FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Sept 26th 2017
12:30 - 2:30 pm
Pharmacy Dept. CMFT

Present:

Name	Title	Organisation	Jan	Mar	May	July	Sept
Elizabeth Arkell (EA)	Medicines Management Lead	UHSM	✓	A	✓	✓	✓
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	A	✓	A	✓	✓
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	A	✓	✓	✓
Dr Paul Chadwick (PC)	Consultant Microbiologist and Chair of Meds Management Committee	SRFT	✓	✓	A	✓	✓
Aoidin Cooke (AC) (or Lorna hand or Vanessa Reid)	Medicines Management and Medicines Information Pharmacist	CMFT	✓	LH ✓	✓	✓	VR ✓
Claire Foster (CF)	Senior Medicines Optimisation Advisor	SM CCG	✓	A	✓	✓	✓
Dr Anne Harrison (AH)	Gp Prescribing Lead	Trafford CCG	A	A	✓	A	A
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	✓	A	✓	A	✓
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	✓	✓	A	✓	✓
Prof Peter Selby (PS)	Consultant Physician	CMFT	✓	✓	✓	A	A
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	A	✓	✓	✓
Lindsay Harper (LH)	Director of Pharmacy	SRFT	✓	✓	A	A	✓
Jonathan Peacock (JP)	Deputy Chief Pharmacist	WWL	✓	✓	A	✓	✓

Zoe Trumper (ZT)	Medicines Management	Pharmacist Wigan Borough CCG	✓	A	✓	✓	✓
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓	✓	✓	✓
Bhavana Reddy (BR)	Head of Prescribing Support	RDTC *(Professional Secretary)*	✓	A	✓	✓	✓
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	✓	✓	A	A	✓

1. General Business

1.1 Apologies

Apologies had been received in advance as noted above.

Guest diabetologists in attendance: Dr Susannah Rowles at Farifield (Bury) Pennine Care and Dr Mark Robinson who sits on the NW Young People and Paediatrics Diabetes Network

1.2 Declarations of Interest:

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

1.3 Draft minutes (July 2017)

The minutes were agreed as accurate record.

1.4 Matters Arising

- **Draft letter to diabetes consultants –** PB confirmed that he had approved a letter drafted by BR and that this letter would be forwarded to the consultants.

- **Vitamin D Grey listing not approved by GMMMG –** BR updated the group on the feedback from GMMMG regarding the proposed grey listing of vitamin D. GMMMG had not approved the recommendation put forward by FMESG as they felt that those on maintenance treatment (following deficiency) should not be prescribed vitamin D and should also be asked to buy it, as they felt it was not equitable to prescribe for deficiency but not insufficiency. The group agreed that further feedback be sought from secondary care consultants and fed back to GMMMG, it was also agreed that a FMESG representative attend GMMMG to aid further discussion of this item.

Action: BR to ask PS to submit a statement to GMMMG to aid discussion of this item.

2. New Drugs

2.1 Fiasp® recommendation final draft – following some minor amendments a final draft recommendation was approved by the group

Action: BR to submit recommendation to GMMMG for approval

Sodium oxybate in the management of narcolepsy with cataplexy in adult patients updated recommendation final draft – the group approved the updates to this recommendation. Following GMMMG approval this agent will be added to the grey list for prescribing only as per the recommendation, it will be listed as a RED drug on the RAG list.

Action: BR to submit recommendation to GMMMG for approval

2.2 Tapentadol use in palliative care – the group considered a request from CMFT, who wish to use tapentadol in palliative care but were concerned that the existing recommendation

prevented this. The group agreed that the current recommendation was appropriate but that some re-wording to support the use in palliative care would be appropriate.

Action: BR to update as above.

2.3 Prazosin for PTSD (unlicensed use) – The group evaluated the evidence for the use of prazosin for this unlicensed indication and noted that:

- NICE guidelines on PTSD do not address the use of prazosin nor do they give any specific recommendations regarding the management of persistent PTSD-related nightmares or sleep disturbances.

- The BAP recommend prazosin as an option for augmentation therapy in PTSD, however, this recommendation is based on the results of the small trials and does not take into account the larger unpublished trial with negative results.

- Recently updated guideline on PTSD, the US VA/DoD recommend against the use of prazosin for the global symptoms of PTSD and state that there is insufficient evidence to recommend for or against the use of prazosin for PTSD-related nightmares. This is a change from the previous version of the guideline which recommended adjunctive prazosin for the treatment of nightmares/sleep disturbances.

According to GMMMG "do not prescribe" criteria the group proposed that prazosin is added to the grey list to be used only within its licensed indication and not for PTSD due to a lack of evidence.

