FORMULARY AND MANAGED ENTRY SUBGROUP

January 24th 2017 Minutes
12:30 - 2:30 pm
Pharmacy Dept. CMFT

Present:

Name	Title	Organisation
Elizabeth Arkell (EA)	Medicines Management Lead	UHSM
Dr Paul Chadwick (PC)	Consultant Microbiologist and Chair of Meds Management Committee	SRFT
Aoidin Cooke (AC)	Medicines Management and Medicines Information Pharmacist	CMFT
Claire Foster (CF)	Senior Medicines Optimisation Advisor	SM CCG
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG
Prof Peter Selby (PS)	Consultant Physician	CMFT
Lindsay Harper (LH)	Director of Pharmacy	SRFT
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.
Bhavana Reddy (BR)	Head of Prescribing Support	RDTC *(Professional Secretary)*
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC

1. General Business

a) Introductions and Apologies

Apologies had been received in advance from Pete Budden, Anne Eccles, Dr Dev and Liz Bailey.

BR chaired the meeting in the absence of PB. PB had commented on papers prior to the meeting and his responses were available to the group for discussion.

b) Declarations of Interest:

One declaration of interest had been raised prior to the meeting by KP relating to agenda item 4.2.1. It was agreed that KP would leave the room for this agenda item. No other declarations of interest were made.

2. Strategic Direction and Governance

2.1 Overview of group responsibilities

BR and MM updated the group on its remit which would cover management of the GMMMG formulary, the Red Amber Green List, the DNP and Grey Lists and new drug applications. It was noted that whilst high cost drugs would be reviewed by FMESG they would need to go to the high cost drugs group for consideration of practical and commissioning issues. All pathways and shared care work would need to go to the pathways and shared care group. There was some discussion around further development of the formulary and the 'majority' rule and how best to incorporate the RAG list, new therapies recommendations, pathways and shared care into the formulary. It was agreed that the formulary should become a more complete document that prescribers could access without having to check other lists. This would be discussed further at a future meeting.

2.2 NPC formulary framework

BR noted that GMMMG had asked that the subgroups complete the NPC competency framework. This had been shared with the papers, however the intention was that the form was completed as a group once the group had been up and running for at least 6 months. A gap analysis of GMMMG formulary development and maintenance processes against NICE good practice guidance had been produced for the current formulary processes. It was proposed that the group tackle some of the amber actions which related mainly to implementation and how the formulary had been implemented on a local level. The NPC competency framework would be tabled for discussion at a future meeting.

3. Red Amber Green List

a) Previous RAG status recommendations for approval.

The group discussed the following proposed RAG status decisions from the previous interface prescribing subgroup. These proposed recommendations had been out for consultation to trusts and CCGs and the comments received were presented. After further discussion the group approved the following RAG status decisions:

Drug and indication	Approved RAG status
Linezolid	RED
Octreotide for acromegaly	RED (NHS E commissioned)
Oral Ketoconazole for Cushing's disease	RED
Degaralix	AMBER (once signed up to Rebate)
Metoject for psoriasis and psoriatic arthritis	AMBER
Nivolumab	RED
Brivaracetam	GREEN (following specialist initiation)
Ulipristal for intermittent treatment of moderate to severe uterine fibroids	GREEN (following specialist initiation)

b) RAG status assessments:

1. <u>Nadolol</u>

The group reviewed the application that had been submitted regarding assigning a RAG status for nadolol. Nadolol is the preferred beta-blocker for adults with long QT syndrome. It was noted that it was licensed for cardiac arrhythmias but it is no longer available in the UK for commercial reasons. The application referenced some clinical trial data showing that nadolol was found to be as effective as propranolol for congenital long Q-T syndrome. It was noted that as an unlicensed product that as per the criteria it may become a RED drug; it was however argued that as the license had not been withdrawn for safety reasons and due to commercial issues that a RED rating would make access for patients particularly difficult as they would expect to be on nadolol for life. Some members felt that GPs would not feel comfortable prescribing something that was now unlicensed. It was noted that the criteria stated that it would only be red if the item wasn't in the BNF and didn't have a body

of expert opinion advocating use. It was agreed that as nadolol was in the BNF it should be proposed for Green (following specialist initiation). The group agreed that this would go out to consultation and feedback from primary care and GPs in particular would be sought prior to finalising the RAG status.

