FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 26th November 2019
12:30 - 2:30 pm
Pharmacy Dept MFT-ORC

Present:

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	July	Aug	Sept	Oct	Nov
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	✓	✓	A	✓	✓	✓	✓	✓	A	A
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A (LB)	✓	A	✓	✓	✓	✓	✓	✓	A
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	✓	✓	A	✓	A	✓	A	A	A	A
Aoidin Cooke (AC)	Medicines Management and Medicines Information Pharmacist	MFT-ORC	✓	A (LH)	✓	A (LH)	✓	✓	✓	A (LH)	✓	A (JL)
Claire Foster (CF)	Senior Medicines Optimisation Advisor	MHCC	✓	✓	✓	✓	A	A (FA)	A	A (FA)	A	A
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	A	✓
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓	✓	A	A	✓	A	A	A	A
Dr Hina Siddiqi (HS)	GP		✓	A	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	✓	✓	✓	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	✓	✓	✓	✓	✓	A	A
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓	✓ +NK	✓	✓	✓ +DN	✓	✓	✓

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above. Peter Selby acted as Chair in the absence of Pete Budden until item 4.4. Anna Swift acted as Chair thereafter. Jane Law, Senior MO Pharmacist RMCH attended on behalf of MFT-ORC.

Members heard that a GMMMG meeting was planned for December 12th at which subgroup attendance would be discussed.

As the group was not quorate, it was agreed that draft actions would be circulated to group members for approval prior to being progressed.

1.2 Declarations of Interest:

Ahead of discussing item 4.4 (DNP Assessment: Voke inhalator) KP declared that he had undertaken some private work with Pfizer who market smoking cessation products, thus he would not participate in this agenda item.

1.3 Draft minutes – October 2019

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

1.4 Matters Arising

Guidance for NHS organisations during the pre-election period prevents consultations from being launched unless considered essential. Thus consultation on actions from October's meeting had been put on hold until after the general election, and would be opened simultaneously with November's actions.

1.4.1 Consultation feedback (September):

No comments had been received via the consultation on proposed actions from September's meeting.

The following actions were agreed accordingly:

- Ferric maltol for iron deficiency in adults to be GREEN and GREY; an amendment to the previous recommendation of GREEN (specialist advice).

- Dapagliflozin with insulin for treating type 1 diabetes to be AMBER (RED pending development of a GM SCP). A link to TA597 to be added to the formulary. It was felt that ongoing input from specialist services was essential.
- Sodium zirconium cyclosilicate for treating hyperkalaemia to be RED. This to be flagged to GMMMG as a significant cost impact is expected base on the reference price (the commercial arrangement was not known at the time of the meeting). Increased workload for secondary care services providing repeat prescriptions for outpatient care of patients with persistent hyperkalaemia is also anticipated. A link to TA599 to be added to the formulary. RDTC to seek further details on commercial agreement to better estimate cost impact.
- A link to NG138: Hypertension in adults: diagnosis and management to be added to the formulary.

ACTION: RDTC to communicate these decisions to GMMMG for information. Decision on sodium zirconium cyclosilicate to go to GMMMG with cost impact prior to actioning on the RAG.

1.4.2 Action log

Updates on the action log were noted:

- Use of omeprazole MUPs in babies and children leaflet: this to be retired from the GMMMG site and instead links added to the Medicines for Children leaflet and nhs.uk advice on choking. Action to be closed from the log.
- A meeting had taken place between dermatologists at SRFT and JCT around queries relating the emollient ladder. It was intended that a revised version would be produced; FMESG to be updated in due course. RDTC to feed in comments from MFT-ORC around product choice and management of inpatients into this review process. A meeting of the dermatology group who authored the pathways is scheduled for December. RDTC to seek an update ahead of January's meeting.
- A re-draft of the guidance for the covert administration of medicines in care homes following initial clinical check by RDTC had been received. FMESG members present supported this being opened for consultation pending a re-check to ensure initial queries had been addressed by the authors.
- The additional notes document from chapter 6 of the formulary could be retired from the action log. RDTC to include any pertinent information contained in this document within the formulary chapter itself. Unnecessary to bring back to the group for approval to enact these inclusions.
- AM had contacted NICE regarding implementation of TA607 Rivaroxaban in CAD/PAD to request assistance in validation of a potential bleeding risk assessment tool for the intervention. A response from NICE was awaited. RDTC had been contacted by the divisional lead pharmacist for heart and lung at MFT around the development of supportive material/ educational materials and would liaise with the specialist team around development of these.

1.4.3 Monitoring log

The monitoring log was noted by the group, along with prescribing figures for Noqdirna® from the previous 12 months. This had been added to the monitoring log to track prescribing growth following a previous recommendation from FMESG that the agent should not be added to the GM formulary. Whilst there had been some growth in prescribing (up 46% vs. the previous 12 months) however total prescribing and spend remains low (218 items totalling £3,300). This re-affirmed FMESG's previous assertion that a clear clinical benefit or need for routine use across GM had not been demonstrated.

