FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Tuesday 23rd July 2019
12:30 - 2:30 pm
Pharmacy Dept MFT-ORC (formerly known as CMFT)

Present:

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	July	Aug	Sept	Oct	Nov
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	✓	✓	A	✓	✓	✓				
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A (LB)	✓	A	✓	✓	✓				
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	✓	✓	A	✓	A	✓				
Aoidin Cooke (AC)	Medicines Management and Medicines Information Pharmacist	MFT-ORC	✓	A (LH)	✓	A (LH)	✓	✓				
Claire Foster (CF)	Senior Medicines Optimisation Advisor	MHCC	✓	✓	✓	✓	A	A (FA)				
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	A (AH)	A	✓	✓	A	✓				
Rachel Macdonald (RM)	Pharmacist	Community pharmacy	A	✓	A	A	A	A				
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	A	✓	✓	✓	A	✓				
Prof Peter Selby (PS)	Consultant Physician	MFT-ORC	✓	✓	A	A	✓	✓				
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	✓	✓	A	A	✓				
Dr Hina Siddiqi (HS)	GP		✓	A	A	✓	A	A				
Lindsay Harper (LH)	Director of Pharmacy	SRFT	A	A	✓	A	A	A				

Name	Title	Organisation	Jan	Feb	Mar	Apr	May	July	Aug	Sept	Oct	Nov
Anna Swift (AS)	Snr. Assistant Director Medicines Management	Wigan Borough CCG				✓	A	A				
Jonathan Schofield (JS)	Consultant Physician	MFT-ORC	✓	✓	✓	✓	A	✓				
Faisal Bokhari (FB)	Deputy Head Medicines Optimisation	T&G CCG	✓	✓	A	✓	✓	✓				
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓	✓	✓	✓	✓				
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	A	A	A	A	A	A				
Carol Dolderson (CD)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓	✓	✓	✓				
Nancy Kane (NK)	Senior Medical Information Scientist	RDTC				✓	A	A				

1.0 General Business

1.1 Apologies

Apologies had been received in advance as noted above. Faduma Abukar (FA) attended from MHCC in the absence of Claire Foster

LL was in attendance until item 2.1.

PS was in attendance until item 3.0.

1.2 Declarations of Interest:

SS declared a personal interest related to item 4.1, so did not participate in discussion of that item.

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

1.3 Draft minutes –May 2019

The minutes from May's meeting were noted. These had been approved by the group virtually, ahead of June's CSB.

1.4 Matters Arising

The FMESG proposed actions for June were out for consultation; closing 20th of August.

1.4.1 Consultation feedback (April):

Consultation comments received on actions from the April meeting were discussed and the following actions agreed accordingly:

- Ertugliflozin to be added to formulary as an alternative treatment option (in line with TA572). The position in therapy to be reviewed once cardiovascular outcome data becomes available.
- The formulary to be updated to reflect NG123: Urinary incontinence and pelvic organ prolapse in women: management.
- Sodium fusidate (oral formulations) to be GREEN (following microbiologist advice, non-formulary).
- Insulin degludec to be Grey and GREEN (specialist initiation, non-formulary) for patients with type 1 diabetes and 2 diabetes mellitus. The current FMESG recommendation to undergo minor amendments to clarify the current positioning, which essentially remains the same. An updated draft of the recommendation to be circulated to the group for virtual approval prior to upload to the GM site. There are no new commissioning implications associated with this recommendation, however it would be flagged to CSB that this recommendation is less restrictive than the most recent NICE recommendations. It was agreed that degludec would be added to the monitoring log to track prescribing trend (as for Toujeo).

ACTION: RDTC to action these recommendations, as pre-support had been sought at June's CSB.

