North Central London
Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) – MINUTES
Minutes from the meeting held on 20th January 2022

Present:	Dr B Subel	NCL JFC Vice Chair	(Chair)
	Prof R Sofat	NCL JFC Chair	
	Mr S Semple	NCL ICS, Interim Chief Pharmacist	
	Dr M Kelsey	WH, DTC Chair	
	Dr K Tasopoulos	NMUH, 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 S Ishaq	WH, Consultant Anaesthetist	
	Ms W Spicer	RFL, Chief Pharmacist	
	Mr J Harchowal	UCLH, Chief Pharmacist	
	Mr G Kitson	WH, Deputy Chief Pharmacist	
	Mr A Stein	NMUH, Deputy Chief Pharmacist	
	Ms J Bloom	MEH, Associate Chief Pharmacist	
	Dr A Scourfield	UCLH, DTC Vice Chair	
	Dr A Worth	GOSH, DTC Chair	
	Ms G Smith	RFL, DTC Chair	
	Mr A Shah	RNOH, Chief Pharmacist	
	Mr T Dean	Patient Partner	
	Mr A Tufail	MEH, DTC Chair	
In attendance:	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 C OBeirne	UCLH, Formulary Pharmacist	
	Ms S Maru	UCLH, Formulary Pharmacist	
	Mr S O'Callaghan	UCLH, Medicines Safety Officer	
	Ms A El Bushra	MEH, Associate Chief Pharmacist	
	Ms M Kassam	MEH, Senior Pharmacist	
	Ms S Y Tan	NHS London Shared Service, Contract and Commissioning Support Pharmacist	
	Ms A Fakoya	NHS London Shared Service, Contract and Commissioning Support Pharmacist	
	Ms A Sehmi	NMUH, Formulary Pharmacist	
	Ms H Thoong	GOSH, Formulary Pharmacist	
	Ms M Thacker	RFL, Clinical Lead Pharmacist	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist	
	Dr D Burrage	WH, Consultant Clinical Pharmacologist	
	Ms A Blochberger	NHSE, Specialised Commissioning Pharmacist	
	Dr K Roy	UCLH, Consultant in Respiratory Medicine	
	Ms R Saggu	NHSE, Chief Pharmaceutical Officer's Clinical Fellow	
	Ms P Sharma	HEE, Chief Pharmaceutical Officer's Clinical Fellow	

Apologies:	Mr S Richardson	WH, Chief Pharmacist
	Mr A Barron	UCLH, Principal 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 H Weaver	NHSE, Specialised Commissioning Pharmacist
	Ms R Clark	NCL CCG, Head of Medicines Management (Camden)

2. Meeting observers

Dr Subel welcomed observers to the meeting.

3. Minutes of the last meeting

The minutes and abbreviated minutes of 18 November 2021 and 14 December 2021 meetings were accepted as an accurate reflection of the meeting.

4. Matters arising

4.1 Accelerated Access Collaborative (AAC) Rapid Uptake Products

The Committee noted the response from NHSEI to the NCL JFC Letter: Inclisiran and AAC Rapid Uptake Recommendations, and agreed that the original letter and response could be shared with other London ICSs to support implementation discussions. Mr Semple outlined that there has been further clarification that ICSs will hold responsibility for implementation of rapid uptake products (RUP), with AHSN support. Ms Sanghvi informed the Committee that JFC had received notice of the proposed RUP shortlist for 2022/23 and submitted consultation comments. She agreed to recirculate these to the Committee.

The Committee noted that plans to establish the lipid pathway and service delivery model for inclisiran had been delayed due to COVID vaccination work. The Committee agreed that a working group should be established in February to take this work forward, with representation from GPs, CCG medicines management teams, PCNs, and specialists. Ms Sanghvi agreed to work with UCL Partners to establish and support a lipid pathway working group, and ensure that final proposals are brought back to JFC for sign-off following consultation.

5. JFC Outstanding Items & Work Plan

These items were included for information only. Any questions should be directed to admin.ncl-mon@nhs.net.

