FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
27th March 2018
12:30 - 2:30 pm
Pharmacy Dept. CMFT

Present:

Name	Title	Organisation	Jan	Mar	May	July	Sept	Nov
Elizabeth Arkell (EA)	Medicines Management Lead	UHSM	✓	LA				
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	✓	✓				
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A	✓				
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	✓	✓				
Dr Paul Chadwick (PC)	Consultant Microbiologist and Chair of Meds Management Committee	SRFT	✓	A				
Lorna Hand	Medicines Management and Medicines Information Pharmacist	CMFT	✓	✓				
Claire Foster (CF)	Senior Medicines Optimisation Advisor	SM CCG	✓	✓				
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	✓	A				
Rachel Macdonald (RM)	Pharmacist	LPC	A	A				
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	✓	✓				
Prof Peter Selby (PS)	Consultant Physician	CMFT	✓	A				
Suzanne Schneider	MI Pharmacist	Bolton FT.	A	✓				

(SS)								
Dr Hina Siddiqi (HS)	GP	Trafford CCG						
Lindsay Harper (LH)	Director of Pharmacy	SRFT	✓	A				
Jonathan Peacock (JP)	Deputy Chief Pharmacist	WWL	✓	✓				
Zoe Trumper (ZT)	Medicines Management	Pharmacist Wigan Borough CCG	✓	✓				
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓				
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	✓	✓				

1. General Business

1.1 Apologies

Apologies had been received in advance as noted above.

1.2 Declarations of Interest:

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

1.3 Draft minutes (Jan 2018)

The minutes were agreed as accurate record, following some minor amendments.

1.4 Matters Arising

- Noted that no significant comments had been received from the GM wide consultation on changes to chapter 11 of the formulary and seek permission from CSB to update the formulary.
- No comments were received on the proposal that sildenafil for digital ulcers be given a green plus statement (with an accompanying information sheet), rather than a red drug, therefore this change will be taken forward

2. Medicines Optimisation

2.1 Revised criteria for the DNP and Grey lists

The group reviewed the revised GMMMG DNP and Grey lists which had been updated to reflect the NHSE Drugs of Low Clinical Value Guidance and criteria, with all items reflecting the NHSE criteria. As agreed at CSB previously items which have previously been assessed by GMMMG but were not included on the NHSE guidance would be opened for GM wide consultation, this was necessary to ensure that the whole of the list would now have undergone GM wide consultation.

Following consultation the revised list issued as guidance by CSB would be submitted to AGG so that CCGs could implement policy to prevent prescribing of these items. There was discussion around the awareness of secondary care prescribers to the DNP and Grey lists. It was noted that there was evidence that some of this prescribing could be attributed to secondary care, which made it particularly difficult to remedy in primary care. CSB reps at FMESG confirmed that this had been discussed at CSB and that whilst there was Chief Pharmacist representation on CSB who could communicate into the Trusts, it was

recognised that a direct route into the Provider board would be beneficial and was being sought.

FMESG will monitor primary care prescribing of DNP and Grey list items, and submit a six monthly report to CSB, but ask that CSB liaise with Trusts to highlight the DNP and Grey lists and the impact of secondary care prescribing of these items on primary care.

Action: MM/AM to open revised lists for GM wide consultation, set up a six-monthly report, and ask CSB to communicate with Providers.

3. Formulary and RAG

3.1 Consideration of GMMMG drugs in diabetes recommendations

The group agreed that the recommendations for insulin degludec and degludec + liraglutide would remain unchanged. The DPP-4 inhibitor, SGLT2 inhibitors and GLP-1 agonists recommendations would be archived as they had now been superseded by NICE guidance, and the formulary would include a link to the NICE algorithm. The statement on insulin biosimilars would be updated and re-issued.

Primary care prescribing data highlighted significantly higher than expected prescribing of insulin glargine 300U/mL (Toujeo®), it was agreed that local audit would aid understanding as to why prescribing was so much higher than envisaged at the time of issuing the GMMMG statement and whether the statement required re-clarification or whether additional work needed to be done to redress this issue via diabetes prescribers. It was agreed that GMSS would draft an audit tool to share with HOMMs and the data would return to the July meeting.

Metformin for prevention of diabetes: The group discussed the indication of metformin SR for prevention of diabetes, and the associated NICE guidance. The group asked for permission from CSB to proceed with the recommendation of this guidance across GM (see attached paper)

Action: GMSS to draft an audit tool to share with HOMMs and the data would return to the July meeting.