Action: MM to open this item for GM consultation via the website

2.4 FreeStyle Libre Flash Glucose Monitoring System – the group continued discussions taken earlier in the year and considered the draft recommendation recommending FreeStyle Libre Flash Glucose Monitoring System be restricted for prescribing in:

- T1DM patients who despite intensive specialist input continue to have poor control of their BG levels and are still unable to meet the requirements of BG testing to achieve improved control. Use of FreeStyle Libre system should only continue if there is a sustained improvement in HbA1c i.e. a minimum reduction in HbA1c of 0.5% or a reduction in hypoglycaemic burden is demonstrated at 6 months.
- In patients who have diabetes and are planning or actively pregnant

The decision of whether Freestyle Libre is appropriate should be made by a diabetologist, and the patient should remain under their care.

The group listened to the views of the specialists in attendance. Dr Robinson explained that the device would be particularly beneficial for young children in the prevention of hypoglycaemic episodes at night. He explained that the NW diabetes network would like to see a GM pathway for use of this device developed to prevent any disparity in separate CCG negotiations. Dr Rowles presented the case for the use of this device in 14 to19 year old patients transferring from paediatric to adult services and in adult patients, including pregnant women. The need for a carefully managed entry of this device due to the cost pressure presented was recognized. It was agreed that the suitability of patients for this device would need to be identified through specialist diabetes teams, and that this would likely ration its use to T1 diabetics and to those with pancreatic failure. Patients would need to have an ability to amend their treatment accordingly and would need to be engaged in their care i.e. taking all necessary steps to manage their condition effectively. The possibility of a structured agreement between the prescriber teams and the patient, to ensure that the necessary steps to the patient goal being reached was considered, there was some discussion as to the patient achieving their "goal" rather than a measured specified reduction in HbA1C. The group discussed whether a shared care arrangement between secondary and primary care would be appropriate.

Action: MM and AM to work to amend the draft recommendation following these discussions and return it for FMESG and GMMMG approval by email.

3. Formulary

3.1 Formulary Amendments

The group considered NICE guidance published in July and August 2017 and MHRA drug safety updates from July and August. It was agreed that the formulary would be updated to reflect TA452 to TA473 as appropriate. NICE NG71 was considered and it was agreed a link to this guidance be included. Links to MHRA guidance on dacalizumab, bendamustine and nivolumab and corticosteroids would be included in the formulary. The group also noted the outputs from the other GMMMG subgroups.

Action: MM to update the formulary chapters as approporiate

3.2 Formulary section review

3.2.1 Formulary section review: Drugs used in diabetes

The group noted that there had been a significant number of responses to the GM wide consultation on the proposed changes to the diabetes chapter, and that a summary of these comments and proposed actions be returned to the November meeting. The group were conscious that the formulary must reflect the needs of the majority of the GM population, and that any proposed changes must be supported by a clear rationale and evidence base.

Action: AM and BR to bring back the relevant information to the November meeting as a paper of proposed changes

3.2.2 Xultophy application

Xultophy (insulin degludec plus liraglutide) had been considered as the subject of a re-review request at the July meeting where BR had been asked to gather further information from the specialist to be considered at this meeting alongside the new trial data. A new evidence summary produced by the RDTC was considered and the group noted that the new data supported use of the product, but it was also noted that additional trials comparing Xultophy with glargine have been completed but are not yet published. A glargine/lixisenatide combination product is also licensed in the UK but not yet launched. NICE CG28 which states that “In adults with type 2 diabetes, only offer a GLP‑1 mimetic in combination with insulin with specialist care advice and ongoing support from a consultant‑led multidisciplinary team” and that NICE Evidence Summary 60 highlighted that:

- Xultophy requires one daily injection, which may be preferable for some people to the two injections required to administer insulin + GLP-1 analogue separately.
- Xultophy offers a fixed dose ratio of degludec + liraglutide, and does not allow the dose of either drug to be altered independently of the other.

Whilst Xultophy remains cheaper than using degludec + liraglutide separately, it costs more than the cheapest combination of long-acting insulin analogue + GLP-1 agonist (Abasaglar® + lixisenatide).

The group agreed that as the glargine/lixisenatide product is licensed that it would be sensible to consider both products together if this product is due to launch in the next couple of months.

Action: MM to check date of launch of the glargine/lixisenatide product and schedule the agents to be considered at the same time if it is due within a couple of months.

3.2.3 Skin chapter review

The group considered a draft version of the skin chapter that was proposed to be opened for GM wide consultation. Included within the proposed changes were the addition of a paraffin free emollient, with a note stating that this is a more costly product and should be restricted to those patients where a paraffin containing emollient was necessary. There was some discussion within the group as to whether this was necessary and if it should be removed, however it was felt that this could be done after the consultation based on the comments received. Additional wording was added to the Treclin® and Mirvaso® listings emphasising the GMMMG position. Ivermectin 1% cream (Soolantra®) was added to the formulary in line with the GMMMG recommendation. Some additional wording was added to support the MHRA warning on chlorhexidine.

