

MILTON KEYNES NHS TRUSTS MEDICINES AND THERAPEUTICS COMMITTEE

**Minutes of the meeting held on Tuesday 30 November 2010
At 1p.m. in the Eaglestone Restaurant Function Room**

PRESENT:

(Chair)

Dr V Jeevanathan (VJ)

MKH NHS Fd ⁿ Trust	MK NHS PCT
Folake Kufeji (FK)	Janet Corbett (JC)
Niall Ferguson (NF)	Matthew Elswood (ME)
Naomi Whitelaw (NW)	Denise Middleton (DMid)
Dushyant Mital (DM)	

1. Apologies for Absence:

Dr Essam Hassan (EH), Dr Nasiri Ahmed (NA), Dr Tina Kenny (TK), Helen Chadwick (HC) and Busola Ade-Ojo (BAO)

2. Declaration of conflicts of interest

None

3. Minutes of last meeting

Minutes approved as an accurate representation of the meeting.

4. Matters arising from previous minutes

i. Letrozole – Mr Chin clarified that Anastrozole will be used 1st line in the majority of patients. Letrozole will be 2nd line and used in patients not suitable for surgery.

ii. Revised TOR – M&TC will be reporting to the Care Standards Committee.

iii. Dabigatran – This was discussed at the Clinical Quality Care Group on the 8th of November. Mr Wetherill undertook to ensure a response to JC's e-mail. She is still awaiting his response. The committee would like to find out what dose other specialist centres are prescribing. FK to contact Nuffield Orthopaedic Centre. **FK**

5. Out patient letter script

The current outpatient letter does not fully provide all the necessary information to GPs for example it does not specify when to review therapy. NW presented the draft Outpatient prescription advice patient information leaflet. This is to make information and advice to GPs more user friendly and clearer as to what follow up management is required. **NW**

Endorsed by M&T committee. NW will take to forms committee.

6. MOBBB Priorities Committee decisions

The use of zoledronic acid for the prevention of skeletal related adverse events (SREs) in patients with advanced malignancies involving bone is a LOW PRIORITY and should not be routinely funded (in either Breast or Prostate Cancer). There is limited evidence of clinical effectiveness and lack of evidence of cost effectiveness.

7. Drug formulary

Update on new electronic formulary

A new electronic format of the trust formulary is being planned to be introduced into the trusts. This will ensure that the drug formulary is visible, accessible and searchable to all users (both primary and secondary care). It will also help to improve adherence and compliance with the formula and make monitoring and dissemination of information much easier.

HC & FK

Licence agreement is currently being signed and plans for data population being put into place. The committee will be kept up to date with developments.

New medicine applications

a) Ella One

Application made by Dr Cathy Bruce for Emergency Contraception within 120 hours of unprotected sexual intercourse or contraceptive failure. It's place in therapy needs to be made clearer.

**HC
Dr Bruce**

Decision: Resubmission of application to show a clear position for its use.

b) Evicel

Application made by for use in securing graft tissue in middle ear surgery and to stop bleeding in HHT epistaxis. There was not enough evidence to show the advantages of this product over the current formulary alternative, Tisseel.

FK

Decision: NOT APPROVED based on the evidence available to the committee. A resubmission showing the failure rates with Tisseel and benefits of replacing it with Evicel would be considered.

c) Sativex

DMid presented this application made by Dr Butterworth for spasticity in multiple sclerosis. The cost-effectiveness criteria could not be demonstrated for this drug generally, due to its high acquisition costs and limited long-term evidence of high treatment failure rates. It may however, be beneficial in some patients. As it currently has a low priority rating (JC has asked for this to be reviewed by MOBBB), the committee felt that requests for the 10 patients in which it's being considered for use should be made to the exceptional circumstances committee for funding.

**FK
Dr
Butterworth**

Decision: NOT APPROVED as currently has low priority statement.
Individual funding requests to be made to the exceptional circumstances committee.

FK
Dr Mital

d) Valganciclovir

Dr Mital presented this application for use of valganciclovir in Active and prophylactic Cytomegalavirus (CMV) retinitis and viraemia in AIDS patients. Oxford hospital formulary we follow currently recommends ganciclovir IV for the induction phase and valganciclovir for the maintenance phase. The use of valganciclovir for both the induction phase and maintenance phase at this trust was felt to be the better option as it removed the need for nursing time and other costs associated with parenteral administration.

Decision: APPROVED for use in Active and prophylactic Cytomegalavirus (CMV) retinitis and viraemia in AIDS patients..

8. Antiretroviral group minutes

- a) Minutes - Ritonavir tablets (item 6 and AOB)
- b) ORH Antiretroviral guidelines

DM felt the Oxford guidelines were out of date and not reflective of practice in other specialist centres (eg London), particularly with the choice of Kivexa. JC mentioned that HIV specialist pharmacists are working across south central in developing guidelines to achieve consistency. JC also commented that the attendance record should accurately differentiate between committee members and those who are attending in support of an application.

9. NICE guidance

FK

- a) **TA195** - Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor.

NOTE: This guidance replaces NICE technology appraisal guidance 126 and 141 issued in August 2007 and April 2008 respectively. It also replaces the remaining recommendations in NICE technology appraisal guidance 36 issued in March 2002.

Additional treatment options are now recommended if rituximab therapy is contraindicated or withdrawn because of an adverse event, specifically:

- If rituximab is contraindicated or withdrawn, adalimumab, etanercept, infliximab and abatacept, each in combination with methotrexate, are now recommended as treatment options.
- If rituximab therapy cannot be given because methotrexate is contraindicated or withdrawn because of an adverse event, adalimumab and etanercept, each as monotherapy, are now recommended as treatment options.