MM to submit a paper to CSB proposing that:

-the formulary is updated to reflect PH38

-that the authors of the GM diabetes strategy focus the majority of their efforts to address the prevention of T2DM in people at high risk in the diabetes as per PH38 within the GM strategy

-that GMMMG include the prevention of T2DM in people at high risk in the diabetes plan to be presented to CSB in Q2 (as per work plan)

3.2 Pitolisant recommendation – final draft incorporating comments from specialists where appropriate

The group agreed that pitolisant for narcolepsy be added to the RAG list as a RED drug, prescribing of this agent was anticipated to occur in less than ten patients across GM per year and so no formal position statement would be issued, as the care of this small group of patients would remain with specialists within the tertiary centre.

Action: MM to include pitolisant with a proposed RED status for pre-approval to CSB and to open for GM wide consultation, after which it could be added to the RAG list if no significant comments raised.

3.3 Lurasidone re-review

FMESG considered a request to review the GMMMG recommendation for lurasidone issued in 2014. The group considered a review of the evidence published since this recommendation, and noted the newer evidence on cost effectiveness presented. PB discussed the potential number of patients who would likely be considered for treatment across GM. The group asked that the agent be assessed for grey list addition which would enable its restricted use in a defined patient group, this information will return to the May meeting for decision.

Action: PB to liaise with mental health specialists regarding the specific patient group that this agent would be intended for and to communicate this to MM, after which this application would be assessed against the available evidence.

3.4 Formulary application: cortiment (budesonide 9mg PR tablets) for UC

The group considered this application against the defined criteria within the formulary assessment tool. It was noted that the applicant wished this agent to be used in those patients who are unwilling to take prednisolone and where other preparations e.g. rectal foams had been ineffective. A red RAG status had been requested. The group noted that Cortiment is the first oral formulation of budesonide to be licensed for UC, and that it is stated that it exerts its action topically in the colon, minimizing systemic absorption. Other formulations of oral budesonide are available (Budenofalk® and Entocort®), however, these are licensed for Crohn's Disease and not UC; they are designed to release the steroid further down the terminal ileum, therefore, are not optimally designed for the treatment of UC.

The group considered current NICE recommendation that suggests considering topical corticosteroids or oral prednisolone as second line options for inducing remission in patients with mild to moderate UC who don't respond to 5-ASA therapy. The use of oral corticosteroids is associated with adverse effects (AEs) which are dose-related, where patients receiving long-term oral corticosteroids (> 3 weeks duration) or those needing frequent courses (3 or 4 per year) are at greater risk. Osteoporosis, diabetes mellitus, hypertension and adrenal insufficiency are potential systemic adverse events attributable to long-term or repeated courses of oral corticosteroids.

Due to its local action, Cortiment is expected to have less adverse effects than systemic oral corticosteroids. It may therefore provide an additional therapeutic option for patients in whom systemic oral corticosteroids may not be suitable. The group expressed disappointment that Cortiment has not been compared with other oral or rectal preparations for UC in clinical trials, which meant that there was no evidence base to demonstrate efficacy.

The group agreed that they were unable to approve this application due to the lack of evidence base against standard therapy.

Action: JP agreed to feedback to the applicant and would return any comment to FMESG.

3.5 Naltrexone to prevent relapse in opioid and alcohol-dependent patients: RAG review

This item was deferred to the May meeting to enable representation from mental health to attend to aid discussion.

3.6 Formulary amendments

The March formulary amendments will be opened on the website for GM consultation and intend to revise the formulary to reflect NICE TA497 to TA510, with the addition of lesinurad to the DNP list in light of its negative TA. The formulary will be updated to reflect MHRA guidance from January and February, with the resulting removal of daclizumab. Deodorants for stoma use will be assessed for the DNP list.

The group noted that a licensed agent for the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults had been launched and agreed to assess this formally in May. It was also agreed that the group would consider the recently updated NHSE guidance “Responsibility for prescribing between primary and secondary care” at the May meeting.

Action: MM to submit the formulary amendments for pre-approval to CSB and to open for GM wide consultation, after which the formulary and associated lists could be updated if no significant comments arise.

4. Horizon scanning and work plan

The RDTC monthly horizon scanning documents from February and March were provided to the group. The group noted that a further metformin PR product had been licensed for reducing the risk of T2DM, but that a price was not yet available, that insulin glargine biosimilar (Semglee®) had received a positive opinion from the EMA, as had ertugliflozin, and that ferric maltol was now indicated for the treatment of iron deficiency in adults. The work plan would be updated to consider these items as appropriate.

Action: MM to request scoping of the above items from the RDTC, and update the work plan

5. AOB

Nothing raised

The next meeting will be held on 22nd May 2018 12.30-2.30pm, CMFT