FORMULARY AND MANAGED ENTRY SUBGROUP

March 28th 2017 Minutes
12:30 - 2:30 pm
Pharmacy Dept. CMFT

Present:

Name	Title	Organisation	Jan	Mar	Apr
Elizabeth Arkell (EA)	Medicines Management Lead	UHSM	✓	A	
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A	✓	
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	A	✓	
Dr Paul Chadwick (PC)	Consultant Microbiologist and Chair of Meds Management Committee	SRFT	✓	✓	
Aoidin Cooke (AC) /Lorna Hand (LH)	Medicines Management and Medicines Information Pharmacist	CMFT	✓	✓ LH	
Claire Foster (CF)	Senior Medicines Optimisation Advisor	SM CCG	✓	A	
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	✓	A	
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	✓	✓	
Prof Peter Selby (PS)	Consultant Physician	CMFT	✓	✓	
Lindsay Harper (LH)	Director of Pharmacy	SRFT	✓	✓	
Jonathan Peacock (JP)	Deputy Chief Pharmacist	WWL	✓	✓	
Zoe Trumper (ZT)	Medicines Management	Pharmacist Wigan Borough CCG	✓	A	
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓	
Bhavana Reddy (BR)	Head of Prescribing Support	RDTC *(Professional Secretary)*	✓	A	
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	✓	✓	

1. General Business

1.1 Introductions and Apologies

Apologies had been received in advance as noted above.
Dr Lalantha Leelarathna (Consultant diabetologist at CMFT) was welcomed to the meeting for discussions around items 2.1 and 2.3.

1.2 Declarations of Interest:

One declaration of interest had been raised prior to the meeting by KP relating to agenda item 4.2.1. As this DOI was over 12 months old, it was no longer deemed to be a DOI as per the GMMMG policy; however KP requested that it still be noted by group members for transparency. No other declarations of interest were made.

1.3 Draft minutes (Jan 2017)

The minutes were agreed as accurate following minor re-wording of the paragraph relating to high-dose fexofenadine.

2. New Drugs

2.1 New drug review: Fast acting insulin aspart (Fiasp®)

The group considered an application from Dr Leelarathna to review fast acting insulin aspart Fiasp®. The group reviewed a draft appraisal from the RDTC for this product and noted that this agent is a new formulation of insulin apart with nicotinamide added to produce a more rapid onset of action. The group noted that clinical trials showed it to be non-inferior to standard insulin aspart (NovoRapid®) when used in a basal-bolus regimen in patients with T1DM or T2DM, and superior to basal insulin alone in patients with T2DM. There was no overall difference in adverse events, although it was recognised that this is a black triangle drug. Fiasp® has the same acquisition cost as NovoRapid, although the group queried whether the patent expiry of NovoRapid due in 2017 may result in cheaper alternative NovoRapid options.

The group understood that Fiasp® may be of benefit to those patients requiring a rapid-acting bolus insulin and those who may desire additional flexibility in the timing of their mealtime insulin, but asked Mr Leelarathna for further clarification on the numbers of patients who he would expect to benefit from Fiasp®, he explained that he sees Fiasp® as a good option for the majority of T1 and T2DM patients. The group queried how many patients currently on NovoRapid required a move to Fiasp and what the real world benefits of this move would be. Whilst they recognised that this agent may be "preferred" by patients wishing flexibility in the timing of dosing, the group were mindful that NovoRapid was due to come off patent this year and whilst there was no "generic" alternative to discuss that further information on the possibility of a "generic" was warranted. The group also expressed reluctance to support the use of this agent with its black triangle status over a more established agent.

Action: Dr Leelarathna to define more specifically those patients who would benefit from this agent over more established therapies and to communicate this to the group. The group will continue their consideration of this application upon receipt of this information. MM to draft recommendation.

2.2 New drug review: Duavive®

The group considered Duavive® (a fixed dose combination of conjugated oestrogens and the oestrogen receptor modulator bazedoxifene acetate) for the treatment of oestrogen deficiency symptoms. The group are minded not to recommend this product for use at this time due to insufficient evidence to quantify the risks/benefits of this treatment vs. current treatment and a lack of long-term safety data.

Action: MM to draft recommendation for subgroup approval

2.3 New Drug review: FreeStyle Libre Monitoring Device

The group considered their draft recommendation for this product based on previous discussions. Dr Leelaranthna commented on the benefits this system offers, particularly in those that avoid testing due to their reluctance to finger-prick testing. The group acknowledged that this form of testing was understandably more pleasant for patients, but were concerned about the cost impact posed when this product became available on the NHS. They recognised the need for their recommendation to rationalise the patient population that would benefit the most from this product. The group asked that further consultation be undertaken with specialist diabetologists in order to identify more specifically the group of patients that would benefit the most from this product to ensure the most effective use of NHS resources.

Action: MM/AM to communicate further with specialists to identify a patient group for this product.

