Milton Keynes Clinical Commissioning Group NHS

Milton Keynes Hospital NHS
NHS Foundation Trust

Milton Keynes Community Health Services

JOINT NHS TRUSTS'
MILTON KEYNES PRESCRIBING ADVISORY GROUP (MKPAG)

Notes of the meeting held on Wednesday 10th April 2013
At 12:45pm in the MKHFT Chief Pharmacist's Office

Present: (Chair) Sue Ashwell (SA), Chief Pharmacist Milton Keynes Hospital NHS Foundation Trust (MKHFT)

MKPAG secretariat and MKHFT

Folake Kujeji	Principal Pharmacist, Medicines Information and Formulary
Dupe Fagbenro (DF)	Senior Pharmacist, MKPAG support

MKCCG

Janet Corbett (JC)	Director of Clinical Development and Chief Pharmacist
Dr Nigel Fagan (NF)	GP and MK GP Prescribing group representative
Natalie McLennan-Murray (NMM)	Pharmacist

MKHFT

Dr Lakshmi Ragunathan (LR)	Consultant Microbiologist
Mark Baverstock (MB)	Advanced Nurse Practitioner, Respiratory and Division of Medicine
Kate Bulbeck (KB)	Matron, Paediatrics Clinical Service Unit (CSU)
Carol Jellicoe (CJ)	Advanced Nurse Practitioner, Acute Pain and Division of Surgery
Steve Melville (SM)	Divisional General Managers' representative

MKCHS

Ann Carr (AC)	Senior Pharmacist

Notetaker: Olie Spring

In attendance:

Dona Unmole (DU) re Levetiracetam (on behalf of Medicine and Neurology); Debbie Morrison (DM) (Oncology Transition Support Pharmacist and observer); Shirley Moon (SM) (observer and deputy for Steve Melville)

* In action column denotes pharmacy staff not present at the meeting but to be involved with implementation are named at the end of the document; see Appendix 1

		ACTION
1.	**Welcome, apologies and introductions** Members of the group introduced themselves and where appropriate stated who they were deputising for. 1.1 Apologies were received from Dr James Bursell (Clinical Director for Paediatrics, Deputy in attendance Kate Bulbeck) , Helen Chadwick (HC, Chief Pharmacist MKCHS, Deputy in attendance Ann Carr), Sheila Begley (Associate Director of Adult and Older people's Services and Deputy Director of Nursing, MKCHS), and Dr Essam Hassan (Consultant Psychiatrist, MKCHS) 1.2 Applicants not able to attend: re Rivaroxaban, Dr Ijaz Medhi, & Dr Denise White 1.3 **It was noted that MKPAG will consider all applications that are at an appropriate stage of completion, whether or not the clinician making the application is able to attend the meeting.** However, wherever possible, all details set out in the application form must be completed and all documents supporting the case provided. Information on	**All**

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	the place of a new drug in therapy, and that the organisation paying for the new drug has been consulted and agrees to fund it, is an **essential pre-requisite** for addition of any drug to the joint formulary. The revised MKPAG application form should assist in this. *Post-meeting note: See Appendix 3 – MKPAG application for version 3.2 May2013* Feedback on the new form is welcomed. The latest version of the application form will be maintained on the MKPAG/formulary page and should be used for all future submissions.	**All**
2.	**Declaration of potential conflict of interests** DF collected declaration forms. No potential conflicts were noted in relation to any of the items on the agenda for this meeting of MKPAG.	**All**
3.	**Any other business, not on the agenda, for consideration at this meeting** None requested	
4.	**Inauguration of MKPAG and operational issues** 4.1 Rationale for change: SA welcomed everyone to the first MKPAG meeting and explained that the changes from the old Medicines and Therapeutics Committee (M&TC) had been made in consultation with MKCCG and MKCHS chief pharmacists and at the request of the MKHFT Medical Director. 4.2 Working arrangements: SA explained that the new MKPAG working arrangements were designed to ensure that the decision-making processes are robust and clear, and follow sound principles about evidence-based care and the ethical framework that has been incorporated into the new MKPAG application form. 4.3 External scrutiny of MKPAG actions and recommendations: SA advised that the new NHS contract for providers, such as MKHFT and MKCHS, requires a web-based formulary to be available from the organisation's web site and to include all relevant drugs recommended for use in NICE Technology Appraisals Guidance (TAGs). The Area Teams from NHS England will be checking that the web formulary is there. It was noted that they and others (including patients and pharmaceutical companies) can challenge the processes used to reach MKPAG recommendations. 4.4 Moving to a more pro-active way of working: SA presented the flow chart that explained the steps and actions involved in adding a drug to the joint formulary, including the place of the PAG in this process. See Appendix 2. SA explained that the MKHFT Pharmacy service is committed to being proactive in supporting both the online formulary as well as the needs of the MKHFT Divisions and CSUs, and the needs and priorities of MKCCG and of MKCHS. 4.5 Taking a whole-system approach and supporting financial balance: MKPAG will look at the issues in prescribing & budgeting across the health system (e.g. Cystic Fibrosis 'year of care' tariffs, and implementation of NICE TAGs) as well as applications for new drugs and new uses for drugs, including new uses for drugs already on the formulary. SA noted that the change from the old M&TC to an explicitly 'advisory' group was made as the budget for drugs is not held by either pharmacy or the MKPAG, but instead is now held by NHS England specialist commissioners and Clinical Commissioning Groups (e.g. NHS MK CCG, including their GP practices), or by MKCHS or by the MKHFT CSUs/Divisions.	

