ITEM 5

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals

Consultation on Batch 17 draft remits and draft scopes

Summary of comments and discussions at scoping workshops

	Batch 17 topics
5.1	Atrial fibrillation - vernakalant (recent onset - first line)
5.2	Gout - canakinumab
5.3	Hepatitis C (genotype 1) - boceprevir
5.4	Hepatitis C (genotype 1) - telaprevir
5.5	Prostate cancer (meta castration resistant) - abiraterone
5.6	Venous Thromboembolism (prevention) hospitalisation - rivaroxaban

Provisional Title	Vernakalant for the treatment of recent onset atrial fibrillation
Topic Selection ID Number	4782
Wave	26
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of vernakalant within its licensed indication for the treatment of recent onset atrial fibrillation
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of vernakalant for the treatment of recent onset atrial fibrillations is appropriate. The proposed remit is not appropriate. Comments received during consultation suggested that the wording should be amended to reflect the time frame specified for recent onset atrial in the marketing authorisation. The manufacturer of vernakalant, Merck Sharp & Dohme, informed the scoping workshop attendees that they had received a letter from NICE stating that the topic selection panel had "... decided this topic is an appropriate one for possible inclusion in the upcoming atrial fibrillation guideline update. As a result, they did not decide a score for it for a TA". The manufacturer was informed at the workshop that as a review of CG36 had not yet been agreed (consideration of review date June 2011) the panel should not have considered the guideline as an option. Although the panel had not scored this technology for a Technology Appraisal, it was decided that the scoping of vernakalant for the treatment of recent onset atrial fibrillation should proceed.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of vernakalant within its licensed indication for the treatment of **rapid conversion** of recent onset atrial fibrillation **≤ 7 days**
Costing implications of remit change	The cost is still unknown. The change to time frame does not affect the original cost impact.
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	Canakinumab for the treatment of acute gout flares and the delay of subsequent flares
Topic Selection ID Number	4780
Wave	26
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of canakinumab within its licensed indication for the treatment of acute gout flares and the delay of subsequent flares.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of cannakinumab for the treatment of gout flares is appropriate. The proposed remit is generally appropriate but should be amended to more closely reflect the intended wording of the marketing authorisation. The manufacturer explained during the scoping workshop that canakinumab is an anti-inflammatory agent intended to be used as a treatment for an acute attack, rather than a maintenance treatment for reducing the rate of flares. The manufacturer explained that because cannakinumab has a half life of approximately 28 days, each dose administered, in addition to the alleviation of pain during the acute attack, may also reduce the frequency of subsequent attacks in the short term. The manufacturer confirmed that it will not be seeking a marketing authorisation for maintenance treatment.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of canakinumab within its licensed indication for the treatment of **gouty arthritis attacks.**
Costing implications of remit change	The cost is still unknown. The change in remit does not affect the original cost impact.
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	Boceprevir for previously untreated genotype 1 chronic hepatitis C and previously treated with peginterferon alfa and ribavirin
Topic Selection ID Number	4863
Wave	26
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of boceprevir within its licensed indication for the treatment of previously untreated genotype 1 chronic hepatitis C and previously treated with peginterferon alfa and ribavirin.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of boceprevir for the treatment of previously untreated genotype 1 chronic hepatitis C and previously treated with peginterferon alfa and ribavirin is appropriate. The proposed remit is not appropriate. It is suggested that the wording be changed to clearly indicate that it applies to both treatment naive and treatment experienced patients. In addition, it is recommended that what previous treatment comprises (i.e. peginterferon and ribavirin) is not specified. It was highlighted that specifying that people had to have been previously treated with peginteferon and ribavirin could result in a potentially disadvantaged group of patients – those who had been treated before the introduction of peginterferon and ribavirin as standard, for example, with non-pegylated interferon. It was noted that this aspect would be dependent on the marketing authorisation received for boceprevir, but flagged as an important consideration. ****** CONFIDENTIAL****Boceprevir has, however, been studied in clinical trials where previous treatment is limited to peginteferon and ribavirin.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of boceprevir within its licensed indication for the treatment of **genotype 1 chronic hepatitis C**
Costing implications of remit change	The cost is still unknown. The change in remit does not affect the original cost impact.
Timeliness statement	Assuming the anticipated date of the marketing authorisation is the latest date that we are aware of and a formal referral is received quickly, issuing timely guidance for this technology will be possible.

