North Central London
Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on Monday 19 November 2018
LG01, 222 Euston Road, London, NW1 2DA

Present:	Dr R Sofat	UCLH, DTC Chair	**(Chair)**
	Dr R MacAllister	NCL JFC Chair	Via phone
	Ms P Taylor	Haringey CCG, Head of Medicines Management	
	Mr A Dutt	Islington CCG, Head of Medicines Management	
	Dr M Kelsey	WH, DTC Chair	
	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	
	Ms K Davies	NEL CSU, Deputy Director Medicines Management	
	Mr P Gouldstone	Enfield CCG, Head of Medicines Management	
	Mr S Richardson	WH, Chief Pharmacist	
	Prof D Hughes	RFL, Consultant Haematologist	
	Mr T Dean	Patient Partner	
	Dr R Woolfson	RFL, DTC Chair	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Mr S Tomlin	GOSH, Chief Pharmacist	
In attendance:	Mr A Barron	NCL MEP, Lead Pharmacist	
	Dr P Bodalia	UCLH, Principal Pharmacist	
	Ms M Kassam	NCL JFC, Support Pharmacist	
	Mr G Grewal	NCL JFC, Support Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Ms S Sanghvi	UCLH, Formulary Pharmacist	
	Ms H Mehta	NMUH, Formulary Pharmacist	
	Ms Y Al-Hayali	MEH, Formulary Pharmacist	
	Ms H Thoong	GOSH, Formulary Pharmacist	
	Mr K Paik	MEH, Lead Pharmacist – Clinical specialities	
	Ms S Rahhal	SWL formulary pharmacist [Observer]	
	Mr H Patel	Islington CCG [Observer]	
	Dr D Thompson	UCLH, Clinical Pharmacologist	
	Dr H Amer	UCLH, Clinical Pharmacologist	
	Dr J Russ	ULCH, Acute medicine registrar [Observer]	
Apologies:	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	
	Mr TF Chan	RFL, Deputy Chief Pharmacist	
	Ms W Spicer	RFL, Chief Pharmacist	
	Ms L Reeves	C&I, Chief Pharmacist	
	Mr C Daff	NHS Barnet, Head of Medicines Management	
	Dr A Sell	RNOH, DTC Chair	
	Mr S Semple	MEH, Interim Chief Pharmacist	
	Ms A Fakoya	NEL CSU, Senior Prescribing Advisor	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist	
	Ms K Delargy	BEH, Deputy Chief Pharmacist	

2. Meeting observers

Dr Sofat welcomed Ms Thoong (GOSH, Formulary Pharmacist) and the following observers to the meeting: Dr Russ (UCLH Doctor), Ms Rahhal (SWL Formulary Pharmacist), and Mr Patel (Islington CCG Prescribing Advisor), and explained the role of the JFC.

3. Minutes of the last meeting

The minutes were approved subject to the following amends:

- Anakinra and tocilizumab for Adult Onset Stills Disease was added to the NCL Joint Formulary (not just RFL) for patients who meet the criteria outlined in NHSE Commissioning Policy 170056P
- Forceval® soluble tablets was added to the NCL Joint Formulary for the prophylaxis of refeeding syndrome (not just NMUH). Mr Barron highlighted that removal of Ketovite® tablets and liquid could be considered as a potential CIP for Trusts

4. Matters arising

4.1 Danazol and oxandrolone for prophylaxis of C1 esterase inhibitor deficiency and other bradykinin-mediated angioedema

RFL clinical team reported that patient numbers prescribed danazol for hereditary angioedema (HAE) prophylaxis are low. Danazol and oxandrolone are both on the RFL formulary predating 1999 (indication not specified). Records indicate oxandrolone has not been used for HAE prophylaxis. Clinicians at RFL request that patients' GPs continue prescribing danazol, particularly if the patient lives outside of region to aid the patient experience; otherwise the hospital will continue to prescribe. The Committee heard from primary care members their view that prescribing of these treatments by GPs is not suitable on the basis that HAE is a rare condition. The Committee agreed that both the initial and long-term prescribing of these treatments should continue within secondary care.

Decision: Approved
Prescribing: Secondary care
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: No

4.2 Omega-3 fatty acid ethyl esters (Omacor®, Mylan) for inherited hypertriglyceridaemia

The applicant for Omacor had not responded to the JFC decision. RFL DTC had reviewed JFC minutes and asked for guidance on how to manage the withdrawal of treatment for patients taking Omacor for primary prevention of pancreatitis. All queries will be discussed with the applicant as a priority.

