

North Central London Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) - MINUTES

Minutes from the meeting held on Monday 18 February 2019 LG01, 222 Euston Road, London, NW1 2DA

Present: Dr R Woolfson RFL, DTC Chair (Acting JFC Chair) (Chair) (via telephone)

Dr R MacAllister NCL JFC Chair

Ms L Reeves C&I, Chief Pharmacist

Barnet CCG, Head of Medicines Management Mr C Daff Mr A Dutt Islington CCG, Head of Medicines Management

Dr A Stuart Camden CCG, GP Clinical Lead Medicines Management

Ms R Clark Camden CCG, Head of Medicines Management

Dr R Urquhart **UCLH**, Chief Pharmacist

Mr P Gouldstone Enfield CCG, Head of Medicines Management

Dr R Sofat UCLH, DTC Chair Mr S Tomlin GOSH, Chief Pharmacist Mr S Semple MEH, Chief Pharmacist Dr S Ishaq WH, Consultant Anaesthetist RFL, Chief Pharmacist Ms W Spicer

Dr K Tasopoulos NMUH, DTC Chair

Ms F Shivji **NEL CSU, Support Pharmacist**

Ms E Mortty NHS Haringey, Deputy Heads of Medicines Management

In attendance: NCL MEP, Lead Pharmacist Mr A Barron

> NCL JFC, Support Pharmacist Ms M Kassam Mr G Grewal NCL JFC, Support Pharmacist Ms I Samuel RFL, Formulary Pharmacist Ms H Mehta NMUH, Formulary Pharmacist Mr J Flor WH, Formulary Pharmacist Dr P Bodalia UCLH, Principal Pharmacist WH, Chief Pharmacist

Apologies: Mr S Richardson

Prof L Smeeth NCL JFC Vice-Chair

Dr M Dhavale Enfield CCG, GP Clinical Lead Medicines Management

Mr G Kotey NMUH, Chief Pharmacist

Dr A Bansal Barnet CCG, GP Clinical Lead Medicines Management

Prof A Tufail MEH, DTC Chair

Mr A Shah RNOH, Chief Pharmacist

Dr T Rashid NHS Haringey, GP Clinical Lead Medicines Management

RFL, Deputy Chief Pharmacist Mr TF Chan

RNOH, DTC Chair Dr A Sell

Ms P Taylor Haringey CCG, Head of Medicines Management

Ms A Fakoya NEL CSU, Senior Prescribing Advisor Mr G Purohit RNOH, Deputy Chief Pharmacist BEH, Deputy Chief Pharmacist Ms K Delargy Prof D Hughes RFL, Consultant Haematologist

Dr M Kelsey WH, DTC Chair

NEL CSU, Deputy Director Medicines Management Ms K Davies

Patient Partner Mr T Dean

2. Meeting observers

The Chair welcomed Dr Tasopoulos (NMUH, DTC Chair) as a new member of the Committee.

3. Minutes of the last meeting

The minutes were accepted as an accurate reflection of the meeting.

4. Matters arising

4.1 Audit proposal for Eslicarbazepine in partial epilepsy as an adjunct for partial onset seizure

At the October 2018 meeting, the Committee considered a proposal for the use of eslicarbazepine in patients in whom oxcarbazepine resulted in intolerable adverse effects. Prof Koepp attended the meeting to discuss the Committees previous recommendation (from the September 2017 meeting), where the application was supported provided it could be undertaken in the form of an evaluation using the 'n-of-1' methodology and double-blinding at the patient and clinician level. Despite best attempts from Prof Koepp and the JFC Secretariat, it was concluded that the only manner to achieve double-blinding is to over-encapsulate the eslicarbazepine and oxcarbazepine tablets which comes at a cost of circa £100k and considered prohibitively expensive.

