FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 28th January 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										
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A										
Dr Hina Siddiqi (HS)	GP		A										
Anna Swift (AS)	Snr. Assistant Director Medicines Management	Wigan Borough CCG	✓										
Jonathan Schofield (JS)	Consultant Physician	MFT-ORC	✓										
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 Shared Service.	✓										
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC	✓										

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above. Jonathan Schofield acted as Chair in the absence of Pete Budden for the first half of the meeting (items 1.4. 3.1 and 4.1). Anna Swift acted as Chair for the remaining agenda items thereafter. Agenda items were discussed out of chronological order to optimise clinician input on priority items; this order is reflected in the minutes.

As the group was not quorate, it was agreed that draft actions would be circulated to group members for approval prior to being progressed.

1.2 Declarations of Interest:

Members had been asked to submit an updated DoI form ahead of the January meeting; no new declarations of interest were made.

ACTION: FMESG members requested to submit an updated DoI form to CD ahead of February's meeting or otherwise state 'no change required to their existing DoI.

1.3 Draft minutes – November 2019

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

1.4 Matters Arising

1.4.1 Consultation feedback October 2019:

Opening of October's consultation had been delayed due to the pre-election period. Consultation comments received to date were considered by the group. As the consultation was not due to finish until the end of the following day, it was agreed that any further comments would be circulated with the draft minutes and actions. The following actions were agreed pending virtual approval:

- Dornase alfa for cystic fibrosis in adults to be RED. This is an amendment of the current AMBER RAG to reflect repatriation of adult cystic fibrosis patients by NHSE.
- Lidocaine plasters for off-label indications to be DNP (criterion 1) in line with NHS guidance on items which should not routinely be prescribed in primary care and the overall lack of evidence to support their use (for off-label indications).
- Ulipristal acetate (EllaOne®) for emergency hormonal contraception to be GREEN, and to replace levonorgestrel as first choice emergency hormonal contraception. This is to reflect guidance from the Faculty of Sexual & Reproductive Healthcare (FSRH) which was updated in December 2017 and the recommendation that ulipristal acetate has been demonstrated to be more effective than levonorgestrel from 0-120 hours after unprotected sex.

And:

- Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease to be 'GREEN (specialist recommendation); treatment should be reviewed at least annually by GP' and annotated 'supportive material in development'. A link to TA607 to be added in chapter 2.

ACTION: RDTC to communicate these decisions to GMMMG for information. The cost impact of TA607 to be flagged (around £1.4 million per year based on the NICE resource impact).

A response had been received from NICE to the enquiry submitted by AM on the group's behalf regarding possible validation of the SMART-REACH model published in the European Heart Journal in September 2019. NICE had notified the team responsible for developing patient decision aids who would undertake further scoping to explore what could be done to support shared decision making around TA607, however in order for NICE to endorse the model, it would need to be submitted by the author/ owner. AM volunteered to contact an author of the SMART-REACH model, to pursue this possibility. It was recognised that it might be several months before NICE published any relevant material. FMESG agreed that the development of local supportive information should be progressed in the meantime and heard that some initial work had been started by the cardiothoracic specialist team at MFT. RDTC to liaise with MFT to help support this going forward.

1.4.1 Consultation feedback November 2019:

Opening of November's consultation had been delayed due to the pre-election period. Consultation comments received to date were considered by the group. As the consultation was not due to finish until the end of the following day, it was agreed that any further comments would be circulated with the draft minutes and actions. The following actions were agreed pending virtual approval:

- Praziquantel for hydatid disease to be RED.

- Albendazole for hydatid disease to be RED.

- Zanamivir solution for infusion for complicated and life-threatening influenza A or B infection to be RED. Cost impact to be flagged to February GMMMG; potentially >£200k if 'flu cases are higher than 28/19 season.

