	No change to original cost estimate of maximum £5 million additional cost for first use. We noted that sequential use may increase costs, and this would remain the same, however, the imminent publication of guidance on treatment after a failure of a TNF inhibitor may result in the costs being additional to those already estimated, rather than new costs.
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 **not** be possible.

Provisional Title	Deferasirox and deferiprone for the treatment of chronic iron overload in people with thalassaemia
Notes	This proposed topic was originally scoped within in Batch 11 in early 2010 and was intended to appraise deferasirox and deferiprone for the treatment of chronic iron overload. After the consultation and workshop, a report on the findings and conclusions were submitted to the DP4 attendees on the 15 April 2010. At the DP4 meeting it was agreed that a revised scope focussing on chronic iron overload in people with thalassaemia should be consulted upon.
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 in people with thalassaemia.
Main points from consultation	There were a number of conflicting views received in response to the second consultation of this revised draft scope. Notably, there is a published HTA monograph addressing the question and these technologies have been licensed and in use for many years. However, it was noted that guidance on the use of these technologies would be useful as there is some inequality in access. Following the second consultation exercise, the Institute is of the opinion that an appraisal of deferasirox and deferiprone for the treatment of chronic iron overload in people with thalassaemia is appropriate. However, the Institute is of the opinion that the proposed remit is not appropriate.
Process (MTA/STA)	MTA
Proposed changes to remit (in bold)	The Institute recommends that the proposed remit is changed to: 'To assess the clinical effectiveness and cost effectiveness of **desferrioxamine,** deferiprone and deferasirox for the treatment of chronic iron overload in people with thalassaemia.' Consultees advised that desferrioxamine should also be included in the remit for completeness as this is also used to treat chronic iron overload. In addition, all 3 drugs are routinely being used as combination therapy with each other; there are a number of ongoing trials assessing this. One manufacturer considered combination therapy within the marketing authorisation, but one did not. Therefore, the Institute requests that the term 'within their

	licensed indications' is not included within the remit to allow for the possibility of appraising combinations of the technologies.
Costing implications of remit change	The change does not affect the maximum cost impact estimate of £8.4 million, that this was based on the additional cost of deferasirox above the cost of desferrioxamine. However, this is a maximum cost impact should final recommendations favour desferasirox to the other drugs.
Timeliness statement	Given that marketing authorisations have already been received, issuing timely guidance for these technologies will not be possible.