Minutes of the GM Formulary Subgroup meeting

Date: 1st September 2016, 12-2pm
Venue: Maternity seminar room, Wythenshawe Hospital
Present: Liz Bailey, Monica Mason, Dev Devapriya, Sarah Jacobs, Helen Burgess, Danielle Timoney, Connie Chen.
Apologies: Jonathan Peacock, Leigh Lord, Charlotte Skitterall, Claire Vaughan, Peter Howarth, Ann Harrison

Declarations of interest:

- HB explained that she had recently attended a market research group on the management of chronic non cancer pain
- CC had received light refreshments funded by Internis during a discussion of the GP education programme
- DT will be attending a Pharmacy Management event discussing "Biologics in the NHS" at the end of September
- DD will be sponsored by Chiesi to attend the European Respiratory Society Meeting in September

None of these declarations were considered to pose a conflict against items on this agenda

Item 3 – Previous minutes
There was no physical FSG meeting or GMMMG meeting in August. The group had submitted comments by email to approve the July formulary amendments, although comments from secondary care were required. These were provided at the Sept meeting and FSG agreed that they would be submitted to GMMMG for approval as follows:

- the formulary will reflect TA398 (Lumacaftor-ivacaftor), TA399 (Azacitidine), TA400 (Nivolumab), NG49 (NAFLD), NG50 (Cirrhosis), NG51 (Sepsis)
- the formulary will also reflect the July MHRA DSU with the addition of warnings for warfarin and calciphylaxis, citalopram and cocaine use

Item 4a –Action log
The group considered outstanding actions and agreed as follows:

- Swollen leg pathway – SJ had been requested by the SCN to reduce the size of this pathway, work had also been done to update the medicines sections of this pathway, it is due to come to the November FSG meeting
- Blephasol/Blephaclean lotion/wipes for Grey list assessment – DT agreed to seek feedback from specialists and to feed this back to MM
- Request to consider empagliflozin as first choice SGLT2 – MM explained that the necessary information had been gathered and this would be added to the November agenda

- PsA/AS pathway – will be submitted to the September GMMMG meeting
- IBD pathway is about to be opened for GM wide consultation
- Asthma pathway is being developed by the respiratory pathways group.

Item 4b – Election of interim Chair and vice chair of FSG
FSG members elected interim co-Chairs (Leigh Lord and Claire Vaughan) and a vice chair (Dr Connie Chen); these positions will be held until the subgroups undergo the proposed restructure. FSG expressed their thanks to Charlotte Skitterall and Dr Helen Burgess for their dedication, hard work and enthusiasm during their time as Chair and vice-chair of FSG respectively.
Action: No further action

Item 5a – Formulary amendments – Sept 2016
It was agreed that the formulary would be updated to include a link to the MHRA DSU (August 2016) warnings on posaconazole i.e. a statement would be added to highlight that tablets and oral suspension are not interchangeable.
As GMMMG did not meet in August there were no new NTS or IPS recommendations for consideration by FSG.
Following publication of the GM COPD pathway it was agreed that chapter 3 of the formulary will be updated to reflect the recently approved COPD pathway i.e. tiotropium handihaler will be replaced with tiotropium SMI (Respimat), umeclidinium DPI (Incruse Ellipta), Fluticasone/vilanterol (Relvar Ellipta) will be added and indacaterol DPI (Onbrez Breezhaler) will be removed from the formulary. A link to the pathway will also be added.
In response to a request from a GM HCP it was agreed that updates will be made to chapter 1 of the formulary to include additional information relating to H.pylori prescribing i.e. dosing information to be added where possible and the format will be simplified.
Action: MM to submit proposed amendments to GMMMG and update formulary following GMMMG approval.

