GMMMG Greater Manchester Medicines Management Group NHS

FORMULARY AND MANAGED ENTRY SUBGROUP

June 13th 2017 Minutes
12:30 - 2:30 pm
Pharmacy Dept. CMFT

Present:

Name	Title	Organisation	Jan	Mar	May
Elizabeth Arkell (EA)	Medicines Management Lead	UHSM	✓	A	✓
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	A	✓	A
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A	✓	✓
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	A	A	✓
Dr Paul Chadwick (PC)	Consultant Microbiologist and Chair of Meds Management Committee	SRFT	✓	✓	A
Aoidin Cooke (AC)	Medicines Management and Medicines Information Pharmacist	CMFT	✓	LH ✓	✓
Claire Foster (CF)	Senior Medicines Optimisation Advisor	SM CCG	✓	A	✓
Dr Anne Harrison (AH)	Gp Prescribing Lead	Trafford CCG	A	A	✓
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	✓	A	✓
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	✓	✓	A
Prof Peter Selby (PS)	Consultant Physician	CMFT	✓	✓	✓
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	A	✓
Lindsay Harper (LH)	Director of Pharmacy	SRFT	✓	✓	A
Jonathan Peacock (JP)	Deputy Chief Pharmacist	WWL	✓	✓	A
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)*	✓	✓	A

1. General Business

1.1 Introductions and Apologies

Apologies had been received in advance as noted above. The group welcomed some new members to the group: SB from Pennine Acute, SS from Bolton FT and AH from Trafford.

1.2 Declarations of Interest:

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

1.3 Draft minutes (March 2017)

The minutes were agreed as accurate record following a minor re-wording of the paragraph relating to naltrexone and updating of the attendance register.

1.4 Matters Arising

Rebate Position Statement

The above statement was approved by the group with no changes. This statement will be published on the GMMMG website once it has been ratified by GMMMG.

Action: BR to take to GMMMG for ratification.

2. New Drugs

2.1 Draft Recommendation: Fast acting insulin aspart (Fiasp®)

The group discussed the draft recommendation and noted the comments received by specialists. The group agreed with the specialist from Salford who stated that Fiasp® would useful in pregnant patients due to the strict one hour post prandial targets. The group was less clear on the proposed use in type 1 patients with post prandial hyperglycaemia. The benefits of treating post prandial spikes in non-pregnant type 1 or type 2 diabetics is unclear as indicated by the NICE guidance.

The NICE guidelines states that *'…., the values achieved by people in the trial associated with reduced diabetes complications are not clear and the impact of hyperglycaemia at different times of day (particularly comparing fasting and pre-meal with post-prandial glucose excursions) on risk for diabetes complications remains uncertain. Indeed, the evidence suggests that only glycated haemoglobin predicts both micro- and macro-vascular disease and SMBG may best be considered as a tool to achieve target HbA1c'*

The group therefore agreed that further clinical data is needed to show the benefits of treating post prandial spikes before Fiasp® can be recommended for use as outlined, particularly as it goes against current advice from NICE. It was also noted that whilst the two products (Novorapid® and Fiasp®) are currently the same price, Fiasp® is classed as a black triangle product which requires extra safety monitoring and therefore it should not be used over NovoRapid except where there are proven benefits such as in pregnant patients.

The group also noted that the applicant has been a paid speaker for Novo Nordisk which is a clear conflict of interests.

It was agreed that use in pregnant patients only should be recommended and the draft recommendation should be adjusted to reflect this.

Action: BR to change recommendation as above and take to GMMMG for ratification.

AM to feedback to Dr Leelanthra and ask for further info.