3. RAG List

3.1 Drugs used by the eating disorder service

FMESG considered the proposed RAG status for drugs used in the eating disorder service and agreed that:

• LH to communicate with the service to discuss vitamin B and the rationale behind product choices and suggested doses. The group accepted the use of Forceval, and agreed that Dalvavit seemed like a sensible option but asked for some clarification on how long "long-term" is.

• Potassium phosphate to be classed as a red drug; the group highlighted concerns regarding hypocalcaemia during electrolyte imbalance, and as these patients are being regularly reviewed by secondary care prescribing should remain with the monitoring in secondary care.

• Primary care members of the group expressed concern regarding SSRI prescribing in children with mental health problems and felt that an update to an existing SCG was not sufficient, they have asked for communication with the Pathways group as to development of a new separate SCG but until this is available agreed these agents will remain RED.

• The use of antipsychotics was to remain red.

• Nutritional supplement drinks: GPs are happy to prescribe cost effective products (a robust evaluation of the most cost effective products may be necessary), however there should be a plan for patients to reengage with food.

Action: AM to send these proposed decisions to GM stakeholders for comment which would return to the May FMESG for final approval.

3.2 Proposed RAG status recommendations post-consultation

The following RAG status decisions were approved at the first meeting of the FMESG and had been sent out for stakeholder consultation with comments being received back from three CCGs but none of the Trusts. Those who did respond agreed with the recommendations as follows:

- Imiquimod for actinic keratosis – green
- Imiquimod for genital warts – green specialist initiation (local commissioning arrangements may vary)
- Pre-meds for patients receiving enzyme replacement therapy – red

A query was raised as to whether there was a need for a RAG status for imiquimod for genital warts as ordinarily this service would be commissioned as a sexual health service by the LA, however a RAG status was assigned but it would be noted that commissioning arrangements would vary locally.

Action: MM to submit these recommendations to GMMMG in April for ratification

3.3 RAG query: Formulary eye chapter

The group discussed a request to review the RAG status of eye preparations within the formulary and agreed that this work be undertaken via a small working group, with draft recommendations to come back to FMESG in due course.

Action: MM to communicate with the specialist and specialist pharmacist at CMFT in the first instance.

3.4 RAG status assessment: Liothyronine

The group assessed liothyronine for a RAG status. Liothyronine prescribing is currently restricted for use only in hypothyroid crisis and short-term post thyroid surgery as per the GMMMG Grey List. The group used the agreed RAG criteria to assess liothyronine for a RAG status as per these indications and it was agreed that a RED status be issued to reflect the continued specialist involvement required for this indication.

Action: It was agreed that these proposals would be distributed to Chief Pharmacists and CCG Leads to gather comments from their organisations and these comments would return to the May FMESG for final approval.

Action: AM to send these proposed decisions to GM stakeholders for comment which would return to the May FMESG for final approval.

3.5 RAG status review: Naltrexone

Naltrexone is listed with a RED status for alcohol disorders but with an "other" status for opioid dependence. The group had been asked to review the latter and considered comments which had been submitted to the previous Interface group to understand the issues around this status. It appeared that the lack of status resulted primarily from the differences in commissioning arrangements across GM. The group agreed that this should not be a reason for a lack of status and that commissioning was only part of the RAG decision process. The group discussed the safety implications of naltrexone having a red vs amber or green status, noting that it has a red status for alcohol disorders. It was agreed that as there were some requirements for ongoing specialist input i.e. the SPC states that ‘‘Naltrexone treatment should be initiated and supervised by suitably qualified physicians" that this agent would need to be red or amber. The group then discussed the different commissioning arrangements and how best to accommodate patients' needs; it was agreed that an amber status would be most appropriate. A request would be sent to the PaGDSG to develop a shared care guideline for the use of naltrexone for opioid dependence and asked that the role of the patient be incorporated into the SCG.

Action: AM to communicate proposal for consultation with GM stakeholders and to return the comments to the May FMESG meeting, MM to request SCG development by PaGDS

Formulary

3.6 Formulary amendments

It was agreed that the formulary will be updated in line with TA420 to TA433, and the January and February MHRA Drug Safety Updates. Prempak C and Premique 0.625 have been discontinued by the manufacturer and will be removed from the formulary; there is no direct alternative to these products to be added to the formulary.

The group noted that a licensed glycopyrronium oral solution for the symptomatic treatment of severe sialorrhoea is now available, and may represent a cost increase against the previously unlicensed product. It was suggested that local work be undertaken by the CCGs to assess this potential cost impact. This item is not currently listed in formulary.

Chapter 2 of the formulary will be updated to include a link to the GMMMG approved PCSK9 inhibitors recommendation for hypercholesterolemia. Rosuvastatin will be added to the formulary as an alternative to atorvastatin (green RAG status), in line with this recommendation. Rosuvastatin as Crestor® is currently more expensive than generic atorvastatin but generic versions have been approved and should be available in the near future.

