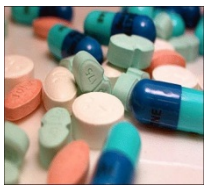
FORMULARY AND MANAGED ENTRY SUBGROUP



Minutes of the meeting held on
Tuesday 22nd January 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	✓										
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	✓										
Claire Foster (CF)	Senior Medicines Optimisation Advisor	MHCC	✓										
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	A (AH)										
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		✓										

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov
Lindsay Harper (LH)	Director of Pharmacy	SRFT	A										
Jonathan Peacock (JP)	Chief Pharmacist	T+G	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										
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 in the absence of Pete Budden and Lindsay Harper.

Ann Harrison (AH), GP MO Prescribing Lead attended to represent Trafford in the absence of Leigh Lord. AH and PS left after item 3.2 due to clinical commitments.

1.2 Declarations of Interest:

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

1.3 Draft minutes- November 2018

The minutes were agreed as an accurate record.

1.4 Matters Arising

1.4.1 Consultation feedback:

Items from the November meeting were out for consultation; closing 15th February. Consultation comments received on actions from the October meeting were discussed.

Semaglutide addition to formulary as first choice weekly GLP1: comments were noted in favour of this action, noting that currently semaglutide has the greater body of evidence of cardiovascular

benefit versus dulaglutide. FMESG heard that semaglutide had been included in current drafts of the GMMMG pathway for antihyperglycaemic therapy in adults with type 2 diabetes. Given multiple comments in support of keeping dulaglutide as an option- particularly around delivery mechanism of product it was agreed that this should remain on formulary as an alternative option.

Action: FMESG to add semaglutide to formulary as first choice weekly GLP1 preparation, with dulaglutide to remain on formulary as an alternate choice weekly preparation.

VSL#3 Grey (GREEN following specialist initiation) status: the group acknowledged that VSL#3 was removed from the drug tariff in November 2018 where it previously had been included under ACBS.

Action: RDTC to draft DNP assessment for VSL#3 and bring to February meeting.

As no comments were received opposing the other actions from October's meeting, the group recommended that these actions as below be progressed.

Action: Dapoxetine for PE to be assigned DNP status on basis of criterion 1, tofacitinib to be added to formulary in line with NICE TA 543.

1.4.2 Verbal recommendation of GREEN (following specialist recommendation) drugs

The group discussed the GMMMG Guidelines on defining RED/AMBER/GREEN/DNP/GREY MEDICINE Status. These state that GREEN (following specialist recommendation) drugs can be initiated by primary care following *verbal* advice from a specialist. Concern had been raised regarding the potential for error to occur in the absence of written information by Manchester APC.

Clinicians in attendance at FMESG felt that the provision for verbal recommendation was necessary to avoid undue delay to patients accessing appropriate medications. Additionally, it was felt that adequate communication was an inherent part of any agreement to take on prescribing responsibility; hence GPs would not undertake prescribing without first being satisfied that they had sufficient information. FMESG agreed that the recommendation should be reworded to strengthen the need for *appropriate agreement* between GP and specialist, rather than remove reference to verbal communication.

Action: new wording for the GREEN (following specialist initiation) guideline to be opened for GM-wide consultation.

1.4.3 Action Log

Updates to the action log were noted. FMESG heard that a commissioning statement for CCGs on the OTC policy had been submitted to CCGs for approval, and that FMESG would continue to be updated on the progress of this work in due course.

It was additionally noted that CCGs were actively undertaking audit of FSL and this item could be closed from the action log and added to the FMESG monitoring log.

A verbal update was provided on scoping that had been undertaken on the license extension of rivaroxaban for CAD/PAD. A number of limitations of the COMPASS trial had been highlighted by the working group particularly relating to the lack of comparison to clopidogrel, and the relevance of the trial data to local populations. FMESG discussed the evidence review initially submitted by RDTC that noted a similar NNT to NNH, and expressed concern regarding the risk of major bleeds vs potential cardiovascular benefits. Additionally, a NICE Evidence Commentary published in July 2018 which questioned the relevance of the trial data to the UK population was also acknowledged by the group.