Item 5b –Exenatide letter
MM explained that a letter from a number of GM diabetes specialists had been forwarded to FSG from IPS regarding the removal of exenatide from the formulary. The group were reminded that exenatide had been removed from the formulary last year following the NTS review of GLP1s and the publication of NICE NG28 which superseded the exenatide NICE technology appraisal. The formulary currently lists lixisenatide as the first choice daily preparation, liraglutide as an alternative daily preparation and dulaglutide as the first choice weekly preparation.MM explained that she had contacted the consultant to seek further information as to why exenatide would need to be included within the formulary, and will update FSG when a response is received.
Action: FSG to await response

Item 6 a – Review of DNP status of liothyronine
FSG were made aware that some GM CCGs had recently received a letter from the Thyroid Patient Advocacy concerning a recent price increase of liothyronine and that some CCGs are now instructing GPs to stop prescribing liothyronine. It also cited the PrescQIPP “Drop list. Whilst no reference was made to the GMMMG DNP list, FSG

had been asked to consider the current DNP listing to ensure that it was appropriate as this is the recommendation followed by GM prescribers. Liothyronine, thyroid extract and Armour thyroid preparations are currently included on the DNP list due to their poor evidence base, the supporting information states that it is not recommended for routine prescribing for the treatment of hypothyroidism and links to CKS hypothyroidism guidance (which references statements from The British Thyroid Association and The Royal College of Physicians). The group considered the DNP assessment tool that was used during the assessment of these products and references the Management of primary hypothyroidism: statement by the British Thyroid Association Executive Committee (June 2015).
FSG agreed that no change was required to the DNP listing and wish to emphasize that the positioning of these agents on the list is due to their poor evidence base.
Action: No action

Item 6 b – Sufentanil sublingual tablet system - DNP assessment
Following the recent "not recommended" statement from NTS, the above agent will be added to the DNP list in line with this recommendation.
Action: MM to add to DNP list following GMMMG approval.

Item 6 c – Dosulepin for fibromyalgia
The group discussed an issue with the prescribing of Dosulepin for fibromyalgia which was occurring within GM. The group considered the following points:

- Dosulepin SPC states: Dosulepin is indicated in the treatment of symptoms of depressive illness especially where an anti-anxiety effect is required. Due to its toxicity in overdose, Dosulepin should only be used in patients intolerant of or unresponsive to alternative treatment options (see sections 4.4 and 4.9). Initiation of treatment for patients who have not previously received Dosulepin should be restricted to specialist care prescribers.

- An Embase search was undertaken to look for evidence for the use of dosulepin in fibromyalgia or sleep, but no information was found.

- BNF does not recommend dosulepin as an antidepressant due to the risk of toxicity in overdose and also recommends it should only be initiated by a specialist.

The DNP list currently includes dosulepin citing safety concerns and links to the NICE "do not do" recommendation. FSG agreed that it would be appropriate to add a note to the dosulepin entry on the DNP list enforcing the restrictions the DNP list places on dosulepin in all cases i.e. licensed and unlicensed uses, based on the risk of toxicity in overdose.
Action: MM to update DNP list as detailed following GMMMG approval

Item 6 d – Diltiazem 2% rectal ointment
IPS had recently assigned a RAG status of Green (following specialist initiation) to diltiazem rectal ointment (which is on formulary), however question was raised as to whether or not this agent should be on formulary at all and if it would not be more appropriate for it to be grey listed. FSG considered the NICE ESM (Jan 2013), current prescribing rates and current product costs and it was agreed that the ointment should remain on formulary, although the cream would remain as a non-

formulary option as it is more expensive. However GM prescribing frequency of the cream is not sufficiently high to warrant DNP assessment.
Action: No further action

Item 6 e – Ezetimibe (for uses outside of NICE recommendation) – Grey list assessment
This item was deferred until the November meeting.

Item 6 f – Flexitol heel balm – DNP assessment
FSG screened Flexitol heel balm for possible DNP assessment. The group considered prescribing data for GM and agreed that it was necessary to check whether this agent was being prescribed appropriately, whether there are more cost effective options available and whether there were particular patient groups who required this product over other options. FSG will consider information relating to this and other similar products and whether or not a formulary amendment of DNP listing is required at the November meeting
Action: DT agreed to contact the diabetes foot clinic and podiatrists to seek opinion, MM to gather information around alternative products available.

