North Central London
Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on 15th October 2020

Present:	Prof R Sofat	NCL JFC Chair	(Chair)
	Dr P Taylor	NCL JFC Vice Chair	
	Dr M Kelsey	WH, DTC Chair	
	Ms W Spicer	RFL, Chief Pharmacist	
	Mr S Semple	MEH, Chief Pharmacist	
	Ms K Delargy	BEH, Deputy Chief Pharmacist*	
	Mr S Richardson	WH, Chief Pharmacist	
	Dr R Urquhart	UCLH, Chief Pharmacist	
	Mr S Tomlin	GOSH, Chief Pharmacist	
	Dr A Sell	RNOH, DTC Chair	
	Dr D Burrage	WH, Consultant in Emergency Medicine	
	Mr P Gouldstone	NCL CCG, Head of Medicines Management (Enfield)	
	Ms R Clark	NCL CCG, Head of Medicines Management (Camden)	
	Mr A Tufail	MEH, DTC Chair	
	Ms G Smith	RFL, DTC Chair	
	Mr A Dutt	NCL CCG, Head of Medicines Management (Islington)	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist*	
In attendance:	Dr P Bodalia	UCLH, Principal Pharmacist	
	Mr A Barron	North London Partners, MEP Project Lead	
	Mr G Grewal	North London Partners, JFC Support Pharmacist	
	Ms M Kassam	North London Partners, JFC Support Pharmacist	
	Ms H Thoong	GOSH, Formulary Pharmacist	
	Ms H Mehta	NMUH, Formulary Pharmacist	
	Ms H Weaver	NHSE, Specialised Commissioning Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Mr F Master	RFL, Formulary Pharmacist	
	Ms A Fakoya	NEL, Senior Prescribing Advisor High Cost Drugs	
	Ms K Davies	NEL CSU, Deputy Director Medicines Management	
	Mr J Kimpton	UCL, Clinical Research Fellow	
	Ms K Saxby	UCLH, Formulary Pharmacist	
	Mr A Lambarth	UCL, Clinical Research Fellow	
Apologies:	Ms P Taylor	NCL CCG, Head of Medicines Management (Haringey)	
	Ms S Lever	NCL CCG, Head of Medicines Management (Barnet)	
	Ms L Reeves	C&I, Chief Pharmacist	
	Mr T Dean	Patient Partner	
	Dr K Tasopoulos	NMUH, DTC Chair	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Dr A Bansal	NCL CCG, GP Clinical Lead Medicines Management (Barnet)	
	Mr A Shah	RNOH, Chief Pharmacist	
	Ms S Stern	NMUH, Chief Pharmacist	

**Deputising for Committee member*

2. Meeting observers

Ms Weaver (NHSE, Specialised Commissioning Pharmacist) was welcomed as an observer of the meeting.

3. Minutes of the last meeting

The minutes and abbreviated minutes of the 17 September 2020 meeting were accepted as an accurate reflection of the meeting.

4. Matters arising

4.1 Tolvaptan for SIADH

At the September JFC meeting, the Committee approved tolvaptan for SIADH in adults (conditional on Trusts incorporating tolvaptan into local hyponatraemia guidance). NCL Paediatricians had expressed an interested in tolvaptan for this indication however had not provided detail on the proposed place in therapy. The Committee heard there was very little data on the dosing, safety and efficacy in paediatrics. The Committee requested further detail from NCL Paediatricians before being able to consider a position for use of tolvaptan in paediatrics. No response has yet been received to date; Ms Thoong offered to follow-up the action on behalf of the Committee.

4.2 Compassionate access for nivolumab monotherapy and nivolumab/ipilimumab combination for metastatic colorectal cancer

Following the September JFC meeting, the Committee virtually approved the follow amendment to the commissioning arrangements for nivolumab in metastatic colorectal cancer.

- Nivolumab monotherapy for dMMR/MSI-H mCRC: Commissioned by NHS England until April 2021 [updating JFC November 2018 decision for compassionate access scheme]
- Nivolumab/ipilimumab combination for dMMR/MSI-H mCRC: Available via compassionate access scheme [JFC October 2019]

5. JFC Outstanding Items & Work Plan

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

6. Members declarations of conflicts of interest

Nil

7. Local DTC recommendations / minutes

7.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
RNOH	June 2020	Indocyanine green	Intraoperative imaging during bone and soft tissue tumour surgery	Decision: RNOH only Prescribing: Secondary care Tariff status: In tariff Funding: Hospital Fact sheet or shared care required: No
UCLH	September 2020	Belantamab mafodotin	Appeal - FoC scheme: Multiple myeloma patients who have received at least four prior therapies and who have demonstrated disease progression on their last therapy	Decision: UCLH only Prescribing: Secondary care Tariff status: N/A Funding: FoC Fact sheet or shared care required: No
UCLH	September 2020	Citrulline	Adult Inherited Metabolic Disorders	Decision: UCLH only Prescribing: Secondary care Tariff status: In tariff Funding: Hospital Fact sheet or shared care required: No