FMESG felt that a GMMMG position should be recommended ahead of the NICE TA being published in August 2019. An ongoing need to scope for the potential GM target population was acknowledged. It was recommended that a position of DNP be issued (Criterion 1) and the decision opened for GM-wide consultation, with a footnote that this recommendation would be reviewed once NICE has published guidance.

Action: FMESG recommend rivaroxaban for CAD/PAD be assigned DNP (criterion 1), with a view to review positioning once NICE publishes. Recommendation to be opened for GM-wide

consultation. RDTC to liaise with working group and encourage engagement with the consultation to help identify potential target population/ local appetite to prescribe.

2.0 Medicines Optimisation

2.1 GMMMG Generic Prescribing Guidelines- update

An updated draft of the GMMMG Generic Prescribing Guidelines was reviewed by the group, following a technical update. The group were happy with the update as a whole but requested the some minor amendments be considered:

- Inclusion of inhalers in Appendix 1- items unsuitable for generic prescribing, and re-wording of 5.5 to reflect 'all inhalers'. This is to align with CSB agreement that all inhalers should be prescribed by brand.

- Clarification regarding branded prescribing of oral contraceptives to state 'the most cost-effective brand should be prescribed' and removal of advice that patients should remain on the same brand, as the group felt this was not sufficiently evidence based.

Action: FMESG approve update with suggested amendments. RDTC to feed-back to author.

2.2 Drugs of Low Clinical Value '2'

The group noted the updated NHSE document 'Items which should not routinely be prescribed in primary care: an update and a consultation of further guidance for CCGs', and considered a summary of proposed GM feedback on the consultation (set to close 28th Feb).

It was acknowledged that FMESG had already undertaken relevant work in relation to a number of the items highlighted by the guidance e.g. the existing DNP status for bath and shower preparations, and silk garments.

In addition to supporting the existing content of the summary, FMESG expressed concern regarding the proposed price cap for BGTS in patients with type 2 diabetes as there are some patient groups who require higher cost strips (e.g. drivers adhering to DVLA conditions). It was also felt unclear why the suggested restriction applied only to patients with type 2 diabetes. Regarding needles for pre-filled and reusable insulin pens, the group highlighted that the guidance would be restrictive to patients with needle-phobia, in addition to points raised about EU Directive on Prevention of Sharps Injuries.

Action: AM to update the summary of suggested GM feedback on national consultation accordingly.

3.0 FMESG Work Plan 2019

The group acknowledged a change in process requested by CSB in December that requires all routine work (e.g. formulary applications, RAG status reviews etc.) to be scoped by FMESG prior to progressing work. All larger projects must be approved by CSB/ CSB chairs at their monthly meeting ahead of work being undertaken.

3.1 Consideration of items for FMESG work plan- items already received

The group considered a number of potential items to be added to the work plan and decided not to add the following items to the work plan:

- *Budesonide oro-dispersible for eosinophilic oesophagitis* (new medicine)- on the basis of small patient numbers (~54 patients across GM per year) and relatively low cost.
- *Dexamfetamine oral solution for narcolepsy* (RAG assessment)- on the basis that patient numbers are likely to be small across GM, only one bottle dispensed in primary care between Nov 17- Oct 18.
- *Oestrogel pump pack (*formulary application)- on basis that use would be in a relatively niche population, there are existing oestrogen preparations on formulary that are lower cost.

Actions:

- *Pentosan for bladder syndrome* to be added to work plan- RDTC to bring NDE to February meeting.
- *Melatonin M/R for the treatment of insomnia in ASD and SMS* to be added to the work plan- RDTC to approach authors of SCP for Circadin in children and adolescents to establish appetite to prescribe new product. NDE currently being drafted- to bring to meeting once complete.
- *ActiPatch for localised MSK pain* to be added to the work plan- RDTC to bring DNP tool to February meeting
- *Utrogestan oral capsules for adjunctive use with oestrogen as HRT in women with an intact uterus* to be added to work plan- formulary application to be brought to February meeting. RDTC to approach author to establish anticipated prescribing figures.