Dr Bodalia informed the Committee that following a second round of enquiries, a slighter cheaper quote from another provider has been received, however at circa £70k the Committee still considered this excessive. As previous, the Committee remained supportive of Prof Koepp running a blinded evaluation which fulfilled their recommended criteria and welcomed an affordable plan to be brought back to the Committee.

4.2 Omega-3 fatty acid decommissioning guidance and management of hypertriglyceridaemia Both documents were approved subject to minor amends from Camden CCG.

Action: Commissioners to feedback progress on the decommissioning of omega-3 fatty acids (in conditions other than hypertriglyceridaemia) in 6 months' time.

4.3 Erenumab FoC scheme

Ms Spicer informed the committee that several London APCs have approved the erenumab FoC scheme, contrary to previous views, and suggested that Dr Athwal will be submitting an appeal against the suspension of approval of the erenumab FoC scheme.

5. JFC Work Plan & outstanding actions

These items were included for information only. Any questions should be directed to Ms Kassam.

6. **Declarations of relevant conflicts of interest**

In relation to Item 9, Dr Korlipara declared that he has received financial support to attend conferences from various pharmaceutical companies, including Bial, and also received an honorarium for speaking at a Bial sponsored neurology conference. Prof Foltynie declared he has received honoraria for speaking at meetings sponsored by various pharmaceutical companies, including Bial.

No additional declarations to those noted in the drug application

7. Local DTC recommendations / minutes

7.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
RFL	Dec-18	Oxetacaine and antacid	Oral mucositis post radiotherapy	Decision: Added to NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
UCLH	Jan-19	Brentuximab plus bendamustine	Hodgkin's lymphoma (approved following positive evaluation)	Decision: UCLH only Prescribing: Secondary care Tariff status: In tariff Funding: Brentuximab from CDF and bendamustine from Trust Fact sheet or shared care required: No

UCLH	Jan-19	Dichlorphenamide	Periodic paralysis – second line for patients who have not responded to acetazolamide	Decision: UCLH only Prescribing: Secondary care only Tariff status: In tariff Funding: IFR Fact sheet or shared care required: No
RFL	Sep-18	Neomycin and metronidazole	Perioperative selective bowel decontamination	Decision: Added to NCL Joint Formulary subject to local Antimicrobial Committee approval Prescribing: Secondary care only Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
C&I / BEH	Unknown	Methylphenidate MR (Equasym XL®, Medikinet XL®) Further work on branded-generic products of Concerta XL® to be undertaken at MOC	ADHD	Decision: Added to NCL Joint Formulary Tariff status: In tariff Funding: CCG / Trust Fact sheet or shared care required: NCL ADHD shared care available
WH	Mar-09	Anidulafungin	Invasive candidiasis	Decision: Added to NCL Joint Formulary subject to local Antimicrobial Committee approval Prescribing: Secondary care only Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No

7.2 Under evaluation

DTC site	Month	Drug	Indication	JFC outcome
WH	Nov - 18	Dexamethasone tablets and liquids	Second line treatment for severe acute exacerbation of asthma in paediatric patients (if intolerant to oral prednisolone)	Decision: WH only Prescribing: Secondary care. Primary care if initiated at WH Tariff status: In tariff Funding: Trust / CCG Fact sheet or shared care required: No
UCLH	Jan -19	Intrathecal fluorescein	Identification of CSF leak	Decision: UCLH only Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No

8. **New Medicine Reviews**

8.1 Diclofenac intravenous bolus (AKIS®) for use in the perioperative period (Dr Ahmad Ziyad, WH)

The Committee considered an application for the use of diclofenac injection (AKIS®) given via an intravenous bolus during the perioperative period for a maximum of four doses. Current practice is to use Voltarol® infusion in this setting.

The Committee heard AKIS had demonstrated non-inferiority to Voltarol in clinical studies and was licenced in 2012. The MHRA approved a license extension for intravenous bolus administration of AKIS in

2017 based on pharmacokinetic studies comparing it to both intravenous infusion Voltarol and intravenous bolus Dyloject® (another diclofenac brand that was in use across NCL until it was withdrawn from the market due to faults in the manufacturing process). The adverse effect profile of AKIS is expected to be similar Voltarol.