UCLH	September 2020	Creatine	Adult Inherited Metabolic Disorders	Decision: UCLH only Prescribing: Secondary care Tariff status: In tariff Funding: Hospital Fact sheet or shared care required: No
UCLH	September 2020	Methionine	Adult Inherited Metabolic Disorders	Decision: UCLH only Prescribing: Secondary care Tariff status: In tariff Funding: Hospital Fact sheet or shared care required: No
UCLH	September 2020	Levetiracetam IV	Second line agent for the management of status epilepticus not responsive to benzodiazepines	Decision: Added to the NCL joint formulary Prescribing: Secondary care Tariff status: In tariff Funding: Hospital Fact sheet or shared care required: No
UCLH	September 2020	Sodium valproate IV	Second line agent for the management of status epilepticus not responsive to benzodiazepines	Decision: Added to the NCL joint formulary Prescribing: Secondary care Tariff status: In tariff Funding: Hospital Fact sheet or shared care required: No
UCLH	September 2020	Methotrexate Injection	Ectopic pregnancy	Decision: Added to the NCL joint formulary Prescribing: Secondary care Tariff status: In tariff Funding: Hospital Fact sheet or shared care required: No
UCLH	March 2011	Rufinamide	Lennox-Gastaut syndrome epilepsy	Decision: Added to the NCL joint formulary Prescribing: Primary and secondary care Tariff status: In tariff Funding: Hospital/CCG Fact sheet or shared care required: Yes, existing NCL shared care guideline in place
MEH	August 2019	Fixapost® (Timolol + Latanoprost) preservative free eye drop	Glaucoma combination therapy - to be used when compliance/cost issues arise; restricted to patients with true preservative allergy and/or people with clinically significant and symptomatic ocular surface disease (evidence of epithelial toxicity and/or severe dry eyes). See NCL guideline for place in therapy.	Decision: Added to the NCL joint formulary Prescribing: Primary and secondary care Tariff status: In tariff Funding: Hospital/CCG Fact sheet or shared care required: No Additional information: Approved in accordance with the NCL glaucoma guideline

8. New Medicine Reviews

8.1 FoC: Liraglutide for maintaining eligibility for bariatric surgery Decision

Deferred to November JFC meeting

8.2 Lamotrigine for short-lasting unilateral neuralgiform headache attacks (Applicant: Dr A Bahra, NHNN)

The Committee considered an application for lamotrigine as a first-line agent for the prophylaxis of short-lasting unilateral neuralgiform headache attacks (SUNHA). SUNHA is a rare headache syndrome with subtypes including SUNA (SUNHA with autonomic symptoms) and SUNCT (SUNHA with conjunctival injection and tearing). The NCL Neurology Transformation Steering Group has developed an outpatient secondary care headache protocol which includes lamotrigine for SUNHA. A small number are proposed to be transferred to primary care once stabilised. Lamotrigine for SUNHA is standard of care at NHNN, however this has not been reviewed by UCLH UMC. The British Association for the Study of Headache guidelines (2019) recommends lamotrigine as the preferred choice (up to 400mg) with topiramate, carbamazepine and gabapentin listed as alternative choices. The Committee heard surgical and non-pharmaceutical approaches, including occipital nerve stimulation and vessel decompression, are restricted to medically intractable SUNHA because they are more costly, have uncertain benefit, are invasive and carry risk of complications including infection and nerve damage.

There are no randomised-controlled trials or case-controlled observational trials to support the use of lamotrigine for the prophylaxis of SUNHA. Evidence is limited to 5 small case-series (n=5 to n=88) in doses of ≤600mg per day. Each series identified patients in the outpatient clinic setting with a diagnosis of SUNCT/SUNA according to the international Classification of Headache Disorders where available. At baseline, patients reported 2 to 600 attacks per day. Limitations of the available evidence are extensive and include; small sample size, lack randomisation or comparators, lack of consistency and detail on the method of documenting or reporting attacks, unclear or inconsistently reported definition of 'response' (including non-numerical measures), absence of information relating to prior preventive treatments, and 3 of the 5 case-series reported data from NHNN so were likely to include the same patients.