2.2 Draft Recommendation: FreeStyle Libre Monitoring Device

The group again considered their draft recommendation for the above product, the recommendation was based on previous discussions. It had been amended in light of comments received by specialists; however the patient group identified by specialists was quite

large and would have a large cost impact with limited evidence of cost effectiveness. The group was not clear on how 'poor control' would be defined and if the FreeStyle Libre device had proven benefits over normal finger prick testing in this group of patients. It was noted that a NICE med tech innovation briefing (MiB) would be available shortly and as there were potentially new trials which the initial review (from September 2016) did not include, it was felt that this item should be put on hold and the MiB briefing reviewed at a future meeting. This had been sent to GMMMG however this item would now be disregarded.

Action: BR to add MiB to agenda for next meeting

2.3 Draft Recommendation: DUAVIVE®

The group reviewed the draft recommendation and approved it with no further amendments.

This would go to GMMMG on Thursday for ratification and following this meeting, the recommendation would be shared on the website.

Action: BR to add to website once approved.

3. RAG List

3.1 Proposed RAG status recommendations from March Meeting (post GM consultation)

FMESG considered the comments received for the proposed RAG status decisions following the last meeting and the proposed RAG status decisions were approved as follows:

- Liothyronine – RED, for use in hypothyroid crisis and short-term use post-thyroid surgery
- Naltrexone – AMBER for opioid dependence.
- Ferric Maltol – GREEN (following gastroenterologist initiation)
- Drugs used by the Eating disorder service.
    1. Potassium phosphate – RED
    2. SSRIs – AMBER
    3. Antipsychotics – RED
    4. Nutritional supplement drinks – GREEN (formulary choices only)
    5. Vitamin B – GREEN (formulary choices only)

For the drugs used by the eating disorder service, it was noted that an SSRI Shared Care Protocol (SCP) for use in children was already available. Patients would be started on SSRI's for depression and so the currently available SCP's would apply to these patients also.

There was some discussion around the Ferric Maltol NTS statement which had been produced and approved last year with specialist input. Concerns had been raised by other specialists around the stipulation that three ferrous salts be tried prior to starting patients on Ferric Maltol. Specialists felt that this would take too long and that it would lead to use of IV iron over Ferric Maltol as there would be an urgency to correct the anaemia by this stage. It was unclear whether earlier use would prove to be cost effective. It was noted that SMC had not approved the use of Ferric Maltol as the company did not present a sufficiently robust clinical and economic analysis to gain acceptance. Therefore this would need to be reviewed.

It was agreed that as the above consultation related to the RAG status only, that an appeal should be made on the NTS recommendation, by the specialists concerned. This could be done via email to the professional secretary. Once an appeal was received this would be added to the workplan and agenda for further discussion and the clinical data could be re-looked at, at this stage.

Action: BR to take RAG status decisions to GMMMG for sign off.

3.2 RAG Assessments

3.2.1 Opicapone

The group discussed Formulary/RAG assessment tool and the adding of opicapone to the formulary following the NTS recommendation. It was agreed that opicapone should be added to the formulary however tolcapone (which was currently in the formulary as second line) should be removed. This would be submitted to GMMMG for ratification in August.

A RAG status of 'Green following specialist recommendation' was assigned. This would go out to consultation and brought back to the next meeting if available.

Action: BR to submit these recommendations to GMMMG for ratification.

AM to send out RAG consultations.

3.2.2 Safinamide

The group discussed Formulary/RAG assessment tool and the adding of safinamide to the formulary following the NTS recommendation. It was noted that apomorphine was in the formulary; and as a third line option it was likely safinamide would be used before this. It was therefore agreed that safinamide should be added to the formulary. This would be submitted to GMMMG for ratification in August.

A RAG status of 'Green following specialist initiation' was assigned. This would go out to consultation and brought back to the next meeting if available.

Action: BR to submit these recommendations to GMMMG for ratification.

AM to add RAG consultations to website and send email to organisations.

3.2.3 Drugs used for metabolic disorders.

An application had been received regarding the above. This was an NHS England commissioned service and currently GPs are not expected to prescribe for these patients. The group therefore agreed that rather than adding in the separate drugs a line for all drugs used in metabolic disorders should be added to the RAG list with a RAG status of RED, NHS England commissioned.

