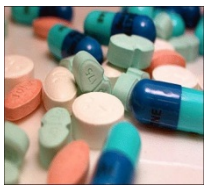
GMMMG Greater Manchester Medicines Management Group NHS

FORMULARY AND MANAGED ENTRY SUBGROUP



Minutes of the meeting held on
Tuesday 26th February 2019
12:30 - 2:30 pm
Pharmacy Dept MFT-ORC (formerly known as CMFT)

Present:

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov
Elizabeth Arkell (EA)	Medicines Management Lead	MFT-WH	✓	A									
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	✓	✓									
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A (LB)	✓									
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	✓	✓									
Aoidin Cooke (AC)	Medicines Management and Medicines Information Pharmacist	MFT-ORC	✓	A (LH)									
Claire Foster (CF)	Senior Medicines Optimisation Advisor	MHCC	✓	✓									
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	A (AH)	A									
Rachel Macdonald (RM)	Pharmacist	Community pharmacy	A	✓									
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	A	✓									
Prof Peter Selby (PS)	Consultant Physician	MFT-ORC	✓	✓									
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓									
Dr Hina Siddiqi (HS)	GP		✓	A									

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov
Lindsay Harper (LH)	Director of Pharmacy	SRFT	A	A									
Jonathan Peacock (JP)	Chief Pharmacist	T+G	A	A									
Zoe Trumper (ZT)	Medicines Management	Pharmacist Wigan Borough CCG	✓	✓									
Jonathan Schofield (JS)	Consultant Physician	MFT-ORC	✓	✓									
Faisal Bokhari (FB)	Deputy Head Medicines Optimisation	T&G CCG	✓	✓									
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓									
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	A	A									
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC	✓	✓									

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above.

Liz Bailey acted as chair until item 1.4.5 when PB resumed as chair.

PS left after item 3.2 due to clinical commitments.

1.2 Declarations of Interest:

No new declarations of interest were received in advance or made at the meeting.

1.3 Draft minutes- January 2019

The minutes were agreed as an accurate record.

1.4 Matters Arising

1.4.1 Consultation feedback:

Items from the January meeting were out for consultation; closing 19th March. Consultation comments received on actions from the November meeting were discussed.

Cannabis-derived, cannabis-based, and hemp products

At the November meeting, FMESG made the following recommendation:

All cannabis-derived, cannabis-based, and hemp products DNP (criterion 1) with the following exceptions:

- Nabilone, when used within its marketing authorisation; RED and GREY (criterion 3)

- Epidiolex (cannabidiol isolated in pure form from cannabis), for children and adults with rare, severe forms of drug-resistant epilepsy; RED and GREY (criterion 1)

The group acknowledged that consultation comments received were supportive of the proposed positioning of these products within GMMMG. It was noted that there had been some concerns that the dual 'RED' and 'GREY' status of nabilone and Epidiolex® may cause confusion in primary care. However the group agreed that the principles of the RAG and DNP/GREY list were well established across GM and decided to proceed with the recommendation as it stands.

Action: This recommendation was agreed in principle at February CSB pending closure of the consultation. RDTC to update formulary and RAG list accordingly

Doxylamine/pyridoxine for N+V in pregnancy

The evidence for doxylamine/pyridoxine for nausea and vomiting in pregnancy was first considered by the group at the September 2018 meeting. At that time, the group felt that there was an insufficient evidence base to support its use over options for which there is extensive clinical experience, and which are recommended in professional guidelines. The group recognised use of existing options was often 'off-label', but felt that guidance from RCOG and the UK Teratology Information Service (UKTIS) was sufficient to place use of these established treatments ahead of Xonvea® in the treatment pathway. It was recommended that Xonvea® be added to the DNP list, as criterion 1 (products which are clinically effective but, due to the nature of the product, are deemed a low priority for NHS funding) and this recommendation opened for GM-wide consultation.

In acknowledgment of a low level of response from primary care with the initial consultation, a decision was made to re-open the consultation in January 2019 with CCG leads actively seeking engagement from primary care practitioners. Comments from this second round of consultation were considered by the group at February's meeting.

The group noted the majority were in favour of DNP status based on extensive clinical experience with the existing options recommended in clinical guidance, uncertainty of the position of Xonvea® within the treatment pathway, and reluctance to prescribe until included in national guidance. An overall low appetite to prescribe this drug in primary care was evident. However, FMESG also discussed concerns that a DNP status may be viewed as opposing GMC guidance on prescribing licensed products ahead of off-label options. The group heard that RCOG had corresponded with the RDTC to confirm that the Green-top Guide on nausea and vomiting would be partially updated to reflect the availability of Xonvea®, however had declined to provide a date for when the update would be published. Additionally, an expected publishing date for guidance from RMOC was noted to be pending.

