Nottinghamshire Joint Formulary Group Meeting Minutes
Thursday 17th October 2019, 2-5pm
Boardroom, Duncan Macmillan House

Present: Debbie Storer (DS), Medicines Information Pharmacist, NUH, (Chair) David Kellock (DK) Consultant, SFHFT 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 Karen Robinson (KR), APC/Formulary Support Technician Deepa Tailor (DT), Interface/Formulary Pharmacist/ Medicines Management Pharmacist City CCG Shadia Jenner (SJ), Interface/Formulary Pharmacist/ Medicines Management Pharmacist Mansfield and Ashfield CCG Naveen Dosanjh (ND), Deputy Chief Pharmacist, Nottinghamshire Healthcare Trust Tanya Behrendt (TB) Deputy AD Medicines Management, Nottingham City CCG
Apologies: Jill Theobald (JT), Interface Efficiencies Pharmacist, Greater Nottingham CCP Nicholas Sherwood (NS), Mental Health Interface Pharmacist, Nottinghamshire Healthcare Trust David Wicks (DW), GP and Local Medical Committee.
In Attendance: Fatema Karimjee, Medicine Management Pharmacist, City Locality

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 subject to a few minor typographical amendments.
4. Matters arising and action log	**Atomoxetine generic:** DS currently looking into for NUH **Melatonin:** No further discussion took place but the item will remain on the agenda for discussion at Novembers APC **Tresiba insulin Degludec:** prescribing data showed volume greater than that predicted on the submission. **Interface team to discuss with submitters** ***** All other items were either completed or included on the agenda. *****
5. New applications:	**a) Dapagliflozin – NICE TA 597- DT** NICE TA597 published 28th August 2019; Compliance with TA required by 26th November 2019. For use with insulin in Type 1 diabetes in adults with BMI of at least 27kg/m^2,

	when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy, only if: • Patients are on insulin doses of >0.5units/kg of body weight • They have completed a structured education programme (including information about diabetic ketoacidosis). • Treatment is started and supervised by consultant physician specialising in endocrinology and diabetes. SPC says initiated and supervised by specialist in type 1 diabetes. Current APC classification of dapagliflozin for **Type 1 diabetes** is Grey – No formal assessment. • 10mg tablets not licensed for use in Type 1 diabetes • 5mg licensed for Type 1 diabetes and must only be administered as an adjunct to insulin. It is amber 3 for Type 2 diabetes (NICE TA418, NG28) **Cost:** Dapagliflozin 5mg tablets (28) = £36.59 **Dosage directions:** Take one orally once daily with or after food. Other SGLT-2 inhibitors include Ertugliflozin, Empagliflozin and Canagliflozin. None of these are licensed for use in Type 1 diabetes, but are amber 3 for treatment of type 2 diabetes. It was noted that there are currently no other antidiabetic oral formulations licensed for use with insulin in type 1 diabetics. Dapagliflozin is the first and only licensed at the 5mg dose, therefore the group did have some safety concerns on DKA, long-term risks and patients being accidentally titrated up to 10mg doses. However, felt the risk would be mitigated with robust education for patients and informing patients that the dose of dapagliflozin should not be increased. Patient numbers were expected to be small and there was consensus from Endocrinology consultants for an Amber 2 classification. The group agreed an amber 2 classification, but prescribing should only be transferred to primary care once a reduction of HbA1c within a 6 month period had been seen. **Action: DT to take to APC, Interface team to consider OptimiseRx message to ensure Type 1 diabetics are not prescribed Dapagliflozin 10mg tablets.** **b) Anastrozole or Tamoxifen 10mg for gynecomastia – Re-submission- SJ** A submission has been received from an NUH breast specialist for classifying anastrozole and tamoxifen 10mg for the off-label indication of gynaecomastia. This is as a therapeutic intervention rather than analgesia for symptom control. Gynaecomastia results from an altered oestrogen-androgen balance in favour of oestrogen, or from increased breast sensitivity to a normal circulating oestrogen level. Anastrozole (a non-steroidal aromatase inhibitor) blocks the conversion of androgens to oestrogens in the peripheral tissues. Tamoxifen is an oestrogen-receptor antagonist.