6. Members declarations of conflicts of interest

Ms Saggu confirmed conflicts relating to non-promotional teaching activities, a panel discussion and a conference attended in relation to several companies that produce inhalers. Dr Roy confirmed historical conflicts relating to teaching activities funded by Chiesi and Astra Zeneca

7. Local DTC recommendations / minutes

7.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
RFL	Oct 2021	Rituximab	Nephrotic disease (Minimal change disease, MCD, and focal segmental glomerulosclerosis, FSGS)	Decision: RFL only Prescribing: Secondary care Tariff status: Tariff excluded Funding: Trust Fact sheet or shared care required: No
RFL	Nov 2021	Plenvu	Bowel cleansing	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No

RFL	Nov 2021	Peg-interferon Alfa-2A	Gastrointestinal neuroendocrine tumours (up to 5 patients per annum)	Decision: RFL only Prescribing: Secondary care Tariff status: Tariff excluded Funding: Trust Fact sheet or shared care required: No
UCLH	Oct 2020	FOC scheme: Belantamab mafodotin†	Treatment of relapsed/refractory multiple myeloma (after 4 previous lines of therapy	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	Oct 2021	Acetylcysteine	SNAP protocol to replace standard NAC protocol for management of paracetamol overdose for use in children and adults (subject to development of a local protocol)	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
UCLH	Oct 2021	Ferinject	Replace Venofer as first-line intravenous iron in paediatrics (subject to development of a local protocol)	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
UCLH	Oct 2021	Simeticone	As a pre-endoscopic drink for improved mucosal visibility	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
UCLH	Nov 2021	FOC scheme: Avapritinib	Advanced systemic mastocytosis (second-line following midostaurin)	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	Nov 2021	FOC scheme: trastuzumab and pertuzumab	HER2 positive cholangiocarcinoma (for patients who are ineligible for the HER2 positive clinical trial)	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	Nov 2021	FOC scheme: futibatinib	FGFR2 positive cholangiocarcinoma (second-line option for FRGR2 positive cholangiocarcinoma for patients who have failed treatment on pemigatinib)	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	Nov 2021	FOLFOX	Second-line therapy for cholangiocarcinoma following progression with gemcitabine and a platinum-based therapy, where a genetically targeted therapy isn't an option and no clinical trials are available	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No

UCLH	Nov 2021	Regorafenib	Cholangiocarcinoma with no targeted mutations where clinical trials and FOLFOX are not suitable	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
UCLH	Nov 2021	Zanubrutinib	In Waldenstrom macroglobulinemia with ibrutinib intolerance and disease progression.	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No

7.2 Approved under evaluation

DTC site	Month	Drug	Indication	JFC outcome
RFL	Nov 2021	Favipiravir	Chronic norovirus	Decision: RFL only Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
RFL	Nov 2021	Lanreotide LAR	Polycystic liver disease	Decision: RFL only Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No

7.3 Not approved

DTC site	Month	Drug	Indication	JFC outcome
UCLH	Nov 2021	Zanubrutinib	1. Relapsed/refractory disease after ≥1 prior treatment with DRC or BR 2. First-line treatment for symptomatic WM patients not eligible for DRC or BR 3. Patient is ibrutinib resistant and has disease progression	Decision: Not approved

[†]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.

7.1 Use of branded methotrexate (Zlatal®) for ectopic pregnancy

The Committee considered a commercially available methotrexate product licensed for intramuscular administration (Zlatal®) for off-label use in the treatment of ectopic pregnancy. The use of methotrexate in ectopic pregnancy is supported by NICE and RCOG guidance. Currently, intramuscular methotrexate for ectopic pregnancy is prepared in aseptic units of local Trusts. NMUH have been using the Zlatal® brand for the past two years both within and outside of regular working hours. The Committee determined that whilst it supported the ratification of Zlatal® for other interested NCL Trusts, the approval would be subject to local Trust DTC risk assessments to consider safe management, availability of different formulations, clinician feedback and development of local guidance or supporting information.

