FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 23rd July 2019
12:30 - 2:30 pm
Pharmacy Dept MFT-ORC (formerly known as CMFT)

Present:

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

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	July	Aug	Sept	Oct	Nov
Faisal Bokhari (FB)	Deputy Head Medicines Optimisation	T&G CCG	✓	✓	A	✓	✓	✓	✓			
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓	✓	✓	✓	✓	✓			
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	A	A	A	A	A	A	A			
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓	✓	✓	✓	✓ +DN			
Nancy Kane (NK)	Senior Medical Information Scientist	RDTC				✓	A	A	A			

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above. Ann Harrison (AH) GP MO Lead for Trafford attended in place of LL. Daniel Newsome (DN) Principle Pharmacist RDTC attended as professional secretarial support.

PS attended until item 3.1.

1.2 Declarations of Interest:

PS highlighted a minor professional DoI in relation to item 1.4.1a. He had been a member of the guideline committee that developed NG132: Hyperparathyroidism (primary): diagnosis, assessment and initial management.

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

1.3 Draft minutes –May 2019

Minutes from July's meeting were noted. These had been pre-approved by the group ahead of August CSB and will be added to the GM site.

1.4 Matters Arising

FMESG proposed actions for July were out for consultation; closing 23rd September. The group discussed that minocycline had been recommended for DNP for the indication of acne, however questions were raised around whether it is possible to DNP on the basis of indication under the current GM framework. It was agreed that this should be investigated further as the ability to DNP on the basis of indication was an underpinning factor in the implementation of the GM Self-Care/ OTC policy. RDTC to take this forward.

1.4.1 Consultation feedback (June):

Consultation comments received on proposed actions from June were discussed. (There had been no meeting in June so these actions had reflected the publication of new NICE Guidance only).

The group also discussed recent changes to the format and level of detail in FMESG consultations and how consulting on TAs fits within the current TOR of the FMESG. It was noted that a review of the subgroup TORs is pending and would address these issues. Limitations of quoting commissioning/ service impacts directly from the NICE resource planner were acknowledged.

The following actions were agreed accordingly:

- Reference to TA583: Ertugliflozin with metformin and a dipeptidyl peptidase-4 inhibitor for treating type 2 diabetes to be added to the formulary.
- Reference to TA585: Ocrelizumab for treating primary progressive multiple sclerosis to be added to the formulary.
- Reference to NG132: Hyperparathyroidism (primary): diagnosis, assessment and initial management to be added to the formulary. It was noted that whilst the NICE resource planner had predicted no significant impact on resources, the guidance may result in an increased use of off-label cinacalcet in this population vs. surgical intervention. Cinacalcet is currently AMBER shared care and is a relatively high cost item- annual cost at max dose = £18,094 per patient (although unlikely to be tolerated at this dose). Cinacalcet is due to come off patent next year however the availability of a generic is not yet known. It is not anticipated that the cost impact would exceed £200k per annum and the increased drug spend would be offset by a reduced spend on surgery.

ACTION: RDTC to action these recommendations, as pre-support had been sought at August's CSB.

1.4.2 Action log

Updates on the action log were noted. The group agreed resolution of the issues around positioning of oral typical antipsychotics and cariprazine with MH services was a priority, otherwise to removed from the action log. The group acknowledged progress of the draft guidance for the Covert Administration of Medicines in Care Home Settings and sought clarity on where this work sat in relation to a similar piece of work being undertaken by GMHSCP; RDTC to clarify for the action log going forward.

1.4.3 Monitoring log

The monitoring log was noted by the group. It was agreed that a paper be brought to September's meeting assessing prescribing trends of ferric maltol over the previous 12 months, along with a RAG amendment form to change from the current position of GREEN (following specialist advice) to GREEN. Prescribing figures for Xonvea® also to be brought to September's meeting for information.

The group noted that data from the ABCD audit on FreeStyle Libre was awaited. RDTC to contact ABCD to ascertain expected date of publication and update the monitoring log accordingly.

It was noted that CSB had requested a baseline monitoring report on OTC spend to be submitted to their October meeting, and that monitoring and assurance thereafter would sit under FMESG's monitoring schedule.

2.0 Medicines Optimisation

2.1 NICE Final Appraisal Document- Rivaroxaban in CAD/PAD

Following previous assessment of the evidence base/ cost-efficacy and scoping of GM appetite to prescribe for this indication FMESG acknowledged publication of the NICE FAD for Rivaroxaban in CAD/PAD. The draft NICE guidance recommends use in a much wider population than FMESG had initially anticipated. Aside from the safety risks, concerns were expressed about the affordability of the TA to the GM economy- both in terms of drug costs, and the cost of assessing existing patients for suitability.