1.4.2 Draft update FMESG recommendations- insulin degludec/ GLP1 + insulin combinations

Both draft documents to undergo minor amendment (as above) and to be circulated to the group for virtual approval prior to upload to the GM site

1.4.3 Consultation feedback (May):

Consultation comments received on actions from the May meeting were discussed and the following actions agreed accordingly:

- Stiripentol to be RED (non-formulary) and GREY for Dravet syndrome & SCN1A variant epilepsy. Stiripentol is indicated in conjunction with clobazam and valproate as adjunctive therapy for refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy, where seizures are not adequately controlled with clobazam and valproate. The previous GM position was RED for paediatric patients only. The new position proposed will allow existing patients prescribed stiripentol for these indications in childhood to continue therapy into adulthood. Additionally, a small number of patients may be initiated on stiripentol in adulthood (approximately 6-8 patients per year). Stiripentol is a high cost drug and there may be a commissioning impact for CCGs as a result of new initiations in adult patients; approximate annual cost is £17,800 (based on maximum dosing in a patient weighing 60kg). This commissioning impact is to be flagged to CSB, along with this recommendation.
- Triamcinolone IM injection (Kenalog) to be RED and Grey for the indication of allergic rhinitis. Use for this indication is not supported by national guidance due to insufficient evidence. There may be a small number of patients who might benefit from therapy under the care of an allergy specialist. FMESG felt that there is insufficient evidence of efficacy or safety to support GPs prescribing and administering for this indication in primary care. There may be commissioning implications associated with referrals to specialist services but this is likely to be low in number.
- Removal of the gender specification in the current GM status for prucalopride (GREEN following specialist initiation. This is in line with the extension of the product licence to include men, and because the available evidence base is for both men and women. There may be a cost impact to GM associated with this recommendation because of an increase in new initiations in male patients, however this is thought to be small; the licence was extended in 2015 and it is thought that current GM prescribing reflects use in both men and women. The annual cost is around £500 to £774 per patient.

- Levonorgestrel intrauterine devices. On the basis of frame size, cost effectiveness and feedback from sexual health services:
    - Kyleena® (levonorgestrel 19.5 mg) to be added to formulary as the first choice option for women requiring contraception
    - Levosert® (levonorgestrel 52 mg) to be added to formulary as an alternative option
    - The positioning of the current formulary option, Mirena® (levonorgestrel 52 mg) to be clarified as an alternative option.
    - A link to a GM comparison table for levonorgestrel intrauterine devices to be included in the formulary to aid prescribing choice.

  Both devices have a lower annual cost than Mirena so some reduction in spend may be seen (Kyleena is around 15% cheaper, Levosert is 25% cheaper). However there may be training implications associated with Levosert which has a different insertion technique to Mirena and Kyleena. The group noted that contraceptives are commissioned by Public Health rather than CCGs, thus are unable to assess commissioning impact. This to be flagged to CSB, along with the recommendation.
- Dexamfetamine for narcolepsy to be RED (pending development of a shared care protocol, after which AMBER would be applied). There may be service implications while a shared care protocol is developed.
- Glycopyrronium oral solution for severe sialorrhoea to be GREEN specialist initiation (non formulary) and annotated 'prescribers should choose the product with the lowest acquisition cost and taking into account shelf-life of the product where appropriate' .
- Certolizumab pegol for treating moderate to severe plaque psoriasis to be RED (in line with TA 574).
- Tildrakizumab for treating moderate to severe plaque psoriasis to be RED (in line with TA 575). No cost impact.
- The formulary to be updated to reflect NG126: Ectopic pregnancy and miscarriage: diagnosis and initial management.
- The formulary to be updated to reflect NG128: Stroke and transient ischaemic attack in over 16s: diagnosis and initial management.
- The formulary to be updated to reflect NG129: Crohn's disease: management.
- The formulary to be updated to reflect NG130: Ulcerative colitis: management.

ACTION: FMESG to a seek support from August CSB to action the above recommendations that are associated with commissioning implications. RDTC to action those without commissioning implications as pre-support had been sought at June's CSB.

The group also discussed consultation comments on the proposal to add hydrocortisone oral granules (Alkindi) to be added to the paediatric RAG list as for doses of hydrocortisone <5 mg only GREEN (specialist initiation). This offers a licensed option, where previously patients were required to manipulate tablets in order to obtain these smaller doses. (There is therefore a risk of over- or under- treating children requiring the smaller doses when tablets are manipulated this way).

The group acknowledged comments received regarding the cost efficacy of the product, but were minded to maintain the original recommendation on the basis of safety. The group recognised that the alternative option for these patients may include unlicensed 'specials' such as liquids and powders for which cost-efficacy could equally not be demonstrated. Additionally it was agreed that adding Alkindi to the Grey list for doses <5mg would help ensure prescribing occurs only in the appropriate patient group. However, agree to await further feedback from paediatric endocrinologists regarding management of patients on dose increments between 5 to 10mg before making a final recommendation to CSB.