Decision: Added to the NCL Joint Formulary
Prescribing: Secondary care only
Tariff status: In Tariff

Funding: Trust

Fact sheet or shared care required: No

Additional information: Approval subject to local DTC risk assessment to consider safe management, availability of different formulations, clinician feedback and development of local guidance

8. New Medicine Reviews

8.1 Review of the inhalers on the NCL Joint Formulary: Amendments to minimise the carbon footprint of inhalers in NCL

The Committee considered several applications made by the NCL Inhaler Sustainability Group to optimise the choice of inhalers for asthma and COPD on the NCL Joint Formulary and promote prescribing of lower carbon footprint inhalers. From a sustainability perspective, there is a preference to use dry powder inhalers (DPIs) over pressurised metered dose inhalers (pMDIs) where clinically appropriate. Applications included (1) addition of Salbutamol Easyhaler® (for patients aged 4 onwards), (2) the triple therapy inhalers Enerzair® and Trimbow® (for use in adults with asthma), (3) preferred use of Salamol® pMDI over Ventolin® pMDI, and (4) restricting the use of Flutiform®.

Salbutamol Easyhaler® was considered for addition to the Joint Formulary to offer patients an additional DPI SABA choice to aid compliance. Licensing for Salbutamol Easyhaler® was supported by Tammivaara et al, which was a 12-week multi-centre, open-label study to compare the efficacy and safety of Salbutamol Easyhaler® and salbutamol pMDI for patients with previous corticosteroid use and who were SABA-responsive (n=115). The primary endpoint, change in peak expiratory flow rate from baseline after 12 weeks, was similar between treatment arms (48 ± 26 L/min vs. 55 ± 30 L/min). Key limitations of the study were the open-label design, the regular use of salbutamol and lack of detail regarding the statistical analysis results.

Enerzair® was considered for addition to the Joint Formulary to offer a triple-therapy combination device for asthma patients, as current low carbon footprint options were approved for use in COPD patients only. Enerzair® licensing was supported by the IRIDIUM study, which was a 52-week, multi-centre, double-blind, double-dummy study to compare the efficacy and safety of Enerzair® and an ICS/LABA combination device (indacaterol/mometasone) for adult patients with symptomatic asthma, at least one previous exacerbation in the previous year and FEV_1 <80% of their predicted value (n=3,092). Patients were randomised to one of five treatment arms (1:1:1:1:1); medium- and high-dose Enerzair®, medium- and high-dose indacaterol and mometasone, and a fifth arm which used fluticasone/salmeterol (which the study was not powered to compare Enerzair® against). The primary endpoint, the change from baseline trough FEV_1 at week 26, was significantly better with high-dose Enerzair® compared with high-dose ICS/LABA (320mL vs. 255mL; treatment difference 65mL [95% CI 31mL to 99mL]). Key limitations of the study were that the majority of patients had only one exacerbation in the previous year, and the primary outcome did not reach the minimum clinically important difference (though the EMA recognised that there was potentially less room for improvement in the chosen patient cohort).

Trimbow® was requested for addition to the NCL formulary, to offer a triple-therapy combination pMDI device for asthma patients, as currently Trimbow® had only been approved for use in COPD patients. Trimbow® licensing for asthma was supported by two parallel, 52-week, multi-centre, double-blind studies to compare the efficacy and safety of Trimbow® and an ICS/LABA combination device (formoterol/beclomethasone) for adult patients with symptomatic asthma, at least one previous exacerbation in the previous year and FEV_1 <80% of their predicted value. The TRIMARAN study (n=1,155) compared medium-dose Trimbow® with medium-dose ICS/LABA, and the TRIGGER study (n=1,437) compared high-dose Trimbow® with high-dose ICS/LABA (with an additional arm comparing against high-dose ICS/LABA with open-label tiotropium, but the study was not powered to detect differences compared with this arm). The first co-primary endpoint, the change from baseline trough FEV_1 at week 26, was significantly better with both medium- or high-dose Trimbow® compared with the relative dose of ICS/LABA (medium dose: 185mL vs 127mL; treatment difference 57mL [95% CI 15mL to 99mL]; high-dose: 229mL vs. 157mL; treatment difference 73mL [95% CI 31mL to 99mL]). The second co-primary endpoint, annualised rate of moderate and severe exacerbations over 52 weeks, was significantly better with medium-dose Trimbow but similar with high-dose Trimbow® compared with the relative dose of ICS/LABA (medium dose: 1.83 vs 2.16; RR = 0.85 [95% CI 0.73 to 0.99]; high-dose: 1.73 vs 1.96; RR = 0.88 [95% CI 0.75 to 1.03]). Key limitations of the study were that the impact of optimising the ICS dose first was not investigated, and the primary outcome did not reach the minimum clinically important difference (though

