

**JOINT FORMULARY COMMITTEE (JFC) – MINUTES  
Minutes from the meeting held on 17<sup>th</sup> February 2022**

<b>Present:</b>	Dr B Subel	NCL JFC Vice Chair	(Chair)
	Mr S Semple	NCL ICS, Interim Chief Pharmacist	
	Dr M Kelsey	WH, DTC Chair	
	Dr K Tasopoulos	NMUH, DTC Chair	
	Mr A Sell	RNOH, DTC Chair	
	Ms G Smith	RFL, DTC Chair	
	Dr A Scourfield	UCLH, DTC Chair	
	Ms K Delargy	BEH, Chief Pharmacist	
	Mr P Gouldstone	NCL CCG, Head of Medicines Management (Enfield)	
	Ms M Singh	NCL CCG, Head of Medicines Management (Barnet)	
	Ms E Mortty	NCL CCG, Deputy Head of Medicines Management (Haringey)	
	Mr A Dutt	NCL CCG, Head of Medicines Management (Islington)	
	Dr R Urquhart	UCLH, Divisional Clinical Director	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Mr G Kitson	WH, Deputy Chief Pharmacist	
	Mr A Stein	NMUH, Deputy Chief Pharmacist	
	Dr D Burrage	WH, Consultant Clinical Pharmacologist	
<b>In attendance:</b>	Ms S Sanghvi	North London Partners, JFC Principal Pharmacist	
	Mr G Grewal	North London Partners, JFC Support Pharmacist	
	Mr R Rajan	North London Partners, JFC Support Pharmacist	
	Ms S Amin	IPMO Programme Team, Lead Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Mr H Shahbakhti	RFL, Formulary Pharmacist	
	Ms A Sehmi	NMUH, Formulary Pharmacist	
	Ms H Thoong	GOSH, Formulary Pharmacist	
	Ms M Thacker	RFL, Clinical Lead Pharmacist	
	Mr S O'Callaghan	UCLH, Medicines Safety Officer	
	Ms A Fakoya	NHS London Shared Service, Contract and Commissioning Support Pharmacist	
	Ms H Weaver	NHSE, Specialised Commissioning Pharmacist	
	Dr S Khan	UCLH, Consultant Neurologist	
	Dr A Sheri	RFL, Consultant Medical Oncologist	
	Dr D Thompson	UCLH, Clinical Pharmacology Registrar	
<b>Apologies:</b>	Dr A Worth	GOSH, DTC Chair	
	Mr A Tufail	MEH, DTC Chair	
	Mr J Harchowal	UCLH, Chief Pharmacist	
	Mr S Richardson	WH, Chief Pharmacist	
	Ms W Spicer	RFL, Chief Pharmacist	
	Mr A Shah	RNOH, Chief Pharmacist	
	Ms N Phul	MEH, Chief Pharmacist	
	Mr S Tomlin	GOSH, Chief Pharmacist	
	Ms S Stern	NMUH, Chief Pharmacist	
	Ms L Reeves	C&I, Chief Pharmacist	
	Ms R Clark	NCL CCG, Head of Medicines Management (Camden)	
	Mr A Barron	UCLH, Principal Pharmacist	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist	

Ms J Bloom	MEH, Associate Chief Pharmacist
Ms A El Bushra	MEH, Associate Chief Pharmacist
Ms S Y Tan	NHS London Shared Service, Contract and Commissioning Support Pharmacist
Ms A Blochberger	NHSE, Specialised Commissioning Pharmacist
Ms M Kassam	MEH, Senior Pharmacist

## 2. Meeting observers

Dr Subel welcomed observers to the meeting.

## 3. Minutes of the last meeting

The minutes and abbreviated minutes of 20 January 2022 meeting was accepted as an accurate reflection of the meeting.

## 4. Matters arising

### 4.1 Anifrolumab FoC scheme

In January 2022, the Committee made a decision not to take forward review of a FOC scheme for anifrolumab for systemic lupus erythematosus as the NICE TA had an expected publication date of April 2022. This NICE TA publication date has been changed to "TBC" as the company will not be able to provide an evidence submission to NICE at this time. The Committee therefore considered it appropriate to circulate the application of anifrolumab to other NCL Trusts and consider for JFC review under usual processes.