- Pentosan polysulfate sodium for treating bladder pain syndrome to be RED and a link to TA610 added in chapter 7 and to the RAG list. This is an amendment of the current GMMMG position of GREEN (following specialist initiation) and GREY for use as a second-line treatment for bladder pain syndrome. Cost impact to be flagged to February GMMMG. The NICE resource impact statement suggests the impact will be <£9k per 100,000 population; this may be as much as £250K per annum across GM.

- Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea to be RED and a link to TA605 to be added in chapter 4 and to the RAG list. This is a CCG commissioned PbRE medicine. Xeomin is recommended only if the company provides it according the commercial arrangement. A place in therapy within GM has not been established; GM High Cost Drug Subgroup will provide recommendation on this if necessary.

- Lanadelumab for preventing recurrent attacks of hereditary angioedema to be RED and a link to TA606 to be added to the RAG list. This is a NHSE commissioned PbRe medicine.

- Voretigene neparvovec for treating inherited retinal dystrophies caused by RPE65 gene mutation to be RED and a link to HST11 to be added to the RAG list. This is a NHSE commissioned PbRe medicine, it recommended only if the company provides it according to the commercial arrangement.

- Ciclosporin for nephrotic syndrome in paediatrics to be RED. This is an amendment of the current GMMMG position of AMBER; all prescribing for this indication has been repatriated to secondary care.

- Zostavax for use outside of the national vaccination programme to be RED and annotated: 'in patients who are eligible to receive vaccination outside of the national vaccination programme (e.g. due to receiving chemotherapy or immunosuppressant therapy) it is the responsibility of the specialist service to administer vaccination; there is no route of reimbursement if administered in primary care'.

- Liothyronine for resistant depression to be DNP (Criterion 1) and annotated: 'there is very limited evidence for thyroid hormones in depression. Where thyroid hormones are necessary due to hypothyroidism, treatment should be initiated with standard levothyroxine. We recommend that existing patients are reviewed by a consultant NHS psychiatrist. See NHSE guidance on items not for routine prescribing in primary care and RMOC Guidance on Liothyronine. All psychiatric patients currently receiving liothyronine should be reviewed by a consultant NHS psychiatrist'

- Voke nicotine inhalator for nicotine replacement therapy to be DNP (Criterion 1) and annotated 'further data is required evaluating the use of Voke® as a stop smoking aid/ comparing their efficacy to established nicotine replacement therapies (NRT) prior to their use within the Greater Manchester region.' PH is the commissioner.

ACTION: RDTC to communicate these decisions to GMMMG for information. The cost impacts of zanamavir infusion and TA610 to be flagged.

1.4.3 Action log

Updates on the action log were discussed and noted as follows:

- It was agreed that the item *SPS Insulin Glargines Product Safety Review* could be closed from the action log.
- An updated draft of guidance for the covert administration of medicines in care home settings had been received. Some further minor amendments and clarifications were required which needed to be approved by the working group prior to being opened for consultation. RDTC to contact Karen O'Brien for an update of the care home guidance; it was suggested the guidance as a whole should be opened for consultation as a single suite rather than in individual stages.
- A non-high cost drug biosimilar statement to be drafted to come to March's meeting along with a review of formulary choice growth hormones. This would be informed by an update to the paediatric shared care protocol for growth hormone this is open for consultation until mid-February. The SCP reflects regional contract products.
- The meeting scheduled for December between dermatologists at SRFT and JCT around queries relating the emollient ladder/ dermatology chapter had been cancelled. Further update was awaited. In the meantime Picato® (ingenol mebutate) had been temporarily removed from formulary and the AK pathway in light of PRAC alert/ EMA suspension of product.

1.4.3 Monitoring log

The monitoring log was noted, along with prescribing figures for Utrogestan® from the previous 12 months. This had been added to the monitoring log to track prescribing growth following an application to FMESG in February 2019. At that time FMESG did not recommend that Utrogestan should be added to formulary based on uncertainty around its cost-effectiveness versus current formulary preparations and agreement that its place in therapy was further down the treatment pathway than that proposed by the applicant; overall patient numbers were expected to be low.