		ACTION
	• Noted therefore that MKPAG will not recommend or withhold a recommendation on use of drugs on a purely financial basis, but will act primarily to test the clinical case and set out clearly for all parts of the MK health system the anticipated organisational impact (e.g. pathway changes, shifts in prescribing) and financial consequences. • Where formulary changes were sought that meant prescribing advice and responsibility was to cross the organisational boundaries a consensus would be sought, with the help of MKPAG members. NMM noted this revised approach appears more patient- and system-focused; • LR requested clarification about what would happen for antibiotics e.g. for the hospital antibiotics formulary or Out-Patient Antibiotic Therapy (OPAT). It was agreed that the approach to availability on the formulary of antibiotics would be consistent with the standard MKPAG process i.e. all changes would need to be based on sound clinical evidence and have financial sign-off within an organisation. MKPAG would review the clinical case and financial implications of the hospital and primary care Antibiotics Formularies and Prescribing Guidelines. 4.5.1 Drugs used and paid for within a single organisation: SA explained that if the application to add a drug to the formulary is supported by MKPAG and is funded internally by a single organisation, then few problems are anticipated, provided clinicians ensure their CSU leads or other budget holders support the clinical and financial case. In these situations there would be a simpler process than for drugs with system-wide activity and/or financial implications. 4.5.2 Drugs that have a clinical and/or financial implications across more than one organisation: SA noted that if any applicant is asking people external their our own organisation to pay the bill, the applicant, with input where appropriate from MKPAG, will need to make a financial case to all funding organisations. Until the funders have accepted the case prescribing needs to stay within the initiating organisation e.g. MKHFT. 4.5.3 Noted that if a sound explanation and all proposals are signed off by all the organisations' approved processes (including organisational sign off on the MKPAG application form) in advance of consideration of applications at an MKPAG meeting this is likely to expedite addition of a drug to the formulary at www.formularymk.nhs.uk 4.5.4 JC mentioned that there may be occasions when the saving on other parts of an organisation's or the health system's budgets outweigh the additional cost of a new drug e.g. by assisting in service redesign, reducing the likelihood of admission/readmission. If prescribing costs go up, it can mean hospital costs going down (e.g. hospital visits, bed stays, nurse time). SA confirmed that applicants and members need to be looking at the whole picture when considering applications for addition to the formulary through MKPAG. 4.6 Developing skills in local decision making. SA proposed that as a group MKPAG members are brought together to spend a few hours or half a day going through key points & skills of effective decision making about medicines, using the national framework that was referred to in the appendix to the invitation to join MKPAG. The group agreed. **Action:** A date before the summer school break will be sought for a half-day meeting and notified to all attendees and the other named contacts for MKPAG.	**FK/SA**
5.	**Applications to add medicines or indications to the MK joint formulary**	

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5.1	**Levetiracetam** 5.1.1 DU presented to the group. Levetiracetam has been recommended by NICE Clinical Guideline (CG) 137. as an option for treatment in some situations. Noted that it is usually 2nd line, and is hard to substitute as we don't have an alternative. Further noted that at MKHFT 25% of all non-formulary drug requests (NFD) for the medical directorate are for Levetiracetam. Issues data from MKHFT indicates that it is being prescribed by a wide range of consultants – it is not localised to one or two doctors, although it is important to note that the application has been fully supported by the neurologists and the Division of Medicine. 5.1.2 JC commented that she didn't receive the application and shared care guidelines. FK agreed to re-circulate the missing forms. SA noted that in future the paperwork would be simplified and apologised that for this first MKPAG meeting there was some excess paperwork that may have caused confusion due to double-running in some cases with both old M&TC and new MKPAG forms. **5.1.3 Recommendation:** For addition to the formulary for use only in line with NICE CG 137, not for the full range of licensed indications. No additional GP or hospital cost anticipated as this is already being used in a number of cases, as a non-formulary drug, in line with NICE CG137 recommendations. **Action: Levetiracetam will therefore be added to formularymk for use only in line with the NICE Clinical Guideline.** All strengths and formulations will be included. • Shared Care guideline to be sent to MKCCG for consideration • JC to seek the views of primary care on the draft shared care protocol • When a final version is agreed this needs to be added to the formularymk web site.	**FK** **DU*** **JC** **FK**
5.2	**Tazobactam/Piperacillin (generic equivalent of Tazocin) for use as a bolus injection for Out Patient Antibiotic Therapy service patients.** 5.2.1 AC presented to the group. Noted the change of licensing in August 2012, and that bolus IV administration is no longer within the licensed indications, following a decision by the EMEA to harmonise labelling between brands, i.e. bolus IV administration is now "off-label" even though a licensed medicinal product is being used. "Off label" means that the IV route of administration is outside the terms of the marketing authorization/product licence and the manufacturer cannot promote this use of their drug via this route. There is however no legal impediment to use in this way. MKPAG was therefore only being asked to review the evidence of effectiveness and the potential benefit of reverting to bolus (as that was the IV administration process used in MK prior to the licensing change). 5.2.2 SA advised that the clinical impact of using bolus over infusion for the IV route had been investigated through the EMEA web site, with the Southampton Regional Medicines Information Centre and with the Southampton Consultant Pharmacist for antimicrobial use and other specialists in that therapeutic area. LR also confirmed the change in August 2012 to recommend infusion rather than bolus for MK patients was mainly to align with European labelling arrangements for companies, and	

