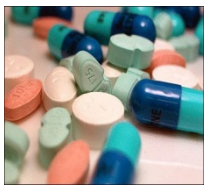
GMMMG Greater Manchester Medicines Management Group NHS

FORMULARY AND MANAGED ENTRY SUBGROUP



Minutes of the meeting held on
22nd May 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	A			
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	✓	✓	A			
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	A			
Rachel Macdonald (RM)	Pharmacist	LPC	A	A	A			
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	✓	✓	A			
Prof Peter Selby (PS)	Consultant Physician	CMFT	✓	A	✓			
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓	✓			

Dr Hina Siddiqi (HS)	GP	Trafford CCG			✓			
Lindsay Harper (LH)	Director of Pharmacy	SRFT	✓	A	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. Jennifer Hyde (Senior Pharmacist Substance Misuse Services, Specialist Services Network) was present for item 3.3

1.2 Declarations of Interest:

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

1.3 Draft minutes (Mar 2018)

The minutes were agreed as accurate record.

1.4 Matters Arising

- Vitamin D status in GM. The group discussed the outstanding issue concerning vitamin D and the rejected DNP/grey status. Whilst the group acknowledged that NHSE had partly addressed this issue in its OTC consultation, it was felt that further clarification was required to support both prescribers and the patient, particularly in relation to use in pregnancy. Manchester CCG had recently produced some guidance and it was agreed that this be taken forward by the PaGDSG to develop a GM wide version.

Action: CF to share guidance with MM for PaGDSG

- Revised DNP and Grey lists post consultation

The group considered the comments received to date as the GM consultation on the revised DNP and Grey lists (to align with the NHSE DLCV guidance) nears closure. It was agreed that if no further comments were received that the lists be approved and added to the GMMMG website. A paper will be submitted to CSB and AGG, requesting implementation of the GMMMG lists across all GM CCGs to support the continued reduction in prescribing and in variation of prescribing of drugs of low clinical value across the whole of GM. The group acknowledged the comments raised regarding the T3 listing, in particular that they felt it should be more specific. However the group agreed that at this stage, and for the purpose of a GM wide position the listing sufficiently reflected that of NHSE, but that it may be revisited in due course if inappropriate prescribing of T3 continued.

Action: AM/MM to submit paper to CSB and AGG

1.5 Meeting frequency

The group agreed to undertake monthly meetings, with a June meeting focusing solely on the GM Self-care/OTC strategy, all CCGs will be requested to submit their work to date or proposals to FMESG prior to the June meeting. There was some discussion on moving the meeting time to start a half hour earlier, but it was agreed that this would be queried and agreed by email with all members post meeting.

Action: MM to schedule monthly meetings and query meeting timings with members.

2. Medicines Optimisation

2.1 NHSE: Responsibility for prescribing between primary and secondary care

The group considered the recently published guidance from NHSE regarding responsibility for prescribing between primary and secondary care, alongside the GMMMG criteria used when issuing a RAG status (based on EL(91)127 "Responsibility for Prescribing between Hospitals and GPs." Aug 2015). The group noted that this revised NHSE guidance replaces EL(91) 127, but as stated was not intended to undo or undermine existing prescribing arrangements that have been deemed to be working well across health communities by primary and secondary care, but to reduce the level of variation and to improve the quality of patient care.

The group considered the issues identified by the previous version of the guidance e.g.patients being caught in the middle where there is lack of agreement over prescribing responsibilities and the risk that they might be left without the medication they need , perverse cost incentives to shift responsibility for medicines between secondary care and primary care, GPs' concerns over taking responsibility for unfamiliar treatment, lack of consultation between professionals over the transferring of prescribing responsibilities, hospitals providing insufficient quantities of medication on discharge, or following out-patient or emergency treatment and patients having to make a special trip to their GP to obtain a prescription immediately after a hospital visit. The group recognised that there can be instances when these situations arise, but felt that this wasn't due to the current GMMMG guidance but rather a lack of adherence or awareness of GMMMG RAG status when prescribing in some instances.

