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	A		
Aoidin Cooke (AC)	Medicines Management and Medicines Information Pharmacist	MFT-ORC	✓	A (LH)	✓	A (LH)	✓	✓	✓	A (LH)		
Claire Foster (CF)	Senior Medicines Optimisation Advisor	MHCC	✓	✓	✓	✓	A	A (FA)	A	A (FA)		
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	A (AH)	A	✓	✓	A	✓	A (AH)	A		
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	A	✓	✓	✓	A	✓	✓	A		
Prof Peter Selby (PS)	Consultant Physician	MFT-ORC	✓	✓	A	A	✓	✓	✓	A		
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓	✓	A	A	✓	A	A		
Dr Hina Siddiqi (HS)	GP		✓	A	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	A		
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓	✓	✓	✓	✓ +DN	✓		
Nancy Kane (NK)	Senior Medical Information Scientist	RDTC				✓	A	A	A	A		

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above. Lorna Hand (LH) attended on behalf of Aoidin Cooke and Faduma Abukar (FA) on behalf of Claire Foster.
Jane Wilson, Director of Pharmacy GM West Mental Health NHS Trust attended to support the discussion of item 4.2.

1.2 Declarations of Interest:

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

1.3 Draft minutes –August 2019

Minutes from August's meeting were noted and supported as an accurate record. To be submitted to October CSB, ahead of upload to the GM-site.

1.4 Matters Arising

Following brief discussion at August's meeting around the possibility of being able to list items as DNP on the basis of indication, the group heard that this had been discussed at September CSB Chairs' Call. The group heard that the following amendments had been approved:

- to allow drug listings to be indication specific 'e.g. Melatonin to be DNP for the indication of jet lag'.
- to allow for indications themselves to be made 'DNP'- this would allow the list of indications proposed through the self-care/ OTC work-stream to be added to the DNP list (e.g. acute sore throat, dandruff, haemorrhoids etc).

It was noted that the current guidance document on RAG listing would need to be updated accordingly and the current GREY list would also benefit from review to ensure listings were clear and appropriate.

ACTION: RDTC to update the *Guidelines on Defining Red, Amber, Green, Grey Status* and highlight any unclear GREY listings for discussion at October's meeting.

1.4.1 Consultation feedback (July):

Consultation comments received on proposed actions from July were discussed.

The following actions were agreed accordingly:

- Aliskiren for essential hypertension in adults to be DNP (criterion 2). This is to reflect guidance from NHSE, the limited place in therapy of this agent and a lack of long-term safety and efficacy data to support its use; it is not recommended by NICE.
- Amiodarone (injection) for serious cardiac arrhythmias to be RED to reflect its appropriate place in therapy.
- Minocycline to be DNP (criterion 1) for the indication of acne. This is to reflect guidance from NHSE and because the use of minocycline for this indication is not supported by GM or national guidance. Additionally the BNF classes minocycline as 'less suitable for prescribing (compared with other tetracyclines)'.
- Needles for pre-filed and re-usable pens costing ≥£5 per 100 to be DNP (criterion 2). *This recommendation does not apply to safety needles.* This is to reflect NHSE guidance- it was noted that many manufacturers have lowered their prices in response to this.
- Reference to NG133- Hypertension in pregnancy: diagnosis and management to be added to the formulary (chapter 2).

ACTION: RDTC to action these recommendations as pre-support had been granted at August CSB. Additionally, the following to be actioned upon approval of the SCP (currently in development):

- Amiodarone (oral) for serious cardiac arrhythmias and dronedarone for the maintenance of sinus rhythm after cardioversion to be AMBER to reflect NHSE guidance and in light of the monitoring requirements associated with their use.

1.4.2 Action log

Updates on the action log were noted.

1.4.3 Monitoring log

The monitoring log was noted by the group.

There had been an ask from CSB that FMESG track prescribing figures for Xonvea, starting 1 year after product launch. The current GM positioning of Xonvea is GREEN and GREY (criterion 1) to be used only when the other preparations currently recommended by RCOG guidance have been tried and have failed. This recommendation will be reviewed once guidance from RCOG, NICE and/or RMOC is available. FMESG noted that overall prescribing Oct-18 to June-19 is low but relatively high-cost for anti-emetics: 109 items totalling £7665. The group agreed that there was no action required at this time but that Xonvea should remain on the monitoring log to be picked up again in 6 months' time (or sooner if national guidance is issued). As prescription figures are low there may be scope for local audit to ensure that prescribing to date is appropriate and in line with the GREY list recommendation.

ACTION: RDTC to update monitoring log accordingly.