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	that use of bolus rather than infusion is expected to have no adverse impact on patients; Consultant Microbiologist supported the application. 5.2.3 SA confirmed the information in the application about the source of the advice from other centres. She also advised MKPAG members that bolus IV administration of Tazobactam/Piperacillin had been recommended by M&TC in November 2012 for use in MKHFT Emergency Department (ED) as part of their initiative to ensure that antibiotics are administered, along with all the other relevant interventions ("Sepsis Six" bundle), within an hour of presentation at the ED for all patients with suspected sepsis and/or with a history of receiving chemotherapy in the previous 6 weeks. 5.2.4 It was noted that MK Community Health Services give IV Antibiotics to approximately 15 patients per day. The application for this 'off-label' use noted that bolus would be much quicker to deliver than infusion and would therefore have major implications on nurse time outside hospital. Noted that the shift back to administration of this drug as a bolus would enable the OPAT service provided by MKCHS to take on (outside hospital) an additional patient for each day. 5.2.5 KB asked whether it would be possible to consider a similar arrangement, for bolus rather than infusion for paediatric patients, to ensure doses were delivered sooner. SA advised that this could be considered by PAG as a subsequent application and that pharmacy would work with paediatrics to consider this. **Recommendation:** Supported for OPAT administration as IV bolus, with immediate effect. **Action:** • MKCHS to implement the necessary arrangements for communication with their nurses delivering this in the OPAT service. • MKHFT pharmacy to work with OPAT service leads to amend prescribing and labelling of OPAT Tazobactam/Piperacillin to match bolus administration. • MKHFT pharmacy to continue to look for the rest of the hospital at whether a switch (back) to bolus administration in all cases would be appropriate.	**FK/KB** **AC/HC** **WM*/TD*** **SA/WM*/ LR**
5.3	**TheraBite** 5.3.1 SA noted the device's place in therapy is as a specialist maxillo-facial device, with small patient numbers. Although it is reimbursable for GP prescribing, it was agreed by MKPAG members that the specialist nature and small numbers mean that no individual GP or practice could be expected to become competent in the adjustment of the device, training of the patients and cutting of pads to size that are required to use this device appropriately. 5.3.2 The current cost to MKHFT is about £3,000 per year for all the devices required. 5.3.3 JC pointed out that the application says GPs will not initiate yet section 1 says otherwise. SA requested that PAG members consider the suitability for shared care or GP initiation. The consensus was that neither would be clinically appropriate or overall in the best interest of patients.	

		ACTION
	Recommendation: For hospital supply only, due to expertise judged by MKPAG to be necessary for safe supply and management not being appropriate for primary care use. **Action:** To be added to the hospital formulary. • MaxFac operational manager as well as the consultant submitting the application to be advised of the MKPAG and CCG position. • Pharmacy to clarify whether the consultant would now wish to supply directly from the clinic, as currently, rather than prescribing and adding a trip to pharmacy for patients. • Noted that MKCCG would add the device to their 'ScriptSwitch' profile for items not to be prescribed by MK GP practices.	**FK** **FK** **JC**
6.	**Formulary Applications received which require further information**	
6.1	**Ulipristal (Esmya)** 6.1.1 DF explained that Mr Hanna had submitted the application in December 2012, and that since then comments had been received from the MK CCG GP prescribing group raising a number of concerns/uncertainties about the application for formulary status for this product. This was noted to be critical as the request is for GP prescribing. 6.1.2 The GP feedback was sent to Mr Hanna, but to date no written response has been received, although Mr Hanna had offered to make himself available on two previous, but cancelled, M&TC dates. 6.1.3 JC explained the primary care feedback, spoecifically that there was very limited experience of the drug. JC noted that the role of this drug compared to the alternatives was not entirely clear to the GP Prescribing group. Advised that the shared care guideline from Kettering Hospital, to which Mr Hanna had drawn our attention, was very general and does not address the uncertainties on place in therapy. The GP prescribing group had suggested that the proposed 50 patient group seemed very low for such a common problem, and the application lacked a comparison to other options such as surgery. 6.1.4 It was agreed that DF follow this up with Mr Hanna to request a response, but to advise that the application will be withdrawn in 3 weeks if no response. *Post meeting note: Mr Hanna nominated a colleague, Mr Nakade, to respond on behalf of the CSU. Time limit for response therefore to be extended.*	**DF**
6.2	**Talc in a 3g pressurized spray** 6.2.1 SA presented the request on behalf of the respiratory services clinical team making the formulary application. The request is to use a 3g ready-prepared aerosol spray, rather than the 5g of sterilised talc powder previously used at MKHFT for pleurodesis. 6.2.2 No published evidence of clinical equivalence between the powder and the pressurized spray had been located through the search by Medicines Information. In addition, it was not clear from the application form why the application is for 75 patients per year, but pharmacy issue records show approximately 20 patients had been treated in the previous year with the talc powder. 6.2.3 MB advised that work for thorascopic pleurodesis has been 'repatriated' from another hospital, and the MKPAG members requested that the applicant be asked to	