The Committee considered the IV risk assessment which found two additional risk factors for Voltarol® infusion as compared with AKIS bolus; Voltarol requires dilution before administration and involves a complex preparation (the final infusion needing to be buffered with sodium bicarbonate to maintain a pH range in which the drug is stable in).

Costs related to Voltarol administration include the use of a bag of Hartmann's (the most commonly used diluent in NCL) and a vial of sodium bicarbonate 4.2% as a buffering agent, which amounts to £7.11 per dose. AKIS, given directly without diluting or buffering, costs £4.80 per vial. This suggests AKIS would be cost-minimising, however the Committee understood that current practice does not routinely buffer Voltarol injection with sodium bicarbonate; this modified formulation has been queried with UCLH Medicines Information service who have concluded that "the addition of Voltarol to a bag of Hartmann's without the use of sodium bicarbonate gives a resultant pH with which Voltarol is stable in". This off-label preparation of Voltarol costs £1.65, eliminating one of the IV risk assessment risk factors, and would result in AKIS carrying a significant budget impact compared to Voltarol.

Dr Ziyad stated that the rationale behind a bolus dose of diclofenac rather than an infusion is that there is a shift in current practice to move away from infusing large amounts of fluid during the perioperative period, and towards the use of opioid sparing analgesia. Diclofenac tablets will always be considered first line where possible, although patients cannot swallow this immediately after surgery. Diclofenac suppositories have also been considered, but this itself carries a budget impact. Although the off-label preparation of Voltarol is seen in practice, Dr Ziyad suggested that clinicians have a desire to use a licensed product wherever possible and made reference to the NPSA Alert on the safe use of injectable medicines, which states that ready to administer preparations of injectable medicines should be used wherever possible. Another potential advantage of AKIS is that it may free up nursing time as an AKIS bolus would be quicker to prepare and administer than Voltarol infusion.

The Committee did not accept that AKIS would lead to a meaningful reduction in nursing time and were unconvinced that the proposed advantages in reducing risk (based on the IV risk assessment tool) would be delivered given that practice is not based on the licensed monograph for Voltarol. Furthermore, the Committee expressed concern that the introduction of AKIS has a high probability of becoming used widely across each area of the Trust, based on experience seen with the introduction of IV paracetamol, which was also originally intended for the perioperative period only. The Committee suggested that these concerns may be alleviated if the cost of AKIS were reduced to price parity with Voltarol, possibly via a London contract.

In camera, the Committee agreed that there were a number of outstanding points which required addressing before a decision could be made: clarify the use of sodium bicarbonate as a buffer as part of the preparation of Voltarol in theatres; investigate whether a reduced price can be negotiated with the manufacturer; and confirm the Voltarol stability data reviewed by UCLH Medicines Information.

Decision: Deferred **Actions:**

- Determine the amount of buffering agent (sodium bicarbonate 4.2% or 8.4%) being used in theatres at sites across NCL
- ii) Negotiate a contract price with the manufacturer of AKIS® (assuming all usage switched from Voltarol® to AKIS®)
- iii) Obtain stability data information from UCLH Medicines Information on the preparation of Voltarol® via the off-label method

8.2 Levonorgestrel 19.5mg intrauterine delivery system (Kyleena®) for contraception (Applicant: Dr S Aung, NUMH)

The Committee considered an application for the use of Kyleena as the first-line contraception device in primary and secondary care. Currently NCL JFC recommends Levosert as the first-line contraception device, and Mirena as an alternative first-line option. Primary care data suggests Mirena is the most commonly prescribed IUD (88-100%). Jaydess is a second-line option in women who have failed fitting of a first-line option, and is restricted to sexual health clinics. The key benefits of Kyleena include the smaller

dimensions of its device and introducer than Levosert and Mirena, and that it is licensed for 5 years rather than 3 years offering benefits over Jaydess.