Action: MM to update the formulary following GMMMG approval

3.7 Formulary applications

3.7.1 Enstilar®

An assessment of Enstilar® for addition to the formulary had begun at the January meeting, however it had been agreed that LH would discuss the application further with SRFT specialists to gain an idea of patient numbers. There was discussion from the group about the appropriate use of steroid preparations in general for plaque psoriasis, with concern that these products were being used inappropriately, and that further discussion around this issue with the specialists would be useful to understand their rationale. LH explained that this application was being taken through SRFT D&T where further discussions around patient numbers would be undertaken and that information would be brought back to the May FMESG meeting.

Action: LH to communicate back to FMESG at the May meeting

3.7.2 Invicorp®

An application to the formulary for Invicorp® (aviptadil/phentolamine mesilate injection) was considered by the group for formulary inclusion. It was noted that this agent was requested for use in ED patients second-line following failure of other ED treatments such as PDE-5Is and other non-injectable ED products. The group considered a review of the evidence by the RDTC and noted that Invicorp demonstrated similar efficacy to alprostadil (currently on-formulary), however the trial limitations were noted i.e. high study withdrawal rates and high non-compliance rates. Whilst Invicorp demonstrated a significantly lower incidence of pain vs Alprostadil, there was a significantly higher incidence of facial flushing, although it has similar safety warnings and precautions to alprostadil. Query was raised as to the unusual distribution of Invicorp from the manufacturer to community pharmacy and the possibility of additional charges this may cause for the primary care prescribing budget and requested further information to be brought to the May meeting.

Action: MM to bring the requested information to the May meeting

3.7.3 Ferric maltol

Ferric maltol is an oral iron preparation licensed for the treatment of iron deficiency anaemia (IDA) in adults with inflammatory bowel disease (IBD). The group considered it for formulary inclusion in line with the GMMMG NTS recommendation (Sept 2016) i.e. 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. It was agreed that a GREEN (gastroenterologist recommendation) status would be assigned to this agent.

Action: AM to communicate proposal for consultation with GM stakeholders and to return the comments to the May FMESG meeting

3.7.4 Ticagrelor NICE TA supporting information for formulary

The group discussed ticagrelor and NICE TA420 alongside a summary of information produced by the Shared Service. The group agreed that this information useful, however asked that where the document recommended review by a cardiologist that this be changed as it was unrealistic that cardiologists would be able to review all these patients. It was agreed that following this amendment a link to this document should be added into the formulary.

Action: AM to amend the document to replace "cardiologist review" with suitable wording to reflect GP or specialist review.

4. DNP and Grey Lists

4.1 DNP assessment: Ezetimibe (for uses outside of NICE guidance)

The group considered a request to assess ezetimibe for the DNP list, for any uses outside of NICE. It had been noted that in some GM practices ezetimibe was being used to augment statin

use where the statin dose is 80mg Atorvastatin and cholesterol is not "to target", without any clinical benefit, resulting in unnecessary polypharmacy. The group reviewed prescribing data for ezetimibe across GM and discussed the issue raised but felt that this was an issue to be handled at local practice level as it would be too difficult to enforce at a GM level.

Action: No further action

4.2 DNP/Grey list assessment: Blephasol lotions and wipes

The group approved the addition of all commercial eyelid cleansing preparations to the DNP list. There is limited evidence to support the effectiveness of these products over traditional eyelid hygiene methods, and so they were deemed an ineffective use of NHS resources. The restriction on prescribing of commercial eyelid cleansing products should represent a cost saving to GM (Primary care spend on Blephasol® products alone was £20k across GM in the last three quarters)

Action: MM to submit recommendation to GMMMG for approval.

5. Horizon Scanning and Work-plan

The group considered the February and March 2017 RDTC Monthly horizon scanning documents and reviewed the work-plan for the May meeting. Baracitinib was noted, however a NICE TA is due in Sept 2017 and so FMESG will await the NICE position.

A number of items were raised and agreed for addition to the work-plan:

- An inhaler guide similar to that for COPD is developed to support the asthma pathway. MM agreed that the RDTC could support this, this would return to the May meeting
- A letter/statement be developed explaining that FMESG does not consider items based on whether they are available via a rebate scheme or not. MM to draft this letter for consideration by the group in May
- The Sodium Oxybate recommendation issued by the previous NTS group be updated to reflect its position on the PbRE list, MM to return this to the May meeting
- The RAG status of safinamide be assessed at the May meeting
- The black triangle symbol be removed from Esmya® in the formulary, MM explained that this will be done in the next round of updates i.e. post the April GMMMG meeting.

6. Additional items

Nomination of vice chair: it was agreed that a secondary care representative be put forward for the position of vice chair as the Chair position was held by primary care. Lindsay Harper was supported by the group for this position.

Action: MM to submit this recommendation to GMMMG for approval

The next meeting will be held on 23rd May 2017 at 12.30pm, CMFT.

Post meeting note: the May 2017 meeting was postponed and took place on June 13th 2017 at 12.30pm.