1.4.3 EMA recommendations: oral methotrexate safety measures

The group acknowledged guidance recently published by the EMA recommending a number of new safety measures around the prescribing of oral methotrexate for inflammatory diseases. A final legally binding decision via the EU Commission is pending; however FMESG expressed concern around the lack of definition of 'specialist expertise' within the recommendations and the potential implications of restricting prescribing to specialists only. This included increased risk of medicines

interactions as a result of specialists not having access to a full list of patients' medications. **ACTION:** FMESG note these recommendations; however conclude that no action is required at present, pending the MHRA issuing further direction.

2.0 Medicines Optimisation

2.1 GMMMG Antimicrobial Guidelines- August 2019 update

The group acknowledged the quarterly update of the GM Antimicrobial Guidelines and supported upload to the GM site. Some minor formatting amendments were requested for the next version.

ACTION: RDTC to upload update to the site. Listed antibiotics not routinely stocked by community pharmacies/ GP surgeries (i.e. oral vancomycin, pivmecillinam, IV ceftriaxone) to be flagged at October CSB. An aim of antimicrobial stewardship is to change the culture around prioritising use of first-line agents based on resistance patterns rather than using second-line options because that's what's in stock; local provision should be made to ensure these agents are available.

2.3 GMMMG Dental Antimicrobial Guideline update

The group noted a draft update to the GMMMG Dental Antimicrobial Guideline. It was agreed that a greater emphasis on self-care and referral to a pharmacist or regular dentist would be appropriate for most of the conditions listed. The over-arching message that 'GPs should not be involved in dental treatment' should also be asserted more firmly.

ACTION: RDTC to feedback comments to author(s) and request the draft be aligned with self-care guidance/ reviewed by the GM Antimicrobial T+G group.

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

A summary of progress was provided. Final sign-off of the GM Commissioning Statement was awaited by some CCG DoCs but was hoped to have been received in time to meet the 'soft' launch date. The group heard that work was progressing to finalise the Self-Care Toolkit with appropriate 'red-flags' for the different healthcare professionals who may use this. 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.

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:

- RAG assessment for dornase alfa for cystic fibrosis to come to October's meeting- proposal to change status to RED for adults, to reflect repatriation of patients by NHSE. The group heard that repatriation of paediatric patients was pending.
- All high strength insulin preparations for Type 1 and Type 2 diabetes to be considered for GREY listing with a similar criteria for use as Toujeo. To come to October's meeting along with prescribing data for high strength and long acting analogues (as per monitoring log/ actions).
- An evaluation of evidence for Voke nicotine inhaler to be added to the work plan once drafted. (RDTC currently scoping this)

ACTION: RDTC to update action log accordingly.

4.0 Formulary and RAG

4.1 Formulary amendments September 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 RAG Assessment: Oral Typical Antipsychotics

The group had received a proposal from GM MH Services to review the RAG status of second generation oral antipsychotics for licensed indications and unlicensed indications that are approved by NICE. These are currently positioned AMBER shared care.

The request had been submitted on the basis that many of these agents have now been licensed since the 1990s, are widely in use, and are included in NICE guidance. As annual monitoring of schizophrenia, bipolar affective disorder and other psychoses is incentivised by QOF, it is recognised that the physical monitoring of patients is done relatively well in primary care.

The group agreed that the level of physical and biochemical monitoring required for these agents was appropriate for ongoing management in primary care. However concerns were noted around monitoring of the mental health conditions themselves and the mechanism/ access to referral back to the consultant should the patient's mental health deteriorate. Additionally, there were concerns that stable patients might remain on agents long-term who without the opportunity of review or de-prescribing. Clear referral criteria would need to cover both of these scenarios.

While open to down-rating the RAG of these agents in the future, FMESG concluded that the complex issues around commissioning and provision of mental health services across GM would act as a barrier to enacting changes at this time. It was acknowledged that Trafford CCG had undertaken a project around provision of mental health services in primary care and questioned whether something similar could be rolled out across the GM footprint. It was suggested further scoping should be undertaken to establish the benefits of the Trafford project, and to understand existing service provision/ limitations across CCGs. This scoping could then be used to inform a proposal to be submitted to commissioners.

ACTION: No action to be taken by FMESG at this time, pending resolution of issues highlighted re. access mechanisms to MH services.

4.3 RAG Assessment: ferric maltol plus monitoring of prescribing trends

The GM position of ferric maltol was reviewed in August 2018 following a licence extension to include adults with iron deficiency (previously licensed only for iron deficiency in patients with IBD). At that time FMESG recommend inclusion of ferric maltol on the Grey List (GREEN specialist advice) *for treatment of iron deficiency in patients with intolerance to, or treatment failure with two oral iron supplements*. On supporting this action, CSB had requested that an assurance report be submitted on the managed impact of the licence extension in 12 months' time (November 2019 CSB).