Provisional Title	Telaprevir for previously untreated genotype 1 chronic hepatitis C and previously treated with peginterferon alfa and ribavirin
Topic Selection ID Number	4550
Wave	26
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of telaprevir within its licensed indication for the treatment of previously untreated genotype 1 chronic hepatitis C and previously treated with peginterferon alfa and ribavirin.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of telaprevir for the treatment of previously untreated genotype 1 chronic hepatitis C and previously treated with peginterferon alfa and ribavirin is appropriate. The proposed remit is not appropriate. It is suggested that the wording be changed to clearly indicate that it applies to both treatment naive and treatment experienced patients. In addition, it is recommended that what previous treatment comprises (i.e. peginterferon and ribavirin) is not specified. It was highlighted that specifying that people had to have been previously treated with peginteferon and ribavirin could result in a potentially disadvantaged group of patients – those who had been treated before the introduction of peginterferon and ribavirin as standard, for example, with non-pegylated interferon. It was noted that this aspect would be dependent on the marketing authorisation received for telaprevir, but flagged as an important consideration. ***CONFIDENTIAL*** .Telaprevir has, however, been studied in clinical trials where previous treatment is limited to peginteferon and ribavirin.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of telaprevir within its licensed indication for the treatment **genotype 1 chronic hepatitis C**
Costing implications of remit change	The cost of Telaprevir has yet to be determined and therefore the cost impact of this topic is not known. There is potential for the topic to be high cost based if it is used in combination or is a significant cost above the cost of current treatments. Diagnosed patient numbers choosing treatment are estimated to be around 5,000, although there are many more people with undiagnosed disease. There may be some offsetting savings, if it prevents complications such as cirrhosis or hepatocellular cancer that may arise from untreated disease.

Timeliness statement	Assuming the regulatory process follows the standard timings and the anticipated 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. However, if the accelerated approval process is used, issuing timely guidance will also be possible.

Provisional Title	Abiraterone for the treatment of metastatic, castration resistant prostate cancer
Topic Selection ID Number	4760
Wave	26
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of abiraterone within its licensed indication for the treatment of metastatic, castration-resistant prostate cancer following previous cytotoxic chemotherapy.
Main points from consultation	Following the consultation exercise and the scoping workshop, the Institute is of the opinion that an appraisal of abiraterone for the treatment of metastatic, castration resistant prostate cancer is appropriate. The proposed remit is not appropriate. During the scoping workshop It was noted that the anticipated wording of the marketing authorisation includes the phrase 'castration-resistant', which was the basis for the term's inclusion in the draft scope. Clinical experts stated that no other term would define the population of interest as accurately as 'castration-resistant'. They clarified, however, that the clinical community more commonly uses the term 'castrate-resistant', rather than 'castration-resistant'. The clinicians noted that they are aware of the sensitivity of the term, and that they fully explain its meaning to patients. The patient experts present said that they did not have any issues with the term 'castrate-resistant' as long as it explained fully to them by clinicians.
Process (MTA/STA)	STA
Proposed changes to remit (in bold)	To appraise the clinical and cost effectiveness of abiraterone **in combination with prednisolone** within its licensed indication for the treatment of metastatic, **castrate-resistant** prostate cancer following previous cytotoxic chemotherapy.
Costing implications of remit change	The cost is still unknown. The change in remit does not affect the original cost impact.
Timeliness statement	Assuming the regulatory process follows the standard timings and the anticipated 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. However, if the accelerated approval process is used, issuing timely guidance will <u>also</u> be possible.

Provisional Title	Rivaroxaban for the prevention of venous thromboembolism in people hospitalised for acute medical conditions
Topic Selection ID Number	4724
Wave	26
Anticipated licensing information	CONFIDENTIAL
Draft remit	To appraise the clinical and cost effectiveness of rivaroxaban within its licensed indication for the prevention of venous thromboembolism in people hospitalised for acute medical conditions.
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 venous thromboembolism in people hospitalised for acute medical conditions 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	N/A
Timeliness statement	Assuming the regulatory process follows the standard timings and the anticipated 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.