	Tamoxifen 10mg would be first line with Anastrozole second line, only if tamoxifen was not tolerated. Patient numbers were predicted to be 100 for NUH and 30 for SFH. Although it was felt that the submission offered no new supporting clinical evidence since the previous submission in 2015, Anastrozole has come down in price, the Association of Breast Surgeons have published guidelines which include Anastrozole for gynaecomastia and surgery for this condition is no longer commissioned as part of the Service Restrictions Policy 2018. Tamoxifen 20mg OD for 3 months is the current treatment option on the local guidelines. Tamoxifen 10mg is less cost effective and could pose a cost pressure estimated at £30K, if patients were prescribed this for the maximum proposed treatment duration of 9 months. Options to overcome this potential cost pressure were discussed. It was agreed that splitting the tablets may not be a suitable option as it couldn't be determined if all generic makes were scored. SH suggested alternate day dosing, given the long half-life of tamoxifen. The group wished to see the cost projection of Tamoxifen 10mg and 20mg tablets for the additional 6 months (9 months total treatment). It is likely that if the Association of Breast Surgery (ABS) guideline (Investigation and Management of Gynaecomastia in Primary and Secondary Care) is adhered to, the spend threshold will go beyond that which can be approved by the APC and a business case will be required. The current, local Gynaecomastia guideline had received minor amendments in May 18 and was due a full review (review date Sept 19) **Action: SJ to feedback cost pressure of using Tamoxifen 10mg tablets to the consultant and ask if Tamoxifen 20mg daily or alternate day dosing would be possible. To explain a business case would be required if these options are not possible.** **SJ to take to APC** **c) Xonvea for nausea and vomiting in pregnancy-SJ** A submission was received from Obstetrics and Gynaecology at NUH requesting a green classification for Xonvea® (10mg doxylamine succinate and 10mg pyridoxine hydrochloride) for the treatment of Nausea and Vomiting in Pregnancy. The application is supported by Obstetrics and Gynaecology at SFT. Xonvea® is currently the only licensed product for Nausea and Vomiting of Pregnancy (NVP) that has not responded to conservative measures. It is currently GREY (no formal assessment) on the local formulary. NUH and SFH consultants have proposed that Xonvea® is put on formulary as an additional second line option to off-label use of antihistamines. Patient numbers are anticipated to be between 220-1030. The predicted cost for 6/52 treatment is £240 per patient based on the maximum daily dose of four tablets. This equates to predicted cost implications of £50-£250K per year.

	The recent NICE evidence review was summarised. One study showed a mean improvement of one point on the PUQE scale (15 points). It was noted that this was statistically significant (p = 0.006) and the MHRA found this to be clinically important for pregnant women suffering with nausea and vomiting of pregnancy. SJ highlighted MHRA advice (included in NICE evidence review) "*because of prescribing hierarchy, the use of other medicines that do not have a specific license for nausea and vomiting of pregnancy over doxylamine / pyridoxine which does, would need to be justified*." There are no direct comparison trials with antihistamines and phenothiazines with Xonvea®. There is extensive clinical experience with antihistamines and phenothiazines and their use in NVP is established. The committee concluded that Xonvea® was not cost-effective. **Action: Grey classification recommended. SJ to take to APC**
6. Formulary amendments	All formulary amendments were accepted, except the following which were discussed further: a) FOR DICUSSION - Suggested amendments **Solifenacin 1mg/ml oral suspension sugar free (Vesicare®)** new formulation. Discussions had taken place with Mr Parkinson, Urology Consultant. The formulation is not cost-effective at higher doses and it was agreed that it would not be added to the Overactive Bladder Guideline. **Action: Recommended green with restrictions with the following comment – For use in cases of swallowing difficulty as third line option, if dissolving solifenacin tablets or using oxybutynin patches is not possible.** **Celecoxib (Celebrex®)** Raised by MM Pharmacist, formulary entry reads: Cox-2 Inhibitor - osteoarthritis, rheumatoid arthritis. Second line to patients unable to tolerate standard NSAID's. NICE NSAIDs - prescribing issues reads: For people at: High risk of GI adverse events — prescribe a COX-2 selective NSAID (for example, etoricoxib, or celecoxib) instead of a standard NSAID, and co-prescribe a PPI. Can the 2nd line formulary message be amended. **Action: SH will carry out a formal review of the safety of celecoxib and bring to APC.** **Sunscreen cream 50 ml (Anthelios XL cream SPF 50+ (La Roche-Posay) 50 ml®)** Raised by Shadia Jenner Mid Notts MM Pharmacist Current formulary choice is Sunsense Ultra 50 DM&D Aug 19 - £5.09 Anthelios XL cream DM&D Aug 19 - £3.94 **Action: KR to check the star ratings are equivalent and take to APC** b) FOR INFORMATION – MHRA All recommendations agreed

	Action: KR Medication safety links to be added to the formulary. For Estradiol cream a maximum of 4 weeks should be highlighted on the formulary.
7. Horizon scanning	Horizon scanning presented. All recommendations were accepted
9. Dates of future meetings	**Next meeting:** Thursday 19th December 2019, Boardroom, Duncan Macmillan House
10. Any other business	• Zantac recall - **Link** SJ tabled Ranitidine Guidance completed by JT. The guidance was approved pending minor changes. More clarity on choices of alternative H2 antagonist were to be made clear on the guidance and as the alternatives are non-formulary, a note in the formulary stating that these may be prescribed during ranitidine stock disruption if PPI is not appropriate. **Action: JT to share guidance and feed back impact at APC** • Diabetes guideline due to be updated March 19. Rosa Bell has started the review process. **Action: SH will feed into the review** • Kelhale® discussion DT tabled the risk assessment for Kelhale® Inhaler, which was produced by JT. Recent supply issues with QVAR® meant an alternative was necessary to consider. Kelhale® is a fine particle formulation directly comparable to QVAR®. Whilst there will be no active switching of patients from QVAR to Kelhale®. It was proposed that Kelhale® would now be recommended first line for new patients. The committee agreed Green first line status on formulary for Kelhale® inhaler. The committee noted that there will be a task and finish group to complete a full review of inhalers for consideration on formulary in the next 3-6 months. **Action: KR to take Kelhale® to APC recommending a Green status, first line to QVAR®. Interface team to consider Optimise Rx message for Kelhale® to increase prescriber awareness of the potency of Kelhale® inhaler and avoid dosing errors.**

The meeting ended at 1605hrs