GMMMG Greater Manchester Medicines Management Group NHS

FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 28th August 2018
12:30 - 2:30 pm
Pharmacy Dept. CMFT

Present:

Name	Title	Organisation	Jan	Mar	May	July	Aug	Sept
Elizabeth Arkell (EA)	Medicines Management Lead	UHSM	✓	LA	A	✓	A	
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	✓	✓	✓	A	✓ (RR)	
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A	✓	✓	✓	✓	
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	✓	✓	A	A	✓	
Dr Paul Chadwick (PC)	Consultant Microbiologist and Chair of Meds Management Committee	SRFT	✓	A				
Lorna Hand	Medicines Management and Medicines Information Pharmacist	CMFT	✓	✓	✓	✓	✓	
Claire Foster (CF)	Senior Medicines Optimisation Advisor	SM CCG	✓	✓	✓	✓	✓ (FA)	
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	✓	A	A	A	✓ (AH)	
Rachel Macdonald (RM)	Pharmacist	Community pharmacy	A	A	A	✓	✓ (AI)	
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	✓	✓	A	✓	✓	
Prof Peter Selby (PS)	Consultant Physician	CMFT	✓	A	✓	A	A	
Suzanne Schneider	MI Pharmacist	Bolton FT.	A	✓	✓	A	A	

(SS)								
Dr Hina Siddiqi (HS)	GP	Trafford CCG			✓	A	A	
Lindsay Harper (LH)	Director of Pharmacy	SRFT	✓	A	A	✓	A	
Jonathan Peacock (JP)	Deputy Chief Pharmacist	WWL	✓	✓	✓	A	✓	
Zoe Trumper (ZT)	Medicines Management	Pharmacist Wigan Borough CCG	✓	✓	✓	✓	A	
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓	✓	✓	✓	
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	✓	✓	✓	✓	✓	
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC				✓	✓	

1. General Business

1.0 Apologies

Apologies had been received in advance as noted above.

In attendance: Faduma Abukar (FA) (Senior MO Pharmacist, Manchester CCG), Dr Ann Harrison (AH) (GP and Associate Clinical Director, NHS Trafford CCG), Roger Roberts (RR) (Director for General Practice Development, Stockport CCG), Adam Irvine (AI) (Chief Executive Officer, GM LPC).

1.2 Declarations of Interest:

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

1.3 Draft minutes (July 2018)

The minutes were agreed as an accurate record, following some minor amendments.

1.4 Matters Arising

1) Consultation feedback:

All items from July meeting out for consultation at time of meeting; closing 17th September.

The group noted that subsequent to the July meeting, the MHRA issued an alert to UK health professionals on restrictions to use and monitoring requirements for ulipristal. The alert states that treatment should be 'initiated and supervised' by a physician experienced in the diagnosis of uterine fibroids, however the group felt that the previous status of GREEN following specialist initiation remained the most appropriate positioning for ulipristal. It was agreed that the current consultation document should be

updated to clarify the positioning of ulipristal, and that additional efforts be made to promote engagement from relevant clinical specialists in the consultation. Development of an information sheet in the standard format used for other GREEN (following specialist initiation) drugs was suggested as a means to clarify monitoring requirements, pending outcome of the consultation.

Action: CD to update current consultation document re. Ulipristal RAG status as discussed.

2) Antibiotic guidelines updates- FMESG approval process:

Following comments made at the last FMESG meeting regarding the most recent update to the antibiotic guidelines, there was some discussion regarding how the review process of these guidelines fits with the standard GMMMG consultation process. At present, the GM antimicrobial guidelines are updated on a quarterly basis to reflect changes in national guidance, local resistance levels, and comments received on the previous version. The Task and Finish group responsible for these updates consist of a multidisciplinary team which includes representatives from across GM, including senior microbiologists, and representation from the GM Antimicrobial Resistance Group. Following initial approval of each new draft by FMESG, the chapter is opened for GM-wide consultation (lasting 6 weeks) before submission to CSB for approval. As a result of the current review and approval process, there may be a delay in the most up-to-date clinical recommendations (particularly reflecting local resistance patterns) from being implemented in practice. It was proposed that instead of the standard GMMMG review process, future updates would be noted by FMESG and the update be approved without GM-wide consultation. As each new version of the update is continually open to comment via the GMMMG website, the group felt that this 'continual consultation' negated the need for the standard 6 week process normally required for guidelines. The group agreed to this more streamlined approach.