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

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
MEH	Apr-18	Tocilizumab	Posterior Uveitis	Decision: MEH only Prescribing: Secondary care Tariff status: Excluded Funding: Trust (internally funded) - not routinely commissioned Fact sheet or shared care required: No

MEH	Apr-18	Rituximab	Posterior Uveitis	Decision: MEH only Prescribing: Secondary care Tariff status: Excluded Funding: Trust (internally funded)– not routinely commissioned Fact sheet or shared care required: No
RFL	Sep-18	Duodopa Intestinal Gel	Parkinson's Disease in line with NHSE clinical commissioning policy ref: D04/P/e	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: Excluded Funding: NHSE Fact sheet or shared care required: No
RFL	Sep-18	Susoctocog	Acquired haemophilia A in line with NHSE clinical commissioning policy 170061P	Decision: RFL only Prescribing: Secondary care Tariff status: Excluded Funding: NHSE Fact sheet or shared care required: No
RFL	Sep-18	N9 pegylated glycoprotein (FOC scheme)	Haemophilia B	Decision: RFL only Prescribing: Secondary care only Tariff status: N/A Funding: FOC Fact sheet or shared care required: No
RFL	Sep-18	Emicizumab	Congenital haemophilia A with factor VIII inhibitors in line with NHSE clinical commissioning policy 170067/P	Decision: RFL only Prescribing: Secondary care only Tariff status: Excluded Funding: NHSE Fact sheet or shared care required: No
UCLH	Oct-18	Pollinex Grasses+Rye and Pollinex Trees	For grass/tree-pollen seasonal allergic rhinitis requiring treatment with subcutaneous immunotherapy	Decision: UCLH only; restricted to RLHIM/RNTNE allergy clinics for patients experiencing adverse reactions to the allum content of Allergovit and UCLH paediatric allergy clinics as first line. Prescribing: Secondary care only Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No

7.2 **Approved under evaluation**

UCLH	Oct-18	Eptifibatide	Management of intra-procedural thromboembolic complications during cerebral aneurysm coil embolisation	Decision: UCLH only Prescribing: Secondary care only Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No

7.3 **Not approved**

Nil

8. **New Medicine Reviews**

8.1 **Erenumab (Aimovig®, Novartis and Amgen) 'pre-NICE zero cost' scheme: Chronic migraine prophylaxis for patients who have failed three previous treatments (Applicant: Dr B Athwal, RFL)**

The Committee reviewed an application for erenumab (pre-NICE zero-cost scheme) for patients with chronic migraine (defined as headache on at least 15 days each month, with the features of migraine headache on at least 8 days per month) and who have failed at least 3 previous preventative pharmacological therapies. This positioning is consistent with NICE TA for Botox for chronic migraine. A NICE TA for erenumab is expected in 2019. Alder, Lilly and Teva are also developing CGRP inhibitors: eptinezumab, galcanezumab and fremanezumab respectively (not yet licensed in the UK at the time the evaluation was conducted).

The Committee considered a phase II, randomised, double-blind, placebo-controlled, multicentre study of erenumab in adults with chronic migraine. Adults with a history of chronic migraine with ≥15 headache days per month, of which ≥8 were migraine days were included. Exclusion criteria included: no therapeutic response to >3 pharmacological prophylactic treatment classes; poorly controlled hypertension; MI; TIA; unstable angina; coronary artery bypass surgery or other revascularization surgery within 12 months prior to screening. Eligible patients were randomly assigned 3:2:2 to receive placebo, erenumab 70mg, or erenumab 140mg once every 4 weeks for a 4-week baseline phase and a 12-week double-blind treatment phase. Acute headache treatments were permitted during the study however migraine preventive drugs were prohibited. Results identified both doses of erenumab led to a greater reduction in monthly migraine days from baseline versus placebo (estimated treatment difference: -2.5 days [95% CI: -3.5 to -1.4] and -2.5 days [95% CI: -3.5 to -1.4] for 70mg and 140mg respectively). The changes in cumulative monthly headache hours were not significant (estimated treatment difference: -9.5 hours [95% CI: -27.0 to 7.9 hours] and -19.3 hours [95% CI: -36.7 to -1.9] for 70mg and 140mg respectively). A subgroup analysis identified a reducing placebo effect and subsequent increasing treatment effect with higher degrees of pre-treatment; the reduction in monthly migraine days for subjects with 0 prior failed medications was -0.5 days (95% CI: -2.4 to 1.5) compared with -4.1 days (95% CI: -4.8 to -2.3) for those with ≥3 prior failed medications.