In terms of safety, the SUNCT/SUNA case-series did not reported adverse events in detail. The Committee however accepted that the risk-profile was expected to be similar to that for licensed indications. Lamotrigine has a low risk of serious events however requires an initial low dose and slow titration to avoid skin reactions. There is an increased risk of teratogenicity associated with the use of lamotrigine, especially if used during the first trimester; patients need to be counselled appropriately.

In terms of cost, it is estimate that 10 patients per annum will be eligible for treatment with a corresponding budget impact of £2,500 per year.

The Committee heard from Dr Bahra that SUNHA are very short in duration and are therefore treated prophylactically rather than acutely; second-line prophylaxis treatment options include carbamazepine and topiramate. The diagnosis of SUNHA is based upon a compatible clinical history in the setting of a normal neurologic examination and is usually managed in secondary or tertiary care.

In camera, the Committee agreed the supportive evidence-base was extremely limited. Whilst Dr Bahra outlined the possible pathological genetic basis, this is not used to identify these patients and clinically it remains a clinical diagnosis as there are no diagnostic tests for the primary headaches. However, the committee agreed that lamotrigine was considered relatively safe, particularly when prescribed by clinicians experienced with the drug for other indications. Lamotrigine was noted as being inexpensive and if successful may negate the need for invasive and costly procedures. An n-of-1 placebo-controlled trial, to expand the available evidence-base, was considered feasible as a study of this type had been completed for topiramate at NHNN. In the absence of a trial, even an n of 1 it is likely that the evidence base for this indication will never be built up. The Committee requested information on requirement for women of childbearing potential to be counselled on the teratogenic risk of specific medications to be integrated onto the secondary care protocol, and for additional SUNHA prophylaxis medications to be put forward for addition to the formulary.

In summary, the Committee were supportive of the addition of lamotrigine for the prophylaxis of short-lasting unilateral neuralgiform headache attacks (SUNAH, including SUNA and SUNCT) to the NCL Joint Formulary subject to inclusion of the teratogenic risk on the protocol. The Committee requested that

NHNN Neurology team consider the feasibility of an n-of-1 trial design in order to substantiate the evidence base.

Decision: Deferred

Actions:

1. ***Integrate onto NCL secondary care headache pathway the requirement for women of childbearing potential to be counselled on the teratogenic risk of lamotrigine***
2. ***Additional SUNHA prophylaxis medications to be put forward for addition to the formulary***

9. Acid suppression therapy in paediatrics and those with swallowing difficulty

In July 2020, the Committee reviewed and did not approve licensed omeprazole suspension because it was not cost-effective. When working to remove omeprazole suspension from NCL Trust formularies, JFC Support identified that omeprazole suspension was required for paediatrics <1 year with a gastric tube. Lansoprazole suspension for this small cohort was considered inappropriate due to limited supportive evidence. The Committee anticipated that the budget impact in primary care would be limited. Owing to the lack of any suitable alternatives, the Committee agreed to retain omeprazole suspension on formulary only for '*paediatrics <1 year with a gastric tube*'; Trusts should remove omeprazole suspension from formulary for all other indications. An NCL guideline would be developed.

10. NCL JFC Glaucoma Guideline

The Committee reviewed an updated glaucoma guideline, developed by MEH and Islington CCG. The main change was the inclusion of Fixtapost® (latanoprost + timolol preservative-free eye drops) as the 1st line preservative-free, combination eye drop. A statement on the use of 1% apraclonidine had also been amended to highlight prescribing restrictions. The Committee heard from Dr Jayaram that preservative-free prescribing may be potentially higher than suggested in the guideline as there is professional and patient preference for this formulation, particularly in patients with a prospect of long-term use.; the clinical rationale for this being that preservatives may impact the surface of the eye and result in symptoms which consequently increase GP and ED attendance and/or treatment with ocular lubricants. The current recommendation to use preservative-free eye drops is in line with NICE. Mr Semple proposed that further work be carried out before broadening the recommendation for preservative-free eye drops. The guideline was approved with the current wording.

11. Next meeting: Thursday 19th November 2020

12. Any other business

NCL JFC vs DTC Application process

GOSH enquired as to which drug application should reviewed by JFC. Applications which impact primary care, are PbRe CCG commissioned medicines, or relevant to other NCL Trusts are reviewed at JFC. Applications which only impact a single Trust can be reviewed at local DTC. Applications for new drugs that are initiated in paediatrics and eventually will require transfer to adult services should also be considered at JFC.

Regional Formulary Project Updates

Mr Semple provided an update on current London region projects. A pan-London formulary harmonisation project is being coordinated by LPP; ophthalmological products are the first to be harmonised. In a related project, LPP are establishing the feasibility of a pan-London red list. Outputs from both projects will be brought back to the Committee (or NCL Medicines Optimisation Committee) when available.