The group agreed that amendments be made to the current GMMMG guidance to to reflect the revised NHSE guidance but that these would be minor and no formal approval was required.

Action: MM to update the GMMMG guidance as discussed and add to the website

2.2 Non-formulary items with a RAG status

The group considered non-formulary items that are currently listed on the GMMMG RAG lists, and agreed that all DNP and Grey list items be added to the formulary clearly indicating their position. It was agreed that the RAG lists would highlight those items that are on formulary, and that non-formulary items with a green status would be considered for formulary inclusion at a future meeting.

Action: MM to update the formulary and RAG lists as agreed, and summarise those items with a green RAG status for future formulary assessment.

3. Formulary and RAG

3.1 Noqdirna for idiopathic nocturnal polyuria: formulary assessment

The group considered a formulary application for desmopressin 25 mcg oral lyophilisate (Noqdirna®) for symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. They noted that Noqdirna is the only licensed treatment for this indication, and that current treatment strategies include lifestyle modifications and trial of medicines such as antimuscarinics, furosemide given in the early afternoon and other formulations/strengths of desmopressin (e.g. 100 microgram tablets); all of which are off-label. The group discussed the safety of this product and discussed whether there was a risk of hyponatraemia, but recognised that this agents has not been assigned a "black triangle" as its safety profile is reportedly similar to other established desmopressin products.

The group noted that this product has been appraised by both the SMC and AWMSG. Both recommend use within the licensed indication but for patients aged ≥65 years. NICE CG97 (management of LUTS in men) recommends considering demopressin in men with nocturnal polyuria if other medical causes have been excluded and they have not benefited from other treatments. Similarly NICE CG171 (management of urinary incontinence (UI) in women)

recommends considering the use of desmopressin to reduce nocturia in women with UI or OAB who find it a troublesome symptom. The group considered the trial evidence but queried the outcomes presented i.e. reduction in rate of nocturnal void and sleep duration until first void, and how these translated into real benefits for patients. The group referred to a recent Drug and Therapeutics Bulletin that highlighted a 0.2 to 0.4 reduction in night time voids, and that the clinical significance of this outcome was negligible.

The lack of GM patient numbers within the application meant that the group were unable to assess a GM impact, and it was agreed that this item should remain non-formulary, as there was no demonstrated need for routine use. Following the meeting this decision would be opened for GM wide consultation, any comments will be considered at the July meeting.

Action: MM to submit this decision for pre-approval pending GM wide consultation.

3.2 New Drug Review: Cariprazine

Cariprazine, (Reagila®▼) for the treatment of schizophrenia in adult patients was identified for assessment by the group through horizon scanning. The agent is currently marketed in the U.S at a cost of $17,520 per patient per year (approx. £13,000), it is due to launch in the UK in September 2018, at an assumed lower cost. The group noted that this oral atypical antipsychotic is a partial agonist at dopamine D2/D3 and serotonin 5-HT1A receptors, with preferential binding to D3 receptors.
An RDTC evaluation of the evidence was considered, the group noted that in three short-term studies for the treatment of acute schizophrenia, the efficacy of cariprazine was superior to placebo, comparable to aripiprazole, but slightly lower than risperidone - although the studies were not designed to compare active-treatment arms. Maintenance of effect had been confirmed in a long-term placebo-controlled withdrawal study. In a long-term active-controlled study, cariprazine was associated with a significantly greater improvement in negative symptoms than risperidone, but the clinical relevance of this result is difficult to interpret. In general, the safety profile of cariprazine is consistent with that of other atypical antipsychotics. However, the incidence of akathisia was somewhat higher for cariprazine compared with risperidone and aripiprazole.
It was noted that the cost of cariprazine was not yet known, but is likely to be significantly more costly than currently available options. The place in therapy for cariprazine is likely to be as an alternative treatment option to the currently available atypical antipsychotics.
The group assessed this agent against the Do Not Prescribe criteria where it met criterion 2 (i.e. products which are clinically effective but where more cost-effective products are available).
Following the meeting this decision would be opened for GM wide consultation, any comments will be considered at the July meeting.