## 5. JFC Outstanding Items & Work Plan

The Committee agreed that applications for prazosin for nightmare disorders, topiramate for cyclical vomiting syndrome and an appeal for Botox for complex abdominal hernias could be reviewed by UCLH DTC due to limited capacity on upcoming JFC meeting agendas. Any questions should be directed to [admin.ncl-mon@nhs.net](mailto:admin.ncl-mon@nhs.net).

### 5.1 Upadacitinib for ankylosing spondylitis

The Committee considered a request to review a FOC (£1 scheme) application for upadacitinib, a JAK inhibitor, for 2<sup>nd</sup> line use in ankylosing spondylitis after conventional therapies. The draft NCL ankylosing spondylitis pathway is currently under development with several NICE TA approved biologic therapies already available for 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> line use. The Committee agreed that it would not be appropriate to consider this application as there was no clinical unmet need identified and the application would undermine prescribing of existing approved NICE TA therapies. This aligns with NCL FOC guidance and criteria for review. However, the Committee encouraged the applicants to work with London Shared Service to determine how upadacitinib should be integrated into the pathway once the NICE TA is published (due August 2022) and support early consideration of commissioning implications.

## 6. Members declarations of conflicts of interest

Nil.

## 7. Local DTC recommendations / minutes

### 7.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
RFL	Dec 2021	Rituximab	Maintenance of biochemical remission in autoimmune hepatitis	Decision: RFL only Prescribing: Secondary care Tariff status: Tariff excluded Funding: Trust Fact sheet or shared care required: No
RFL	Dec 2021	Tocilizumab and sarilumab	Treatment of Cytokine Release Syndrome/Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS) and Haemophagocytic Lymphohistiocytosis (HLH)	Decision: RFL only (supportive therapy to facilitate clinical trials) Prescribing: Secondary care Tariff status: Tariff excluded Funding: Trust Fact sheet or shared care required: No

UCLH	Dec 2021	Natalizumab (subcutaneous formulation)	Rapidly evolving severe relapsing-remitting multiple sclerosis (RES) and highly active relapsing-remitting multiple sclerosis (RRMS)	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: Tariff excluded Funding: NHSE Fact sheet or shared care required: No Additional information: Use is in line with NICE TA127
UCLH	Dec 2021	FOC scheme: Lerglitazone <sup>†</sup>	Adult men with X-linked adrenoleukodystrophy with active lesions consistent with cerebral involvement	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: N/A – Free of charge Funding: N/A – Free of charge Fact sheet or shared care required: No
UCLH	Dec 2021	FOC scheme: Luspatercept <sup>†</sup>	For 5 patients with non-transfusion dependent $\beta$ -thalassaemia who responded to the investigational medicinal product (sotatercept) in a phase 2 clinical trial	Decision: UCLH only Prescribing: Secondary care Tariff status: N/A – Free of charge Funding: N/A – Free of charge Fact sheet or shared care required: No
RFL	Jan 2022	FOC scheme: Olaparib <sup>†</sup>	Germline BRCA1/2- mutated, HER2-negative metastatic breast cancer (previously treated with taxane and anthracycline based chemotherapy)	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: N/A – Free of charge Funding: N/A – Free of charge Fact sheet or shared care required: No

**7.2 Not approved**

DTC site	Month	Drug	Indication	JFC outcome
UCLH	Dec 2021	FOC scheme: Triheptanoin	Long chain fatty acid oxidation disorders	Decision: Not approved

<sup>†</sup>The relevant commissioner should be notified in line with NCL Free of Charge scheme guidance. Approval is conditional on the provision of a free of charge scheme agreement and funding statement.

**7.3 Parenteral aztreonam for as a therapy option reserved for microbiologist advice**

The Committee considered a request to add parenteral aztreonam, a monocyclic beta-lactam antibiotic, to the NCL Joint Formulary. This has historically been available at NMUH and RFL. The Committee approved the ratification of parenteral aztreonam, to be added to the NCL Joint Formulary on the advice of local microbiology teams only, where other suitable formulary options are exhausted due to resistance or severe allergy.

