NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Consultation on Batch 10 draft remits and draft scopes

Summary of comments and discussions at scoping workshops

Batch 10 Topics
Diabetes (type 2) - exenatide (long acting 2nd line in combination)
Metastatic breast cancer - fulvestrant
Non-hodgkin's lymphoma - bendamustine
Multiple myeloma - bendamustine
Osteoarthritis - diacerein
Rheumatoid Arthritis - rituximab
Chronic lymphocytic leukaemia - bendamustine
Urothelial tract carcinoma – vinflunine
Batch 10 topics deferred to Batch 11
Depression – quetiapine
Depression – agomelatine
Idiopathic pulmonary fibrosis - pirfenidone
Generalised anxiety disorder – Quetiapine
21st wave minded referral – 'pre' scoping topic
Renal failure - On-line haemodiafiltration

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Provisional Title	Long-acting exenatide for the second-line (dual therapy) or third-line (triple therapy) treatment of type 2 diabetes.
Topic Selection ID Number	3406
Wave	22
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of long-acting exenatide, within its licensed indication, for the second- or third-line treatment of type 2 diabetes
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of long-acting exenatide for the second-line (dual therapy) or third-line (triple therapy) treatment of type 2 diabetes is appropriate. The Institute is of the opinion that the proposed remit is not appropriate. Consultees felt that specifying only a line of treatment was not accurate as people may receive a number of different monotherapies and dual therapies, and referring to dual/triple therapy more accurately reflects that it is the increase in the number of agents used that is important. The Institute recommends that the remit should be amended to describe line treat more accurately.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	The proposed remit is not appropriate. The remit should be changed to: To appraise the clinical and cost effectiveness of long-acting exenatide, within its licensed indication, for the second-line **(dual therapy)** or third-line **(triple therapy)** treatment of type 2 diabetes.
Costing implications of remit change	In view of the clarification of the place as second-line (dual therapy) or third-line (triple therapy) the original estimated population will be reduced. However, as the cost of the long acting version of the drug compared with current exanatide preparations is not yet known it is still not possible to assess the cost impact.
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.

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Provisional Title	Fulvestrant for the treatment of locally advanced or metastatic breast cancer
Topic Selection ID Number	4182
Wave	23
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost-effectiveness of high dose fulvestrant within its licensed indication for the treatment of locally advanced or metastatic breast cancer
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of high dose fulvestrant for the treatment of locally advanced or metastatic breast cancer is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes 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.

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Provisional Title	Bendamustine for the treatment of non-Hodgkin's lymphoma
Topic Selection ID Number	4343
Wave	23
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of bendamustine within its licensed indication for the treatment of people with indolent (low grade) non-Hodgkin's lymphoma (NHL) who are refractory to rituximab or a rituximab-containing regimen
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of bendamustine for the treatment of non-Hodgkin's lymphoma is appropriate. The Institute is of the opinion that the proposed remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes proposed remit
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.

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Summary of comments and discussions at scoping workshops

Provisional Title	Bendamustine for the treatment of advanced multiple myeloma
Topic Selection ID Number	4344
Wave	23
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of bendamustine in combination with prednisolone within its licensed indication for the treatment of advanced multiple myeloma
Main points from consultation	The anticipated marketing authorisation restricts the population to approximately 20-40 patients or less per year. In addition, workshop attendees indicated that there is no clinician demand for this drug as a first-line treatment. Therefore following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of bendamustine for the treatment of advanced multiple myeloma is not appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes to proposed remit – referral not sought
Costing implications of remit change	No impact on original cost estimate; however, if there is no clinician demand then cost impact is likely to be nil.
Timeliness statement	

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Provisional Title	Diacerein for the treatment of osteoarthritis
Topic Selection ID Number	2979
Wave	23
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of diacerein within its licensed indication for the treatment of osteoarthritis.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of diacerein for the treatment of osteoarthritis is appropriate. The Institute is of the opinion that the draft remit is appropriate.
Process (MTA/STA)	MTA
Proposed changes to remit (in bold)	No changes 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.

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Provisional Title	Rituximab for the treatment methotrexate-naive rheumatoid arthritis and of rheumatoid arthritis after the failure of disease-modifying anti-rheumatic drugs
Topic Selection ID Number	4476
Wave	24
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of rituximab within its licensed indications for the treatment of **methotrexate-naive** rheumatoid arthritis or 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 rituximab for the treatment of rheumatoid arthritis after the failure of disease-modifying anti-rheumatic drugs is appropriate. An appraisal for the treatment of methotrexate-naive rheumatoid arthritis is not appropriate. The manufacturer indicated that the regulatory submission will no longer include people with methotrexate-naive rheumatoid arthritis. Therefore the Institute is of the opinion that the draft remit should be amended to only consider rituximab for the treatment of rheumatoid arthritis after the failure of disease-modifying anti-rheumatic drugs.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	The proposed remit is not appropriate. The remit should be changed to: To appraise the clinical and cost effectiveness of rituximab within its licensed indication for the treatment of rheumatoid arthritis after the failure of disease-modifying anti-rheumatic drugs.
Costing implications of remit change	The removal of methotrexate-naive patients from the remit will considerably reduce the population affected by this appraisal. However, the appraisal was considered originally to be low cost and this is unlikely to change.
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.