The evidence supporting the application is a Phase II and Phase III open-label, multi-centre, randomised trial, the same evidence that the Committee reviewed when approving Jaydess in February 2016. The primary outcome, pregnancy rate calculated as a Pearl index, was similar amongst assessed levonorgestrel devices however the Phase II trial was not powered to test non-inferiority [Phase III Pearl Index: Jaydess: 0.33 (CI: 0.16–0.60), Kyleena: 0.31 (CI 0.15–0.57)]. The Committee heard that the limited data available indicated adverse effects were similar to Mirena and Jaydess.

Dr Aung explained that in his experience Kyleena is easier to fit and has resulted in patients experiencing less pain. The Committee heard that adopting Kyleena rather than Levosert as the first-line contraception device in primary and secondary care would result in a budget impact of up to approximately £15,000 per annum across NCL. Dr Aung emphasised the necessity to have Kyleena available in primary care, and that the budget impact would be offset by avoidance of referrals into secondary care as well as shortening and improving the patient journey. Dr Aung added that Levosert is not suitable for use in primary care as staff are not familiar with the two-handed technique and there is also a higher risk of uterine perforation.

In summary:

- Kyleena (£15.20/pt/year) might be preferred to Mirena due to the smaller size and lower cost (£17.60/pt/year), however it is not licensed for heavy menstrual bleeding and endometrial hyperplasia
- Kyleena might be preferred to Levosert due to the smaller size and single-handed administration technique, however it is more expensive (£13.20/pt/year) and is not licensed for heavy menstrual bleeding
- Kyleena was preferred to Jaydess due to the lower cost (£23.07/pt/year)

In camera, the Committee were supportive of the proposed advantages associated with Kyleena, which included easier administration and improving the patient journey, whilst ensuring that the number of intrauterine devices are rationalised. The Committee agreed that Kyleena should be added to the NCL Joint Formulary and that Jaydess should be removed.

Drug: Kyleena® levonorgestrel 19.5mg intrauterine delivery system

Decision: Approved (first-line for contraception)

Prescribing: Primary and Secondary care

Tariff status: In tariff **Funding**: Trust / CCG

Fact sheet or shared care required: No

Drug: Jaydess® levonorgestrel 13.5mg intrauterine delivery system

Decision: Removed from formulary

8.3 Low-dose rivaroxaban and aspirin for the prevention of major cardiovascular outcomes in patients with peripheral arterial disease (Dr Daryll Baker, RFL)

The Committee considered an application for the use of low dose rivaroxaban in combination with aspirin for the prevention of cardiovascular outcomes in patients with peripheral arterial disease (PAD).

The Committee considered a randomised, double-blind, double-dummy, placebo-controlled, international, multi-centre trial (n=27,395) to evaluate the effectiveness of rivaroxaban alone or in combination with aspirin for the prevention of major cardiovascular events in patients with coronary arterial disease (CAD) or PAD. Participants were excluded if they had a high risk of bleeding, a history of haemorrhagic or lacunar stroke, severe renal impairment, severe heart failure, or those that required dual antiplatelet, oral anticoagulant or non-aspirin antiplatelet therapy, amongst other criteria. Participants were randomised to one of three treatment arms; rivaroxaban 2.5mg BD with aspirin 100mg OD; rivaroxaban 5mg BD with placebo (aspirin) OD; or aspirin 100mg OD with placebo (rivaroxaban) BD. Patients were stratified and baseline characteristics were largely similar between treatment arms. The primary endpoint was a composite of cardiovascular death, myocardial infarction or stroke.