1.4.4 Feedback on rivaroxaban CAD/PAD proposed positioning

The group considered comments on the draft positioning statement for rivaroxaban in CAD/PAD. The draft had been disseminated with an aim to obtain views from primary care, however only two responses from GPs had been received. The remainder of comments were from consultant cardiologists, but were noted to be very helpful, particularly highlighting a need for clarity of who would be responsible for the ongoing bleeding risk assessment. The group agreed that the comments gathered to-date had been very helpful in informing the need for supportive guidance for prescribers once the NICE guidance is published. It was agreed that the item would be re-discussed at the August meeting, as it was expected that a draft of the TA would be available to inform the group.

1.4.3 Action Log

Updates on the action log were noted, including a supportive paper detailing progress of the GM Wound Care Formulary. It was agreed that RDTC would liaise with MH services to bring back a paper on the GMMMG positioning of oral typical antipsychotics and cariprazine at August's meeting. The additional notes on chapter 6 to also be added to the agenda for August.

1.4.4 Monitoring log

The monitoring log was noted by the group. No action was required on this item at this time.

2.0 Medicines Optimisation

2.1 Drugs of Limited Clinical Value '2'

Following the publication of further guidance from NHSE on drugs/ drug groups which should not routinely be prescribed in primary care, the group considered the GM positioning of the additional items that had been added in the revised policy. The following recommendations were proposed:

- Aliskiren (currently GREEN following specialist initiation, non-formulary). To be DNP to reflect guidance from NHSE. FMESG acknowledged that in clinical practice, this agent was reserved as a last resort option where safer and more established therapies had failed to control hypertension. Additionally there is a lack of long-term safety and efficacy data to support its use; it is not recommended by NICE. There are no commissioning implications expected as a result of this recommendation as patient numbers are small, there may be some service implications in the meantime while existing patients are referred back to the initiating consultant for review and discontinuation.
- Amiodarone and dronedarone (currently both GREEN following specialist initiation, on formulary). The group acknowledged that these agents hold a place in therapy. However intended use of amiodarone should be short-term only. The NHSE guidance directs that these agents should be shared care, which the group agreed was appropriate in light of the monitoring requirements associated with their use. It was noted that a prospective author for the development of the SCP had contacted the group, however further scoping was required to define the exact cohort to whom the SCP would apply. The group recommend amiodarone injection to be RED, and oral amiodarone and dronedarone to be AMBER with shared care.
- Minocycline for acne (currently no GM position for this). The group acknowledged that use of minocycline for this indication was not supported by national guidance, and it that it had not been included in the GMMMG dermatology pathway for acne. Additionally the high incidence of undesirable side-effects render it a less suitable option for treating infections and this was reflected in the BNF: '*Less suitable for prescribing (compared with other tetracyclines, minocycline is associated with a greater risk of lupus-erythematosus-like syndrome; it sometimes causes irreversible pigmentation)'.* Minocycline to be assigned DNP for acne accordingly. There are no commission implications expected as a result of this

recommendation as patient numbers are small and the alternative (and more suitable) antibiotics for acne cost less than minocycline.

- Needles for pre-filled and re-usable pens. The group noted NHSE guidance of an upper price-limit of £5 per 100 needles, and that many manufacturers had already lowered their prices to account for this. FMESG recommend that the current GM position of £6 per 100 needles be updated to align with the NHSE guidance (i.e. lowered to £5), with the exception of safety needles. The relevant cost chart to be updated accordingly in the formulary.

ACTION: FMESG to open these recommendations for GM wide consultation, and seek pre-support to action at August CSB.