A network meta-analysis (NMA) suggested the treatment effect for erenumab was similar to that of Botox (-2.4 days vs. -2.0 days respectively), when compared to placebo.

Erenumab was generally well tolerated in episodic and chronic migraine trials. Commonly reported adverse events by one year include injection site reactions, nasopharyngitis, upper respiratory tract infection and influenza. CGRP has a cardiovascular protective role and patients with prior cardiovascular disease were excluded from the study; despite this, arteriosclerosis, MI, and occurrences of electrocardiogram T-wave inversion were present in three patients after a year of follow-up.

Erenumab is formulated as pre-filled pen suitable for self-administration therefore is considered to be more convenient than botulinum toxin which must be administered by specialists in an outpatient clinic.

The Committee heard from Dr Athwal that chronic migraine has a detrimental impact on patients' quality of life and productivity and there are limited treatment options available, particularly for those who have tried ≥3 preventive migraine treatments. The only licensed medication in this situation is botulinum toxin, which requires administration by a trained clinician in the outpatient setting; as such clinics are at capacity. The applicant expressed a desire for erenumab to be positioned as an alternative to botulinum toxin, to improve patient access to effective therapies, but clarified that the highest unmet need was for those who had not responded to botulinum toxin.

The pre-NICE zero-cost scheme is open to recruitment until 30th September 2019 or a publication of a NICE TA, whichever is sooner. Patients enrolled on the scheme who respond to treatment at 12 weeks, as defined as 50% reduction in migraine days after 12 weeks of treatment, will receive FOC drug until (i) 90 days post positive NICE TA, (ii) 36 months post negative NICE, or (iii) 30th September 2022, wherever is sooner.

Using list prices, the annual treatment cost of erenumab is £5,038 compared with £3,259 (inc. VAT, administration and market forces factors) for botulinum toxin. This incremental cost was considered difficult to justify given the similar treatment effect observed in the NMA. Patient numbers were anticipated to be approximately 530 across RFL and UCLH in the first year, if positioned as an alternative to botulinum toxin.

In camera, the Committee acknowledged the poor quality of life associated with refractory chronic migraine. Erenumab is the first of a new class of medications which early data suggests is modestly

effective in migraine prophylaxis. The Committee were unable to support the proposal to use erenumab as an alternative botulinum toxin as it would interfere with established NICE treatment pathways. It was acknowledged that the scheme would result in more patients being on treatment 90 days post-NICE which would increase budget pressure on CCGs, however this was balanced against the efficiency savings associated with using the FoC scheme to identify patients who benefit from the intervention (40% of those treated) thereby minimising NHS funds spent on medicines in whom the drug is ineffective. The Committee agreed patients in whom botulinum toxin had failed had the greatest unmet clinical need.

In summary, the Committee agreed to approve the erenumab pre-NICE zero-cost scheme for patients who are contraindicated to botulinum toxin, or have failed botulinum toxin according to the NICE TA stopping criteria: "*defined as less than a 30% reduction in headache days per month after two treatment cycles*." All patients must consent to the terms of the FOC scheme (including risk of treatment withdrawal in the event of a negative NICE recommendation). Erenumab should not be offered to patients with poorly controlled hypertension, MI, TIA, unstable angina, coronary artery bypass surgery or other revascularization surgery within 12 months prior to screening, in line with the study exclusion criteria. Clinicians should use the 'erenumab FOC' Blueteq form if made available by NEL CSU.

Action: Applicant to clarify the following points:

- **Estimate of patient numbers in the approved cohort**
- **Confirmation that exclusion criteria in practice will mirror the clinical trial protocol ahead of NICE TA publication**

Post meeting note: TBC

Decision: Approved for use in headache clinics under a consultant neurologist specialising in headache disorders for patients who are contraindicated or have failed botulinum toxin
Prescribing: Secondary care only
Tariff status: N/A
Funding: FoC
Fact sheet or shared care required: No

8.2 Nivolumab (OPDIVO®, *Bristol Myers Squibb*) for mismatched repair deficient metastatic colorectal cancer – Compassionate Access Scheme (Applicant: Dr K Shiu, UCLH)

The Committee considered an application for nivolumab *in absentia* for the treatment of mismatched repair deficient (dMMR) metastatic colorectal cancer (mCRC) under a compassionate access scheme.