A sub-group analysis on the PAD cohort (n=7470) was conducted and published separately. At baseline, 65.7% of patients with PAD had polyvascular disease. Results from the primary efficacy outcome of this subgroup analysis found benefits in favour of the low-dose rivaroxaban and aspirin arm versus aspirin alone (HR 0.72; 95% CI 0.57 - 0.90; p=0.0047). The primary safety outcome of a composite of bleeding

found it was more prevalent in the rivaroxaban and aspirin group versus aspirin alone (HR = 1.61; 95% CI 1.12 - 2.31; p=0.0089). A component of this safety outcome, with the highest occurrence rate in the low-dose rivaroxaban and aspirin arm, was gastrointestinal bleeding (HR = 2.28; 95% CI 1.31 - 3.96; p=0.0027). In order to offset the risk of bleed versus the benefits observed, the investigators reported the 'net clinical benefit' (a composite of cardiovascular death, myocardial infarction, stroke, and critical organ or fatal bleeding) which favoured the low dose rivaroxaban and aspirin arm (HR = 0.75; 95% CI 0.60-0.94; p=0.011). Strengths of the study include the analysis of the intention to treat population, the international multi-centre design and the large patient numbers involved. Weaknesses include the early termination of study, exclusion of high-risk patient groups, higher discontinuation in test arms and the non-significant findings in the PAD alone population (which represents just 9.1% of the total COMPASS population – HR = 0.89; 95% CI 0.55-1.44; p=0.63869).

The application indicated 500 patients across NCL would be eligible for treatment which was associated with an annual cost pressure of £362,880, predominantly in primary care. The SMC reviewed and approved the combination therapy with a restriction for use in patients with CAD only, who are not using dual antiplatelet therapy. The manufacturer confirmed it was not seeking approval for use in patients with PAD alone, and the data used to make the SMC decision will also be reviewed by NICE in their technology appraisal (expected publication August 2019). The Committee heard that the CAD population included in the SMC review includes those with polyvascular disease. If polyvascular PAD alone was considered (rather than both poly- and monovascular PAD), the number of eligible patients across NCL would be 325 with a budget impact of £235,872.

Dr Baker reinforced the findings of available evidence in patients with symptomatic PAD. Current practice is to use aspirin alone which mirrors the control arm in the study well. Dr Baker applied to use rivaroxaban with aspirin in all patients with PAD, however acknowledged the absolute benefit was greater in patients with polyvascular disease, and was happy to restrict use to this cohort. Other risk factors would be managed in these patients (such as blood pressure control, exercise classes and additional medications such as statin therapy). Further information from the trial on the use of a concomitant PPI is not currently available, however Dr Baker supported its use in the absence of definitive data to suggest otherwise. Vascular consultants are aware of the risk that even a small dose of rivaroxaban can cause, therefore Dr Baker recommended restricting this to vascular consultant initiation only and the use of JFC approved documentation for DOAC counselling.

In camera, the Committee reflected on the published data in relation to the submitted application, noting that as use of the medicine moves away from the study eligibility criteria, the potential for risk grows whilst the opportunity for benefit reduces; this is particularly important for an intervention such as rivaroxaban and aspirin where the risk/benefit is marginal (reduction in MACE of 1.1 events/100 patient years balanced against an increased risk of major bleeding of 0.72 events/100 patient years). The EMA identified that use in patients >75 years old demonstrated increased risk of bleeding with a non-significant reduction in the primary efficacy outcome. The Committee were also interested to hear from the general cardiovascular community, given that the primary outcome and the greatest benefit was cardiovascular risk reduction rather than limb ischaemia or amputation.

In summary, the Committee required evidence of a collaborative approach between Vascular and Cardiology Consultants before it could approve the application. A clear patient pathway is required to include medical management of associated risk factors and a review of cardiovascular outcomes. The Committee requested that the inclusion and exclusion criteria for rivaroxaban and aspirin were closely aligned to the trial with the added restriction of adult patients <75 years old with polyvascular disease.