		ACTION
	clarify whether the new product and additional £10,000 per year cost was associated with additional activity. SA to contact the Divisional accountant to clarify the position for this service development. 6.2.4 *Post meeting note: The Registrar who prepared the application on behalf of the team undertaking the procedures advised that the changes to a thorascopic procedure cannot be carried out using the sterile powdered formulation of talc.* **Recommendation:** For hospital supply only for thorascopic pleurodesis. **Action:** • To be added to the hospital formulary as soon as confirmation is received from the Medicines Division that use is as advised to MKPAG and that the numbers of patients indicated on the MKPAG form (75pts pa) is consistent with those in the business case submitted to MKHFT. • To continue in the interim to supply as a non-formulary (NFD).	**SA** **FK** **NB***
7.	**Implementation of medicines subject to a positive recommendation in NICE Technology Appraisals Guidance (TAGs)**	
7.1	**NICE TA261: Rivaroxaban for the treatment of DVT and prevention of recurrent VTE** 7.1.1 SA noted that both consultants making the application were unable to attend the meeting due to other duties and that there were some complex issues relating to the application that needed to be resolved. It was therefore suggested and agreed that these points would be addressed with the clinicians by pharmacy outside of the MKPAG meetings. Noted that the initial request for this treatment was suggested to simplify treatment for patients for whom frequent trips to hospital to manage dosing with Low Molecular Weight Heparin (LMWH) and warfarin against the INR target may be difficult e.g. those with poor mobility. 7.1.2 The drug is already on the formulary, as it has been given a positive NICE recommendation "as an option" for this indication. Noted the following still needs to be addressed: • Before GPs are asked to take on prescribing it is necessary for the specialists to clarify the target patient group and pathway/criteria for patient selection. • Noted that the Newer Oral Anticoagulants ("NOACs") such as rivaroxaban, dabigatran and apixaban are about £700 a year more expensive than warfarin (even when the cost of testing INR is allowed for). • However, if used in patients for whom long-term Low Molecular Weight Heparin (LMWH) would be the only clinically appropriate treatment, the cost is similar to that for LMWH. • If rivaroxaban were used in the early phase in place of LMWH before switching to warfarin may be difficult to implement as patients would not perhaps want to be switched subsequently to warfarin, as it a drug that needs regular blood test. • Noted, there is no simple method to reverse over-coagulation with NOACs and hospital admission related to their use had already been reported at MKHFT. 7.1.3 DF noted that the application indicated 500 patients who may meet the criteria for	**DF**

		ACTION
	this drug in this indication, whereas the NICE TAG Costing Statement indicates about 150 patients for the MKHFT catchment area. • DF was requested to find out from Drs Medhi and White what the reason may be for this apparently substantial difference. • It was considered acceptable for this matter to be followed up by pharmacy and criteria for starting and stopping be agreed then shared with the GP prescribing group. • The applicants would be advised that it was not appropriate to request GPs to prescribe rivaroxaban for this indication until these matters are resolved. 7.1.4 SA noted that NICE recommended this as an option for this indication, but that 110 patients with a previous VTE would have to be treated to avoid 1 symptomatic VTE event, when using rivaroxaban compared with LMWH followed by warfarin (2.1% vs 3% risk – see NICE TAG and cited clinical trials). 7.1.5 Noted that a number of patients are on long term treatment, but all the clinical trials were for a maximum of 12 months, after which efficacy vs warfarin is unproven. 7.1.6 Noted that the CSUs have yet to sign off the hospital implications of this application. Noted that the CCG will not be able to comment or agree to ongoing GP prescribing until the outstanding issues have been resolved re patient numbers, place in pathway, starting and stopping criteria and target patient group for GP continuation. **Recommendation:** to obtain further information and clarify the starting and stopping criteria and patient selection criteria before requesting GPs to prescribe. **Action**: To discuss with the consultants what might be the source of the variance between their expected patient numbers and the NICE costing template for this indication. • To work with Dr White and the DVT service to ensure that the patient selection criteria for this 'Newer Oral AntiCoagulant (NOAC) treatment are explicit and as unambiguous as is possible. • *Post-meeting note: this has been raised at the MKHFT VTE group meeting and issues explored which will subsequently be discussed in detail with Dr White.*	**DF**
8.	**Recently published NICE Technology Appraisals (TA)**	
	The MKPAG discussed how in future they would wish to see this information presented. Agreed that the agenda will in future show which TAs have been published because the work has been terminated, and for those where a positive recommendation to the NHS has been made, to include with the agenda whether the recommendation was dependent on criteria defining where the intervention was judged cost-effective, and number of MK patients suggested by NICE as meeting the cost-effectiveness/funding criteria, and the anticipated MK cost indicated by NICE for recommended interventions. Agreed that in future only costing templates will be circulated as attached documents with the agenda, as these now include the summary of the recommendation(s), as well as information on how NICE has estimated the cost impact.	**FK/SA** **FK**
8.1	**NICE TA266 Cystic Fibrosis (CF)– mannitol dry powder for inhalation.**	

		ACTION
	Recommended as an option with restrictive conditions on where use is recommended Potential alternatives include hypertonic saline (reviewed and accepted by MK M&TC in 2012) or dornase alpha HOSPITAL SUPPLY ONLY. One patient only pa anticipated for MK. Funded through NHS England "CF year of care tariff". **Action:** Pharmacy to find out and advise MKPAG how CF year of care tariff will be implemented for MK patients and MKHFT; to liaise with specialist nurse and consultant. NICE states: *Who can have mannitol dry powder for inhalation?* *You should be able to have mannitol dry powder for inhalation if you cannot use rhDNase, and other osmotic drugs are inappropriate for you, and your lung function is rapidly getting worse.*	**SA/DM**

8.2	**NICE TA267 Chronic Heart Failure – Ivabradine**
	Recommended as an option with restrictive conditions on where use is recommended, Hospital initiation with on-going GP prescribing.
	CCG to fund GP prescribing; NICE anticipates 23 patients pa for MK at an additional drug cost of about £10,000 pa for each incident round.
	