ACTION: Noqdirna to remain on the monitoring log to recheck prescribing figures in 6 months' time. To be retired from the monitoring log or to be assessed for GREY list/ RAG position depending on prescribing data.

2.0 Medicines Optimisation

2.1 SPS Insulin Glargines Product Safety Review

A recently published update to the SPS *in use product safety assessment report for insulin glargines* was noted by the group. In particular this highlights safety concerns associated with the different product strengths of Toujeo® and Toujeo Doublestar® preparations.

ACTION: The group agreed the following actions should be taken in response to this document:

- The current grey listing of insulin glargine- high strength (Toujeo) should be annotated to highlight the different strengths of the Toujeo products.
- RDTC to liaise with LPC to establish if any actions around education and awareness are planned in response to the document.
- AM to raise a communication via CCG leads around ensuring an alert is added to GP prescribing systems for both strengths of Toujeo.
- RDTC to check GM prescribing data to ascertain how much is being prescribed generically rather than by brand to inform if further work is needed to around the safe prescribing of insulins.

2.2 Local appeals against implementation of NHSE guidance

FMESG reviewed a proposal to include an additional GM position on responding to appeals within the *GMMMG Commissioning Statement: Conditions for which over the counter items should not routinely be prescribed in primary care*. The proposed position directs that appeals be managed locally at CCG level and that this process should be GP/ practice lead. The group supported inclusion of the proposal in the commissioning statement, highlighting the importance of ensuring any such issues are resolved efficiently.

ACTION: AM to update the commissioning statement accordingly, RDTC to upload to the site as V3.

2.3 Inhalers steering group (verbal update to group)

AM updated the group on the formation of an inhaler steering group that had been established to consider the carbon footprint/ greenhouse gases impact of inhalers in GM. This work as in early stages however the aim would be to work towards reducing GM use of inhalers with high greenhouse gas burden which would ultimately impact on GM formulary and pathway choices associated with a move away from MDIs to DPIs. Four task and finish groups has been set up; guideline, implementation, monitoring, and industry engagement. The guideline group would feed in to PaGDSG and FMESG going forward however no action was required by the GM subgroups at present.

3.0 FMESG Work Plan 2019- 2020

3.1 Consideration of items for work plan

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

- Praziquantel and albendazole to be added to the RAG list as RED for hydatid disease. These are unlicensed pharmacy specials. LFT monitoring may be indicated for both (plus FBC for albendazole). Praziquantel is subject to P450 interactions (particularly CYP3A4) and is dosed according patient body weight. Patient numbers are small; there are approximately 10 cases of hydatid disease in England and Wales per year. Patients are managed by infectious diseases specialists, usually in conjunction with the hepatobiliary surgical team.
- Zanamivir solution for infusion for complicated life-threatening influenza A or B infection to be added to the RAG list as RED. This is to reflect the appropriate care setting for this product.

ACTION: The above recommendations to be opened for GM-wide consultation.

The group also considered a request to consider i-Port Advance injection port for use in type 1 diabetes. The product is not listed in the drug tariff and cannot be prescribed on FP10. 3 IFRs had been received for this product in the past 6 months from different sites across GM. Annual cost per patient is around £870. FMESG members considered that some further scoping would be required to understand this item further- this should include some indication of patient cohort and place in therapy. This would help FMESG understand the priority of this work better and whether it was the best subgroup to address this. It was also noted that there are similar products for subcutaneous administration available and some consideration should be made to include these in scoping.

ACTION: AM/ JCT to undertake additional scoping as suggested.

3.2 Monthly horizon scanning document November 2019

The RDTC monthly horizon scanning document for November was considered by the group. The license extension for Toujeo to include adolescents and children from the age of 6 was noted. FMESG request that RDTC undertake a review of the evidence in the paediatric population to help inform the place in therapy for this age group.

Additionally, a MHRA DSU was noted for Picato® (increased incidence of skin tumours seen in some clinical studies). This is included in the GMMMG dermatology pathway for the management of AK. The group heard that the dermatology group who had authored the pathways were planning to discuss this at their December meeting and would feedback around any changes in recommendation/ suggested amendment to the formulary and pathway. A link to the DSU to be added in chapter 13 of the formulary in the meantime.

ACTION: RDTC to update action log accordingly. To await feedback from the dermatology group meeting in relation to Picato.