In light of the issues discussed, FMESG recommended that a holding GREY list position (criterion 1) would be appropriate, with a view to revisit once guidance from RCOG, NICE, and/ or RMOC has been published.

Action: FMESG recommend Xonvea® to be assigned GREY list position*: to be used only when the other preparations currently recommended in RCOG guidance have been tried and have failed.* This is based on Criterion 1: there is a lack of robust evidence of effectiveness, and will be reviewed once guidance from RCOG, NICE and/or RMOC is available. Support from CSB to be sought (April's meeting).

As no comments were received opposing the other actions from January's meeting, the group recommended that these actions be actioned, as they had been agreed in principle at February's CSB.

Action:

- Sodium hyalonurate bladder instillations- RAG list to be updated to reflect generic product name.

- Insulin glargine biosimilars- Semglee® to be added to formulary as a first-line option alongside Abasaglar®. Cost chart for insulin analogues to also be added to chapter 6.
- Adalimumab- all adalimumab listings be updated to reflect that the first choice product is Amgevita® .
- Imiquimod (Aldara®)- to be assigned GREEN (specialist initiation) positioning for superficial basal cell carcinomas.
- Anthelios XL SPF®- to replace Uvistat® on formulary on basis of being fragrance and paraben free.
- Terbutaline injection- to be assigned RED positioning in line with RAG status of salbutamol injection.

1.4.2 Dental letter/ POM mouth care

FMESG were asked to revisit the previous recommendation on POM toothpastes and mouthwashes: *only dentists should prescribe such products due to the risks of patients developing fluorosis*. Comments had been received via CCG leads from Dr Craig Barclay, Consultant Restorative Dentistry/Honorary Professor in Maxillofacial Rehabilitation, requesting that this positioning be reconsidered. Dr Barclay had expressed concern that the GMMMG positioning was contrary to national guidance for patients with head and neck cancer that had received radiotherapy and that a lack of mechanism by which dentists could provide repeat prescriptions would prevent appropriate treatment of these patients on an ongoing basis.

The issue had also been raised at the CCG Lead team meeting, with the team witnessing a number of requests out to GPs for patients with oral cancers where the secondary care team hadn't initiated the prescribing, and there was no strength specified on the prescription. It was felt that further discussions were needed to ensure that the GM position adequately reflected the needs of this population of patients.

FMESG noted that there was a different clinical need in this population who may suffer permanent reduction in saliva production as a result of radiotherapy. The Royal College of Surgeons of England / The British Society for Disability and Oral Health Clinical Guidelines on The Oral Management of Oncology Patients Requiring Radiotherapy, Chemotherapy and/ or Bone Marrow Transplantation (2018) states as a Key Recommendation: '*Those patients receiving radiotherapy to the head and neck region, or total body irradiation prior to bone marrow transplantation are at higher risk of dental caries and should receive dietary advice and fluoride preparations appropriate to their age.'*

The group acknowledged that although some work had been undertaken towards development of PGDs to allow dentists to provide repeat prescriptions for these items, this issue had not yet been solved. It was agreed that the population requiring prescription of these items should be clearly defined and a criteria for use established to ensure appropriate GM positioning. The criteria should address duration of treatment in this group/ review of ongoing therapy, and the strength of product to be prescribed.

Action: RDTC to contact Dr Barclay to establish prescribing criteria for these products in patients following radiotherapy for head and neck cancers. GM positioning to be clarified accordingly and corresponding letter issued to GPs and dental services across GM.

1.4.3 DVLA Blood Glucose Monitoring guidance

A newly issued DVLA guideline on blood glucose testing requirements for drivers with diabetes was noted by the group. The update now allows drivers to use flash and continuous glucose monitoring devices to take glucose readings before/ during breaks in driving. There was no change in recommendation related to the frequency of testing and drivers must still confirm their blood glucose levels with finger prick testing if their blood glucose is ≤4mmol/L, experiencing symptoms of hypoglycaemia, or the glucose monitoring system gives a reading that is not consistent with the symptoms they are experiencing (i.e. presence of symptoms of hypoglycaemia that is not reflected by the reading). Those who drive for a living must still use finger prick testing.