	Action: Cardiologists to be requested to identify how their current clinical practice compares with this new TA. MKPAG to be advised of cardiologists response.
	
	NICE states:
	Who can have ivabradine?
	• *You should be able to have ivabradine if all of the following apply:*
	  • *You have symptoms of heart failure and your heart isn't contracting properly, but your condition is stable.*
	  • *You have a regular heartbeat of 75 beats per minute or more.*
	  • *You are given ivabradine alongside standard drugs for heart failure, or instead of beta-blockers if you cannot take them.*
	  • *Your left ventricular ejection fraction or LVEF for short (the amount of blood pumped out by the left side of your heart) is below 35%.*
	If you are eligible for ivabradine as above, before starting ivabradine you should first have 4 weeks of treatment with standard drugs for heart failure to see if the right combination and dose of standard drugs alone can treat your symptoms.
	Treatment with ivabradine should be started by a specialist. But after that either a GP with a special interest in heart failure or a heart failure specialist nurse can adjust your dose and monitor your condition.
		FK

8.3	**NICE TA268 Melanoma (stage III or IV) – ipilimumab** Recommended as an option with restrictive conditions on where use is recommended, Hospital only; NHS England to fund; NICE indicates 1 or 2 patients pa for MK area; Patient Access Scheme on price.at full price £75,000 to £150,000 pa for a 10-week course of treatment. **Action:** DM to confirm that this is not MKHFT provision by contacting dermatologists;	**DM**

		ACTION
	NICE states: *Ipilimumab is recommended as an option for treating advanced (unresectable or metastatic) melanoma in people who have received prior therapy, only if the manufacturer provides ipilimumab with the discount agreed in the patient access scheme.*	
8.4	**NICE TA269 Melanoma (BRAF V600 mutation positive unresectable metastatic) – Vemurafenib** Recommended as an option with restrictive conditions on where use is recommended, Hospital only; NHS England to fund; NICE indicates 2 patients pa for MK area; Patient Access Scheme on price.at full price £100,000 pa for the two patients. **Action:** DM to confirm that this is not MKHFT provision by contacting dermatologists NICE states: *Vemurafenib is recommended as an option for treating BRAF V600 mutation-positive unresectable or metastatic melanoma only if the manufacturer provides vemurafenib with the discount agreed in the patient access scheme.*	**DM**
8.5	**NICE TA270 Leukaemia (acute myeloid) – decitabine** **TERMINATED APPRAISAL** Not recommended for NHS funding. No evidence submission was received from the manufacturer of the technology and therefore this drug would not be eligible for funding through the Cancer Drugs Fund (CDF). **Action:** Pharmacy cancer team to note the TA and the position in relation to the CDF.	**DM/TO***
8.6	**NICE TA271 Diabetic Macular Oedema – fluocinolone acetonide intravitreal implants** Not recommended for NHS funding; not cost effective. **Action:** NOT for addition to the formulary. To confirm this position with Ophthalmologists	**FK**
8.7	**NICE TA272 Urothelial tract carcinoma (transitional cell, advanced, metastatic)** Not recommended for NHS funding; not cost effective. **Action:** NOT for addition to the formulary. Confirm this cancer is not managed at MKHFT	**FK/DM**
8.8	**NICE TA273 Hyperplasia (benign prostatic) - tadalafil** **TERMINATED APPRAISAL** Not recommended for NHS funding. No evidence submission was received from the manufacturer of the technology **Action:** To confirm this position with Urologists To add this information to ScriptSwitch	**FK** **JC**
8.9	**NICE TA274 Macular Oedema (diabetic) – ranibizumab (*Updated 16 April 2013)*** Recommended as a possible treatment for some people with DMO, with restrictive conditions on where use is recommended. Hospital only; CCGs to fund; NICE indicates around 50 patients for MKCCG of whom about 40 are expected to opt for treatment in one or both eyes, including a prevalent pool of patients which means that costs will be higher in the first three years of use, reducing to a steady-state after four years; Patient Access Scheme on price. NICE estimates about £464,000 for MK CCG population in first 12 months of implementation, reducing by year 4 to about £90,000 pa. (see final page for more detail)	

