GMMMG Greater Manchester Medicines Management Group

FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 25th February 2020
12:30 - 2:30 pm
Pharmacy Dept MFT-ORC

Present:

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov
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	✓									
Lisa Kershaw (LK)	Medicine Guideline and Formulary Pharmacist	MFT-WH	✓	✓									
Claire Foster (CF)	Senior Medicines Optimisation Advisor	MHCC	✓	✓									
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	A	✓									
Prof Peter Selby (PS)	Consultant Physician	MFT-ORC	A	A									
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓									
Dr Hina Siddiqi (HS)	GP		A	A									
Anna Swift (AS)	Snr. Assistant Director Medicines Management	Wigan Borough CCG	✓	✓									
Jonathan Schofield (JS)	Consultant Physician	MFT-ORC	✓	A									
Faisal Bokhari (FB)	Deputy Head Medicines Optimisation	T&G CCG	✓	A									

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM JCT (non-voting)	✓	✓									
Carol Dolderson (CD)	Lead Pharmacist Medicines Management *(Professional secretary)*	RDTC (non-voting)	✓	✓									

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above.

Although attendance was balanced, the lack of a secondary care physician meant that the group was not quorate. It was agreed that draft actions would be circulated to group members for approval prior to being progressed.

Dr Murugesan Raja, Clinical Lead for Respiratory Medicine for MHCC (GP) was in attendance for item 2.1 to support discussions around the tobacco addiction guidance. Fiona Campbell, Lead Respiratory Pharmacist, MFT- ORC also attended for this item but did not take part in the discussion.

1.2 Declarations of Interest:

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

1.3 Draft minutes – January 2020

Minutes from January's meeting were noted and supported as an accurate record, following minor amendment. To be submitted to April GMMMG, ahead of upload to the GM-site.

1.4 Matters Arising

1.4.1 Action log

Updates on the action log were discussed. It was noted that a draft update of the GMMMG wound care formulary was due to come to March's meeting. Professor Ball, Clinical Lead for Endocrinology, MFT had kindly agreed to supply some brief background information on the place in therapy of demeclocycline for SIADH for March's meeting.

1.4.3 Monitoring log and draft annual summary of assurance undertaken

The monitoring log was noted, along with a draft annual summary of assurance undertaken by FMESG. It was noted that there was nothing to be flagged to GMMMG within the assurance summary and this would be submitted to April's GMMMG 'for information only'. No additional actions required at present.

2.0 Medicines Optimisation

2.1 Tobacco Addiction Treatment Guidance

The group considered draft tobacco addiction treatment guidance for GM.

Dr Raja provided some background into the development of this guidance which had been progressed by a multidisciplinary team of specialists derived from the COPD Guideline Working Group. The guidance aims to provide recommendations on optimal treatment choices for smoking cessation and to address inconsistencies in what treatments are available across the GM footprint and across primary care/ secondary care interface divide. Following a period of GM-wide consultation in 2019, new sections on management in pregnancy and in adolescents had been added to the suite.

Key aspects of the guidance were noted, including:

- Provision of very brief advice as the first step, followed by pharmacotherapy *plus* referral to a specialist stop smoking service
- Positioning of varenicline as first choice (in non-pregnant adults) based on evidence of effectiveness as a single intervention as well as in combination with behavioural support
- Combination NRT as second choice (first choice in pregnancy and adolescents) reinforcing the benefit of combining both long and short-acting NRT versus single preparation
- Bupropion as third choice based on more complex monitoring/ interactions and cautions
- Inclusion of advice on the use of e-cigarettes in light of their place as a harm reduction intervention

FMESG were in support of the clinical content of the guidance as a whole but requested some further clarification be made in relation to offering these interventions on prescription for quit attempts versus 'maintenance' prescribing. While it was recognised that all interventions are considered cost-effective versus continued smoking, the group agreed that the commissioning and financial impact of implementing the guidance needed to be established before considered for approval by GMMMG- particularly in relation to the impact of offering combination NRT.

ACTION: FMESG recommend the following amendments prior to circulation to members for virtual approval to submit to April GMMMG.

- Clarification re. maximum duration of therapy for prescribing versus (i.e. 48 weeks per quit attempt) versus ongoing 'maintenance' replacement.
- Inclusion of further cautions relating vaping of unregulated or oil based/ CBD products in line with MHRA drug safety update issued in January 2020. To highlight risks of passive exposure is unknown and precautions advised to minimise exposure to family members etc. (as for smoking indoors).
- Details of finance and commissioning impact to be included in coversheet.
- RDTC to clinically check new sections on pregnancy and adolescents
- Formulary to be updated to reflect guidance upon approval by GMMMG.

3.0 FMESG work plan

3.1 Consideration of items for work plan

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

- RAG re-assessment for all listings for steroid eye drops to come back to March's meeting with the aim to rationalise based on duration of use and steroid potency and irrespective of preservative content.
- A review of formulary choice GLP-1s to come back to March's meeting along with an RDTC comparison chart of the current CV evidence for all GLP-1s

ACTION: CD to update work plan accordingly.

3.2 Monthly horizon scanning document- February 2020

The RDTC monthly horizon scanning document for February 2020 was considered by the group. Key items of interest noted to be on the NICE work plan / TAs in development: crisaborole for mild to moderate atopic dermatitis and bempedioc acid (+/- ezetimibe) for adults with primary hypercholesterolaemia or mixed dyslipidaemia.

ACTION: The group requested RDTC prepare a new drug evaluation for oral semaglutide for consideration at a future meeting.

