Nottinghamshire Joint Formulary Group Meeting Minutes

Thursday 25th April 2019, 2-5pm
Room A01, Duncan Macmillan House

Present: Tanya Behrendt (TB) Deputy AD Medicines Management, Nottingham City CCG (Chair) David Kellock (DK) Consultant, SFHFT Debbie Storer (DS), Medicines Information Pharmacist, NUH Esther Gladman (EG), GP Prescribing Lead, Nottingham City CCG Steve Haigh (SH), Medicines Information Pharmacist, SFHFT Steve May (SM), Chief Pharmacist, SFHFT Laura Catt (LC), Prescribing Interface Advisor, Nottinghamshire County CCGs Irina Varlan (IV), Interface/Formulary Pharmacist, NUH Karen Robinson (KR), APC/Formulary Support Technician Naveen Dosanjh (ND), Deputy Chief Pharmacist, Nottinghamshire Healthcare Trust Deepa Tailor (DT), Interface/Formulary Pharmacist/ Medicines Management Pharmacist City CCG Nicholas Sherwood (NS), Mental Health Interface Pharmacist, Nottinghamshire Healthcare Trust
Apologies: Jill Theobald (JT), Interface Efficiencies Pharmacist, Greater Nottingham CCP David Wicks (DW), GP and Local Medical Committee.

Agenda item	Notes
1. Apologies	Noted (see above).
2. Declarations of interest	None declared from JFG members.
3. Minutes of previous meeting	The minutes from the last meeting were accepted by the group with the following 2 corrections; Agenda item 7, page 5: Oxycodone; Action was to share the comments as opposed to sharing the risk assessment. Agenda item 10, page 6: Naltrexone; All A2 in Nottinghamshire was with the exception of the Nottinghamshire Recovery Network.
4. Matters arising and action log	**Naltrexone** Minor amendments had been required to the information sheet this will be taken to APC May 19. ***** All other items were either completed or included on the agenda. *****
5. New applications:	**a) Noqdirna® (Desmopressin, Ferring Pharmaceuticals)for nocturia** A formulary submission has been received from urology department at NUH. Noqdirna® contains desmopressin, a synthetic analogue of anti-diuretic hormone arginine vasopressin (AVP). It is indicated for symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. It is currently the only licensed product in UK for treatment for nocturia due to idiopathic nocturnal polyuria in adults.

Currently Desmopressin has the following APC classifications:
Amber 2 – Nasal spray for diabetes insipidus
Amber 2 – Oral for diabetes insipidus
Green – Oral for nocturnal enuresis

The submission request is for Amber 3 in line with the Nottinghamshire Male LUTS clinical guideline with an additional request of an Amber 2 classification for use in women as a first line treatment option within the licensed indication.

Noqdirna® dosing regimen (dosing is gender-specific):

- Women: 25 microgram daily, one hour before bedtime, administered sublingually without water.
- Men: 50 microgram daily, one hour before bedtime, administered sublingually without water.

A dose increase with this product is not recommended in elderly patients ≥ 65 years.

The decision tree was followed and the JFG recommended that Noqdirna® should be considered for an Amber 2 classification, under specialist recommendation with a view of adding Noqdirna® to the LUTs guideline at box 5. A prescribing information sheet may be required for prescribers to clarify the place in therapy and the monitoring requirements recommended at 3 months. It was suggested that input from Healthcare of the Elderly and Continence specialists would also be beneficial.

Action: DT to contact the submitter to confirm monitoring requirements and the responsibility for them, the defined cohort of patients and seek input from the Healthcare of the Elderly and the Continence teams

b) Softacort® (Hydrocortisone sodium phosphate 0.3% PF single use eye drops) for ocular surface inflammation

A submission has been received from the Ophthalmology Department at NUH for Softacort® (hydrocortisone sodium phosphate 0.3% PF eye drops) with a request for an Amber 2 classification to be used in all patients with ocular surface inflammation requiring steroids, instead of Predsol®.
Softacort® is currently listed on the formulary as Grey-no formal assessment.

The submission proposes the use of Softacort® in ocular surface conditions where intraocular penetration is not desirable and for which Prednisolone PF UD is currently being used.
There have been multiple supply issues with prednisolone eye drops recently, with patients having to come on and off the medication. (N.B: The submitters state that Predsol® will still be used for intraocular inflammation).

The predicted patient numbers were small. The JFG decided that more information is required before reaching a decision and more clarity is required regarding the place in therapy. The impact of using this new eye drops in the Secondary Care Trust should also be reviewed.

Action: IV to gain confirmation for the intention of Softacort®'s place in therapy, obtain prescribing data from the Trusts and to take to the APC.

c) Ertugliflozin as monotherapy or with metformin for treating type 2 diabetes (NICE TA 572)

NICE TA 572 published 27th March 2019;
Compliance with TA required by 27th June 2019.
The NICE recommendation is on the basis of the following:
"Canagliflozin, dapagliflozin and empagliflozin are options for treating type 2 diabetes in adults. They are taken with metformin or on their own (that is, as monotherapy) if metformin is not appropriate. They are sodium-glucose cotransporter 2 (SGLT-2) inhibitors, as is ertugliflozin. Indirect comparisons show that ertugliflozin has similar overall health benefits to canagliflozin, dapagliflozin and empagliflozin. The acquisition cost of ertugliflozin is lower than the acquisition costs of these other drugs. Ertugliflozin is therefore recommended as an option for treating type 2 diabetes as monotherapy or with metformin in line with the previous recommendations for SGLT-2 inhibitors.