- b) **TA197** - Dronedaron for the treatment of non-permanent atrial fibrillation

Second-line treatment option for patients whose atrial fibrillation is not controlled by

first-line therapy (usually including beta-blockers), **and**

- who have at least one of the following cardiovascular risk factors:
 - hypertension requiring drugs of at least two different classes
 - diabetes mellitus
 - previous transient ischaemic attack, stroke or systemic embolism
 - left atrial diameter of 50 mm or greater
 - left ventricular ejection fraction less than 40% (noting that the summary of product characteristics [SPC] does not recommend dronedarone for people with left ventricular ejection fraction less than 35% because of limited experience of using it in this group) **or**
 - age 70 years or older, **and**
- who do not have unstable New York Heart Association (NYHA) class III or IV heart failure.

c) TA198 - Tocilizumab for the treatment of rheumatoid arthritis

Tocilizumab, in combination with methotrexate, is recommended for the treatment of moderate to severe active rheumatoid arthritis in people whose rheumatoid arthritis has responded inadequately to one or more tumour necrosis factor alpha (TNF- α) inhibitors **and**:

- whose rheumatoid arthritis has responded inadequately to rituximab **or**
- in whom rituximab is contraindicated or when rituximab is withdrawn because of an adverse effect.

Local note: Use of certolizumab would be preferable as the manufacturer provides the first 12 weeks of treatment free of charge to all patients starting treatment.

d) TA199 - Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (review of technology appraisal guidance 104 and 125)

This review and re-appraisal has resulted in an extension to the guidance:

- Etanercept, infliximab and adalimumab are all recommended for the treatment of active and progressive psoriatic arthritis, based on specific criteria. Treatment choice should be started with the least expensive drug (taking into account drug administration costs, required dose and product price per dose).
- The guidance recommends that treatment should be discontinued if people's disease does not show an adequate response on the Psoriatic Arthritis Response Criteria (PsARC) at 12 weeks. Healthcare professionals should also consider continuing treatment if people's skin disease has a Psoriasis Area and Severity Index (PASI) 75 response at 12 weeks in the absence of an adequate PsARC response. This assessment should be done by a dermatologist to determine whether continued treatment is appropriate on the basis of the skin response alone.

e) TA200 - Peginterferon alfa and ribavirin for the treatment of chronic hepatitis C (part review of technology appraisal guidance 75 and 106)

This appraisal addresses extensions to the marketing authorisations for peginterferon alfa-2a and peginterferon alfa-2b. All other recommendations in TA75 and TA106 still stand.

f) TA203 - Liraglutide for the treatment of type 2 diabetes mellitus

Liraglutide 1.2 mg daily in triple therapy regimens (in combination with metformin and a sulphonylurea, or metformin and a thiazolidinedione) is recommended as an option for the treatment of people with type 2 diabetes, only if used as described for exenatide in 'Type 2 diabetes: the management of type 2 diabetes' (NICE clinical guideline 87); that is, when control of blood glucose remains or becomes inadequate (HbA1c \geq 7.5%, or other higher level agreed with the individual), and the person has:

- a body mass index (BMI) \geq 35 kg/m² in those of European descent (with appropriate adjustment for other ethnic groups) and specific psychological or medical problems associated with high body weight, **or**

- a BMI < 35 kg/m², and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity-related comorbidities.

Liraglutide 1.2 mg daily in dual therapy regimens (in combination with metformin or a sulphonylurea) is recommended as an option for the treatment of people with type 2 diabetes, only if:

- the person is intolerant of either metformin **or** a sulphonylurea, or treatment with metformin **or** a sulphonylurea is contraindicated, **and**
- the person is intolerant of thiazolidinediones **and** dipeptidyl peptidase-4 (DPP-4) inhibitors, or treatment with thiazolidinediones **and** DPP-4 inhibitors is contraindicated.

Liraglutide 1.8 mg daily is not recommended for the treatment of people with type 2 diabetes.

g) TA204 - Denosumab for the prevention of osteoporotic fractures in postmenopausal women

Denosumab is recommended as a treatment option for the primary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures:

- who are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments **and**
- who have a combination of T-score, age and number of independent clinical risk factors for fracture.

Denosumab is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures who are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments.

10. Feedback from PCT prescribing group

None to discuss

11. QIPP

National Key Therapeutic Topics for 2010/2011 was presented by JC. This document highlighted the therapeutic areas concerned, with local actions for implementation across MK.

12. Reports from audits

Audit register will be set up from now onwards to monitor the decisions of the committee.

FK

13. Any other business

NF reminded that anything which needs discussing/approving is brought to this committee before taking to the clinical board.

14. Confirmation of Dates for 2011

The dates for 2011 were agreed (see table below).

Please note change of June meeting to 1st week in July.

The date of the next meeting was confirmed as

Tuesday 15th February 2011, Eaglestone Function Room, Time 1.00pm.

Month	Venue	Day	Time
February	Eaglestone Function Room	15-Feb	13:00 - 14:00
April	Eaglestone Function Room	19-Apr	13:00 - 14:00
July	PCT Boardroom	5-Jul	13:00 - 14:00
September	Eaglestone Function Room	20-Sep	13:00 - 14:00
November	Facilities Drawing Room	15-Nov	13:00 - 14:00