		ACTION
	Action: Ranibizumab (Lucentis) is already on the formulary for use to treat Wet Age-Related Macular Degeneration (ARMD) in patients who meet NICE criteria for initiation and stopping. • To continue discussion with ophthalmology team, to ensure that all patients treated with ranibizumab for DMO can be shown to meet the inclusion and stopping criteria. Implementation arrangements should be in place by 1st June 2013. • CCG to make provision for funding of patients treated in line with NICE criteria. • Hospital budget predictions for use of ranibizumab to be amended; to be tracked separately from ranibizumab use for ARMD NICE states: *Ranibizumab is recommended as an option for treating visual impairment due to diabetic macular oedema only if:* • *the eye has a central retinal thickness of 400 micrometres or more at the start of treatment* ***and*** • *the manufacturer provides ranibizumab with the discount agreed in the patient access scheme revised in the context of this appraisal* *and* *The summary of product characteristics states that treatment should be given monthly and continued until maximum visual acuity is reached – that is, until visual acuity has been stable for 3 consecutive months. Thereafter, visual acuity should be monitored monthly. Treatment is resumed if monitoring indicates a loss of visual acuity caused by diabetic macular oedema, and continued until visual acuity has remained stable for 3 consecutive months. The interval between doses should not be shorter than 1 month.* *Contraindications to ranibizumab include known hypersensitivity to the active substance or to any of its excipients, active or suspected ocular or periocular infections and active severe intraocular inflammation.* *Adverse reactions of treatment are mostly limited to the eye. Those commonly reported in clinical trials include vitritis, vitreous detachment, retinal haemorrhage, visual disturbance, eye pain, vitreous floaters, conjunctival haemorrhage, eye irritation, sensation of a foreign body in the eye, increased production of tears, blepharitis, dry eye, ocular hyperaemia, itching of the eye and increased intraocular pressure. Nasopharyngitis, arthralgia and headaches are also reported as common adverse reactions.* *For full details of adverse reactions and contraindications, see the summary of product characteristics.*	**SA/DM** **JC** **SA/ADP***
8.10	**NICE TA275 Stroke and Systemic embolism (prevention, non-valvular atrial fibrillation) – apixaban** Recommended as an alternative for this indication to warfarin, dabigatran or rivaroxaban. Not cheaper than other newer oral anticoagulants (dabigatran and rivaroxaban) "NOACs" Substantially more expensive than warfarin (about an extra £700 pa per patient even after testing costs have been factored in). **Action**: Place in therapy to meet CCG policy on use of NOACs, targeting only where warfarin cannot be used.	**DU/FK**

		ACTION
8.11	**NICE TA276 Colistimethate sodium and tobramycin dry powders for inhalation for treating pseudomonas lung infection in Cystic Fibrosis.** Recommended as an option with restrictive conditions on where use is recommended, Hospital only; NHS England to fund through CF "Year of Care" tariff **Action:** To be added to the formulary, marked for restricted use only To confirm with CF nurse specialist and consultant the arrangements for funding of CF at MKHFT and therefore how this PbR-excluded drug needs to be charged to commissioners. NICE states: *Tobramycin dry powder for inhalation (DPI) is recommended as an option for treating chronic pulmonary infection caused by Pseudomonas aeruginosa in people with cystic fibrosis only if:* • *nebulised tobramycin is considered an appropriate treatment, that is, when colistimethate sodium is contraindicated, is not tolerated or has not produced an adequate clinical response* ***and*** • *the manufacturer provides tobramycin DPI with the discount agreed as part of the patient access scheme to primary, secondary and tertiary care in the NHS.* *Colistimethate sodium DPI is recommended as an option for treating chronic pulmonary infection caused by P. aeruginosa in people with cystic fibrosis only if:* • *they would clinically benefit from continued colistimethate sodium but do not tolerate it in its nebulised form and thus tobramycin therapy would otherwise be considered* ***and*** • *the manufacturer provides colistimethate sodium DPI with the discount agreed as part of the patient access scheme to primary, secondary and tertiary care in the NHS.* *NOTE FOR IMPLEMENTATION Issued March 2013: NICE has been made aware that colistimethate sodium dry powder for inhalation is not available at the time of publication of this guidance. We are investigating the consequences for the funding direction for this part of the guidance. The guidance and implementation requirements for tobramycin dry powder for inhalation stand as indicated in section 5 of the document.*	**FK** **DM/SA**
8.12	**NICE TA277 Methylnaltrexone for treating opioid-induced bowel dysfunction in people with advanced illness receiving palliative care.** **TERMINATED APPRAISAL** Not recommended for NHS funding. No evidence submission was received from the manufacturer of the technology **Action:** • To confirm this position with palliative care and pain specialists • To add this information to ScriptSwitch	**FK** **JC**
9.	**Audit & follow up of previous formulary recommendations**	
	SA advised that this section had been added to the agenda to ensure that where products were included in the formulary for limited indications, or recommendations made that related to specific service redesign plans, applicants may be requested to provide further information for MKPAG at a later date, to review practice against proposed/anticipated outcomes.	