The Committee considered an ongoing, Phase 2, open-label, single-arm, multi-centre, international, 2-stage design trial of nivolumab monotherapy in adult patients with recurrent or metastatic dMMR/MSI-H (microsatellite instability high) CRC. Adults with a histological diagnosis and disease progression during or after, or intolerant of, at least one previous therapy, including fluoropyrimidine and oxaliplatin or irinotecan were included. Patients were given nivolumab 3mg/kg every two weeks until disease progression, death, unacceptable toxicity, withdrawal of consent or study end. The primary endpoint was the local investigator's objective response according to the RECIST criteria. Results from a data cut from January 2017 identified 74 patients with dMMR/MSI-H mCRC of which 31.1% (95% CI: 20.8 to 42.9%) responded to nivolumab. The median time to response was 2.8 months, median progression free survival was 14.3 months and 12 month overall survival was 73%. Improvements were found in symptoms and global quality of life compared to baseline. Adverse events include adrenal insufficiency, increased ALT levels, gastritis, pain, arthritis, increased lipase and increased amylase. 5 patients (7%) discontinued due to increased ALT, colitis, duodenal ulcer, acute kidney injury and stomatitis. Study weaknesses include the small sample size, the lack of a comparator, the open-label design, the heterogeneity of the study population, the interpretation of patient reported outcomes, discordance of MSI status between investigators and blinded independent reviewers, and the risk of selection bias.

Nivolumab has been granted an accelerated approval by the FDA for dMMR or MSI-H CRC, however this indication was not approved by the EMA due to uncertainties that the benefit outweighed the risk.

The Committee heard that the compassionate access scheme would be available for either two years post marketing authorisation or until a NICE technology appraisal is available (whichever is sooner). The Committee anticipated that some patients would require treatment for ≥2 years however the BMS scheme lacked the usual guarantee of FOC drug supply "until disease progression". The Committee agreed dMMR mCRC was a rare condition with very limited treatment options, and nivolumab appeared to offer some improvement in quality of life for these individuals. The Committee agreed BMS should

offer further assurances that patients who benefit from nivolumab should continue to receive FOC drug until nivolumab is routinely commissioned for this indication. Subject to these reassurances being obtained, the Committee approved the use of nivolumab in dMMR mCRC patients under the FoC scheme.

Action: To liaise with Bristol Myers Squibb to determine the length of treatment access under the compassionate access scheme

Post meeting note: Bristol Myers Squibb would not commit to unconditional FoC medication beyond two years post marketing authorisation if the drug is not reimbursed. Each patient would be reviewed by BMS individually for continuation beyond this time-point.

Decision: Approved pending DTC acceptance of terms of the compassionate access scheme (see post-meeting note)
Prescribing: Secondary care only
Tariff status: N/A
Funding: FoC
Fact sheet or shared care required: No

8.3 Lorlatinib (Lorbrena®, Pfizer): Compassionate Access Scheme: Anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer previously treated with a second generation tyrosine kinase inhibitor (Applicant: Dr K Shiu, UCLH)

The Committee considered an application for lorlatinib to treat anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer previously treated with a second generation tyrosine kinase inhibitor (alectinib or ceritinib) *in absentia*.

The Committee considered an ongoing, multicentre, open-label, single-arm Phase II trial of patients with histologically or cytologically ALK-positive or ROS1-positive, advanced NSCLC, with or without asymptomatic treated or untreated CNS metastases. Patients were enrolled into six different expansion cohorts (EXP1–6) on the basis of ALK or ROS1 status and previous therapy. All patients received lorlatinib 100 mg orally once daily continuously in 21-day cycles. An objective response was achieved in 32.1% (95% CI: 15.9 to 52.4%) of 28 patients with one previous non-crizotinib ALK TKI (EXP3B) and 38.7% (95% CI: 29.6 to 48.5%) of 111 patients with ≥2 previous ALK TKI (EXP4–5). Lorlatinib was associated with a slight improvement in quality of life from baseline.

Treatment options after failure of a second generation ALK tyrosine kinase inhibitor (TKI) are limited to single-agent chemotherapy which is minimally effective in this setting. In November 2018 the FDA granted accelerated approval to lorlatinib for patients with ALK-positive metastatic NSCLC whose disease has progressed on crizotinib [first-generation] and at least one other ALK TKI for metastatic disease or whose disease has progressed on alectinib or ceritinib as the first ALK TKI therapy for metastatic disease. Pfizer have confirmed that lorlatinib will continue to be provided on a free of charge basis for as long as the patient is deriving clinical benefit (as determined by the treating physician).