Decision: Deferred

Actions: Applicant to create a patient pathway in conjunction with Cardiology consultants for patients <75 years old with polyvascular disease, providing assurance of medical management of associated risk factors and a clear patient pathway between both specialities in the management and review of cardiovascular outcomes.

9. Results from evaluation: Opicapone for Parkinson's disease

The Committee considered the results of an evaluation, as undertaken at the NHNN site, of opicapone with 'end of dose OFF time' in patients who are intolerant or non-responsive to first-line entacapone. The evaluation was previously justified by the Committee as the licensing RCT was inconsistent with the proposed positioning.

Declarations of interest from applicants were acknowledged by the Committee.

The Committee reviewed an audit of 33 patients which had been verified by one specialist pharmacist and JFC Support. At baseline 100% of patients initiated opicapone due to problematic OFF time, 86% had discontinued entacapone due to insufficient benefit or adverse effect and all were eligible for advanced therapies. Results found that opicapone was continued in 48% of patients beyond 6 months. The primary causes of opicapone discontinuation were: 'peak dopinergic AEs' (60%); 'other AE' (13%); and lack of efficacy (13%). Of those who continued treatment there was a mean reduction in OFF time per day of -2.45 hours (SD=1.88), an improvement in ON time after each levodopa dose of 0.86hrs (SD=0.61) and some reported a reduction in freezing.

The Committee considered the audit to be of good quality with good adherence to inclusion criteria, a near complete dataset and relevant outcomes monitored. Opicapone was found to lead to clinically meaningful improvements in approximately half of patients. The Committee also noted that patients in whom opicapone was ineffective or not tolerated had been withdrawn from this treatment.

In terms of cost, opicapone is significantly more expensive than generic entacapone however entacapone was not an appropriate comparator (positioning is after entacapone failure) and the annual cost was justified by the benefit observed.

In summary, the Committee agreed a well-constructed audit had been completed which suggested the effectiveness of opicapone in the intended cohort. The Committee agreed to add opicapone to the NCL Joint Formulary for patients with significant daily OFF time and end of dose fluctuations, in whom entacapone has failed, and the only remaining options are invasive advanced therapies (deep brain stimulation, apomorhine, or levodopa-carbidopa intestinal gel). Opicapone was therefore restricted to centres who can offer advanced therapies (NHNN and RFL).

Decision: Approved

Prescribing: Initiation at NHNN and RFL; Continuation in Primary care

Tariff status: In tariff **Funding**: Trust / CCG

Fact sheet or shared care required: No

10. VSL#3 for maintenance of remission of pouchitis

This item was deferred

11. Densoumab for treatment of osteoporosis in renal impairment

This item was deferred

12. Oral Bisphosphonates: sodium clodronate for adjuvant breast cancer

At the February 2016 meeting, the Committee reviewed an application for the use of bisphosphonates as first-line adjuvant therapy for post-menopausal women with early breast cancer to prevent bone recurrence and cancer mortality. The Committee concluded that IV zolendronic acid was the most cost-effective bisphosphonate for this indication. In making this decision, the Committee reviewed a large meta-analysis which also formed the basis for the NICE 2017 Evidence Summary that concluded "optimal choice, dosage and duration of bisphosphonate treatment for preventing recurrence and improving survival in women with early breast cancer is unclear". CCO/ASCO 2017 guidance however recommend IV zolendronic acid or sodium clodronate for this indication.

More recently, RFL and UCLH have requested sodium clodronate for a small number of patients who are not eligible for IV zolendronic acid due to adverse effects or lack of IV access. The Committee re-reviewed the meta-analysis and concluded that whilst the majority of evidence was for zolendronic acid and clondronate, there were no between group differences between the individual bisphosphonate agents. The Committee also reviewed an abstract of an interim analysis of a Phase III trial of bisphosphonates as adjuvant therapy in primary breast cancer (NCT00127205) which is expected to complete in 2020. Patients with stage I-III breast cancer receiving adjuvant systemic therapy were randomised to receive 3 years of sodium clodronate, ibandronate or zoledronic acid. Results report no evidence of differences in efficacy by type of bisphosphonate. The primary outcome, disease free survival, did not differ across arms in a log-rank test (p = 0.71), 5-year disease free survival was 88% in the clodronate and zolendronic acid arms, and 87% in the ibandronate arm; overall survival was 93% in all 3 arms. Differences in the type of toxicity were reported, however the overall grade differed little across arms.