4.0 Formulary and RAG

4.1 Formulary amendments November 2019

Suggested formulary amendments were noted and approved as follows:

- Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea to be added to formulary and RAG as a RED drug, along with a link to NICE TA605. This is a CCG commissioned PbRe medicine. It is already on formulary for migraine prophylaxis and hyperhidrosis in line with respective NICE TAs (both RED RAG).
- Lanedelumab for preventing recurrent attacks of hereditary angioedema to be added to the RAG list (but not formulary) as a RED drug, along with a link to NICE TA606. This is a NHSE commissioned PbRe medicine.
- Voretigene neparvovec for treating inherited retinal dystrophies caused by RPE65 gene mutations to be added to the RAG list (but not formulary) as RED drug, along with a link to NICE HST11. This is a NHSE commissioned PbRe medicine.
- Pentosan polysulfate for bladder pain syndrome with glomerulations or Hunner's lesions to be RED, with a link added to NICE TA610. This is an amendment of the current GMMMG position of GREEN (following specialist initiation) and GREY for use as a second-line treatment for bladder pain syndrome, where conservative measures have failed. The NICE TA states that it may be considered as an option if it is used in secondary care and if the company provides it according to the commercial arrangement. There is a small amount of existing prescribing within primary care; 10 items July - September 2019 (totalling £4,600).
- Ciclosporin for nephrotic syndrome in paediatrics to be RED. This is an amendment of the current position of AMBER as all prescribing for this indication has been repatriated to secondary care.
- Zostavax® for use outside of the national shingles vaccination programme to be RED and annotated 'In patients who are eligible to receive vaccination outside of the national vaccination programme (i.e. due to receiving chemotherapy or immunosuppressant therapy)

it is the responsibility of the specialist service to administer vaccination; there is no route of reimbursement if administered in primary care.'

ACTION: RDTC to open the above recommendation for GM wide consultation.

Additionally, the group agreed that links to CKS and BSSM guidance on erectile dysfunction should be added in section 7.4.5 of the formulary; the GMMMG guidance on PDE5 inhibitors to be retired thereafter.

4.2 Guidelines on defining RED AMBER GREEN Status- 2019 update

The GMMMMG Guidelines on defining RAG status have been pending review since September, when GMMMG approved the proposal that DNP drug listings could be indication specific and that indications themselves could be made DNP. An updated draft was considered at November's meeting. Key changes in the draft version include:

- Better alignment with NHSE recommendations on shared care and what medicines are/are not suitable for this
- Clearer information on classification of AMBER and GREEN medicines
- Aligning of explanations of RAG status with those that feature on the RAG page of the website.
- Removal of conflicting and confusing language that 'treatments that have been recommended' would include those with a DNP status,
- Removal of non-essential information/ information outside of the scope of the guideline.

FMESG members in attendance agreed that further comments should be welcomed on this update.

ACTION: CD to send draft round FMESG members to seek further comment. Also to check with CCG leads which areas have opted out of particular SCPs/ developed their own to help inform the future review of these documents as part of PaGDSG work stream.

4.3 DNP Assessment: liothyronine for resistant depression

As per previous scoping, the group considered a DNP assessment for liothyronine in the treatment of resistant depression. This had been triggered by recent discussions in response to updated guidance from RMOC and in recognition of the lack of evidence to support the use of liothyronine for this indication. The group expressed that the RMOC recommendation that 'consultant NHS endocrinology advice is also recommended' for any patients receiving ongoing liothyronine for resistant depression was of limited benefit unless the patient had a confirmed diagnosis of hypothyroidism. Following consideration of an evidence summary for liothyronine in resistant depression, the following recommendation was agreed:

Liothyronine for resistant depression to be assigned DNP status (criterion 1): there is very limited evidence for thyroid hormones in depression. Where thyroid hormones are necessary due to hypothyroidism, treatment should be initiated with standard levothyroxine. We recommend that existing patients are reviewed by a consultant NHS psychiatrist. See NHSE guidance on items not for routine prescribing in primary care and RMOC Guidance on Liothyronine.

ACTION: The above recommendation to be opened for consultation. RDTC to share consultation link with MH Services.

4.4 DNP Assessment: Voke® inhalator

As per previous scoping, the group considered a DNP assessment for Voke inhalator. The product was first licensed in 2014 but has only been launched at the end of 2019. It is a hybrid of Nicorette® 10mg Inhalator (the reference product is no longer marketed) and is available as a GSL medicine. A similar electronic device e-Voke was assessed by the NTS in 2016, although this product was never launched. At that time e-Voke was assigned a DNP status on the basis that

further data was required evaluating the use of e-Voke as a stop smoking aid, and comparing its use to other NRT therapies. The evidence used to support the licencing of Voke is identical to that for e-Voke (i.e. based on the same reference product) and there has been no new evidence published since the evidence was reviewed in 2016.

The group considered that while smoking reduction/ cessation is a priority within GM, the role of FMESG is to support the use of product for which there is evidence. At present there is insufficient data to support the use Voke or e-Voke ahead of existing options for stopping smoking. Additionally, there were concerns that the reference product was no longer marketed and whether this indicated a lack of efficacy (a higher strength version is still available).

The group recommended that the current DNP (criterion 1) for e-Voke be expanded to include Voke: further data is required evaluating the use of Voke® and e-Voke® as a stop smoking aid/ comparing their efficacy to established nicotine replacement therapies (NRT) prior to their use within the Greater Manchester region.

ACTION: The above recommendation to be opened for consultation. To be made clear that PH is the commissioner.

5.0 AOB

Nil

The next meeting will be held on 28th January 2020, 12.30-2.30pm, MFT-ORC.