The draft NICE guidance recommends: *"Assess the person's risk of bleeding before considering rivaroxaban. Treatment should only be started after an informed discussion with them. Treatment should only be started after an informed discussion with them about the risks and benefits of rivaroxaban, weighing up the risk of atherothrombotic events against the risk of bleeding. The risks and benefits of continuing treatment with rivaroxaban should be regularly reviewed."* The group recognised that this recommendation would be challenging to follow in practice due to the lack of a valid bleeding risk assessment tool for this population. It is uncertain how prescribers would confidently and effectively assess bleeding risk/ risk-benefit profile for individuals, unless NICE develop an appropriate decision aid to support the final TA.

In recognition of the complexity of assessing risk-benefit profile within the target population, initial scoping around GM specialists had identified a preference that this would be a 'specialist initiation' intervention. However the broad populations proposed by the FAD are currently being managed in primary care and not sitting under the care of specialist clinicians. In order to restrict initiation to specialists only, there would be significant commissioning and service implications which would be costly and onerous to services. In light of these facts, FMESG would recommend that clear supportive material would need to be made available prior to prescribing being undertaken in primary care.

The group agreed that no additional action was required on this item until the final TA is published (this is expected ahead of September's meeting).

2.2 NHSE OTC Guide/ self-care policy (verbal update)

The group heard that an update paper had been submitted to August CSB. This had included a request to proceed with the DNP listings of products for short-term use/ for conditions which are self-limiting which had received the support of CSB. The GMMMG commissioning statement has been approved by CCGs pending clarification of the exceptionality criteria by directors of commissioning, and work is being undertaken to finalise a Self-Care Toolkit. Going forward, monitoring and assurance of this work would sit under FMESG. The commissioning statement and list of DNP indications would be uploaded to the GM site following final sign-off. The list of lines to be made DNP/ assessed for GREY listing would also follow.

It was aimed that the 'soft' launch would take place in September, with the 'full' launch scheduled for April 2020.

ACTION: RDTC to prime GM site for upload of the GM Commissioning Statement once final sign-off by CCG DoCs has occurred.

2.3 RMOC Liothyronine Guidance update

FMESG reviewed an updated final draft of the RMOC *Guidance for Prescribing of Liothyronine*. Key changes in the updated guidance included clarifying the roles of GPs versus NHS consultants in the withdrawal or adjustment of liothyronine treatment, additional guidance to strengthen the need for endocrinology involvement for use within psychiatric indications, and amended wording of 'no benefit' to 'lack of evidence of benefit'.

Helpful comments had been gathered from endocrinology; these were in support of the recommendations from RMOC, however emphasised that the recommendations around use in treatment resistant depression could be made stronger to prevent initiation in the first place.

The group considered that the current GM position is largely in aligned with the RMOC recommendations; with the exception that liothyronine is GREEN (following specialist initiation) where RMOC recommends that share care arrangements should be considered. It was noted that RMOC provided a helpful example template for shared care and that adoption of a similar protocol across GM may help ensure that any new initiations are done in line with GMMMG recommendations. FMESG agreed to amend the current positioning to AMBER and retain the current GREY listing criteria, but remove the recommendation for annual review by an NHS

endocrinologist as it was agreed GP review was sufficient. Instead provision should be made within the SCP for GPs to refer back to endocrinology if TSH level is abnormal (in line with RMOC example SCP).

ACTION: FMESG recommend liothyronine (T3) be AMBER and GREY; where levothyroxine has failed, endocrinologists treating patients under the NHS may recommend liothyronine in exceptional circumstances for individual patients after a carefully audited trial of at least 3 months duration, in line with BTA guidance. This recommendation to be opened for GM-wide consultation and pre-support to action sought from October CSB. RDTC to identify author for SCP.

4.4 Testosterone Information Sheets for GPs

This item was moved further up the agenda to allow discussion whilst PS was in attendance.

At April's meeting, the group had considered scoping for a RAG assessment for testosterone products when used within licensed indications in men. The request had been to consider whether the level of monitoring required for these products was sufficient to warrant changing to AMBER. Following consideration of a RAG assessment at May's meeting, along with recommendations from the British Society of Endocrinology and American Endocrine Society the group agreed that AMBER status was not necessary. Instead, the group agreed that development of supportive information may be helpful for GPs, similar to other GREEN (following specialist initiation) documents.

At the August meeting, FMESG reviewed a draft information leaflet. This was approved by FMESG pending minor amendment.

ACTION: RDTC to enact amendment then upload to GM site. Hyperlink to the document to be included on the RAG listing for testosterone and within chapter 6 of the formulary.