3) Naltrexone RAG status: MM fed-back regarding the group's previous recommendation that RAG status for both opioid dependence and alcohol disorders remain unchanged, pending submission of a paper on the practice of commissioning without prescribing provision. CSB approved maintaining the current status, pending the paper on commissioning without prescribing provision being raised.

Action: MM to present a draft of this paper at the September FMESG meeting.

2. Medicines Optimisation

2.1 OTC prescribing- review of items listed on GMMMG formulary

In response to the NHSE recommendations on OTC items not to be routinely prescribed, a review was undertaken to highlight which of these items are currently included in the GMMMG formulary, along with suggested formulary amendments.

There was some discussion regarding the GMMMG definition of 'OTC'. The group agreed that the following statement be applied to those items annotated 'OTC' in the formulary:

OTC: Available to purchase in pharmacies. There is an expectation that these items are not prescribed on the NHS for minor and self-limiting illness in keeping with NHSE guidance.

Action: RDTC to update formulary chapters to reflect this statement.

Dry eyes: The Group highlighted concern regarding the joint categorisation of 'dry eyes' with 'sore/tired eyes' within the NHSE recommendations. It was felt that that this was an oversimplification of terms that does not adequately acknowledge the population of patients who suffer chronic dry-eye. (NICE CKS defines dry eye syndrome as a 'chronic condition characterised by inflammation of the ocular surface and reduction in quality and/or quantity of tears'). The group noted that the NHSE guidance applies to 'mild to moderate' dry eyes but

does not specify the 'severe' criteria for which supply of lubricants on prescription would be appropriate. Given the wide inter-patient variance in use of these products, the group recognised that it would be challenging to implement this guidance in practice without more clearly defined criteria. Additionally, a lack of adherence by optometrists/opticians to the current GMMMG pathway was noted. This was particularly in relation to bypassing of hypromellose as the first-line choice in favour of more costly alternative choices, recommending use of preservative-free preparations outside of the appropriate population, and referral of patients aged over 60 to attend their GP for prescriptions. The group agreed that it was important to seek engagement from optometrists going forward to ensure GMMMG recommendations are implemented in practice- this is in keeping with the recently issued GM-wide ophthalmology letter. The group expressed concern that rather than following GMMMG formulary, patients may be recommended to purchase more costly products without having tried preparations which are lower cost and considered first-line.

Prevention of dental caries: The group noted that whilst some fluoride toothpastes (~1500 ppm) can be purchased over the counter, the strengths generally recommended in clinical practice by dentists (and therefore prescribed on the NHS) are higher and only available on prescription. Thus the NHSE recommendations may not reflect the target populations for these products. These items are included in the Grey List with GREEN RAG status following specialist (dentist) initiation.

MM and AM updated the group on a recent discussion with Dr Dympna Edwards (GM Consultant in Dental Public Health) and Deborah Moore (GM Specialist Registrar in Dental Public Health), which had included discussion on prescribing of high fluoride toothpastes and why this was not routinely undertaken by GPs. GMMMG reasserted its position that prescribing of high fluoride toothpastes should remain with dentists, the possibility of a PGD to support the supply of high fluoride toothpastes was discussed and will be further investigated by Deborah.

Vitamins and minerals: The group were asked to consider appropriate wording for the DNP statement regarding vitamins, minerals and antioxidants for inclusion in the formulary. It was acknowledged that the wording of the statement should reflect the right of the prescriber to make a judgment call of whether or not a patient would take action to change their lifestyle/diet or self-medicate, depending on the clinical circumstances. This is in keeping with NHSE's exceptions to the OTC guidance which states that NHS supply may be appropriate if *the person prescribing thinks that a patient cannot treat themselves for example because of mental health problems or severe social vulnerability*. The group agreed that the following DNP statement should apply: 'Vitamins, minerals, and antioxidants are DNP when used for supplementation in people who have no clinical indication for use'.

Action: RDTC to update DNP list and chapter 9 of formulary accordingly

Benzydamine oral rinse/ oral spray: These are currently included in chapter 12 of the GMMMG formulary under 'Drugs for Oral Ulceration and Inflammation'. It was highlighted that these are a treatment option for oral stomatitis in palliative care and for the prevention of oral mucositis secondary to radiotherapy. There was concern that the OTC status may prevent patients within these populations from appropriately accessing these preparations. The group agreed that these items should be assigned a RAG status of GREEN (for use in palliative care).