**Decision:** Approved

**Prescribing:** Secondary care only

**Tariff status:** In tariff

**Funding:** Trust

**Fact sheet or shared care required:** No

**Additional information:** On the advice of local microbiology teams only, where other suitable formulary options are exhausted due to resistance or severe allergy

**7.4 Ibandronic acid for the prevention of skeletal events in metastatic breast cancer patients**

The Committee considered a request to add ibandronic acid, an oral bisphosphonate, to the NCL Joint Formulary for the prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases where denosumab or IV bisphosphonates are not appropriate. Ibandronic acid is on the Joint Formulary in an off-label indication for use in post-menopausal women with breast cancer and medium to high risk of relapse not receiving

adjuvant chemotherapy. Ibandronic acid is licensed in metastatic patients, though this currently has historically been on formulary at NMUH only. The Committee supported the ratification to the Joint Formulary, and supported the addition of the indication in to the NCL factsheet for ibandronic acid which is currently in development.

**Decision:** Approved

**Prescribing:** Secondary care initiation; primary care continuation

**Tariff status:** In tariff

**Funding:** Trust and CCG

**Fact sheet or shared care required:** Yes (to be incorporated into NCL factsheet)

## 8. New Medicine Reviews

### 8.1 ProPrams to prevent necrotising enterocolitis in pre-term neonates (Applicant: Dr C Kortsalioudaki)

The Committee considered an application for ProPrams®, a probiotic food supplement which consists of the following Gram-positive bacteria: Bifidobacterium infantis (350 million CFUs); Bifidobacterium lactis (350 million CFUs); and Streptococcus thermophilus (300 million CFUs). ProPrams® is proposed for the prevention of necrotising enterocolitis (NEC), in pre-term neonates born <32 weeks' gestation, and neonates born between 32 and 34 weeks who weigh <1.5kg. There are currently no alternative prophylactic agents for this indication.

The ProPrams® trial was a phase III, placebo-controlled, double-blind study to assess the safety and efficacy of ProPrams® for pre-term neonates born <32 weeks' gestation and weighing <1.5kg (n=1,099). Patients were randomised to receive one dose daily, which contained B. infantis (300 million CFUs); B. lactis (350 million CFUs); and S. thermophilus (350 million CFUs), or placebo. Infants were treated until discharge from hospital or term corrected age. The primary endpoint, incidence of at least one episode of late-onset sepsis before 40 weeks' post-menstrual age or discharge home, was not significantly lower with probiotics compared to placebo (13.1% vs. 16.2%; RR: 0.81, [95% CI: 0.61 to 1.08]). The incidence of NEC (secondary endpoint) was significantly lower in the treatment group (2.0% vs. 4.4%; RR: 0.46, [95%CI: 0.23 to 0.93]). Key limitations of the study were the different constitution and dose of bacteria in the study, NEC reported only as a secondary outcome, an unmet sample size calculation, and the omitted data regarding duration of treatment.

The Committee heard that a Cochrane review (October 2020) summarised the evidence base of probiotics for prevention of NEC as low-to-moderate level of certainty due to uncertainty about optimal strain and lack of established regimen of dosing and timing of administration. UpToDate (January 2022) does not recommend probiotics as prevention for routine care due to a lack of consensus on the optimal regimen and insufficient data, and the low-quality level of evidence due to marked heterogeneity and potential bias amongst clinical trials.

In terms of safety, infants treated with probiotics had no incidence of late-onset sepsis with probiotic species. The Committee was informed however, that there have been cases of bacteraemia from bacterial probiotic strain or contamination of the product reported in the past.

The Committee was informed that ProPrams® is a food supplement without a marketing authorisation from MHRA. It has however, a European GMP certification. Furthermore, ProPrams® is the only probiotic product available in the UK that consists of the combination and dosage of bacteria as recommended by the position paper released by European Society for Paediatric Gastroenterology Hepatology and Nutrition that recommends probiotics for prevention of NEC (March 2020).

The Committee questioned whether safety and quality control measures were employed in the manufacturing process, such as surveillance of genetic mutations to identify potential antibiotic-resistant strains. The Committee noted that the mechanisms behind the pathophysiology of NEC are uncertain and there is variability in incidence of NEC across neonatal units. The Committee requested further information regarding prevalence of NEC cases in NCL neonatal units to help ascertain the clinical significance of the study data and applicability locally.

In terms of budget impact, ProPrams® is expected to cost an additional £30,000 per annum as compared to standard care (projection only includes UCLH neonatal units). RFL, WH and GOSH have also expressed interest to adopt probiotics for prevention of NEC.