The revised draft will return to the FMESG for approval following the consultation and any necessary work.

Action: MM to add the draft chapter to the GMMMG website for consultation, after which comments will be sent to the GMSS and lead authors.

4. RAG list

4.1 RAG consultation response

BR confirmed that the RAG status's proposed at the May meeting i.e. agents for metabolic disorders, modafnail for all unlicensed indications, safinamide for PD and Opicapone for PD had been agreed by GMMMG and had been added to the website.

Action: No further action

4.2 RAG assessments

4.2.1 Stiripentol for epilepsy

A request to issue a RAG status for stiripentol for epilepsy (Paediatric patients with SCN1A genetic epilepsy stable on stiripentol since childhood transferring to adult services) was considered by the group. This agent is currently listed as red for paediatrics but has no RAG status in adults. It was agreed that for adult patients stable on this drug, since childhood, with the identified genetic mutation, it should be AMBER under an SCP, but for those without the mutation it should not be prescribed at all (as per the position of the Epilepsy CG Group). The high cost of this agent was noted (between £18 and £21k per adult per year) but that patient numbers were expected to be low. A SCP will be requested to be produced by the Pathways group.

Action: MM to add this proposal to the GMMMG website for consultation but also to submit to GMMMG for approval in principle. If there are no significant comments raised during the consultation this item will be added to the DNP list mid-November.

4.2.2 Modafanil for Parkinson's Disease (PD)

At the July meeting the group had agreed to add modafanil to the grey list for PD and for narcolepsy with/without cataplexy. Whilst the RAG status for use for narclopesy would remain amber that further advice would be sought from the specialists regarding the RAG status for us in PD.

At this meeting the group considered the review of evidence presented and the responses from the specialists and it was agreed that an amber status would be issued. It was noted that Parkinson's patients would remain under the care of their Parkinson's specialist for this condition. The group agreed that it would be appropriate that this agent was given an amber status, although the mainstay of monitoring would be undertaken by the Parkinson's team. A SCP will be requested to be produced by the Pathways group.

Action: MM to add this proposal to the GMMMG website for consultation but also to submit to GMMMG for approval in principle. If there are no significant comments raised during the consultation this item will be added to the DNP list mid-November.

4.2.3 Pasireotide for Cushing's Disease

The group considered a request to review Pasireotide Signifor® 0.3 mg, 0.6mg and 0.9mg solution for injection for use in Cushing's Disease in line with NHSE policy. There is currently no listing on the RAG list and the group supported the proposal to add it as a red drug. It was noted that this was an NHSE commissioned indication for a rare condition affecting 1 or 2 people in every million per year.

Action: MM to add this proposal to the GMMMG website for consultation but also to submit to GMMMG for approval in principle. If there are no significant comments raised during the consultation this item will be added to the DNP list mid-November.

5. DNP and Grey Lists

5.1 Atorvastatin 30mg and 60mg strengths

The group noted the recent licensing of atorvastatin 30mg and 60mg tablets and a subsequent request to add them to the DNP list. The group assessed these agents via the DNP criteria and proposed their addition on the basis that these products are not a cost effective use of NHS resources, being considerably more expensive than the evidence based 10mg, 20mg, 40mg or 80mg atorvastatin, currently listed on formulary.

Action: MM to add this proposal to the GMMMG website for consultation but also to submit to GMMMG for approval in principle. If there are no significant comments raised during the consultation this item will be added to the DNP list mid-November.

5.2 Cough medicines

The group considered a request to add cough medicines to the DNP list and noted that in the previous 12 months there had been GM primary care spend of £56k on cough preparations. The group assessed cough preparations i.e. suppressants and expectorants as per BNF chapter 3.9 using the DNP criteria. It was proposed that these agents will be added to the DNP list on the basis of their poor evidence base (NICE CKS: Common Cold, August 2016). The group also noted the MHRA advice issued in April 2009 regarding safe use of cough and cold medicines in children under 12 years. Cough preparations are available to buy OTC and are part of minor ailments schemes.

Action: MM to add this proposal to the GMMMG website for consultation but also to submit to GMMMG for approval in principle. If there are no significant comments raised during the consultation this item will be added to the DNP list mid-November.

6. Horizon Scanning and Work-plan

6.1 Monthly horizon scanning documents (August and Sept)

6.2 Work-plan

The group noted that Trimbow was on the workplan to be considered by FMESG but that it had already been incorporated into the GMMMG COPD pathway whilst not being on formulary. It will be considered by formulary in November.

Saxenda for obesity has now been licensed and will be re-reviewed by the group in November

7. Additional items

7.1 AOB

Nothing raised.

It was agreed that meetings would continue to be held on the third Tuesday of every other month in 2018, starting on the 22nd January 2018.

The next meeting will be held on 28th November 2017 at 12.30pm, CMFT.