Action: RDTC to update RAG list and chapter 12 of formulary accordingly

The group also acknowledged a need for the provision of clear information on differences in licensing restrictions for products as there may be subtle differences between similar items (eg. licensed age groups for topical steroids).

OTC policy update

AM updated the group following presentation of the draft GM OTC Policy at CSB on 9th August. The view from NHSE that local consultation and engagement should be undertaken had been discussed, as had the request for a GM wide approach supported by GMMMG. It was recognised that GM CCGs are at different stages of implementation of this work, and that a GM approach rather than a local CCG approach may slow progress in some areas. The group highlighted that the different minor ailment formularies across the CCGs would need to be reviewed in line with the NHSE recommendations as supply via this route still constitutes NHS prescribing. Additionally, these formularies should match OTC advice within the GMMMG formulary.

FMESG agreed that their role in the development of this policy was complete and they would look to monitor the prescribing of these items to measure implementation GM wide, appreciating that the pace of change would vary between CCGs based on their baseline and implementation rate.

The group requested definition of the term ACBS in relation to sun protection within the policy.

Action: FMESG members to communicate any further comments based on the OTC listings for formulary presented within 14 days of the meeting, thereafter RDTC to open for GM wide consultation. OTC policy to be added to the GMMMG website, FMESG to close this action unless further direction from CSB is received.

3.0 Formulary and RAG

3.1 Formulary amendments August 2018

The suggested formulary amendments for August 2018 were approved, including:

- Sodium hyalonurate: amendment of currently listed 0.4% PF unit-dose preparation to more cost-effective multi-dose bottle.
- Dupilumab for treating moderate to severe atopic dermatitis: The group noted that HCDSG were defining criteria for initiation of this product within the NICE TA (30 day TA- published 01/08/18). It was agreed that dupilumab would be added to formulary in line with NICE and that the criteria agreed by HCDSG would be included.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval

3.2 Green Drugs not currently listed on Formulary

The group reviewed agents that have GREEN RAG status but are not currently listed in the formulary. GM primary care prescribing data for 2017/18 were taken into consideration.

A theme of two therapeutic groups was noted within the document- namely alternative agents for Parkinson's Disease, and alternative anti-convulsants. The group noted that these agents would be reserved for situations of treatment failure/ intolerance of first-line options. Acknowledging that new additions to the formulary should meet the needs of the *majority of adult patients* it was felt that the medications listed as a whole did not meet the criteria for formulary inclusion. The group recommended that these drugs be included within the Grey List (GREEN RAG status) in order to clearly define the suitable population/ criteria for their use.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval

3.3 RAG status review: typical oral antipsychotics

Haloperidol and chlorpromazine are currently listed within the GM formulary with no RAG status. The group considered an application to assign an AMBER RAG for their use in psychiatric indications, and a GREEN RAG for use in palliative care. Atypical antipsychotics have an Amber status with a shared care protocol in place; the monitoring requirements for typical antipsychotics are the same (with the exception that haloperidol requires a baseline ECG). It

was proposed that the shared care protocol for atypicals be updated to include typical agents- this SCP is currently being updated by the author. The group recommended that the RAG status of typical antipsychotics should reflect that of the atypicals (AMBER with shared care), and that GREEN status should be assigned for use in palliative care.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval

3.4 RAG status review: megestrol

Megestrol is currently included within the GM formulary as a progestational agent for certain hormone dependent neoplasms, such as breast cancer, with no RAG status assigned. The group considered a proposal to assign a RAG status of GREEN following specialist initiation, in line with of tamoxifen and aromatase inhibitors. The group agreed this was an appropriate RAG positioning.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval

3.5 RAG status review: oral ketamine

Oral ketamine may be used off-license for palliative care, and for end of life care. It is currently included on the formulary with an AMBER status for short-term use at the end of life, subject to local arrangements. It also has an AMBER status for use in palliative care- the RAG entry states 'SCP/information sheet available'. However there are currently no SCPs in place for either indication. It was proposed that the group reconsider RAG status on the basis of previous recommendations made by the Interface Prescribing Subgroup in 2016: RED for long-term use and short-term use at end of life, and AMBER for use in palliative care (development of SCP required).

