

Nottinghamshire Area Prescribing Committee

Nottinghamshire Joint Formulary Group Meeting Minutes

Thursday 22nd Oct 2020, 2-5pm On line Microsoft teams meeting due to COVID 19

Present:

David Kellock (DK) Consultant, Sexual Health, SFHFT (Chair)

Esther Gladman (EG), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG

Lynne Kennell (LK), Interface/Formulary Pharmacist, SFHFT

Shary Walker (SW), Interface/Formulary Pharmacist, NUH

Karen Robinson (KR), APC and Formulary Support Technician, NHS Nottingham and Nottinghamshire CCG

Laura Catt (LC), Prescribing Interface Advisor, NHS Nottingham and Nottinghamshire CCG Tim Hills (TH), Assistant Head of Pharmacy, Nottingham University Hospitals NHS Trust (deputising for

Irina Varlan (IV), Specialist Interface Efficiencies Pharmacist, NHS Nottingham and Nottinghamshire CCG

Asifa Akhtar, GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG

In attendance:

Dr Sherif Gonem,(Respiratory physician NUH) and Bryony Millar, Respiratory pharmacist NUH for item 5 Dr Alex Croom, Consultant Allergist, NUH for item 5

Apologies:

Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist NHS Nottingham and Nottinghamshire CCG

Jill Theobald (JT), Interface Efficiencies Pharmacist, NHS Nottingham and Nottinghamshire CCG Matthew Elswood (ME), Chief Pharmacist, Nottinghamshire Healthcare Trust

David Wicks (DW), GP and Local Medical Committee.

Debbie Storer (DS), Medicines Information Pharmacist, NUH

Steve Haigh (SH), Medicines Information Pharmacist, SFHFT

Hannah Godden (HG), Mental Health Interface Pharmacist, Nottinghamshire Healthcare Trust Steve May (SM), Chief Pharmacist, SFHFT

Agenda item	Notes
1. Apologies	Noted (see above). The meeting was not quorate but as the JFG offered recommendations rather
	than decision making the meeting was continued.
2. Declarations of interest	Nothing declared from members of the group. Submitting clinicians for item 5a), Sherif Gonem & Dominic Shaw, Respiratory Physicians NUH have declared conference fees and Speaker and advisory fees from Astra Zeneca.
3. Minutes of previous meeting	Were accepted as an accurate record of the meeting.
4. Matters arising and Action Log	Celecoxib (Celebrex®) - LK will bring a formal review of the safety of celecoxib to a future JFG. Action: LK to review
	Cyproterone - The MHRA bulletin regarding cyproterone was highlighted at Aug JFG. It is not possible to identify its indicated use locally via ePACT, the alert has been passed to the MSO's for further investigation.

Sotagliflozin (SGLT2/1) TA622, Feb 2020 - not yet available in the UK. **Action:** KR to check launch date and price prior to APC, Nov 20

Betesil® (Betamethasone) Plaster, 6 month prescribing data to be brought to JFG Dec 20.

Cinacalcet, ePACT usage data to be reviewed Feb 21.

Utrogestan- Green classification was approved at APC. Update to the table of menopausal products is in progress. Supply problems guidance was no longer available on the British Menopausal Society website so this has not been added to the formulary as initially planned.

Action: KR/ LK to finalise update of the HRT choices table and share via e mail

Staladex® 10.72mg implant pre-filled syringe (leuprorelin): Reviewed against current products to ascertain any potential for cost savings and potential savings are small. Both NUH and SFHT did not wish to pursue it at this current time. GREY no formal assessment classification actioned.

Slow K: Red classification was agreed at APC.

Xailin Night: Product will be added to Eye Lubricant guideline when it is next updated. This is planned for early next year.