Sodium clondronate (1600mg OD) costs £936/pt/annum compared with £204/pt/annum for ibandronic acid (50mg OD) indicating a preference for ibandronic acid.

In summary, the Committee agreed that the available evidence indicated equivalence in efficacy between zolendronic acid, sodium clodronate and ibandronic acid therefore the least expensive agent should be made available, where required, in addition to the currently established zoledronic acid. The Committee therefore agreed to add ibandronic acid onto the NCL Joint Formulary for patients who cannot receive IV zolendronic acid. The Committee would review the final results of NCT00127205 when published and action accordingly.

Drug: Sodium clodronate for adjuvant breast cancer (second line to zolendronic acid)

Decision: Not approved

Drug: Ibandronic acid for adjuvant breast cancer (second line to zolendronic acid)

Decision: Approved

Prescribing: Secondary care

Tariff status: In tariff **Funding**: Trust

Fact sheet or shared care required: No Additional notes: Dose is 50mg once daily.

13. Cannabis and cannabis related products: Position statement and patient information

The position statement and patient information were both updated following the outcomes at the January 2019 JFC meeting. The Committee approved both documents subject to minor amends.

14. DMARD quick reference guide

The guide has been approved by the Shared Care Working Group and was brought to JFC for ratification. One of the key changes was the statement that the responsible clinician should refer patients using hydroxychloroquine at the appropriate time point to ophthalmology for assessment. The Committee heard that the need for ophthalmic monitoring is advised by the Royal College of Ophthalmologists, although this is now subject to further inquiry by MHRA and NHS Improvement. The document was approved and will be reviewed again should any new information be made available from the MHRA.

15. Guideline for blood glucose & ketone monitoring for adults with diabetes

This document was updated with removal of the InsuLinx device and the addition of a link to NCL/LPP/LDCN guidance for Freestyle Libre. The Committee approved the document.

16. Freestyle Libre for Cystic Fibrosis-related diabetes

The Committee heard an enquiry from GOSH related to the access of Freestyle Libre (under the NCL implementation plan) for patient under their care with Cystic Fibrosis-related diabetes (CFRD). The Committee noted that the NCL guidance is an adaptation of LPP/LDCN guidance and JFC Support has seen evidence that LPP/LDCN intended for this cohort to be included due to the similarity to type 1 diabetes in terms of insulin deficiency. An estimated 35 patients would be eligible across NCL, with only a proportion opting for Freestyle Libre. The estimated budget impact was up to £16,000 across NCL. The Committee agreed patients with CFRD were eligible for Freestyle Libre provided they met the specified inclusion and continuation criteria.

17. NCL JFC Chair advert

The Committee were in agreement with the NCL JFC Chair recruitment process and for the post to be advertised on NHS jobs.

18. Next meeting

Monday 18th February 2019, 4.30 – 6.30pm, Venue: LG01, 222 Euston Road, London, NW1 2DA

19. Any other business

A protocol for the use of C1-esterase inhibitors in hereditary angioedema was presented to the Committee. The protocol is as per NHSE commissioning guidance and is for implementation at RFL and UCLH.

The Committee agreed to review an application for paclitaxel and carboplatin for squamous cell carcinoma of the anus, the only available evidence to support the application is a Phase II abstract of a trial sponsored by the Royal Marsden Hospital. This is a rare cancer and it is unlikely that a Phase III clinical trial will be conducted.