The group acknowledged that the change in guidance may reduce use of test strips for some patients, but not the current eligibility criteria for patients to receive flash glucose monitoring devices. The group agreed that there was no need to change the GM positioning as a result of this update, however it was noted that new guidance was expected from NHSE on April 1st on the eligibility criteria and access to these devices so would be re-discussed at April's meeting.

1.4.4 Action log

Updates on the action log were noted. This included addition of the GMMMG Wound Care Formulary review - scoping for which was submitted to February CSB who supported progression of this as part of the FMESG work plan. The nominated lead for the work is Stephen Woods who will liaise with FMESG as the update work progresses.

1.4.5 Monitoring log

A new monitoring log was noted by the group, including a schedule for when draft assurance papers should be brought to future meetings. The group agreed that this should be reviewed and updated more fully once the CSB work plan was finalised.

2.0 Medicines Optimisation

2.1 GMMMG Antimicrobial Guideline- Feb 19 update

An updated draft of the GMMMG Antimicrobial Guidelines was reviewed by the group, following its quarterly update by the GM Antimicrobial Task and Finish Group. FMESG noted the adoption of new NICE Guidelines within the document, and a number of associated amendments within the document. The group heard concerns regarding the inclusion of nitrofurantoin as a treatment option for lower UTI in children as there are high costs associated with procurement of the oral suspension (£446.95, BNF 2019) and a high level of wastage of remaining suspension following completion of the course. It was questioned whether cefalexin had been considered as an alternative instead. Additionally it was noted that a specialist antimicrobial pharmacist had voiced concern regarding the change from nitrofurantoin to trimethoprim for LUTI in men. Whilst it was assumed that this reflected a strategy to avoid overuse of fluoroquinolones, there was an additional concern that this would drive up trimethoprim resistance which was another growing concern. It was questioned whether the reasoning behind this choice could be documented within the summary of changes section.

Action: RDTC to feedback these comments to Stephen Woods for consideration by the task and finish group, prior to uploading an amended version.

2.2 Update on GMMMG OTC Policy (verbal)

LB provided a summary on the progress of this work across GM. The group heard that an interim report to GMMMG had been presented at February's CSB and work was progressing to open local consultations within CCGs in April with an aim for 'soft launch' of the policy across GM in June. Further work was ongoing to take in to consideration support of socially vulnerable groups and exceptions from the policy. It is planned that the GM Minor Ailments Scheme will be reviewed soon after implementation. FMESG will continue to be updated as this work progresses.

2.3 Liothyronine- GMMMG Positioning

At the November 2018 meeting of FMESG, the group considered newly issued Guidance – prescribing of liothyronine published by RMOC. At that time FMESG agreed that the current GMMMG positioning was largely in line with recommendations from RMOC, and that no actions were required. However, the group were asked to reconsider this item at February's meeting- in particular alignment with the RMOC recommendation: 'In most circumstances, the primary care prescribing of liothyronine (T3) is not supported for any patient.'

The group noted some aspects of the GMMMG positioning that could be clarified to better align with the RMOC recommendations including consideration of assigning AMBER for shared care, more firm recommendations on the transfer of prescribing responsibility, and re-wording of the current GREY listing to define 'exceptional circumstances' more clearly. FMESG also heard that there may local variance in adherence to GMMMG positioning and that further clarification of the DNP listing may be warranted, in line with terminology used in the RMOC guidance.

The group felt that that development of a shared care protocol was not necessary at this time in light of liothyronine possessing the same monitoring requirements as levothyroxine and that work by RMOC on national shared care protocols may address this in time. It was agreed that the current GREY listing should be expanded to clarify restrictions to prescribing, in line with RMOC and BTA guidelines. The wording of the current DNP listing to be clarified similarly.

Action: GREY listing statement for liothyronine to be updated as follows: 'where levothyroxine has failed, endocrinologists treating patients under the NHS may recommend liothyronine in exceptional circumstances for individual patients and after a carefully audited trial of at least 3 months duration, in line with BTA guidance. DNP listing statement to be updated as follows: Liothyronine combination products and unlicensed thyroid extract products (including Armour Thyroid and ERFA Thyroid) are DNP (criterion 2).

3.0 FMESG Work Plan 2019

The group acknowledged that the CSB work plan for the 2019 was pending and would be considered by the group when available.