** All other items were either completed or included on the agenda. **

5. New applications

A) Fluticasone furoate/ vilanterol Ellipta (Relvar, GSK) for asthma- Dr Sherif Gonem (Respiratory physician) NUH, and Respiratory Pharmacist Bryony Miller joined at 2.30pm

NB. Submitting clinicians (Sherif Gonem & Dominic Shaw, Respiratory Physicians NUH) have declared conference fees and Speaker and advisory fees from Astra Zeneca.

LK presented the submission for Relvar and provided a background overview of the previous submissions. The APC had previously reviewed a joint application for Fluticasone furoate and vilanterol (Relvar® Ellipta®, GSK) to be added to the formulary for asthma and COPD in July 2014. The APC did not support the application, partly because of the packaging originally being blue and the potential for confusion with reliever inhalers. The formulation for both indications was classified as GREY-non-formulary. Following a packaging change and a successful appeal, it was classified AMBER 2 for COPD but an appeal against the GREY classification in asthma was upheld because of concerns regarding the high potency of fluticasone, without an option to step down in corticosteroid dose in line with BTS guidelines.

A formulary application has now been received from respiratory physicians for Relvar to be re-considered for adults with asthma. The Specialist Asthma service wish to have it as a once daily treatment option for patients where multiple day regimes have failed to achieve asthma control. Relvar is a Dry Powder Inhaler that needs minimum inspiratory flow rate and requires minimum dexterity to use effectively. If effective it may prevent the need to step up to more expensive monoclonal antibody treatment. When used in this way, it is most likely the patient will start on a high intensity regime and step down to 92/22 if their asthma remains under control for at least 6 months. After the initial prescription, it is

requested that this would be prescribed by GPs, but this patient group would remain under the care of the Specialist asthma service so regular review will ensue.

Relvar and also Symbicort offer the ability to include a chip device. This would help to monitor concordance prior to patients being moved to monoclonal antibody treatment. Use of the device however has not yet been introduced locally as there are some questions that need addressing with trust information Governance and the manufacturer.

Since previously reviewing Relvar for asthma there have not been any new substantial blinded randomised control trials, but there has been a real world open label study that found Relvar to be more effective than standard care in less severe asthma patients and a study that has shown that the systemic potency of fluticasone furoate is less than other corticosteroids, but with much higher airway potency.

After discussion, the JFG felt it had a place in therapy and recommended that it is added to the formulary with an AMBER 2 classification for patients with severe asthma being treated at Step 4 of the BTS guidance

Action: LK to take to APC.

B) Grazax traffic light reclassification- Dr Alex Croom, Consultant Allergist, NUH joined at 3.40pm

SW presented an AMBER 1 formulary application that had been received from a Consultant Allergist at NUH for sublingual Grazax for the treatment of seasonal allergic hay fever due to grass pollen in patients who have failed to respond to standard anti-allergy treatments.

Grazax was approved for use within NUH paediatrics with a red classification in 2009. The adult service is currently using Pollinex which is an unlicensed subcutaneous preparation. It was recommended in 2019 after an external audit from the Royal College of Physicians that they switch to this sublingual preparation as not only is it licensed, but also offers a superior safety profile and would release Specialist Nurse time.

Sublingual immunotherapy is recommended in BSACI guidelines

Dr Alex Croom explained that Grazax treatment was for a niche group of patients who were effectively disabled due to their allergy. Concordance was required in order for the medication to be effective. The submission was for three years treatment with the aim that after three years, patients could then be treated with more conventional hay fever preparations and not require further supplies of Grazax. Only new patients are initiated with Grazax as it is not appropriate to change patients' immunotherapy partway through a course.

The request for an AMBER 1 classification reflected the process utilized in Leicestershire, but primary care will not be expected to conduct any patient monitoring; Specialist nurses will continue to follow up patients at three monthly intervals via telephone.

The JFG felt that its use was a sensible step going forward but its potential classification and appropriateness of prescribing in primary care was discussed in depth with a RED classification being favored.

The JFG agreed that a classification needs to be decided first before discussing the benefits of the Shared Care Agreement and the Medicine Information Sheet at this point. Therefore, the submitted Shared Care Protocol and Medication Information Sheet were not reviewed by JFG.