again the EMA recognised that there was potentially less room for improvement in the chosen patient cohort).

The proposal to use Salamol® pMDI in preference to Ventolin® pMDI was supported by data from PrescQIPP and recommendations by Greener Practice, which demonstrated that Ventolin® currently has double the carbon footprint than Salamol®. Similar data also supported the proposal to restrict prescribing of Flutiform®, which carries double the carbon footprint over other ICS/LABA devices due to the use of HFA227ea as a propellant (whereas other formulary inhalers use HFA134a, a propellant which carries a lower carbon footprint).

In terms of safety, the active ingredients and excipients of all proposed devices are well known to clinicians, having been used in other formulary inhalers. In terms of budget impact, JFC Support conducted a cost and carbon analysis to estimate the impact of switching 80% of current pMDI inhalers used in NCL to lower carbon impact choices. This was estimated to reduce the carbon footprint in NCL by 72%, but would cost an additional £458,500 per annum.

The Committee heard from several members of the NCL Inhaler Sustainability Group, who confirmed cross-sector, multidisciplinary support for formulary switches to inhalers with a lower carbon footprint, to support the NHS net-zero agenda and Greener NCL Board plans. The Committee were informed of pan-London work underway to harmonise inhaler choices, with cross representation from the NCL Inhaler Sustainability Group. NICE/SIGN guidance for adults is also expected to be updated with sustainability considerations in 2-3 years. In addition, it was noted that some pharma companies are considering reformulating their inhaler devices. Therefore the current proposals were noted to be an interim list of inhalers on formulary, which would require regular updates as the inhaler market and evidence base changes. The Committee requested further information on the timelines of the pan-London work and whether the proposed NCL position aligned with other ICSs, to ensure that the effort to implement switches was appropriately timed.

In camera, the Committee was satisfied with the level of efficacy and safety data supporting the proposed additions to formulary, and were convinced of the benefits in reducing carbon impact from the proposed changes to the Joint Formulary. The Committee were supportive of the efforts to evaluate sustainability of medicine choices and agreed that this aligned with other workstreams across the ICS. However, the Committee noted the significant budget impact and questioned whether further cost modelling work could quantify the benefit of driving better quality respiratory care alongside inhaler switches, in order to offset the budget impact, for example reducing oversupply of salbutamol inhalers. The Committee also discussed the need for pharma companies and national organisations to take responsibility for sustainability and address the budget impact of greener inhaler choices upstream. The Committee noted the changing landscape in terms of

In summary, based on the available evidence, the Committee agreed that the proposed formulary changes were clinically appropriate, however requested further review of options to offset the significant budget impact, and ensure alignment with pan-London work, before making a final decision.

Decision: Deferred

8.2 Dapagliflozin for type 1 diabetes mellitus

In October 2021, the marketing authorisation for dapagliflozin (a sodium-glucose transport 2 inhibitor) for the treatment of type 1 diabetes (T1DM) was withdrawn. The manufacturers AstraZeneca stated this was due to commercial reasons and not due to safety concerns. Subsequently, the previously approved NICE technology appraisal (TA597) for dapagliflozin in T1DM was withdrawn. The Committee therefore reviewed the NCL formulary status for dapagliflozin in T1DM.