Action: MM to submit this decision for pre-approval pending GM wide consultation

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

A proposal to change the RAG status of naltrexone for opioid (amber) and alcohol dependent (red) patients to green was considered by the group. It was noted that NICE CG115 (Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence) stated that this treatment should remain under specialist community alcohol teams and was PHE commissioned.

In terms of safety issues and monitoring requirements it was noted that the SPC stated that liver function test (LFT) abnormalities have been reported in obese and elderly patients taking naltrexone who have no history of drug abuse, that LFTs should be carried out both before and during treatment, and that in patients with impaired hepatic or renal function. Liver function tests should be carried out both before and during treatment. The group noted that Naltrexone treatment must begin only when the opioid has been discontinued for a sufficiently long period (about 5 to 7 days for heroin and at least 10 days for methadone).

There was discussion around NICE CG115: Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence, in particular section 1.3.6.8 which states that “service users taking oral naltrexone should stay under supervision, at least monthly,

for 6 months, and at reduced but regular intervals if the drug is continued after 6 months. Do not use blood tests routinely, but consider them for older people, for people with obesity, for monitoring recovery of liver function and as a motivational aid for service users to show improvement. If the service user feels unwell advise them to stop the oral naltrexone immediately." Also NICE CKS - Alcohol - problem drinking (last revised in July 2016) which states that naltrexone and disulfiram (Antabuse®) are options that should only be considered in secondary care.

A senior pharmacist for substance misuse attended the first part of this discussion where she explained that the reason for this change in RAG status was that whilst treatment is initiated within the specialist service, there is then a difficulty in discharging patients to the tier 3 recovery services as there is no or insufficient prescribing facility within these services. This results in the patients becoming stuck in the middle of an inadequate system, with no access to medication. The group asked how these patients are accessing this information currently, JH explained that they don't. The group asked if this issue had been added to a risk register as it was clearly unacceptable.

There were two GPs present at the meeting who expressed their concerns about being asked to prescribe this medication for patients without any other involvement in their treatment, they queried how they would know if the patient was attending the appropriate counselling and if continuation of prescription would be appropriate. They felt that the prescriber would need assurance that the patient was being seen by the recovery services regularly. There was a lengthy discussion around the unacceptable practice of commissioning of these types of services without a prescribing component, and it was agreed that this was the action that needed to be taken forward. FMESG agreed that a paper would be produced for submission to CSB detailing the issue with non-health commissioners commissioning such services without consideration and provision of a prescribing component. It was agreed that the lack of a commissioned prescribing facility within these services did not make a reasonable case to issue a green RAG status, and that naltrexone for all uses be given a RED RAG status, (this is a move from amber for opioid dependence) as prescribing and monitoring of the patient should be linked, but currently GPs are being asked to prescribe without any overview of the patient and progress/support. GPs cannot prescribe for these patients in isolation of monitoring/concomitant treatment. This proposal is open for GM consultation. A paper will be raised with CSB and then AGG/Strat board to challenge the practice of commissioning without inclusion of prescribing provision.

Action: MM to submit this decision for pre-approval pending GM wide consultation, and to raise the issues discussed at the June CSB meeting, with a paper to follow for the October CSB meeting.

3.4 DNP assessment: dicycloverine

Dicycloverine was approved for DNP inclusion as per NHSE criteria 2 (products which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation). The price of dicycloverine increased between January 2014 and October 2016. It currently costs significantly more than other antispasmodic drugs. A 28 day supply of dicycloverine tablets 10mg to 20mg TDS currently costs around £155 to £197 compared to £3.65 for mebeverine 135mg TDS. GM CCGs spent over £587,000 on dicycloverine between April and December 2017-18. This proposal would be opened for GM wide consultation.