4.0 Formulary and RAG

4.1 Formulary amendments February 2020

Suggested minor formulary amendments and clarifications were noted and approved as follows:

- Lustrombopag to be added in chapter 9 as a RED drug in line with TA617: Lustrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure.
- RAG status for imiquimod 5% cream for superficial basal cell carcinomas to be amended to GREEN (following specialist recommendation). This is an update from the current status of GREEN (following specialist initiation).

4.2 New Drug Evaluation: Inbrija® levodopa inhaler for 'off' episodes in Parkinson's Disease

Inbrija was noted in the horizon scanning at October 2019's meeting of FMESG; it was agreed that RDTC would present a new drug evaluation for this intervention. This was considered at February's meeting. Inbrija offers an alternative to oral co-beneldopa dispersible and a non-invasive alternative to subcutaneous apomorphine where 'off' episodes are unpredictable and rescue therapy is needed. Evidence for the intervention is limited to comparison against placebo, where greater improvements in daily 'off' time were observed in patients with more severe symptoms. As no active comparator was used in the pivotal trials, the efficacy of Inbrija compared with existing rescue therapies for 'off' episodes. The cost and launch date was not yet known, however it was anticipated that Inbrija would be a significantly more costly option than dispersible co-beneldopa.

The group agreed that clinician opinion should be sought to help understand place in therapy compared to dispersible co-beneldopa and whether there are any subsets of PD patients who may benefit from the intervention. Additionally some insight into potential duration of use before escalating to e.g. M/R levodopa preparations or apomorphine would be helpful.

ACTION: RDTC to contact suggested clinicians at PAHT and Bolton FT to help inform future discussions. NDE to come back with this supporting information once price and launch date are known.

4.3 RAG Assessment: testosterone supplementation in menopausal women with low sexual desire

Following scoping at January's meeting, it had been agreed that a RAG assessment for testosterone for menopausal women with low sexual desire should be considered in full at February's meeting.

NICE NG23 states: *consider testosterone supplementation for menopausal women with low sexual desire if HRT alone is not effective.* There are currently no licensed products for this indication; however guidance on testosterone replacement in menopause has been published by the British Menopause Society and includes advice on off-label use of testosterone gels licensed for male hypogonadism. The group recognised that while there is evidence to support use of testosterone for menopausal women with hyposexual sexual desire disorder (HSDD) in line with NG23, there is currently insufficient evidence to support its use to enhance cognitive performance and mood.

The group recommend that testosterone for menopausal women with low sexual desire (HSDD) be GREEN (specialist initiation) and GREY; only if HRT alone is not effective. RAG status to be annotated 'Testogel® or Tostran® (off-label use).'

ACTION: RDTC to open this recommendation for GM-wide consultation.

4.4 RAG Assessment: cariprazine for schizophrenia in adults

Following scoping at January's meeting, it had been agreed that a RAG assessment for cariprazine for schizophrenia in adults should be considered in full at February's meeting.

FMESG acknowledged that the current recommendation of DNP had been made in May 2018 based on an RDTC evaluation. In three short-term randomised, placebo-controlled trials, the efficacy of cariprazine was noted to be superior to placebo, comparable to aripiprazole, but slightly lower than risperidone- although the studies were not designed to compare active-treatment arms. 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.

FMESG noted that while significantly more expensive than most first-line antipsychotics/ generically available options, the annual cost of cariprazine was less than other alternate choice antipsychotics including lurasidone, paliperidone, and quetiapine M/R. Cariprazine may provide an alternative treatment option for patients with predominantly negative symptoms who have trialled and failed generic antipsychotics. Its safety profile is akin to other antipsychotics but is associated with a higher incidence of akathisia in the first few weeks of treatment versus risperidone or aripiprazole and carries the same monitoring as other second-generation antipsychotics.

The group recommended that cariprazine be re-assigned to RED (pending development of a shared care protocol; AMBER thereafter) and GREY: for use in patients with negative symptoms where at least 2 generic antipsychotics such as (amisulpride, olanzapine, risperidone, aripiprazole or clozapine) have been trialled and have failed. And annotated: 'Less is known regarding long term safety and adverse effects of cariprazine versus more established antipsychotics'.

ACTION: RDTC to open this recommendation for GM-wide consultation.

5.0 AOB

The prescribing status of Xonvea was discussed in light of the recent MHRA drug safety update on 'ondansetron: small increased risk of oral clefts following use in the first 12 weeks of pregnancy'. The MHRA alert had been issued in response to PRAC recommendations in 2019. FMESG recommended that the current positioning of GREEN and GREY; *to be used only when the other preparations currently recommended by RCOG guidance have been tried and have failed'* be upheld. This was based on official responses from both the UK Teratology Information Service (UKTIS) and European Network of Teratology Information Services (ENTIS) that had been issued in response to the PRAC recommendations, which highlighted that the evidence of a potential increased risk of orofacial cleft is very small. There was recognition that ondansetron is an effective second-line antiemetic, with extensive clinical experience. Less is known about the safety of alternative treatment options including Xonvea in terms of drug safety in pregnancy. And concern that there is insufficient evidence of Xonvea's efficacy to place it ahead of ondansetron in the treatment pathway; this may lead to adverse outcomes as a result of less effective control of maternal nausea and vomiting.

ACTION: FMESG recommend no action necessary re. prescribing status of Xonvea.

Following brief discussion it was agreed that a review of the formulary position/ RAG listing of both trazadone and lorazepam be scoped at March's meeting in light of increasing trend to prescribe for Behavioural and Psychological Symptoms of Dementia (BPSD).

A minor amendment to be made in chapter 2 of the formulary to clarify that oral anticoagulants are listed in alphabetical order (rather than prescribing preference). A link to the NICE decision support tool for anticoagulant choice in patients with AF also to be added.

The next meeting will be held on 24th March 2020, 12.30-2.30pm, MFT-ORC.