GM primary care prescribing data for Utrogestan demonstrated that prescribing had almost tripled in the past 12 months (versus the preceding 12 months) but remained relatively low (2441 items totalling £24,995.55). The group felt this growth was likely to have been driven by supply problems with other HRT preparations, particularly since the product has been available for more than 10 years without having seen a significant uptake in prescribing before this time. It was agreed that no further action was needed at this time in terms of asserting a GM position for Urtogestan but that prescribing growth should be checked again in 6 months.

ACTION: Utrogestan to remain on the monitoring log to recheck prescribing figures in 6 months' time. High strength and long-acting insulin analogues to be retired from the FMESG monitoring log as this will be picked up by PaGDSG assurance reporting on the GMMMG insulin pathway. As the GMMMG recommendation for pentosan had now being superseded by TA610, there was agreement that it could also be retired from the monitoring log.

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 cariprazine for the treatment of schizophrenia in adults to be brought back in full to February's meeting.
- RAG assessment for testosterone replacement in menopausal women with low sexual desire to be brought back in full to February's meeting.
- A DNP/GREY list assessment for demeclocycline for SIADH to be brought back in full to February's meeting. RDTC to contact Professor Steve Ball Clinical Lead for Endocrinology MRI for comment to help understand place in therapy/ patient cohort and inform discussions ahead of February's meeting.

The group also considered a proposal to DNP paracetamol mucilage/ paracetamol mixture 1g/10mL for topical use in patients with sore mouth or throat resulting from cancer treatment. This treatment does not feature in the UK Palliative Care formulary and is not included in the recently approved GMMMG Palliative Care Guidance. Additionally, the Scottish Palliative Care Guidelines makes the following recommendation: 'Soluble paracetamol and/or aspirin used as a mouthwash provides no topical effect. Do not advise patients to use this as a mouthwash'. The group heard that this product is manufactured at the Christie and should no longer be recommended outside the Trust due to the lack of evidence and prohibitive cost of procuring as an unlicensed special. Additionally, products dispensed against FP10 prescriptions for paracetamol suspension in community were acknowledged to bear little resemblance to that formulated by the Christie. It was not possible to assess the scale of primary care prescribing as the product does not appear on ePACT 2.

ACTION: FMESG recommend that paracetamol mixture/ mucilage 500mg/5mL be positioned DNP (Criterion 1); recommendation to be opened for GM wide consultation.

4.0 Formulary and RAG

4.1 Formulary amendments January 2020

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

- The RAG listing for vitamin B compound and compound strong to be updated to align with the RMOC Position Statement for oral vitamin B supplementation as follows:
    - Vitamin B compound to be removed from the current RAG position of GREEN (specialist initiation). Where indicated, only vitamin B compound **strong** should be prescribed
    - The current Grey listing to be expanded 'only to be used on the advice of a dietician for *medically diagnosed deficiency or chronic malabsorption*, or *for short-term use* in secondary care to prevent "re-feeding syndrome"

    - A link to the RMOC position statement to be added to formulary and corresponding RAG entry.

- A link to TA613: fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy to be added in chapter 11. Fluocinolone acetonide intravitreal implant is not recommended as an option for treating chronic diabetic macular oedema that is insufficiently responsive to available therapies in an eye with a natural lens (phakic eye). Formulary entry to be clarified that fluocinolone acetonide is only recommended in line with TA301 (i.e. only in patients with a pseudophakic lens and providing the manufacturer provides the implant with the discount agreed in the patient access scheme).
- Links to TA614: Cannabidiol with clobazam for treating seizures associated with Dravet syndrome and TA615: Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome to be added to the RAG list entry for Epidyolex.
- The current DNP listing for cannabidiols to be clarified with additional wording: cannabis-derived, cannabis-based and hemp products DNP; excluding nabilone, Epidyolex *and Sativex when used within their marketing authorisation.*
- Owing to discontinuation by the manufacturer, Insuman Comb 15 cartridges, Insuman Basal vial and Insuman Comb 25 vials to be removed from the formulary. Reference to Insuman Comb 15 also to be removed from the GMMMG Insulin Guidance for Type 2 Diabetes. A notification to be published on the newsfeed of the GMMMG website.