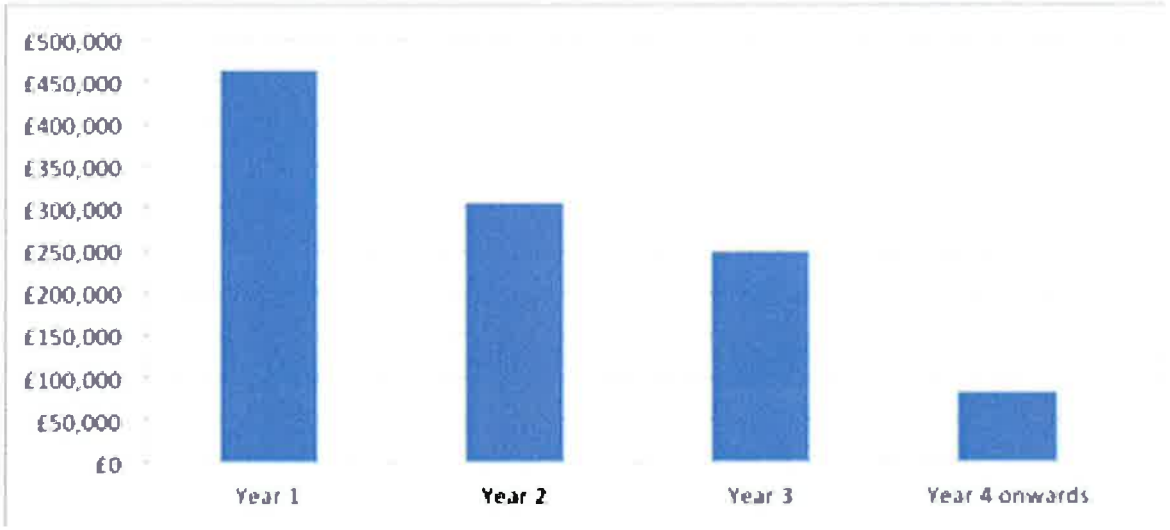
		ACTION
	MKPAG could use that information to continuously improve its decision-making processes, recommendations and interactions with both applicants and funders. It was anticipated that, particularly where the costs of treatment were increased through a formulary application, information would be sought to confirm whether the anticipated changes elsewhere in the system were realised as expected e.g. simpler patient pathways or less expensive procedures or staff time released.	
9.1	**Ferric Carboxymaltose (Ferinject)** Ferinject had been reviewed by MK M&TC in April and June 2012 when submitted by the Medical Division (planned care unit physicians) as a means to shorten the time required for iron infusions. At that time the additional cost of Ferinject, compared with the formulary IV iron products (Venofer and Cosmofer) was estimated to be around £42,000 pa. The saving on nursing time was also calculated and judged to be a similar value, although it had not been stated for M&TC whether the Division anticipated that they would reduce the nursing establishment as a result. Ferinject was not supported by M&TC and was not added to the formulary. http://www.formularymk.nhs.uk/91-Anaemias-and-some-other-blood-disorders/ Subsequently the Division made arrangements to use Ferinject in their Planned Care Unit, to support clinical service redesign, and releasing nursing staff time to take on additional activity. • This was discussed with the Divisional Clinical Director by the Divisional pharmacist and chief pharmacist in February 2013 and a positive report on the impact of a period of use of Ferinject on work-flow was received. **Action:** • However, as this product is still not on the formulary, the Division of Medicine should be asked to confirm formally whether, in the light of their experience of cost and workflow, they wish to have Ferinject added to the formulary and whether they require any specific criteria or limitations to be included in the formulary entry e.g. for use on Planned Care Unit only. • This can then be reported to the next meeting of MKPAG and appropriate action taken on formulary status.	**FK** **FK**
10.	**Chairman's action for information & oversight**	
	SA explained that Chairman's action facility for MKPAG will only be used to expedite relatively simple decisions where there is an urgent need for a decision and good evidence of efficacy and the budget impact is clearly accepted by the persons directly affected. All Chairman's actions should normally be subject to review by the full MKPAG, including the completed application with notes added on action taken, to ensure that all decisions are tested and decisions are consistent with MKPAG processes for local decision making.	**SA** **FK**
10.1	**Nitrofurantoin MR (Macrobid)** A formulary application for the addition of modified release nitrofurantoin was received from MKCCG and MKCHS. The rationale for its inclusion in the formulary was to save time for carers/nurses visiting patients at home and in care home settings. There was no	

		ACTION
	indication that the modified release, twice-daily preparation was deemed to be any more or less effective as an antibacterial agent. A copy of this application and the subsequent correspondence is available to MKPAG members if required from MKPAG secretariat. • It was requested that this be expedited to enable its inclusion in the primary care antibiotics formulary that was about to be published after review by the MK GP Prescribing group. • Discussion of this proposal, prior to Chairman's action to sign off this change, involved community and hospital specialist antimicrobials pharmacists. Through this it was established that the proposed gains would be appropriate to support community use, but not routine hospital use, of this product. **Action:** Nitrofurantoin MR was added to the formulary for community use. http://www.formularymk.nhs.uk/5113-Urinary-tract-infections/ *Nitrofurantoin* *Tablets 50mg, 100mg* *Oral Suspension 25mg/5ml* *MR Capsules 100mg (restricted to use in primary care where compliance with four times a day dosage schedule is in doubt)*	
10.2	**Intranasal Diamorphine** A formulary application is being prepared for the use of a metered-dose preparation of diamorphine for intra-nasal use in MKH Emergency Department (ED) for children with severe pain and a defined range of injuries. The clinicians in the ED have indicated that they believe early adoption of this intervention would be advantageous, both for the patients and for the workflow through the department. A newly-licensed preparation is about to become available, to take the place of injectable morphine or (slower acting) morphine oral solutions. This information had been brought to the April MKPAG to gather views from members, to inform the final stages of the development of the formulary application by the MKHFT ED specialists and if appropriate, prompt adoption of this preparation into clinical practice in this limited and defined patient group. The full application would be brought to MKPAG at a subsequent meeting to advise them of the full case and actions taken by the Chairman.	**SA**
11.	**Antimicrobials**	
11.1	**Antimicrobial Stewardship Group (AMSG)** Approved minutes of the December 2012 group meeting were circulated with the MKPAG agenda. LR explained that the minutes of a later AMSG meeting will be agreed at their next meeting. Noted that the antimicrobial stewardship group is making efforts to include the community in its discussions and decisions. LR will provide an update after the next AMSG meeting SA advised MKPAG that to cover the maternity leave of one of the hospital part-time antimicrobial pharmacists, MKHFT pharmacy have seconded two pharmacists from their existing duties to cover this in an 'acting-up' capacity and so provide additional support for	**LR**