Despite an absence of comparative data for lorlatinib, the Committee agreed the risk-benefit over single-agent chemotherapy was likely to be favourable and therefore approved the use of lorlatinib for the proposed place in therapy under the compassionate access scheme.

Decision: Approved
Prescribing: Secondary care
Tariff status: N/A
Funding: FoC
Fact sheet or shared care required: No

8.4 High dose fexofenadine for the treatment of chronic spontaneous urticaria

The Committee considered the addition of high-dose fexofenadine use for the treatment of chronic spontaneous urticaria. Existing NCL guidance includes high-dose cetirizine and loratadine only, however when updating this guideline authors requested the addition of high-dose fexofenadine.

The Committee considered one open-label case series with 37 subjects. At baseline, the mean urticarial activity score (UAS) was 3.6 out of 6. Fexofenadine was given as 180mg daily for 1 week; if the patient remained symptomatic, they were given 360mg for the 2nd week; again, if the patient remained symptomatic, they were given 540mg from week 3. At the end of 4 weeks, the mean UAS was 0.2. There was a response in 36 out of the 37 patients, with rare mild adverse effects; 1 patient with mild sedation, and 2 patients with headache. The Committee noted that the design of the study (open-label case series)

makes it difficult to scientifically conclude efficacy of treatment without eliminating bias, further compounded with the absence of a comparator such as a placebo. Despite these limitations, the evidence was considered of marginally higher quality than that for high-dose loratidine which is already on formulary.

In terms of safety and tolerability, a review by Philpot EE (2000) found fexofenadine to be preferred to loratidine as it is generally non-sedating at high doses, is not metabolised by the cytochrome P450 pathway and does not have any significant cardiac effects.

The incremental cost of fexofenadine compared with cetirizine and loratidine was noted, and there was concern that the approval of fexofenadine could bring about a change in routine antihistamine prescribing away from the most cost-effective agents. It was confirmed that fexofenadine would be restricted to patients who have not had an adequate response to high-dose cetirizine and this approval was limited to chronic spontaneous urticaria.

Representatives from GOSH stated their clinicians use four-fold dosing of antihistamines for a range of allergic disorders and questioned if fexofenadine has use in other allergic disorders; this was noted to be out of scope of the evaluation so no decision could be made. The Committee approved the use of high dose fexofenadine for chronic spontaneous urticaria.

Decision: Approved
Prescribing: Primary and secondary care
Tariff status: In Tariff
Funding: Hospital/CCG
Fact sheet or shared care required: No

9. Proposal to remove alimemazine 10mg tablets and alimemazine (7.5mg/5mL and 30mg/5mL) solution from the NCL joint formulary for all indications

The Committee considered a proposal to remove alimemazine from the joint formulary for all indications. Alimemazine, a sedating antihistamine, is licensed for use in urticaria and pruritus, and in premedication to anaesthesia in children aged 2-6 years.

The Committee heard how the original product, Vallergan®, was granted a marketing authorisation in July 1998. Following the end of the patent, generic products by a company named Primegen was granted a marketing authorisation in 2015. Subsequently, Vallergan was removed from the market. This left the market open for Primegen to boost drug cost 30 fold.

Camden CCG and RFL have already completed work to remove alimemazine from their prescribing recommendations. Camden CCG's review of alimemazine for urticaria and pruritus identified a lack of evidence suggesting superiority of alimemazine over alternatives and concluded alimemazine is no longer cost-effective. RFL DTC has already removed alimemazine from their formulary, including previous use as a sedative pre-MRI scan for paediatric patients, where alternatives such as chloral hydrate solution and midazolam are now recommended.

Data from ePACT-2 for 6 months from April 2018 identified £63,000 of spend in primary care. DEFINE data suggests the largest current user within secondary care in NCL is GOSH at £12,000 over the same 6 month period, with some residual use at RFL. Prescribing at GOSH is largely for retching and vomiting post-surgery, and epidermolysis bullosa for which GOSH is a national centre. GOSH representatives agreed that given the low cost-effectiveness the use of alimemazine is now unjustifiable and agreed to work with clinicians to remove alimemazine from their formulary.

In summary, the Committee considered the evidence and supported the proposal to remove alimemazine (tablets and liquid) from Trust Formularies and CCG preferred lists for all indications.