There was a query around prescribing of pre-meds prior to enzyme replacement therapy which had been discussed at a previous meeting. This again was an NHS England commissioned service and GPs are not expected to prescribe for these patients. It was noted that SRFT issue pre-meds via home care and this is funded by NHS England. The same should therefore apply to CMFT as they are providing the same service. The NHS England manual states that *'CCGs are not expected to commission any elements of this service'.* GMMMG agreed that this includes provision of pre-meds. Manchester CCG would pick this query up with CMFT contracting on behalf of the CCGs.

Action: BR to submit these recommendations to GMMMG for ratification.

AM to add RAG consultations to website and send email to organisations.

3.2.4 Modafinil Status Review

A request had been received from Wigan CCG to review the current RAG status of modafinil as Pan Mersey APC have a Green (specialist initiation) RAG status. The current GMMMG RAG status for the licensed indication (Sleepiness associated with narcolepsy) is Amber. All other non-licensed indications are RED. It was noted that the license for modafinil had been restricted due to safety concerns relating to psychiatric disorders, skin and subcutaneous tissue reactions as well as significant off-label use and potential for abuse. A local SCG is available from Salford Trust for the narcolepsy indication. A GMMMG version will need to be developed. The group agreed that the AMBER status for narcolepsy should remain as there is some monitoring required and the patient needs to remain under specialist. The group agreed however that the RED RAG status for unlicensed indications should be removed from the RAG list and that these indications should be assessed for the DNP/Grey List.

Post meeting note: a query has been received regarding the use of modafinil for use in patients with Parkinson's disease; use in these patients is unlicensed but is recommended by NICE guidance, this will need to be considered in the DNP/Grey list assessment.

Action: BR to add modafinil DNP assessment to agenda for July.

3.2.5 Octreotide

AM introduced this agenda item. A proposed change to RAG status for octreotide for Intestinal secretion inhibition for palliative care use had been received following review of the palliative care guidelines. It was noted that use is likely to be at short notice and towards the end of life particularly in the management of GI obstruction syndromes. It was felt that this particular use warranted a separate RAG status entry of Green following specialist palliative care recommendation. The group discussed this proposal however no decision made as further information was required. Members queried whether this is needed in an emergency and what would the duration of treatment be. Also would this be classed as true end of life care or is it palliative? There were also questions around whether any other drugs would fall into this same category. The group felt that GPs would require specialist input and support to prescribe octreotide in these circumstances and felt that AMBER status was probably more in keeping with the monitoring requirements and specialist nature of the indication.

ACTION: AW to check with specialist and bring back to future meeting.

4. Formulary

4.1 Formulary amendments

It was agreed that the formulary will be updated in line with NICE TAs 434 to TA 443 and updated TAs: 180 and 340. Links to the MHRA safety guidance will also be included.

The group discussed the formulary entry for buprenorphine and agreed that any reference to brand names should be removed. All formulary entries should be generic however the following statement will be included: *'Patches should be prescribed by brand as the frequency to be applied may vary between brands'.*

Action: MM to update the formulary following GMMMG approval

4.2 Formulary applications

4.2.1 Enstilar®

The group discussed the Enstilar® application again. LH had discussed this with specialists at SRFT as proposed at the last meeting. There were still concerns around use of this preparation first line which is what was proposed and the amount of steroid used. The clinical trial data showed that patients were using more of the Enstilar® product overall during the trial period when compared to Dovobet®. Therefore whilst Enstilar® is the same price as Dovobet®, more product was used thereby increasing costs. It was also unclear as to whether the perceived 'better efficacy' is due to better patient adherence, greater steroid consumption or better absorption of product in the foam delivery versus ointment. There was some discussion 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 should take place prior to the approval of any other combination steroid products. It was felt that current NICE guidance for Psoriasis was not being followed and patients are often left on potent corticosteroids for longer than 8 weeks.