3.0 FMESG Work Plan 2019

3.1 Consideration of items for FMESG work plan

The group discussed the items for consideration and recommended the following actions:

- Estradiol matrix patches for the induction of puberty to be added to the paediatric RAG list as AMBER. Current SCP for ethinylestradiol tablets to be updated to include this as the first-choice option. Ethinylestradiol tablets (currently AMBER) to be assigned additional GREY list positioning (criterion 2): only to be used when estradiol matrix patches are unsuitable/ not tolerated due to skin reactions.
- Further evidence to be sought on comparative efficacy/ actions of topical testosterone preparations to allow FMESG to consider a formulary application for Testavan® in full.
- A full formulary application to be sought for a request to review formulary choice artificial saliva preparations.
- Dapagliflozin in type 1 diabetes; formulary application and RAG assessment to come back for full discussion at September's meeting along with associated TA (publication expected 28th August). It was noted that the anticipated spend on this for GM may exceed £2 million per annum based on figures from 2018 Prescribing Outlook.
- Sodium zirconium cyclosilicate: RAG assessment to come back for full discussion along with associated TA (publication expected 4th September). It was noted that the NICE FAD was only supportive of use if the company provides it according to the commercial arrangement.

3.2 GMMMG Workplan/ significant developments 2019-20

The group noted the approved GMMMG Workplan and associated FMESG work streams. This includes the OTC/Self-care work, drugs of limited clinical value and associated assurance reporting. The group questioned whether the antimicrobial guidance would continue to sit under FMESG once

the new Antimicrobial Stewardship Subgroup is formed; this would be clarified ahead of the next meeting.

4.0 Formulary and RAG

4.1 Formulary amendments August 2019

All suggested formulary amendments were noted and approved.

ACTION: RDTC to open these recommendations for GM wide consultation and seek pre-support to action from October's CSB.

4.2 DNP Tool- Melatonin products for jet lag + update of the GM Travel Abroad Policy

At July's meeting, FMESG noted the availability of two newly licensed melatonin products for short-term treatment of jet lag in adults, and agreed that a DNP assessment should come back to August's meeting as a full agenda item.

At the August meeting, the group agreed that Melatonin for the short-term treatment of jet lag in adults be made DNP (Criterion 1). This was in line with NHS and GMMMG policy for prescribing 'just in case treatments' for travel and poor evidence base of efficacy. Additionally, the group recommended the GM Travel Abroad Policy undergo technical update to include an extra bullet point for this recommendation. It was agreed that the policy should also be updated to provide clarity that GPs should not prescribe norethisterone to delay menstruation on NHS prescription.

ACTION: RDTC to open the above recommendation for GM-wide consultation, and carry out technical update of the Travel Abroad Policy.

4.3 GM positioning statement for melatonin products

The group discussed whether there was a need to develop a GM positioning statement/ recommendation for melatonin products in light of the newly licensed products which have been launched in the preceding 6 months. A letter issued by NHS Fife to their stakeholders was provided as an example for the group to consider.

FMESG heard that there had been instances where community pharmacies had been contacted by specials manufacturers who requested a statement of clinical need for children being prescribed unlicensed preparations of melatonin. These requests were in line with MHRA guidance for specials manufacturers which states that checks should be undertaken to ensure specials are not supplied when a licensed alternative exists and that documentary evidence should be obtained by specials manufacturers where there is special need for an unlicensed special ahead of a licensed alternative. The group noted an example 'statement of clinical need' form that had been issued by NHS Fife but considered that development of a similar form for GM would not be necessary now that the SPC for the Colonis branded liquid had been amended to state unsuitable for use in children and adolescents. However the group agreed that a note should be added to the Paediatric RAG list that Colonis branded liquid is not suitable for use in children and adolescents due to safety and efficacy concerns and include a hyperlink to the SPC.

It was noted that work to update the current melatonin SCP was progressing with an updated draft expected to open for consultation in the next couple of weeks. The group expressed the importance of ensuring that the appropriate place in therapy of Slenyto vs. Circadin is evident in the update. The paediatric RAG list would be updated to include Slenyto for use within licensed populations once the SCP had been approved.

ACTION: RDTC to add statement on Colonis branded liquid to paediatric RAG list.

5.0 Horizon Scanning and work plan

5.1 Monthly horizon scanning documents August 2019

The RDTC monthly horizon scanning document for August was considered by the group. The group noted EMA positive opinions for cannabidiol (agreeing this should be flagged to HCDSG), and a levodopa inhaler (Inbrija®) for 'off-episodes' in Parkinson's Disease; a new drug evaluation for this is being drafted by RDTC.

ACTION: RDTC to bring NDE for Inbrija® to future meeting once drafted. Dr Rebecca Davenport suggested as potential clinician who may wish to comment on NDE ahead of this meeting.

6.0 AOB

The group discussed meeting times for 2020 and agreed to proceed with the current pattern, time and venue if able. RDTC to contact MFT to confirm room bookings.

The next meeting will be held on 24th September 2019, 12.30-2.30pm, MFT-ORC.