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Provisional Title	Bendamustine for the treatment of chronic lymphocytic leukaemia
Topic Selection ID Number	2746
Wave	23
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of bendamustine within its licensed indication for the first-line treatment of patients with chronic lymphocytic leukaemia.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of bendamustine for the treatment of non-Hodgkin's lymphoma is appropriate. The Institute is of the opinion that the draft remit is appropriate.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	No changes 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.

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Provisional Title	Vinflunine for the treatment of transitional cell carcinoma of the urothelial tract
Topic Selection ID Number	4184
Wave	23
Anticipated licensing information	Marketing authorisation was granted in September 2009
Draft remit	To appraise the clinical and cost effectiveness of vinflunine within its licensed indication for the treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of vinflunine for the treatment of transitional cell carcinoma of the urothelial tract is appropriate. Consultees highlighted that the draft remit should reflect the marketing authorisation which states: 'monotherapy for the treatment of advanced or metastatic transitional cell carcinoma of the urothelium after failure of a prior platinum-containing chemotherapy regimen'. The Institute recommends that the remit should be amended to reflect the marketing authorisation.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	The proposed remit is not appropriate and should be amended to state: 'To appraise the clinical and cost effectiveness of vinflunine **monotherapy** for the **second-line** treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract **after failure of prior platinum-containing chemotherapy**
Costing implications of remit change	Original costing work assumed population based on second-line treatment, therefore original cost estimate of low cost remains appropriate.
Timeliness statement	Given the date of the marketing authorisation and the expected referral date of this topic, issuing timely guidance for this technology will not be possible.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

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Summary of comments and discussions at scoping workshops

Provisional Title	Depression - quetiapine
Topic Selection ID Number	4325
Wave	23
	A scoping workshop was arranged for January 2010; this workshop was cancelled due to the severe weather conditions and has been rearranged for March 2010. The written consultation for this was held in December 2009 therefore an additional consultation will not be necessary. A summary of comments and discussions from the scoping workshop will be presented with the batch 11 block scoping report.

Provisional Title	Depression - agomelatine
Topic Selection ID Number	4243
Wave	23
	A scoping workshop was arranged for January 2010; this workshop was cancelled due to the severe weather conditions and has been rearranged for March 2010. The written consultation for this was held in December 2009 therefore an additional consultation will not be necessary. A summary of comments and discussions from the scoping workshop will be presented with the batch 11 block scoping report.

Provisional Title	Idiopathic pulmonary fibrosis - pirfenidone
Topic Selection ID Number	4219
Wave	23
	A scoping workshop was arranged for January 2010; this workshop was cancelled due to the limited information available due to communication problems with the manufacturer and has been rearranged for March 2010. The written consultation for this was held in December 2009 therefore an additional consultation will not be necessary. A summary of comments and discussions from the scoping workshop will be presented with the batch 11 block scoping report.

Provisional Title	Generalised anxiety disorder - quetiapine
Topic Selection ID Number	4333
Wave	23
	A scoping workshop was arranged for January 2010; this workshop was cancelled due to the severe weather conditions and has been rearranged for March 2010. The written consultation for this was held in December 2009 therefore an additional consultation will not be necessary. A summary of comments and discussions from the scoping workshop will be presented with the batch 11 block scoping report.

Provisional Title	On-line haemodiafiltration for established renal failure
Topic Selection ID Number	2390
Wave	21st wave
Anticipated licensing information	Not applicable
Draft remit	Not applicable: Pre-scoping Workshop
Main points from consultation	Following the consultation exercise and the pre-scoping workshop, NICE is of the opinion that a technology appraisal of on-line haemodiafiltration for established renal failure would not be appropriate. A key uncertainty in the use of this technology is the population for which it is most appropriate. Interest in the use of this technology is primarily for those who are likely to be on long-term haemodialysis and have limited prospects for a transplant, or may have poorer outcomes on haemodialysis. Consultees highlighted that current evidence about the use of on-line haemodiafiltration in these patients is limited, and that the benefit of this technology for these patients may not be answered by ongoing clinical trials, that enrol patients who are considered appropriate for haemodialysis. Identification of the most appropriate population will require both clinical judgement and evidential support and in light of the evidence base may not be resolved by a technology appraisal. It may be more

	appropriately dealt with in the context of a clinical guideline. Any positive recommendations from NICE are likely to reflect the use of on-line haemodiafiltration as a treatment option, rather than as a replacement for haemodialysis. The key cost of implementing this guidance would be the capital cost for replacing or converting haemodialysis machines, or purchasing haemodiafiltration machines to enable both modalities to be provided as an option. Strict water standards for some machines may also require some renal units to improve their water plants. These costs are subject to NHS capital replacement programmes. The need for guidance to align with capital replacement programmes means the three month funding directive will not be appropriate and will hinder implementation of the guidance and the ability of NICE guidance to reduce variations in care management. It is recommended that consideration is given to whether NICE may add value to the NHS by producing a clinical guideline or a short clinical guideline or this topic.
Process (MTA/STA)	MTA
Proposed changes to remit (in bold)	Not applicable – referral not sought
Costing implications of remit change	N/A
Timeliness statement	N/A