Post meeting note:

It was noted that after discontinuing this in 2016, Sanofi have advised they are reintroducing this back to the UK market and supplies will be available to order from AAH, Alliance and Phoenix from the beginning of February therefore a RAG status for nadolol will no longer be assigned.

2. Imiquimod RAG status review

The group was asked to assign a RAG status for Imiquimod cream. It was noted that there are two strengths 3.75% which is normally used for actinic keratoses (AK) and 5% which is normally used for genital warts.

Imiquimod 5% is already included in the formulary for the management of anogenital warts and the 3.75% cream was included in the NTS recommendation for management of actinic keratoses.
The group agreed that Imiquimod should be Green for AK however this is not the first line option and link to the NTS recommendation should be included. The group then discussed the anogenital wart indication. It was agreed that this would normally be initiated by GUM clinics therefore a recommendation of Green following specialist initiation for anogenital warts was proposed.

3. High dose fexofenadine - RAG status review

The group had been asked to review the RAG status of fexofenadine when used for higher than licensed doses for dermatological conditions such urticaria. The group reviewed the application. Higher than licensed doses are classified as off label use so this would fall under the RED RAG status, however it was noted that there is wholesale body of opinion on using higher than licensed doses of antihistamines such as the BSACI guidelines as well as the European Academy guidelines. These guidelines recommend an upper limit of 4-times the standard doses. The group noted that fexofenadine was not in the GMMMG formulary, and as such it was felt that other more established cheaper antihistamines should be used first line such as high dose cetirizine or high dose loratadine. The group agreed that high dose fexofenadine would not be assigned a RAG status as it was non formulary.

4. Pre-meds for patients receiving enzyme therapy – RAG status review

A request had been received to assign a RAG status to the pre-meds issued for patients prior to them receiving enzyme replacement therapy as some GPs had received requests to prescribe these drugs. The majority of these pre-meds are IV infusions. It was noted that all IV preparations are already RED on the RAG list (unless a local arrangement is in place in which case there may be some rare exceptions) however the remaining medicines such as chlorphenamine, paracetamol PR etc. cannot be made RED on the RAG list as there are no safety issues associated with the prescribing of these drugs in primary care. It was noted that this was primarily a commissioning issue and wasn't around safety. This is an NHS England service and it is expected that the pre-medication is commissioned as part of this and GP's should not be asked to prescribe any medicines relating to this service. The NHS England manual states that *'CCGs are not expected to commission any elements of this service'*
It was also noted that Salford Royal has appropriate processes in place to ensure all pre-meds are delivered via homecare for this particular procedure. This model should be adopted elsewhere. The group agreed to include statement on top of the RAG list that states **'***that any pre-meds for procedures/services commissioned by NHS England where GPs are not expected to be involved in the patients care must be provided by secondary or tertiary care provider'*

ACTION: The above RAG status decisions will be sent out for consultation to all Trusts and CCGs for further comment before coming back for final approval to the next FMESG meeting.

c) Drugs used by the eating disorder service – for RAG and formulary considerations.

Dr Whittaker from the CAHMS team at CMFT had been invited to attend the meeting to discuss this agenda item however as she hadn't made the meeting this agenda item would be deferred and discussed at a later date or via email.