2.2 OTC Lines for DNP

As part of the ongoing NHSE OTC Guide/ self-care policy development and implementation across GM, the group considered a list of medicines for DNP allocation. These were medicines identified from ePACT and Joint Commissioning Team Business Intelligence reports, and had been narrowed down to around 3,000 items from an initial list of 10,000. The aim of the agreeing the list of items to DNP was to allow clinical decision support tools within primary care to incorporate these lines in time for the 'soft launch' of the OTC policy. Acknowledging that a deal of work had already gone into refining the list to a manageable size, FMESG discussed issues around collating and simplifying lines further. It was agreed that the list would be divided and shared around operational leads to be reviewed in smaller blocks. A need to ensure that the list was reviewed by a range of clinical specialists was also highlighted to ensure that OTC items sometimes used for long-term clinical conditions were not unintentionally rendered DNP (e.g. oral rehydration sachets used for patients with high output stomas, vitamin D preparations for patients with osteomalacia). It was recognised that further discussion would be required around how the list should be best hosted on the GM site.

ACTION: LB to divide list and share among CCG operational leads in order to produce a final list for submission to August CSB. This list to come back to August's meeting for further discussion on incorporation within formulary chapters/ publication on the GM site.

3.0 FMESG Work Plan 2019

3.1 Consideration of items for FMESG work plan

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

- GMMMG formulary choice growth hormones to be reviewed at August's meeting, in light of the discrepancy between formulary choice preparations and those preparations listed in the GM SCP. The group recognised that a previous piece of work had been undertaken by CMFT-ORC which had been challenging due to the complexity of prescribing considerations when choosing the most suitable product for a patient.

The group considered a request to amend the current RAG position of modafinil for sleepiness associated with narcolepsy and Parkinson's disease. The group agreed that there were sufficient monitoring requirements for this agent to uphold the current positioning of RED pending development of SCP. No action required.

3.2 Newly licensed melatonin products- scoping for work plan

The group noted the availability of two newly licensed melatonin products for short-term treatment of jet lag in adults, and agreed that a DNP assessment should come back to August's meeting accordingly.

FMESG had planned to scope the liquid preparation for a GM position in children (in view of the safety concerns relating to the propylene glycol content, and the significant cost pressure versus unlicensed liquids). However, an amendment to the product SCP issued immediately prior to the meeting stated that the product should not be used in children and adolescents aged 0-18 years due to safety and efficacy concerns. FMESG agreed that no action was required at present.

ACTION: RDTC to draft a DNP tool for the August meeting for the licensed melatonin products in short-term treatment of jet lag in adults.

4.0 Formulary and RAG

4.1 Formulary amendments July 2019

The group decided that a suggested amendment to the sodium hyalonurate choices should be addresses at a future meeting, pending the development of an eye lubricant formulary by MFT, as this would help inform formulary choices as a whole. The other suggested formulary amendments were noted and approved.

ACTION: RDTC to open these recommendations for GM wide consultation and seek pre-support to action from August's CSB.

4.2 Skin chapter update

FMESG began undertaking a review of the Chapter 13 Skin in September 2017, however the chapter update was put on hold pending completion of the new GMMMG dermatology pathways. These pathways are now approved for GM use.

The group considered a draft update of the skin chapter that had been aligned with the pathways. It was agreed that the formulary emollient choices would remain unchanged at present whilst there was some ongoing discussions around these. The group requested addition of annotations to the pathway and formulary of which emollients were suitable to be prescribed as soap substitutes, and specifying that Dermol® is suitable for short-term use only.

Additionally, the group requested review of Trimovate® on the steroid pathway and recommended this be removed from the formulary on the basis of poor evidence around the use of topical antimicrobials, its high cost, and recurrent issues around product availability. The group heard that some APCs recommend prescribing a steroid cream and an antifungal cream as separate products instead.

The group supported the update of the other elements of the chapter to reflect the pathways, with some minor amendments clarifying positioning.

ACTION: RDTC to feedback comments to pathway authors and await response. Remaining amendments to be actioned.

4.3 Testosterone Leaflet

Due to time pressure, this item was referred to August's meeting.

5.0 Horizon Scanning and work plan

5.1 Monthly horizon scanning documents June and July 2019

The RDTC monthly horizon scanning document for June and July were considered by the group. The group recommended no additional action was required at present on the basis of these documents.

5.2 Work plan

It was noted that the GMMMG Work Plan was being updated. A final version would be considered at a future meeting, once agreed by CSB.

6.0 AOB

Nil.

The next meeting will be held on 27th August 2019, 12.30-2.30pm, MFT-ORC (formerly known as CMFT).