3.1 Consideration of items for FMESG work plan

The group considered potential items to be added to the work plan and decided to proceed with the items as follows:

- *Vardenafil for ED: proposed review of RAG status to align positioning with other PDE5 inhibitors.* The group agreed that the current RAG listing of 'RED for severe distress caused by impotence' was not consistent with the positioning of other agents in this class, not in line with clinical guidelines, and was too restrictive. Given the higher cost of this agent versus the current formulary options (sildenafil and tadalafil) which are GREEN for ED, FMESG agreed that vardenafil should not be considered for formulary inclusion and should be removed from the RAG list.
- *Ciclosporin 0.1% eye drops emulsion (Verkazia®) for vernal keratoconjunctivitis/ severe allergic eye disease in 4 to 18 years of age: formulary application.* The group noted that a formulary application had been received for this item with a request to position as GREEN following specialist initiation on the PAED RAG list. The group requested that this item come back as a full agenda item at March meeting.

Actions: vardenafil to be removed from RAG list. Application for Verkazia® to be added to the action log to come to March meeting as a full item.

4.0 Formulary and RAG

4.1 Formulary amendments February 2019

The suggested formulary amendments for February 2019 were noted and approved by the group. Additionally, the group recommended that listings for levomenthol in aqueous cream be updated to state 'Choose product with lowest acquisition cost. Prescribe by brand name.'

Action: RDTC to open these decisions for GM-wide consultation.

The group additionally noted discontinuation of aciclovir eye ointment (no RAG) with stock anticipated to be available until June 2019, subject to demand. The first line alternative is ganciclovir 0.15% eye gel which is currently positioned GREEN (following specialist initiation). A proposal to update the RAG status to GREEN to minimise additional referrals to ophthalmology as a result of the discontinuation of the aciclovir product was considered. The group felt that ocular

herpes should be managed by eye specialists and thus the RAG positioning should remain unchanged.

A query related to the RAG listing for naloxegol for treating opioid induced constipation- GREEN (following specialist advice) was also discussed. It was acknowledged that there is no stipulation made in NICE TA345 that initiation must be on the advice of a specialist, and thus GM positioning may be viewed as more restrictive than NICE. The group felt that opioid induced constipation was a multifactorial condition for which specialist input was appropriate and that the current positioning should stand.

4.2 DNP Assessment: Actipatch® for the management of localised MSK pain

Actipatch® was scoped for consideration of addition to FMESG's work plan at January's meeting. The group noted that there had been some prescribing of Actipatch® across GM since it's addition to the Drug Tariff in May 2018 (46 items totalling £600 between May to Oct). RDTC were asked to prepare a DNP Assessment tool to bring to February's meeting**.**

At February's meeting, the group considered a summary of evidence and agreed that the place in therapy for this device was unclear due to an absence of robust evidence and uncertainty surrounding the clinical importance of unpublished trial findings. It had not been incorporated into any relevant clinical guideline to-date. It was noted that patients could purchase this device over the counter or online if they wished. FMESG concluded that there was inadequate evidence to recommend Actipatch® be considered as an alternative option to conventional analgesics and recommended it for DNP (criterion 1).

Action: this recommendation to be opened for GM-wide consultation.

4.3 DNP Assessment: Fortacin® for the treatment of premature ejaculation in adult men

At January's meeting of FMESG, the group noted the release of a new licensed topical preparation for the treatment of PE. RDTC were asked to bring back a DNP tool to be considered at February's meeting. The only other licensed prescription-only product to treat PE in the UK is dapoxetine; this was assessed by FMESG in October and added to the DNP list following GM-wide consultation.

At February's meeting the group considered a summary of evidence for Fortacin® and other topical local anaesthetics for PE (including off-label use of EMLA® cream). The group acknowledged that the clinical importance of the primary outcomes for Fortacin® is not clear, and there are potential for adverse effects for men, and their partners. It was also agreed that there was not sufficient evidence to support use of other topical local anaesthetic preparations for this indication, including the off-label use of EMLA cream, and lidocaine 9.6% w/w spray (licensed 'P' medicine). Although associated with personal distress and interpersonal difficulty, PE is primarily a symptomatic disorder with no known clinical sequelae or complications and was not felt to be a high priority for NHS funding by the group. FMESG agreed that licensed and off-label topical anaesthetics for management of premature ejaculation be made DNP (criterion 1).

Action: this recommendation to be opened for GM-wide consultation.