In summary, based on the evidence available the Committee could not recommend the use of ProPrem<sup>®</sup>, however deferred the decision requesting further information on:

- Baseline prevalence of NEC in NCL Trusts and number of patients predicted to receive ProPrem<sup>®</sup> from other sites (RFL, WH, GOSH)
- Quality control data from the manufacturers of ProPrem<sup>®</sup>
- The data the applicants plan to collect as part of their ProPrem<sup>®</sup> evaluation

**Decision:** Deferred

## 8.2 Rotigotine, gabapentin and pregabalin for restless legs syndrome (Applicant: Dr S Khan, UCLH)

The Committee considered a request to add rotigotine, gabapentin and pregabalin to the NCL Joint Formulary for restless legs. All three medications are already in use at NHNN, but have not previously been formally reviewed for addition to the NCL Joint Formulary, and required assessment for suitability of transfer of prescribing to primary care. All three medications were recommended by NICE in a clinical knowledge summary as first-line options in the treatment of restless legs. The Committee considered a rapid risk assessment for each medication in turn. Trials used the International Restless Legs Scale (IRLS) as an outcome of interest.

Rotigotine, a non-ergot dopamine agonist, was supported by several clinical trials. Hening et al conducted a 6-month, double-blind, randomised, controlled trial to assess the efficacy and safety of rotigotine versus placebo in patients with moderate to severe idiopathic restless legs syndrome (n=505). Patients were randomly assigned to receive placebo or rotigotine at 0.5, 1, 2 or 3mg/24 hours delivered by transdermal patch. In the first co-primary endpoint, the decrease from baseline to end of maintenance in IRLS score, was significantly reduced with rotigotine versus placebo for both the 2mg/24-hour rotigotine dose (difference in IRLS score = -4.5 [95% CI -6.9 to -2.2]) and the 3mg/24-hour dose (difference in IRLS score = -5.2 [95% CI -7.5 to -2.9]). In the second co-primary outcome, item 1 assessment (severity of symptoms) in the clinical global impression score, was significantly lower for both the 2mg/24-hour dose (-0.65 [95% CI -1.0 to -0.3]) and for the 3mg/24-hour dose (-0.9 [95% CI -1.3 to -0.5]). Results for the lower doses were improved compared to placebo but did not reach statistical significance. Positive results were supported by further studies from a double-blind RCT by Trenkwalder et al, a double-blind RCT by Oertel et al and a 5-year open-label continuation study by Oertel et al.

The majority of evidence for gabapentin, a gabapentanoid which is a structural analogue of GABA, lay with the prodrug, gabapentin encarbil. Lee et al (2011) conducted a 12-week, double-blind, randomised, controlled trial to assess the efficacy and safety of gabapentin encarbil at two different doses versus placebo in patients with moderate to severe primary restless legs syndrome (n=325). In the first co-primary endpoint, the decrease from baseline to week 12 in IRLS score, was significantly reduced with gabapentin encarbil versus placebo for both the 1200mg dose (adjusted mean treatment difference = -3.5 [p<0.0015]) and the 600mg dose (adjusted mean treatment difference = -4.3 [p<0.0001]). In the second co-primary outcome, proportion of responders rated as “very much” or “much” improved on an investigator-rated clinical global impression-improvement scale, was significantly better for both the 1200mg dose (77.5% vs 44.8% [p<0.001]) and for the 600mg dose (72.8% vs 44.8% [p<0.0001]). Positive results were supported by further studies from a single-blind RCT by Bogan et al, a double-blind RCT by Kushida et al and a 52-week open-label continuation study by Ellenbogen et al.

Pregabalin, another gabapentanoid which is a precursor molecule of GABA, was supported by a study by Allen et al, who conducted a 52-week, double-blind, randomised, controlled trial to compare the efficacy and safety of pregabalin with placebo or two different doses or pramipexole in patients with moderate to severe primary restless legs syndrome (n=719). Patients were randomised to receive pregabalin 300mg daily, pramipexole 0.25mg daily, pramipexole 0.5mg daily or placebo. The study had 3 co-primary endpoints. In the first co-primary endpoint, the reduction from baseline to week 12 in IRLS score, was significantly reduced with pregabalin compared to placebo (4.5 points [p<0.001]). In the second co-primary outcome, proportion of responders rated as “very much” or “much” improved on an investigator-rated clinical global impression-improvement scale, was significantly better for pregabalin compared to placebo (71.4% vs 46.8% [p<0.001]). In the third co-primary outcome, the rate of “augmentation” (i.e., worsening of symptoms due to dopaminergic treatment) over a period of 40 or 52 weeks was significantly lower with pregabalin versus 0.5mg pramipexole (2.1% vs 7.7% [p=0.001]) but was not significantly better with

pregabalin versus 0.25mg pramipexole (2.1% vs 5.3% [p=0.08]). Positive results were supported with a patient clinician report of patient experience in 16 patients by Sommer et al.