3.2 Consideration of items for FMESG work plan- scoping

A list of drugs of likely significance to primary care prescribing in 2019-20 was considered by the group, with the purpose of identifying items of relevance for FMESG. The group noted that some of these items had already been added to the work plan and agreed that the addition of further items should wait until the CSB workplan for 2019 is finalised.

Action: list to be brought back to the group for consideration once CSB work plan available, to allow for appropriate prioritisation of items.

4.0 Formulary and RAG

4.1 Formulary amendments January 2019

The suggested formulary amendments for January 2019 were noted and approved by the group.

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

4.2 Noqdirna- summary

A New Medicines Request for Noqdirna for idiopathic nocturnal polyuria was first considered by FMESG in May 2018, at which point the group recommended that it should not be added to formulary as a routine use and benefit across GM was not demonstrated. This recommendation was opened for GM-wide consultation and multiple comments in favour of the addition of Noqdirna were received.

The group reviewed a summary of progress on this item to date, noting ongoing uncertainty regarding the definition of improvement expected, and concern regarding the accuracy of anticipated population/prescribing figures. Primary care prescribing data for GM from Nov 17- Nov 18 demonstrates a low level of prescribing, occurring in most CCGs- a total of 149 items were dispensed at a cost of £2,400. Additional data of all primary care prescribing since Noqdirna was launched demonstrated that 43% of prescribing had occurred in the <65 year population which did not align with the population proposed by the original applicant.

Action: The group agreed that their original recommendation not to add to formulary should still stand but with a view to track prescribing across GM.

4.3 GREEN non-formulary drugs

In May 2018, FMESG were provided a list of non-formulary medicines with a GREEN RAG status and were asked to discuss the implications of having GREEN status for non-formulary medicines. The list of medicines were subsequently considered for formulary inclusion and for Grey Listing, but were felt not to fit with the inclusion criteria for either.

At January's meeting, the group were asked to make a final decision regarding the status of non-formulary GREEN medicines. It was agreed that those drugs classified as GREEN should be removed from the RAG list (domperidone for inadequate lactation, Circadin in over 55yrs, ropinirole in restless legs, sodium fusidate, and trihexyphenidyl for drug-induced parkinsonism). Those classified as GREEN following specialist initiation/advice will be clearly annotated on the RAG list as 'Non-formulary' and 'off-label' or 'unlicensed' accordingly. The group as a whole did not feel that inclusion of these items on the RAG list was promoting prescribing, and primary care clinicians present highlighted that inclusion of these items within the list was helpful to refer to in clinical practice.

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

4.4 Respiratory Chapter update

At November FMESG, the group reviewed a copy of the respiratory chapter which had been updated to bring it in line with the GMMMG asthma and COPD pathways. It was proposed that all drugs not included in the pathways should be removed from formulary.

The group decided that all drugs recommended in the pathways should be listed as first choice, with all others currently on formulary rationalised as appropriate and listed as alternatives.

At January's meeting, the group considered a re-draft of the chapter which accounted for the above discussions. The group agreed to the amendments made, however requested the addition of Oxis Turbohaler as an additional LABA choice, based on cost efficacy and consistency of device with other options..

Action: FMESG to seek support from CSB to update the chapter as above. Recommendation for addition of Oxis Turbohaler to be opened for GM-wide consultation (as this had not been included in the consultation on the asthma or COPD pathways).

5.0 Horizon Scanning and work plan

5.1 Monthly horizon scanning documents December 2019, January 2019

The group reviewed these documents and noted the following new products: prolonged-release injectable formulation of buprenorphine for treatment of opioid dependence, generic apomorphine injection for PD, and lidocaine/prilocaine spray for PE.

Action: RDTC to pre-scope the injectable buprenorphine and apomorphine products and bring back as a scoping item at a future meeting. To bring back a DNP tool for the lidocaine/prilocaine and other topical preparations for this indication to February's meeting.

5.2 Workplan

The updated GMMMG workplan was noted and discussed. No further action was suggested.

6.0 AOB

No other items were raised.

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