Action: SW to contact the paediatrics and find out how the paediatric service is managing their patients who are prescribed with Grazax under a RED classification.
SW to take to APC.

C) Naldemedine (Rizmoic, Shionogi Ltd) for treating opioid-induced constipation- NICE TA651

A NICE technology appraisal guidance [TA651] was published on 30th September 2020 for Naldemedine for the treatment of opioid-induced constipation (OIC).

SW presented the TA. Naldemedine is recommended for opioid-induced constipation in adults who have had laxative treatment.

SW provided current ePACT data for Naloxegol which is an alternative oral agent for OIC and currently AMBER 2. Consultants at NUH and SFHT have estimated that they have initiated treatment of this for 10 patients this year. Naldemedine offers a less costly option.

An AMBER 2 classification was felt to be appropriate. Consideration as to its place in the treatment pathway would be raised and SW will check with the consultants if they favor one or the other, and seek their opinion as to whether we could promote naldemedine as the first line option as it is cheaper for OIC.

Action: SW to consult with consultants at NUH and SFHT and present to APC

Post meeting note – Naldemedine is a black triangle medication, whereas naloxegol isn't.

6. Formulary amendments

a) FOR INFORMATION - Log of minor amendments carried out

Lithium Carbonate – Priadel is no longer being withdrawn from the UK market so to remain AMBER 2. Camcolit and Essential Pharma amended to GREY.

Tranylcypromine - Traffic light reclassification from GREY to RED (restricted to NHCT) agreed at TMOG meeting on 12th October 2020.

Lecicarbon C (Sodium hydrogen carbonate & sodium dihydrogen phosphate) suppositories - Temporary reclassification to GREEN for paediatric patients currently using bisacodyl suppositories. Bisacodyl suppositories are currently unavailable due to a manufacturing problem and there are no other suitable preparations available on the formulary for some patient.

Ceftriaxone - Alternative to cefotaxime during supply problems, Added to local meningitis guidance as an option for treatment whilst cefotaxime unavailable on advice of Dr Weston.

Sumatriptan 6mg/0.5ml solution for injection pre-filled disposable devices - Formulary entry clarified to ensure most cost-effective preparation is prescribed.

b) FOR DECISION - Suggested amendments

Clonidine - Request to classify on the formulary for patients with Tourette's syndrome. Some queries had arisen from primary care regarding patients that are currently prescribed it. LK had contacted the Neurologists and they confirmed further details about its use for Tourette's.

Recommend AMBER 2 for Tourette's indication.

Adrenaline 1 in 1000 topical solution to reduce surface bleeding in palliative care for example from a fungating tumour. Unlicensed indication.

Recommend AMBER 2 for palliative care.

Lacosamide tablets and oral solution, brivaracetam tablets and oral solution, perampanel tablets and oral suspension, eslicarbazepine tablets and oral suspension – Indicated for epilepsy with an AMBER 2 classification. There is a restriction that secondary care needs to prescribe the medication for the first 6 months of treatment before transfer to primary care. A request has been made to remove the restriction that patients need to be stabilised prior to transfer to primary care with the caveat that clear guidance on dose titration and maximum doses should be provided by the Neurologist. This had recently been agreed for zonisamide (generic).

Recommend removal of restriction subject to LK ensuring that there are no complicated requirements as part of dose titration regimens.

Methadone solution for injection - Request from Alpna Chauhan (palliative care consultant, SFH) to classify injection as RED. Recommended that this is passed to DTCs for decision.

Recommend LK/ DS to take to DTCs

Esomeprazole IV – Not currently classified and not used within the trusts. **Recommend** as GREY

Combined Hormonal Contraceptives (CHC) to add some information to the formulary about tailored COC regimes. Although unlicensed, this is supported by the FSRH and discussed in the BNF.

Recommend to add additional advice similar to that provided by Derbyshire and link the FSRH document.