4.4 DNP Assessment: VSL#3® and Vivomixx® for maintenance of ileo-anal pouchitis

The probiotics VSL#3® and Vivomixx® have now been removed from the Drug Tariff by the ACBS on the basis of insufficient evidence of clinical effectiveness. At January's FMESG, the group noted this removal and requested that a DNP tool be submitted to February's meeting.

The ACBS committee had concluded that the original studies on VLS#3® were small and described higher rates of pouchitis in the control groups than would be expected in clinical practice. A Cochrane review felt that there was 'low quality evidence' of benefits. Additionally, the ACBS- along with the MHRA- felt that any product to prevent a clinical condition such as pouchitis would be classed as a medicine and thus should be regulated accordingly. The ACBS also considered NHSE's consultation on conditions for which over the counter items should not be routinely prescribed which recommends that probiotic product should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness.

FMESG also noted that clinical recommendations on the use of VSL#3® were based on only one source (ECCO Guidelines), and highlighted that patient numbers in the original trials were small. Primary care prescribing spend VSL#3® and Vivomixx® products these items totalled £32,706.91 (~500 items) from Dec 17 to Nov 18. FMESG recommend these products are assigned DNP status (criterion 1).

Action: this recommendation to be opened for GM-wide consultation.

4.5 Formulary application: Utrogestan® oral capsules for adjunctive use with oestrogen as HRT

At January's FMESG, the group scoped a formulary application for Utrogestan® oral capsules for adjunctive use with oestrogen as HRT in women with an intact uterus. The group asked that the formulary application be brought in full to February's meeting. A formulary inclusion tool was also provided by RDTC and primary care prescribing data to aid decision making.

The group considered the application and felt comments that micronised progesterone may carry a lower risk of breast cancers versus synthetic progestogens were not backed by robust evidence. There was concern that there may be a disproportionate trend in prescribing Utrogestan® as a result of such statements, when in fact there was no advantage associated with Utrogestan® in this respect. It was acknowledged that individual tolerance of progestogens may vary considerably, thus there may be a place in therapy for Utrogestan® in patients who have unsuccessfully trialled different combination therapies. However the group agreed that the proposed as second-line formulary choice was not reflective of its true place in therapy, which would be further down the treatment pathway (i.e after failure of 2 progestogens). It was also noted that adjuvant use with an oestrogen preparation carried cost implications versus combined preparations, depending on the oestrogen preparation chosen. Thus there was uncertainty around the cost-effectiveness versus current formulary choices. In addition, the group acknowledged comments that had been submitted by Dr Seif, Consultant Gynaecologist St Mary's hospital respect to this application; these were in alignment with general thoughts of the group.

The group agreed that based upon the above facts, and that overall patient numbers requiring this preparation would be low, Utrogestan should not be included in the GM formulary.

Action: Utrogestan® not to be added to formulary. To be added to the monitoring table and reviewed in February 2020, depending on prescribing trends.

4.6 New Drug Evaluation: Pentosan for the treatment of bladder pain syndrome

At January's FMESG, the group recommended that the newly licensed pentosan preparation (Elmiron®) should be added to the work plan for February's meeting.

The group considered the evidence summary for pentosan and noted that the quality of the evidence was limited by the relatively small patient numbers; however this was reflective of the low prevalence of the condition. The absence of other licensed medicines for bladder pain syndrome was highlighted. Use of unlicensed pentosan preparations within GM prior was already established prior to the availability of the licensed product. As there was variance in the products dispensed/ procured, the financial implications of the licensed product would be challenging to establish. The cost for one year's treatment with Elmiron® 100mg TDS is expected to be around £5000 (DM+D 2019) which appears to be significantly more than the off-label use of alternative agents/ therapies.

The group felt that the best course of action would be to contact urology services to clarify pentosan's place in therapy, in order that that GMMMG positioning be appropriate. If this could not be clarified then FMESG would consider a restrictive positioning based on the high cost of the product and limited evidence base associated with the low patient numbers in trial data.

Action: RDTC to contact urologists to establish where pentosan sits in the treatment pathway and discuss at March's meeting.

5.0 Horizon Scanning and work plan

5.1 Monthly horizon scanning documents February 2019

The RDTC monthly horizon scanning document for February was considered by the group. The group recommended no additional action was required at present on the basis of these documents.

5.2 Work plan

It was noted that the GMMMG Work Plan was being updated following February's CSB. An update version would be considered at March's FMESG.

6.0 AOB

No other items were raised.

The next meeting will be held on 26th March 2019, 12.30-2.30pm, MFT-ORC (formerly known as CMFT).