The following amendments were also agreed (due to a commissioning/ cost/ or service impact, these would be opened for GM wide consultation):

- Fluoride toothpaste 5000ppm GREEN (specialist recommendation) and GREY; only for patients at risk of caries secondary to treatment for head and neck cancers. And annotated: 'To be continued for as long as natural teeth remain. **The prescribing of fluoride mouthwashes and toothpastes for other indications should be by dental prescription only, and in line with GMMMG Commissioning Statement: Conditions for which over the counter items should not routinely be prescribed in primary care.'**
    - The existing position to be retired: *prescription only toothpastes and mouthwashes GREEN following specialist initiation and GREY; only dentists should prescribe such products due to the risk of patients developing fluorosis.*
- Oral pyridoxine to be GREEN (specialist recommendation) and GREY; for prophylaxis and treatment of pyridoxine deficiency that may occur during isoniazid or penicillamine therapy. And annotated 'see BNF for recommended doses'. It was recognised that that there are no licensed OTC products that provide pyridoxine as a single ingredient. Combination products that contain pyridoxine do so at very low doses (0.8mg to 4mg) per dos and the inclusion of other vitamins and minerals within these products precludes the option of taking multiple doses to reach a target daily dose of pyridoxine.

The following NICE guidelines would be included in the consultation document 'for information' only:

- A link to NG144: Cannabis-based medicinal products to be added in chapter 4 of the formulary. There is a potentially significant cost impact associate with spend on Sativex as a result of this guidance. Based upon the NICE resource impact for the guidance, GM spend for the first year is expected to be around £22k rising to £386k per year by year 4. The GM position of Sativex is currently under review; neurology at SRFT working to provide information on patient numbers and proposed GM criteria for initiation.
- A link to NG145: Thyroid disease: assessment and management to be added to formulary in chapter 6. NICE anticipates this guidance will result in small savings; based upon the resource impact for the guidance, GM savings for the first year are expected to be around £5k, rising to an annual saving of £50k by year 5. There may be some service/ resource

impact associated with offering radioactive iodine as a first-line treatment for adults with Graves' disease.

- A link to TA616: Cladribine for treating relapsing–remitting multiple sclerosis to be added in chapter 8 (this will supersede the current link to TA493). There is no significant cost or resource impact associated with the TA; because cladribine is less costly and needs less frequent dosing and monitoring than some of the other treatment options. Cladribine is NHSE commissioned for MS.
- A link to NG147: Diverticular disease: diagnosis and management to be added in chapter 1. NICE anticipates this guidance will result in significant savings; based upon the resource impact for the guidance, GM savings for the first year are expected to be around £12k, rising to an annual saving of £260k by year 5.
- A link to NG148: Acute kidney injury: prevention, detection and management to be added in chapter 2. There is no significant cost or resource impact associated with this guideline; there maybe cost savings associated with early recognition and treatment/ reduced admissions for management.

2.0 Medicines Optimisation

2.1 Colchicine for pericarditis- information sheet for GPs

A draft supportive information sheet for GPs on colchicine for pericarditis pain was considered by the group. Development of this material had been prompted by website access data which highlighted that the 2016 NTS recommendation on colchicine for this indication was one of the most frequently accessed documents on the GMMMG site. It was agreed that the recommendation itself was not very helpful for prescribers from a practical point of view and that scoping had failed to identify any existing national supportive information.

Some comments had been submitted by AS ahead of the meeting and the group suggested some additional amendments to the draft.

ACTION: RDTC to update the draft accordingly and circulate for virtual approval along with the draft minutes and actions of the meeting.