It was noted that the applicant had acted as a consultant and speaker for Leo Pharmaceuticals which is a clear conflict of interests. The group were also made aware of emails received from specialist nurses (at the request of the company) outlining how useful Enstilar® was. All correspondents had been sent a standard email outlining how decisions are made and that anecdotal information will not be used to make a decision.

After further discussion the group agreed that Enstilar® should not be added to the formulary at this time, however a review of current topical options for psoriasis within the formulary should take place and this should be brought in line with the above NICE guidance for plaque psoriasis.

Action: BR to add Review of Skin section to workplan

4.2.2 Invicorp®

The group discussed the above application. It was noted that no further detail on the unusual mechanism described could be found and no response had been received from the company when their medical information department had been contacted. However on contacting a community pharmacy representative it was noted that Invicorp® could be ordered in the usual way with no extra costs. The group agreed to add Invicorp® to the formulary for those patients who have failed on PDE5 inhibitors and find Caverject® injections painful.

There were some queries around whether the auto-injector would be available however currently only the ampoules are licensed in the UK. The pack comes with needles already so additional costs wouldn't be incurred.

Action: MM to add to the formulary once ratified by GMMMG in August.

5. DNP and Grey Lists

5.1 DNP assessment: Vitamin D for maintenance

The group considered a request to assess maintenance vitamin d treatment for the DNP/Grey list. The request had been received following the large increase in Vitamin D prescribing across GM. It was noted that the request covered maintenance treatment following deficiency as well as insufficiency. On discussion the group felt that those patients who were diagnosed as being deficient should be treated and maintenance therapy prescribed. However as there is limited evidence on treating asymptomatic insufficient patients the group agreed that these patients should be directed to purchase OTC supplements, alongside advice on lifestyle and diet.

It was noted that treating insufficiency is a grey area and advice to take vitamin D supplementation will depend upon the level within the insufficient range and whether the patient has any symptoms. Levels will also vary depending on the season (of blood testing) and likelihood of other sources of vitamin D being effective (e.g. sunlight exposure, dietary change) Currently, there is no grade A level evidence that prescribing supplements to this group will produce health benefits.

The group therefore agreed that the Grey list would state that Vitamin D Maintenance Treatment is approved for maintenance for vitamin d **deficient** patients only. i.e. ongoing maintenance can be prescribed for those diagnosed as deficient. Insufficient patients should be directed to leaflets to improve diet and to buy supplements OTC. It was noted that suitable supplements are available at £3.50 for 90 tablets, at a once a day dose.

Action: MM to update Grey list once item has been ratified by GMMMG in August.

5.2 DNP/Grey list assessment: Nefopam

It was noted that a request had been received from Stockport CCG to consider nefopam for the DNP list, following an increase in prescribing costs and safety concerns in overdose.

The group discussed this application. It was noted that nefopam appears to be no more potent than NSAIDs. Considering its high cost, no evidence of superior efficacy over other analgesics and side effect profile there is no clear rationale for the routine use of nefopam. The group also noted that overdose is toxic and can be fatal causing seizures, heart block, cerebral oedema and ventricular tachycardia. Caution is recommended in renal and hepatic impairment and in the elderly due to potentially increased exposure to nefopam. The group were minded to add nefopam to the DNP list however they agreed that further feedback from specialists should be sought. It was felt that nefopam is sometimes used in renal or hepatic failure over other analgesics and feedback on this would be useful. Members agreed to liaise with their specialists and forward feedback to the professional secretary for further discussion at the next meeting.

Action: Members to contact specialists re: feedback on nefopam.

6. Horizon Scanning and Work-plan

The group considered the April and May 2017 RDTC Monthly horizon scanning documents and reviewed the work-plan for the July meeting.

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

- Re-review of Saxenda now that this has been licensed
- Dupilumab for atopic dermatitis/eczema

The July agenda was already full with several applications and re-reviews from specialists.

7. Additional items

There was no other business discussed and the meeting concluded.

The next meeting will be held on 25th July 2017 at 12.30pm, CMFT.