The group discussed issues around the supply of the oral liquid which is an unlicensed special subject to variation in cost and availability of supply in community. Use of ketamine in short courses as an opiate-sparing agent was acknowledged, however this was felt to be too specialist in nature/ requiring specialist input and monitoring outside the scope of primary care, rendering it unsuitable to meet the criteria for shared care. On this basis, the group recommended that oral ketamine be allocated a RED RAG status for both indications. It was noted that the SCN are understood to be producing guidance to support "End of Life" treatment, and GMMMG would look to support this work through the PaGDSG.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval

3.6 Grey List assessment: ferric maltol

Ferric maltol is currently not included in the GMMMG formulary, but does have a GREEN RAG status following gastroenterologist recommendation in adults with iron deficiency anaemia (IDA) and inflammatory bowel disease (IBD). One month's treatment with ferric maltol costs £47.60. In 2016 the NTS made the following recommendation regarding its use: *The group recommends the use of oral ferric maltol as an alternative option to IV iron, in patients with mild to moderate IDA with IBD who have tried at least three oral ferrous salts and have a reported intolerance to oral ferrous salts due to adverse effects after an adequate trial. The initiation or recommendation to use ferric maltol should be made by a Gastroenterologist.*

Ferric maltol had a license extension in March 2018. The indication was widened to 'adults with iron deficiency' from 'adults with iron deficiency anaemia in patients with IBD'. This license extension was not based on any new clinical evidence but was granted on the basis that patients with IBD are the 'worst case' population who are commonly intolerant of oral iron products. Two further clinical trials are still ongoing.

In response to this license extension, FMESG were asked to consider approval of ferric maltol on the Grey List for 'treatment of iron deficiency when intolerant to or treatment has failed with

two oral iron supplements'. The group agreed that it would be reasonable to consider an additional oral option for patients who have struggled with other iron supplements as an alternative to initiating parenteral iron. Noting the previous NTS recommendation to try 3 oral agents before using ferric maltol, the group felt this was an unrealistic expectation of patients and may delay clinical response. FMESG recommend inclusion of ferric maltol on the Grey List (RAG status – green specialist recommendation) for treatment of iron deficiency in patients with intolerance to, or treatment failure with, two oral iron supplements.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval, NTS recommendation to be updated accordingly.

3.7 RAG status review / consideration for shared care: penicillamine

Penicillamine is licensed for a number of indications including severe active rheumatoid arthritis and Wilson's Disease. It currently has an RAG status of Amber for rheumatoid arthritis, however there is no SCP in place. Penicillamine is not included in the GMMMG formulary for any indication (including RA) and has no RAG positioning for other indications. For 2017/2018 total GM spend on penicillamine (all indications) was £44,000 (355 items for 36 patients).

RA: The most recent BSR/ BHPR guideline for prescription and monitoring of DMARDS (2017) does not include penicillamine as a treatment option for RA, and states: *Monitoring guidance for penicillamine is no longer included in this document because this drug has disappeared from routine use as a DMARD in contemporary practice.* Similarly NG100 Rheumatoid arthritis in adults: management which was published in July contains no reference to penicillamine. The current rheumatology RAG status of AMBER dates back to at least 2005 so does not account for the up-to-date clinical guidance in relation to penicillamine as a DMARD.

The group considered a proposal to remove penicillamine from RAG classification for the indication of RA. The group felt that there were very few patients receiving penicillamine for RA in clinical practice and this was reflected by the low prescribing figures across GM. On this basis it was felt that an AMBER status (and development of a SCP) for this indication was unnecessary. Thus FMESG recommend removal of penicillamine from the RAG list for the indication of RA.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval

Wilson's Disease: An application for shared care in the treatment of Wilson's disease has been received but not yet considered by GMMMG. The incidence of Wilson's disease is estimated to be 1 per 30,000 (British Liver Trust), hence usage across GM is expected to be low. The group was asked to consider whether development of a SCP for this indication was needed. AM highlighted that penicillamine is NHSE commissioned for adults with Wilson's disease, as part of the service specification for Metabolic Disorders in Adults. The group recognised that there is no route to repatriate prescribing for existing patients back to secondary care. It was agreed that development of a SCP should proceed, with penicillamine to be added to the RAG list with AMBER (NHSE commissioned) positioning.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval, SCP author to be contacted.