In terms of safety, there is experience in the use of all three medications for other indications. There is risk of misuse and abuse of pregabalin and gabapentin (both are schedule 3 controlled drugs subject to prescribing regulations). In terms of budget impact, all three medications are currently prescribed for restless legs in NCL, and therefore no additional budget impact was expected for the sector.

The Committee heard from Dr Khan that restless legs syndrome can have a marked effect on a patients' quality of life. Patients cannot fall asleep at night and struggle with daily activities the following day. In her experience, routine options of pramipexole and ropinirole usually have good effect; pregabalin would be the next option used, and rotigotine or gabapentin are usually reserved for those in whom previous therapeutic choices have not worked. In terms of stopping criteria, treatments would only usually be stopped if a contraindication arises (e.g., augmentation, impulse control disorder) or for loss of efficacy.

*The Committee heard from Dr Khan that restless legs syndrome can have a marked effect on a patients' quality of life. Patients cannot fall asleep at night and struggle with daily activities the following day. In general, pregabalin or dopamine agonists (e.g., In her experience, routine options of pramipexole and ropinirole) are commonly used first-line, with choice of agent guided by co-morbidities and symptom profile. usually have good effect; pregabalin would be the next option used, and Rotigotine or gabapentin are also treatment options, usually reserved for those in whom previous therapeutic choices have not worked. In terms of stopping criteria, treatments would only usually be stopped if a contraindication arises (e.g., augmentation, impulse control disorder) or for loss of efficacy.*

In camera, the Committee considered the proposal and were supportive of the clinical evidence for efficacy of all three medications (noting that pramipexole and ropinirole are already on the NCL Joint Formulary). The Committee agreed that rotigotine, pregabalin and gabapentin were suitable for addition to the NCL Joint Formulary, and appropriate for continuation of prescribing in primary care provided further details were clarified regarding the monitoring requirements, stopping criteria and how/when to refer to the specialist. This could be in the form of a guideline or via addition to the NCL Prescribing Recommendations guidance.

In summary, the Committee agreed to add rotigotine, pregabalin and gabapentin to the NCL Joint Formulary for Restless Legs Syndrome.

**Decision:** Approved

**Prescribing:** Primary and Secondary care

**Tariff status:** In tariff

**Funding:** Trust/CCG

**Fact sheet or shared care required:** JFC Support to work with the applicant and Deferred to the NCL NPR group for consideration

### **8.3 FOC scheme: olaparib as adjuvant therapy for high-risk BRCA-mutated HER-2 negative early breast cancer (Applicant: Dr A Sheri, RFL)**

The Committee considered a free-of-charge (FOC) scheme for olaparib, a poly(adenosine diphosphate-ribose) polymerase (PARP) inhibitor, as adjuvant therapy for one year in patients with BRCA 1/2 mutated HER-2 negative high-risk early breast cancer, previously treated with neoadjuvant or adjuvant chemotherapy. Patients who have HER-2 negative but oestrogen receptor and/or progesterone receptor positive early breast cancer currently have no alternative therapy available in this setting; however patients with triple-negative breast cancer with residual disease (irrespective of BRCA mutation) are offered 8 cycles of capecitabine due to high risk of recurrence.

The OlympiA trial was a Phase III, placebo-controlled, double-blind study to compare the efficacy and safety of olaparib and placebo for patients with germline BRCA 1/2 mutation, HER-2 negative breast cancer after chemotherapy (n=1,836). Patients were randomised to olaparib 300mg twice daily or matching placebo for 1 year and were followed up for up to 5 years. The primary endpoint, the proportion of patients with invasive disease-free survival at 3 years, was significantly better with olaparib compared to placebo (85.9% vs. 77.1%; HR: 0.58 [95%CI: 0.41 to 0.82]). The secondary outcome, the proportion of patients with distant disease-free survival at 3 years, was significantly better with olaparib compared to placebo (87.5% vs. 80.4%; HR: 0.57, [95%CI: 0.39 to 0.83]). A further secondary outcome, overall survival at 3 years, was numerically better but did not pass a pre-defined threshold of <0.01 to demonstrate

significance between olaparib and placebo (59 deaths vs 86 deaths; HR = 0.68 [99% CI 0.44 to 1.05]). Key limitations of the study include the lack of capecitabine as a comparator in the triple-negative population

In terms of safety, compared to placebo there were a higher number of patients receiving olaparib who required dose reductions (228 vs 47 patients) or adverse events that led to discontinuation (90 vs 38 patients). The most common adverse events grade 3 or higher in >1% of olaparib patients were anaemia, reduced neutrophils, reduced white cell count, fatigue and lymphopaenia. As olaparib is on the NCL Joint Formulary in other indications, there is experience in its use.