		ACTION
	activities in the hospital around antimicrobial stewardship. • Noted that given the importance of this work to both patient safety and financial balance pharmacy has made this a priority. • The three MKHFT pharmacists now working on this have an agreed and coordinated programme of work that should mean that the hospital antibiotics formulary, audits of prescribing of antimicrobials, policy on the use of antifungals and IV to oral switches can all be given effective support, working in partnership with the microbiologists. • Further information on the work of the specialist antimicrobials pharmacist team is available on request.	
11.2	**Empirical Guidance for antibiotic prescribing for adults in primary care** MKPAG were advised that this guidance has recently been updated and signed-off by the MK GP prescribing group. SA noted that the specialist antimicrobials pharmacist in MKCHS has highlighted the changes and the new guidance had been circulated to GP practices and prescribers once the formulary variation for Nitrofurantoin was agreed through MKPAG Chairman's action. This updated primary care guidance is available on-line. *Post meeting notes:* *1. Antibiotics are one of the most common therapeutic areas where inappropriate requests are made to GPs for them to prescribe.* *Consultants and other hospital prescribers will be reminded that the NHS contract requires that where a treatment is needed for a clinically urgent reason then the hospital is required to make a supply. In this situation "clinically urgent" is to be taken to mean that it is judged that treatment needs to start in 5 days or less after a hospital visit to the Emergency Department or out-patient clinic or ambulatory care service.* *2. Supply of Fosfomycin for resistant bacteria in UTIs is being arranged to reduce the need for IV antibiotics in these cases. Further information will follow.* *3. Noted that Doxycycline is a first-line option for both hospital and primary care use for patients with an exacerbation of COPD. This will help in the preparation of information for both hospital/CHS and GP practice clinicians and patients dealing with this.*	**SA** **WM/JC** **SA**
12.	**Date of next meeting** **Wednesday 29th May 2013. 12.45pm to 2pm. Please note DATE as incorrect information was included on the meeting April agenda.** **Venue: Eaglestone Restaurant Function Room** Agenda items to be submitted no later than Wednesday 15th May. Applications for new drugs to be submitted ASAP in all cases. • **Members who notify by Tuesday 22nd May their attendance at MKPAG will be sent a hard copy of papers** • **All other members and corresponding members will receive papers by email.**	**ALL**

Ref 8.9 Ranibizumab for DMO – NICE, MKCCG estimated costs

Prevalent population eligible for ranibizumab	52
Estimated uptake	75%
Population anticipated to receive ranibizumab	39
VAT rate	20%



MKCCG Ranibizumab in DMO costs

Appendix 1
Other persons marked as having a role in implementing MKPAG decisions

5.1	DU*	Dona Unmole, Directorate Pharmacist, representing Medicine CSU	Levetiracetam Shared Care Guidance
5.2	WM*	Wasima Maroof, Directorate Pharmacist – Antimicrobials	Tazobactam and Piperacillin – OPAT bolus injections
6.2	NB*	Nick Beason, Senior Pharmacy Technician, Homecare and Procurement	Talc Spray NFD supply
8.5	TO*	Toks Ogunbanjo, Principal Pharmacist Aseptic and Cancer Services	Decitabine and CDF

Appendix 2
Flow chart (Excel) of the MKPAG process for medicines review and formulary consideration

Appendix 3
Updated MKPAG formulary application form - Version 3.2

Proposed Process for Clinical Engagement by MK Prescribing Advisory Group

NOTE 1 HORIZON SCANNING AND FORMULARY MANAGEMENT: Pharmacy MKHFT is responsible for horizon scanning e.g. NICE, clinical trials, UKMi and Prescribing Outlook and for ensuring that the MK joint formulary remains up to date. The formulary leads for MKCCG, MKCHS and MKHFT will each ensure there are discussions with the clinicians in their areas when there may be new drugs, or new uses for drugs, to be considered for addition to the formulary, including drugs for restricted use.

NOTE 2 DRUGS TO BE PRESCRIBED BY GPs: All drugs for which, if approved, the majority of the costs would fall on primary care (GPs) or MKCCG must be submitted for consideration by the MK GP Prescribing Group.

NOTE 3 DRUGS EXCLUDED FROM PbR TARIFFS: If a drug is on the list of those excluded from the Payment by Results tariff, then use can be considered through MK PAG but cannot normally be approved or used unless and until the protocols for its use and funding at MKHFT are agreed with the relevant commissioners and the MKHFT contract team (to ensure we receive the necessary income). Pharmacy will advise clinicians on the actions to be taken and will support the discussions with the commissioners.