Decision: Removal of alimemazine from the NCL joint formulary for all indications

10. Cannabis based products for medicinal use – interim statement and patient information

The Committee reviewed an interim statement and a patient information sheet for cannabis based medicinal product (CBPMs).

On November 1st 2018 the Misuse of Drugs Regulations was amended which has allowed the prescription of unlicensed CBPMs for human use by clinicians on the specialist register. Prior to this amendment one cannabis based medicinal product, Sativex®, was granted a marketing authorisation in the treatment of

symptoms related to multiple sclerosis. Following the amendment to the Misuse of Drugs Regulations, production of [unlicensed] CBPMs will begin, with all new products initially being manufactured as specials. Trusts are anticipating interest from clinicians and patients in the prescribing and supply of CBPMs. A statement from NHSE identified chronic pain, chemotherapy induced nausea and vomiting, and two distinct forms of childhood-onset epilepsy (Dravet's syndrome and Lennox-Gastaut syndrome) as potential indications. NCL Trusts have also received interest for some adult epilepsies and insomnia.

The position statement was drafted in order to enforce a position of safe and equitable treatment in that no prescribing or supply of CBPMs will be undertaken until JFC has reviewed a full evaluation of medical cannabis and the products that will be available for use. JFC will review CBPMs in January 2019. Separate documents have been created – one for medical professionals, and one for patients. It was clarified that this includes continuing prescribing for patients already on treatment; such patients should be referred back to their initiating clinician for further supplies if clinically indicated.

The Committee requested JFC Support contact NHSE about issued identified with using the interim statement, including the safety and legality of products currently in use by patients, and advice on assessing equivalence between new and existing products. It was also suggested to contact SPS to find out about any potential work into the various formulations of CPBMs. Once both parties have been contacted and any advice has been included on safety and legal aspects of patients already on medical cannabis, the documents will be circulated for approval via Chairs Action.

Action: JFC to contact SPS and NHSE for current work being undertaken into the CBPMs and any potential impact that the JFC interim position statements will have. Once complete, interim statement and patient information sheet to be updated and approved via Chairs Action.

11. Volanesoren for familial chylomicronaemia syndrome EAMS – FDA rejection

In June 2018, JFC approved an EAMS for volanesorsen to treat familial chylomicronaemia. During the Committee's original review, it was minuted that "the Committee had concerns about the safety profile, however took reassurance that the FDA voted to approve the drug (12:8 in favour)".

The subsequent FDA rejection of volanesorsen was considered by the Committee. Akcea had not declared why the FDA rejected volanesoren, however unresolvable concerns about drug safety were considered likely. The Committee agreed that until it is known why the FDA rejected volanesorsen (a move which signals that the benefits do not outweigh the risks) the Committee could not support use of this medicine. The approval for the volanesorsen EAMS was therefore withdrawn.

Decision: Not approved

12. Biosimilar adalimumab product choice

The CMU framework tender process has allocated NCL the following adalimumab biosimilars:

- Hyrimoz® (Sandoz; citrate containing): First-line 40mg dose,
- Amjevita™ (Amgen; citrate free): Second-line 40mg and first-line 20mg

Both biosimilars were added to the NCL Joint Formulary.

Decision: Approved
Prescribing: Secondary care
Tariff status: Excluded
Funding: CCG or NHSE
Fact sheet or shared care required: No

13. Next meeting

Monday 21st January 2019, 4.30 – 6.30pm, Venue: TBC

14. Any other business

14.1 Immediate release (IR) oxybutynin for hyperhydrosis

The Committee heard a request to add oxybutynin IR for hyperhidrosis to the NCL Joint Formulary. Oxybutynin is already on the RFL formulary for this indication, a decision which predates their DTC records.

NICE has published a favourable Evidence Summary in March 2017; data from three randomised, placebo-controlled trials indicate oxybutynin is associated with an improvement in quality of life and patient-reported hyperhidrosis severity.

Based on the prior approval at RFL DTC and the more recent positive NICE Evidence Summary, the Committee approved the use of IR oxybutynin for generalised hyperhidrosis across NCL. Oxybutynin MR for the same indication is still under evaluation at RFL and was not added to the NCL Joint Formulary.

Decision: Approved
Prescribing: Primary and secondary care
Tariff status: In Tariff
Funding: Hospital/CCG
Fact sheet or shared care required: No
Additional notes: Starting dose of 2.5mg titrated up to 5mg twice daily according to response.