Clinical effectiveness against comparators:
Ertugliflozin monotherapy is clinically effective compared with placebo
Ertugliflozin in a dual-therapy regimen with metformin is clinically effective compared with placebo
Ertugliflozin has similar clinical effectiveness to canagliflozin, dapagliflozin and empagliflozin in both monotherapy and dual therapy
Adverse events with Ertugliflozin are likely to be similar to those with canagliflozin, dapagliflozin and empagliflozin in monotherapy and dual therapy. It is appropriate to assume that all resource use and costs, other than drug acquisition costs, are identical for Ertugliflozin and its comparators."

Further discussions took place around cardiovascular outcomes and its comparison to other GLT2. Amber 3 classification was suggested.

Action: NS to gain more clarity around the cardiovascular points. The diabetes guideline will require an update to include the new medication. To take to APC.

d) Jorveza® (Budesonide 1mg orodispersible tabs) for eosinophilic oesophagitis

Budesonide orodispersible tablets (Jorveza®) is currently classified as Grey on the Nottinghamshire Joint Formulary-with no formal assessment. A submission was received from the Gastro-enterology Department at SFHFT and supported by NUH, requesting an Amber 2 classification.
Currently, Jorveza® is the only licensed product in the UK for eosinophilic oesophagitis in adults.

The current practice so far has been to use off-label corticosteroid formulations to manage eosinophilic oesophagitis, but they are not optimised for oesophageal delivery.
Off-label use of PPI's may provide symptomatic relief, but does not address inflammatory aspects of the disease.

The predicted use of this product is a small patient group. For NUH 10patients/year, for the Treatment Centre 15pts/year and for SFH 15pts/year.
Per year, for 10 new patients the cost would be between £3,230 and £6,460, depending how many patients require the 6weeks or 12 weeks course.

	This medication is not for continual use. An endoscopy would be required to clarify the present of eosinophilic oesophagitis. The advantages of this mediation are: - the availability of a formulation easy to use, without having to mix it using store cupboard ingredients increases compliance. - good control or EoE can avoid unpleasant symptoms and admissions to hospital requiring expensive and risky endoscopic treatments (endoscopic oesophageal dilatations and surgery). There is a Nice TA in development due in Oct 19. A number of questions were raised such as why an oral corticosteroid course would not work and what happens if a patient does not respond to treatment after the 12 weeks course. What will the review at 6 weeks consist of and can this be done by a GP? How often does this patient cohort relapse and how many courses are these patients likely to need in a year? Will DEXA scans be required for patients needing more than a course per year? **Action: IV to clarify the questions above with the submitter and bring to the APC meeting for further discussion of classification in the interim. To be reviewed once the NICE TA is published in October 19.**
6. Formulary amendments	All formulary amendments were accepted, except the following which were further discussed: • Azelastine and fluticasone, Dymista**.** Request had been made for Dymista to be changed from Amber 3 to Green by Yujay Ramakrishnan Consultant ENT and Skull base Surgeon, Head of Service ENT, QMC. It was felt a number of patients were being referred without previously trying Dymista. Dymista is listed in the allergic rhinitis pathway at step 4 and as Amber 3 it can be prescribed by GPs. To leave as Amber 3 but add to the Bulletin and Hint and Tips. • Mexiletine hydrochloride, Namuscla® 167 mg. New product license indicated for the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders. Price quoted in FA 750/100 actual DM&D (Dictionary of Medicines and Devices) £5000 for 100capsules. Currently classified as Amber 2 for ventricular arrhythmias **only** all other indications grey. The number of patients currently being treated for the Amber 2 classification is being sought. Neurology also to be contacted to enquire if it is currently being used outside the Amber 2 classification. • Humalog Junior Kwikpen®- request to reclassify from Grey to Amber 2 since Insulin Lispro 100units/ml, the medicine contained in both Humalog Kwikpen and Humalog Junior Kwikpen is exactly the same. The only difference is that the junior pen is able to dial in half units, allowing smaller dosing increments than the Humalog kwikpen. The proposal was generally accepted but the group would like to see pictures or placebo pens of both at the APC before ratification.
7. Horizon scanning	Horizon scanning presented. All recommendations were accepted, with the exception of: • Dapagliflozin (SGL2 inhibitor), Forxiga®**.** Dapagliflozin **5mg** is now licensed for use in type 1 diabetes mellitus as an adjunct to insulin in

	patients with BMI ≥ 27 kg/m2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy. Leave as Grey and await NICE TA expected Sept/Oct 19. • Perampanel 0.5mg/ml oral suspension, Fycompa®**.** Suggested as Amber 2 however further cost estimates need to be addressed due to the flat pricing of the tablet form, any specials currently being prescribed also need to be considered.
8. Melatonin (Slenyto®) for discussion	**Slenyto®** is an MR Melatonin product licenced and indicated for the treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. Data is available for up to 2 years' treatment. The patient should be monitored at regular intervals (at least every 6 months) to check that Slenyto® is still the most appropriate treatment. After at least 3 months of treatment, the physician should evaluate the treatment effect and consider stopping treatment if no clinically relevant treatment effect is seen. If a lower treatment effect is seen after titration to a higher dose, the prescriber should first consider a down-titration to a lower dose before deciding on a complete discontinuation of treatment. Melatonin use within the county is average compared to the rest of the country. However some counties have zero prescribing with a non-formulary status. To date Melatonin has not been reviewed formally for use within Nottinghamshire. It was suggested that the funding of a sleep hygiene service could be a more cost effective option above prescribing. **Action: NS review the evidence for both MR and IR for all children and to submit the review to RMOC. Recommended as Grey for now.**
9. **Dates of future meetings**	**Next meeting:** Thursday 20th June, Boardroom Duncan Macmillan House, Porchester Rd, Nottingham NG3 6AA, 2-5pm
10. Any other business	NUH had reviewed Oxycodone although an alternative brand of oxycodone could be used it was felt there would be an increased safety risk.

The meeting ended at 1600hrs