In terms of budget impact, olaparib is available free of charge from the company. However, it will require an additional 12 outpatient appointments and 12 blood tests (plus interventions for adverse effects as required) compared with no treatment. The FOC scheme will close in December 2022; patients enrolled before that time will be able to continue access to FOC stock until it is available and commissioned on the NHS.

The Committee heard from Dr Sheri that capecitabine is currently only available to patients with triple negative breast cancer irrespective of BRCA mutation who have residual disease at surgery after neo-adjuvant chemotherapy, and olaparib would be preferred in patients with BRCA mutated triple-negative breast cancer on the basis of having a targeted therapy available.

*In camera*, the Committee considered the available evidence and concluded that there was a strong case to use olaparib in HER-2 negative patients where no other treatment option is available. However, the Committee recognised that there is a small cohort of patients with triple-negative breast cancer who would currently have access to capecitabine, and it was unknown whether there was any difference in efficacy or safety between olaparib and capecitabine. The Committee did not feel it could make a decision in this defined cohort until more information could demonstrate a benefit in efficacy or safety, particularly as the December 2021 NCCN guidance for breast cancer states there are no data on sequencing or to guide selection of one agent over the other.

In summary, the Committee agreed to add olaparib to the NCL Joint Formulary as adjuvant therapy for patients with BRCA 1/2 mutated, HER-2 negative high-risk early breast cancer. However, based on the evidence available and unknown benefit/risk compared to capecitabine, the Committee could not recommend the use of olaparib for patients with BRCA 1/2 mutated, triple negative breast cancer who have residual disease at surgery following neo-adjuvant chemotherapy. The Committee would defer the decision in this population until the applicant could provide more evidence to demonstrate a positive benefit/risk ratio.

**Drug:** Olaparib for BRCA 1/2 mutated, HER-2 negative, high risk early breast cancer following adjuvant or neoadjuvant chemotherapy (where no other therapies are available)

**Decision:** Approved

**Prescribing:** Secondary care only

**Tariff status:** N/A – Free of charge

**Funding:** N/A – Free of charge

**Fact sheet or shared care required:** No

**Drug:** Olaparib for BRCA 1/2 mutated, triple-negative, high risk early breast cancer with residual disease on surgery following neoadjuvant chemotherapy (where capecitabine remains an option)

**Decision:** Deferred

## 9. Formulary position of pregabalin for neuropathic pain

The Committee considered the formulary position of pregabalin for the treatment of neuropathic pain in NCL following requests to remove the current restriction to trial gabapentin prior to pregabalin. This treatment hierarchy was recommended by the JFC in 2013 due to the higher cost of pregabalin at the time and comparable efficacy to gabapentin.

The Committee noted that pregabalin has been available off-patent for neuropathic pain since 2017 and NICE guidance no longer restricts the order of pharmacological therapies for neuropathic pain. The Committee discussed risk of misuse, diversion and inappropriate prescribing of gabapentanoids. NICE considered the risk of misuse in a recent guideline update and were reassured by the reclassification of pregabalin and gabapentin to schedule 3 controlled drug status, increased direct experience with both medicines, and the manufacturers updated SPCs which warn against misuse, dependence & withdrawal.

The Committee also heard that NICE exclude sciatica and trigeminal neuralgia in their definition of 'neuropathic pain' – and that gabapentanoids are specifically advised against for sciatica and lower back pain due to no evidence of benefit but with evidence of harm.

The Committee considered it appropriate to remove the formulary restriction as there is no longer a significant difference in drug acquisition cost, and allow clinician discretion to choose between gabapentin and pregabalin. The Committee also considered it appropriate to exclude trigeminal neuralgia and sciatica from the formulary approval (as per NICE guidance).

**10. Any Other Business**

N/A

**11. Next meeting**

Thursday 17<sup>th</sup> March 2022