Action: MM to submit this decision for pre-approval pending GM wide consultation.

3.5 Grey list assessment: Lurasidone

Lurasidone was assessed and proposed for Grey list inclusion, with an amber RAG status, the aripiprazole SCP will be amended to reflect this decision. This decision is open for GM consultation. The group reached this decision with consideration to the facts that NICE guideline on the management of psychosis and schizophrenia in adults – CG178 (last updated March 2014) state that the choice of an antipsychotic agent should be based on the metabolism extrapyramidal, cardiovascular, hormonal and other adverse effects. NICE does not favour use of one antipsychotic drug over another. The Scottish Medicines Consortium (SMC) and All

Wales Medicines Strategy Group have both accepted lurasidone for restricted use and as an option for treatment of schizophrenia respectively. The SMC have accepted it for use within NHS Scotland in patients where weight gain and metabolic adverse effects are to be avoided. Lurasidone is a second generation antipsychotic medicine. Other agents within the same class include amisulpride, aripiprazole, olanzapine, quetiapine, risperidone and clozapine – all of which are currently on the GMMMG Formulary as either first line or second line options.

It was agreed that a GREY status accommodating for prescription in the following patients was appropriate i.e. For the treatment of schizophrenia in adults aged 18 years and older who require antipsychotic treatment, who have previously had a trial of but not responded to aripiprazole, and who fulfil one of the following criteria:

- Patient gained weight on other antipsychotics and there is a need for the BMI to move towards the normal range
- Patients for whom there is a need to avoid weight gain and metabolic adverse effects, e.g. patients with diabetes, cardiovascular disease
- Patients with a prolonged QTc interval

It was estimated that there would be thirty to forty patients across GM a year who would fulfil this criteria for use.

Action: MM to submit this decision for pre-approval pending GM wide consultation

3.6 Formulary amendments May 2018

The formulary amendments for May 2018 were approved, the formulary will be updated to reflect recent guidance from NICE and the MHRA, in addition Ciprofloxacin ear drops (assigned a grey status (green RAG status) for use in cases of proven pseudomonas only will be added to the formulary. These decisions including their cost impact/commissioning implication where appropriate will be opened for GM wide consultation.

Action: MM to submit this decision for pre-approval pending GM wide consultation

3.7 Rivaroxaban for prevention of CV events: scoping

As agreed at the March meeting the group agreed to consider at this stage the evidence associated with the use Rivaroxaban in combination with aspirin for prevention of major cardiovascular events in coronary or peripheral artery disease using the summary of evidence from the NIHR attached for this purpose. The group recognised that this would potentially have a significant cost impact across GM, and agreed that the cardiac network be approached to ascertain their intentions.

Action: MM to highlight this scoping to CSB and request a contact from the cardiac network to ascertain the appetite for this intervention to be taken forward across GM.

4. Horizon scanning and work plan

Monthly horizon scanning documents and work plan

The RDTC monthly horizon scanning documents from April and May were provided to the group. The group agreed that tadalafil in place of avanafil, Therabite for the DNP list and a RAG status for zulcopentixol should be considered. The group also noted that sufentanil was likely to receive a license extension in July. It was agreed that the wound formulary submitted by MFT be considered alongside the current GMMMG version. The work plan would be updated to consider these items as appropriate.

Action: MM to update the work plan

5. Additional items

5.1 Communication to hospitals, opticians etc regarding adherence to chapter 11 of the formulary

It was agreed that communication be undertaken (via a letter from FMESG) to hospitals, opticians and the LOC regarding adherence to Chapter 11 of the formulary

Action: MM to draft letter with the support of CF

5.2 GPs refusing to prescribe GMMMG approved unlicensed medicines (communication to GPs requested)

Item deferred, pending further communication.

The next ordinary meeting will be held on 24th July 2018 12.30-2.30pm, CMFT, however an extraordinary meeting will be held on 26th June to focus solely on the GM OTC policy