Methylphenidate MR capsules (Ritalin XL°) - brand not currently on the JF (currently Equsaym XL and Medikinet MR are AMBER 1).

Recommend add brand to the JF as another option for prescribers.

Potassium hydrogen carbonate sodium alginate (Acidex[©]) - JT requested as another option in case of supply disruptions (issues have been noted in some areas).

Recommend Add to formulary with a GREEN classification as a 2nd line option. Peptac to remain 1st line.

Testosterone gel request for use in low libido in post-menopausal women. **Recommend** add to formulary with a GREY classification (no formal assessment) for the above use

Lofexidine discontinued.

Recommend re-classify as GREY

Metformin for use in antipsychotic associated weight gain (off-licence). Considered addition to formulary as an adjunct to attenuate or reduce weight gain following antipsychotic medication. Recommended by BAP guidelines on the management of weight gain, metabolic disturbances and cardiovascular risk associated with psychosis and antipsychotic drug treatment in the context of NICE PH38 Type 2 diabetes: prevention in people at high risk.

Recommend adding this new indication as AMBER 2 with a link to the relevant BAP and NICE guidance.

Gentamicin liquid. Request was based on one patient. **Recommend** no change to the formulary for one patient

Rivaroxaban. Primary care queries received about cardiology patients discharged from NUH on rivaroxaban 2.5mg BD for 3 months post TAVI (bioprosthetic valve replacement). This is an unlicensed indication and NUH have a local protocol that provides guidance.

Recommend Defer to DTC for consideration of a RED classification

c) FOR INFORMATION: MHRA or other safety bulletins All noted.

Recommend adding MHRA link to the JF where appropriate

Action: LK to take to APC

7. Horizon scanning

a) New publications for review

Bempedoic acid 180 mg film-coated tablets alone or in combination with Ezetimibe. Indicated for adults with primary hypercholesterolaemia.

Recommend GREY no formal assessment. Nice TA expected within the next few months

Estradiol hemihydrate 10 micrograms (Vagirux®) vaginal tablets.

Recommend Highlighting to efficiencies pharmacists for consideration as a more cost effective alternative to Vagifem

Melatonin 3 mg film-coated tablets (Syncrodin®) indicated for the short-term treatment of jet-lag in adults.

Recommend GREY no formal assessment

Lefamulin, oral/IV (Xenleta®). A novel pleuromutilin antibiotic.

Recommend GREY no formal assessment

Pridinol, oral (Myopridin®) Central and peripheral muscle spasm.

Recommend GREY no formal assessment

Acetylcysteine 600mg tablets (Mucolight®) indicated for the adjunctive therapy of respiratory tract disorders.

Recommended review once price available

Betamethasone 0.5 mg / Calcipotriol 50 microgram ointment (Dalonev[®]) indicated for the topical treatment of stable plaque psoriasis vulgaris.

Recommended review once price available

Timolol / bimatoprost 0.3 mg/ml + 5 mg/ml eye drops (Eyzeetan®) indicated for the reduction of intraocular pressure (IOP) in adult patients.

Recommend removing brands stated on formulary as price matched to formulary products listed

Vardenafil 10 mg Orodispersible Tablets generic. Vardenafil is GREY removed as Avanafil was a more cost effective second line option.

Recommend GREY no formal assessment

Hydroxychloroquine 300mg Film-Coated Tablets generic, indicated for adults treatment of rheumatoid arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight. Paediatrics treatment of juvenile idiopathic arthritis (in combination with other therapies), discoid and systemic lupus erythematosus. There are no strengths stated on formulary. SCPs state that doses are 200mg or 400mg.

Recommend no action needed at present but add to SCPs at next update.

Alclometasone dipropionate 0.05 % w/w Cream, generic indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. Previously moved to GREY due to discontinuation.