3.8 RAG status review: lanthanum

The group was asked to review positioning of lanthanum within the RAG list. At present it holds RED status as a phosphate binding agent in dialysis (NHSE commissioned) and also RED in the non-dialysis CKD population (CCG commissioned). Prescribing data for 2017/18 documents 1,641 items for 250 patients across GM (cost= £200,700). The group were asked to consider a proposal to amend RAG status for the non-dialysis population to GREEN (following specialist initiation). The group highlighted an uncertainty around the size of this population, and their management in relation to follow-up and monitoring by nephrology teams. The group agreed

that further information regarding the management of this population would be required in order to assess RAG status appropriately.

Action: RDTC to contact GM renal team to establish information on population, follow-up and monitoring arrangements, and bring this back to the Sept FMESG meeting.

3 Horizon scanning and work plan

Monthly horizon scanning documents and work plan

The RDTC monthly horizon scanning document for August was reviewed.

The group noted the EMA positive opinion regarding a new modified-release preparation of melatonin (Slenyto®) indicated for the treatment of insomnia and adolescents aged 2-18 with autism spectrum disorder/ or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. This would potentially provide a licensed option to a population currently receiving off-licensed Circadin® and unlicensed liquid 'specials'. MM fed-back that RDTC are currently scoping this product for production of a new drug evaluation.

The work plan was reviewed and the following discussed:

- *Rivaroxaban for CV reduction:* MM highlighted that FMESG had been invited to attend the Cardiovascular SCN meetings in September and would seek discussion on this and the implications of the new European antihypertensive guidelines (RDTC currently looking at the evidence base for these). MM/AM will feedback to the group after this meeting. Additionally, the need for a 'CV-themed' FMESG meeting was discussed, the date of which TBC.
- *Doxylamine + pyridoxine for N&V in pregnancy:* a review document has been produced by RDTC which MM will bring to the September meeting. Additionally the group agreed that a consultant obstetrician should be given the opportunity to comment on, RDTC to seek attendee for the Sept meeting.
- *Commissioning without prescribing provision:* MM will present a draft of this paper at the September FMESG meeting, prior to submission to CSB and then AGG/Strat Board.
- Freestyle Libre: FMESG to audit the prescribing of FSL across GM, AM has requested information from the CCGs but has had a limited response. It was suggested that data be obtained from the ABCD audit, AM agreed to investigate further. AM to return this data to the September FMESG meeting, where the group will consider the current FSL recommendation.

Action: RDTC to update the work plan as appropriate.

4 Additional items

Toujeo: at the July meeting, FMESG agreed that in the absence of a defined population for use, there is insufficient evidence to support routine use of Toujeo over other analogue insulins, and did not recommend formulary inclusion pending further information from the applicant defining target population. The group agreed that this recommendation should still stand, and that a Grey List positioning should be assigned as per previous NTS recommendations to make the restrictions on its use clearer within the formulary. The group plan to audit patients currently on Toujeo to ascertain why prescribing figures are much higher than expected- it was acknowledged that some time would be needed for this data to be gathered. Thus the group recommended Toujeo's inclusion in the Grey List in line with the current GMMMG recommendation.

Action: RDTC to open these decisions for GM-wide consultation and seek CSB pre-approval

Insulin preparations for pumps: the group discussed whether insulin preparations for pumps (eg. NovoRapid Pumpcart) would require submission formulary application paperwork (and subsequent assessment) in order to be included in the formulary. It was also noted that there is

no sub-section for insulin pump consumables on the GMMMG diabetes chapter. The group agreed that the preparations need not undergo a formal application process and that the formulary be updated to include preparations for pumps where appropriate (ie. the insulin is already on formulary). The need for inclusion of insulin pump consumables will be addressed at a future meeting.

Action: RDTC to add to the work plan. MM to update formulary accordingly

Addition of new members to FMESG: it was noted that Dr Jonathan Schofield (Consultant Physician MFT) who had attended the July meeting had expressed and an interest in joining FMESG. The group agreed to proceed with his application in line with the process for adding new members.

Meeting frequency: it was agreed that the group would proceed with monthly meetings, with an ongoing plan to review meeting frequency depending on the workplan. Additionally the group agreed to proceed with the current pattern of meeting times and dates for 2019.

The next ordinary meeting will be held on 25th September 2018 12.30-2.30pm, CMFT.