Post meeting note: *Dr Whittaker is unable to make the next meeting therefore this agenda item will be dealt with via email prior to the service starting in April.*

4) Formulary

4.1 NICE TAs, MHRA and National Guidance.

The group reviewed the December horizon scanning document and approved the following:

- TA 417 – include link to TA in chapter 8
- TA418 - include link in chapter 6
- TA419 – need to include link to TA in relevant chapter alongside the RED RAG rating

The clinical guidelines were noted for information but no further action was necessary. It was noted that opicapone would need assessing for formulary or the grey list at a later date. It was agreed that links to the MHRA alerts on spironolactone from Dec 16 and the healthcare professionals' letters regarding apremilast and lenolidomide new advice should be linked to in the relevant chapters.

4.2 Formulary applications

1. Enstilar application

The group discussed the consultant application for the addition of Enstilar® (Calcipotriol/betamethasone) to the GMMMG formulary. Enstilar® is a topical treatment for patients with chronic plaque psoriasis on the body and trunk who require a topical corticosteroid plus a vitamin d analogue. It was noted that Enstilar is a combination product containing a synthetic vitamin D3 analogue and a synthetic topical corticosteroid (in the same proportions as in Dovobet®; 50 micrograms/g + 0.5mg/g) and licensed for topical treatment of psoriasis vulgaris in adults. Dovobet is already included in the formulary; It is not clear what the advantages of Enstilar® over Dovobet® are especially as Dovobet® is due to come off patent shortly. The group therefore agreed that the clinical trial quoted that compared Dovobet to enstilar should be critically appraised and brought back to the meeting. It was also agreed that further information on how many patients the specialists want to use this in should be obtained and whether it should be reserved for those patients who don't have any improvement with Dovobet ointment. LH noted that this hadn't been through the D&T at SRFT.

ACTION: LH to discuss with specialists at SRFT and report back at next meeting. RDTC to appraise clinical evidence and bring back to next meeting for further discussion.

2. Treclin application

The group discussed the letter received from the GPWSi dermatology. It was noted that NTS had already reviewed Treclin gel. The recommendation stated that it should not be used

routinely i.e. not first or second line use but maybe suitable for use in patients in whom other combination products have failed or are not tolerated and where a topical antibacterial/retinoid combination is indicated. The group reviewed the CKS guidance which does recommend the use of an antibacterial/retinoid combination. Treclin had also been approved by the SMC and was included in the European Guidelines which the applicant had attached to his correspondence.
The group therefore approved the addition of Treclin to the formulary this would need to be added as a new line under topical retinoids with antimicrobials.

ACTION: Treclin gel to be added to formulary once ratified by GMMMG.

3. Aripiprazole – amendment to first choice as per other agents

The group reviewed the application that had been received from the mental health trust chief pharmacists and approved the addition of aripiprazole to the formulary as joint first choice, particularly as it was now available as a generic.

ACTION: Aripiprazole to be added to formulary as joint first choice once ratified by GMMMG.

4.3 Asthma Pathway Chapter update

AM presented the final version of the asthma pathway to the group; the pathway is based on the updated BTS guidelines. It was noted that NICE now had a draft guideline out for consultation which is very different to the BTS guidance. The group stated that it was not helpful to have two different national guidelines. The group were not sure what evidence had been used to draft NICE guidance as it included the use of leukotrienes much earlier in the pathway than previously. The group were encouraged to comment on the draft NICE guidance although it was noted that GM could agree to approve the GM pathway over the NICE CG if there was sufficient specialist backing. It was agreed that the products contained in the pathway would be updated once it had been approved by the pathways subgroup.

5) New Drugs

The new drugs agenda items were deferred to the next meeting as there wasn't sufficient time to discuss these items.

6) Horizon Scanning and Work plan

AM asked that the fast-acting insulin aspart (Fiasp®) was added to the agenda for the next meeting. It was noted that as DUAVIVE and eluxadoline had not yet been discussed these would also move to the agenda for next time.
In addition Ferric Maltol and Opicapone would be added for a formulary assessment.
The remaining outstanding RAG status decisions would also need to be discussed in March.

7) AOB

No other business was raised and the meeting concluded. It was agreed that some items may be followed up via email in-between the bi-monthly meetings.

The next meeting would be 28th March 2017 at 12.30pm, CMFT.