Recommend review once price available

Risperidone 1 mg, 2 mg, 500 microgram orodispersible tablets, generic. ePACT shows approximately 20-30 pts Notts wide, but liquid is more cost effective **Recommend** add a note to the JF to make it clear that orodispersible are nonformulary and to use liquid instead if a patient is experiencing is swallowing difficulties.

Sodium Valproate/ Valproic Acid (Each tablet contains 133.2 mg sodium valproate and 58.0 mg valproic acid equivalent to 200 mg sodium valproate), (Dyzantil® 200 mg prolonged-release tablets).

Recommend GREY no formal assessment

Bilastine 10mg orodispersible tablets (Ilaxten®). Bilastine tablets GREY. **Recommend** no further action

b) NICE Evidence summaries

Noted

8. Rosacea Guideline

KR informed the group of a request for a local Rosacea guideline. At present there is no current antimicrobial guideline for the management and treatment of Rosacea. This has been raised by one of the Medicines Optimisation Team (MOT) Pharmacists.

Dermatologists (Dr Patel and Dr Ayob at NUH) have recommended and provided

a link to <u>NICE Clinical Knowledge Summary for Rosacea</u>. This contains a number of different resources including the British Association of Dermatology (BAD) Rosacea patient information leaflet.

Also recommended was the Primary Care Dermatology Society (PCDS) Rosacea - Primary Care Treatment Pathway. This is corporately sponsored and although the range of treatment options within this guide has been reviewed by the PCDS Executive Committee, they do not consider NHS costs or any local prescribing restrictions.

In order to assess whether the PCDS guidelines would be suitable for recommendation by the APC as a Rosacea resource, the product treatment options were compared to our current formulary options for rosacea/skin. A number of products would require possible reclassification if this link was used. In addition to the papers that were circulated, KR shared a comparison of formulary products against the NICE CKS.

The main variances to the current joint formulary were discussed. These included clonidine and doxycycline 40mg (Efracea®) of which a small amount was being prescribed in primary care.

The general consensus was to use the NICE CKS guideline, but the opinion of Dr Weston should be sought on the treatment options.

Action: KR to contact dermatologist to establish if clonidine is being used by dermatology for the rosacea indication and for what causation ie, rosacea linked to flushing in postmenopausal woman.

KR to contact Dr Vivien Weston at NUH to discuss products recommended by NICE CKS, i.e. doxycycline 40mg (Efracea®) and doxycycline 100mg in combination with lymecycline. If these products were supported, a full formal assessment would be required.

9. Testosterone gel product comparison

SW informed the group that during the recent update of the Testosterone Information Sheet, it was raised whether there are other cheaper testosterone preparations that could be added to the formulary.

Tostran 2% gel is the current preferred product for testosterone transdermal application for adult hypogonadism and this is classified as AMBER 2. The other testosterone transdermal preparations: Testim, Testavan, and Testogel 16.2mg/g are classified as GREY.

SW provided a cost/dose comparisons table and noted that products are not interchangeable due to different dosage regimens of each individual preparation but it has been reported that some preparations other than the Tostran 2% gel have been prescribed in primary care, using the recommended dose for Tostran 2%, resulting in patient confusion.

Testavan had been rejected previously because the packaging is not environmentally friendly despite it being the cheapest.

Samples of these preparations had been obtained from the manufacturers and were demonstrated by SW. Discussion took place regarding the environmental impact of the various packaging and the recycling potential.

JFG recommended Testogel pump as the preferred option being environmentally friendly and cost effective. Prescribing should be by brand to new patients only as the products are non-interchangeable.

The environmental aspect of the Testavan device should also be fed back to the

	Action: SW/ LK to investigate recycling options for packaging SW to feedback to manufacturer of Testavan regarding environmental concerns SW to take to APC
10.	Dates of future meetings Next meeting: 17 th December 2020 2-5pm, via Microsoft teams
	Chair rota: Noted
	Dates for 2021 meetings: Noted. The February meeting will be 25 th February so that half term is avoided.

The meeting finished at 4.50pm