At September's meeting the group considered prescribing data for ferric maltol from July-18 to June-19. It was noted that there had been some growth in prescribing over this time but that overall numbers were relatively small (342 items totalling £13,660 over 12 months). The group also considered an amendment to the current RAG listing to remove the current restriction of 'specialist recommendation'. The group agreed that the current restriction to specialist recommendation was not clinically necessary, or in line with the product licence and may delay patients from receiving an effective treatment. It was however noted that the GM positioning was less restrictive than other localities (including Pan Mersey, South East London, Birmingham and Surrounds, Nottinghamshire formularies).

The group recommend RAG be amended to GREEN, with current GREY listing maintained. To remain on the monitoring log with a view to revisit prescribing trends in 6 months' time. No need to submit assurance report to CSB at this time.

ACTION: RDTC to open this recommendation for GM-wide consultation and update monitoring log accordingly.

4.4 Formulary application: Dapagliflozin in Type 1 Diabetes

The group considered a formulary application for dapagliflozin in type 1 diabetes, supported by the newly published NICE TA and NICE resource impact estimate. It was noted that this intervention reduces glucose variability with improved HbA1c and minor reduction in insulin requirements, however at a cost of increased hypoglycaemia. The risks of hypoglycaemia mean that target population have good hypo-awareness and are compliant with DKA monitoring advice.

The proposed positioning within the formulary application was GREEN specialist initiation. However FMESG noted that NICE and the SPC both specify that treatment be 'initiated and supervised by specialists in type 1 diabetes'. The group acknowledged that the monitoring requirements are not extensive and mostly relate to the stabilisation phase (initial one to two weeks of treatment) and agreed that at RED RAG would be overly restrictive/ impractical. It was agreed that an AMBER (RED pending development of SCP) positioning be proposed. Authors to be identified to develop an SCP which would specify the duration of specialist prescribing before transfer to primary care, along with the frequency of follow up.

ACTION: RDTC to open this recommendation for GM-wide consultation and seek pre-support to action from October CSB. Author(s) of SCP to be identified.

4.5 TA consideration/ RAG assessment: Sodium Zirconium Cyclosilicate

FMESG considered a RAG assessment for sodium zirconium cyclosilicate for hyperkalaemia, supported by the newly published NICE TA and NICE resource impact estimate. It was noted that NICE only recommend use if the company provides it according to the commercial arrangement. Based on the NICE resource impact (using the reference price because the commercial arrangement price is unknown) the anticipated cost to GM for the first year is around £50k, rising to £800k a year by 2023/24. It was noted that a similar product patiromer is on the NICE workplan (due Feb 2020).

The group recommend that sodium zirconium cyclosilicate be assigned RED RAG status to allow trusts to avail the PAS.

ACTION: RDTC to open this recommendation for GM-wide consultation and seek pre-support to action from October CSB.

5.0 Horizon Scanning and work plan

5.1 Monthly horizon scanning documents September 2019

The RDTC monthly horizon scanning document for September was considered by the group. The group noted updated NICE medical technologies guidance for PICO negative dressings for closed surgical wounds. It was questioned whether this fell under the scope of the GM wound-care formulary update.

ACTION: RDTC to check if PICO will be encompassed in the wound-care formulary, if not the group requested that a RAG assessment be brought to October meeting with a view to assign a RED status. It was also requested if relevant Public Health England publications could be flagged in future versions of the horizon scanning document- CD to raise this as a query at RDTC.

6.0 AOB

The group heard that ABCD data had been sought for the FSL audit- however it was yet to be confirmed if all GM sites had participated with the audit. Confirmation to be obtained from ABCD regarding which sites had provided data ahead of submission of an assurance report to CSB. Concern was highlighted that monitoring outcomes was a stipulation of the commissioning recommendation for FSL and that this might not be happening in practice.

Following a brief re-discussion of GM positioning of liothyronine, the group requested a DNP tool for liothyronine for psychiatric indications be brought to October's meeting.

The group also discussed UKCPA's concerns around Insulin Lispro Sanofi highlighted by a letter to Sanofi requesting a name change to promote greater differentiation from the reference product. FMESG were minded that no action was required to the GM formulary at this time in recognition of the need to optimise uptake of biosimilar medicines. However it was highlighted that the current GMMMG guidance on uptake of biosimilars is focussed on high cost drugs and would warrant expansion to support uptake on non-PBRe drugs.

The next meeting will be held on 22nd October 2019, 12.30-2.30pm, MFT-ORC.