2.2 SPS product safety assessment- Alkindi

A recently published SPS *in use product safety assessment report* for Alkindi® was noted by the group. The safety assessment report summarises practical safety considerations associated with the new product and its unfamiliar presentation of 'granules in capsules for opening'. Safety concerns highlighted in the report relate to the novel presentation, the risk of choking/ administration errors, and mis-selection when prescribing or dispensing.

Medicines for Children had been contacted to check if there was a plan to add a leaflet on Alkindi to their suite of online resources; a response was awaited.

ACTION: The group agreed the following actions should be taken in response to this document:

- RDTC to pursue distribution of the safety assessment and suggested wording for dispensing labels via the GMMMG cascade distribution list. It was suggested this would be a useful way to communicate safety information such as relevant SPS product safety assessments going forward.

2.3 GMMMG Dental Antimicrobial Prescribing Guidelines

A revised draft of the GM Dental Antimicrobial Prescribing Guidelines was considered by the group. A previous version of the update had been considered at September 2019's meeting at which time the group requested greater emphasis on self-care and referral to a pharmacist/ regular dentist where appropriate, as well as reinforcing the over-arching message that GPs should not be responsible for managing dental conditions.

The group approved the draft update but requested that 'outside the dental setting' be removed from the title ahead of upload to the GM site.

ACTION: RDTC to contact author and request the necessary amendment prior to uploading on the GM site. Also to contact the Manchester Local Dental Committee and inform them of the update.

3.0 FMESG Work Plan

3.2 Monthly horizon scanning documents- December 2019 and January 2020

The RDTC monthly horizon scanning documents for November 2019 and January 2020 were considered by the group.

ACTION: The group requested RDTC scope information on the impact of gammaCore on oxygen use for cluster headache to help the group understand the magnitude of cost saving associated with the technology.

4.0 Formulary and RAG

4.2 Guidelines on defining RED AMBER GREEN Status- 2019 update

A revised draft the GMMMMG Guidelines on defining RAG status was approved for upload following minor amendment. The key aim of the update was to clarify the new classifications of DNP and reinforce the scope of Grey listing. The group noted that RMOC are expected to issue national guidance on RAG listing which should inform a more comprehensive review of the GMMMG guidance when published later this year.

ACTION: RDTC to amend draft and then upload to the GM site.

5.0 AOB

The group discussed proposals to update the GMMMG RAG list as part of the OTC work including how best to host information on exemptions. As there was limited capacity within the RAG list columns to detail exemptions for each OTC line, it was agreed that the wording should be made clearer to direct readers to see the full commission statement for more information. Limitations of hosting the information on the RAG list were acknowledged, however it was felt that the self-care tool kit would remedy this once published as it would act as the central source for information.

Although the lines on the RAG list were based on NHSE phraseology e.g. 'infrequent constipation' and 'mild irritant dermatitis' it was recognised that alternative listings may be more logical for some entries in order to improve search-ability. Additionally some lines of the RAG had now been superseded by the OTC lines and could now be retired (e.g. cough medicines, lactase drops for infant colic). RDTC had not been involved in this work-stream (other than facilitating hosting of the commissioning statement on the site) and thus were unaware of the nuances of this work, thus requested that amendments be submitted as a formal direction to RDTC.

ACTION: AS to draft necessary amendments and send to LB for approval prior to directing to RDTC. Once enacted, RDTC to add link to the OTC statement on the homepage and add to the newsfeed.

It had been agreed at November's meeting that the OTC commissioning statement be updated to include a GM position on responding to appeals. As such a statement would also be relevant the *NHSE items which should not routinely be prescribed in primary care* guidance it was agreed that a standalone document be developed for appeals against GM positions related to NHSE guidance.

ACTION: AM to draft GM position on appeals against NHSE guidance.

The next meeting will be held on 25th February 2020, 12.30-2.30pm, MFT-ORC.