Item 6 g – Alimemazine – DNP assessment
FSG considered the recent price increase in alimemazine which is currently a non-formulary item. It was noted that between April 2014 and March 2015 a 1.9% item growth across GM equated to 211% cost growth against the previous year (Total items 9450, total spend £623k). FSG assessed alimemazine for DNP inclusion and in the absence of any strong evidence recommending alimemazine over other sedating antihistamines FSG it was agreed that alimemazine should be added to the DNP list as its increased price now meant that alimemazine was not a cost effective use of resources.
Action: MM to add alimemazine to the DNP list as above following GMMMG approval.

Item 6 h – Dymista reassessment of DNP listing
NTS recently re-reviewed their NTS recommendation for Dymista® and have amended this to *"approved as a third line treatment option if an intranasal antihistamine or glucocorticoid is not considered sufficient".* The reasoning being that Dymista® was shown to be slightly more effective than monotherapy (fluticasone nasal spray) in clinical trials, and the current list price is cheaper than the two separate constituents. It was noted that there is however no data comparing Dymista® to use of a combination of a steroid nasal spray and an antihistamine tablet which is more common current practice.
IPS recently gave Dymista a green status.
FSG were asked to consider whether Dymista should be removed from the grey list and if it should be assessed for formulary inclusion. FSG discussed that Dymista had previously been listed on the Grey list as it was not a cost effective use of resources, however the price reduction now changed this position and Dymista should be removed from the Grey list. FSG agreed that it be added to the formulary for use when a combination product is required, however the listing should be clear that it is only used following failure of current first line formulary choices.
Action: MM to add Dymista to the formulary following GMMMG approval

Item 7 a – Macular pathway – scoping document
SJ presented a scoping document for a macular pathway. CCGs had requested a pathway for drug treatments for macular conditions in order to consolidate the use of ophthalmic high cost drugs across GM. It had been agreed that this pathway would

be based on the Lancashire Medicines Management Group's pathway (consent had previously been sought and obtained).The pathway will reflect current NICE guidance but will provide a framework to ensure that CCGs don't commission outside of NICE recommendations. FSG agreed that the pathway should go out for GM wide consultation via the website.
Action: SJ to forward completed pathway to MM for GM consultation

Item 7 b – Anal irrigation systems pathway – draft 1 for comment
MM presented the first draft of an anal irrigation pathway which was based on the emailed advice from a GM nurse specialist. Whilst this pathway provides a starting point, work is needed to develop the pathway further e.g. to include information regarding referral to a dietician, CBT and counselling and this will need to be sought from specialists across GM.
Action: MM/SJ to seek input from specialist departments across GM.

Item 7 c – NW Urticaria Pathway – comments from GM specialist departments
SJ provided a verbal update to FSG regarding meetings with the GM specialists concerning this pathway. The group felt that this pathway was not suitable for GMMMG approval as it does not meet the needs of primary care, in particular it needs to include guidance on referral criteria i.e. list all the steps/processes to prevent GP inappropriate referral. It was agreed that in order to develop this pathway further the authors would need to engage more fully with primary care and the current services available that CCGs refer to currently.
Action: MM to feedback to the pathway author as above.

Item 7 d – GM Antibiotic Guideline – scoping document
SJ presented a scoping document detailing the development of a GM wide antibiotic guideline, and explained that she is working with Public Health using resistance data to highlight areas of prescribing variation. The group asked whether there was any dental involvement in this work, SJ explained that there isn't currently however there could be. It was also noted that Peter Howarth (not present at the meeting) is involved in work with an aim to decrease antibiotic prescribing. SJ explained that she is meeting with PHE next week to focus on UTI data and a draft of the guideline as far as it is developed will be circulated to the group after this meeting.
Action: SJ to circulate draft guideline to FSG for comment.

Item 8 - AOB
Nothing raised.

Date of next meeting: Thursday 3rd November 2016, 12-2pm, Maternity Seminar Room, UHSM. N.B. the FSG will communicate virtually in October