The Committee considered an application for the continued use of dapagliflozin for patients specified in NICE TA597 with body mass index (BMI) ≥27 kg/m2 when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy, and only if insulin doses ≥0.5 units/kg of body weight per day, patients complete a structured education programme on diabetic ketoacidosis (DKA), and treatment is started and supervised by a diabetes specialist regularly. NICE TA597 also states to stop dapagliflozin if there has not been a sustained improvement in glycaemic control (a fall in HbA1c level of about 0.3% or 3 mmol/mol). NICE Committee specified these criteria to minimise the risk of DKA.

The DEPICT trials were 24 week, phase III, placebo-controlled, double-blind studies to assess the safety and efficacy of dapagliflozin for adult patients with inadequately controlled T1DM (HbA1c between 58.5 to

91.3 mmol/mol), who were prescribed insulin for 12 months or longer, required a total insulin dose of ≥0.3 units/kg/day and had a BMI≥18.5kg/m^2 (n=1,591). The primary endpoint, adjusted mean change in HbA1c from baseline at week 24, was significantly lower with dapagliflozin compared to placebo (-0.44% vs. -0.01%; p<0.001) in the subset specified by the NICE TA. The percentage reduction in mean body weight was greater with dapagliflozin (-3.11% vs. -0.01%; p<0.001). Key limitations of the studies highlighted by NICE were that patient characteristics in the trials, such as proportion of smokers and concomitant medication use, were dissimilar to the NHS patient population, and that the studies did not assess microvascular or macrovascular complications.

In terms of safety, dapagliflozin had a higher risk of euglycaemic diabetic ketoacidosis (DKA) compared to placebo (4% vs. 1%). NICE acknowledged the high risk of DKA and set out specific criteria in their (now withdrawn) TA to restrict use and minimise DKA risk. Patients were eligible for dapagliflozin in T1DM if they had BMI ≥27 kg/m2 and insulin alone did not provide adequate glycaemic control despite optimal insulin therapy (insulin doses ≥0.5 units/kg body weight/day). Patients had to complete a structured education programme on DKA, with treatment started and supervised by a diabetes specialist. NICE TA597 also specified stopping criteria, namely that dapagliflozin should be reviewed regularly every 6 months and stopped if there was no sustained improvement in glycaemic control (a fall in HbA1c level of about 0.3% or 3 mmol/mol). In NCL, dapagliflozin is on the red list for the T1DM indication and restricted to specialist prescribing only. The Committee heard that consultation with secondary care diabetes specialists indicated NICE criteria was always fulfilled during patient initiation and patients were carefully selected based on competency to recognise and manage signs and symptoms of DKA. Ketone and glucose monitoring requirements are outlined in NCL JFC guidelines. In the diabetologists' experience, a small number of patients have shown significant benefit with dapagliflozin for T1DM when managed according to the NICE TA criteria.

The Committee noted that the risk of DKA with dapagliflozin was highlighted in an MHRA Drug Safety Update and that the US FDA did not approve licencing of dapagliflozin for T1DM patients due to concerns over DKA. With the withdrawal of the license, risk minimisation materials for dapagliflozin in T1DM for patients and healthcare professionals are also no longer available.

The Committee questioned whether existing patients demonstrated sufficient awareness of recognising and managing DKA and whether the stopping criteria were enforced. The Committee acknowledged that dapagliflozin is licensed in other clinical conditions (e.g. chronic heart failure, chronic kidney disease, and in type 2 diabetes), therefore GPs must be judicious in distinguishing indication as dapagliflozin is on the NCL Red List for T1DM only.

In summary, the Committee agreed that dapagliflozin should be removed from the NCL formulary for T1DM and that patients should not be newly initiated on treatment, due to withdrawal of the license and NICE TA, and high-risk safety concerns with off-label treatment. However, the Committee also agreed that existing patients who are stabilised and deriving benefit should be allowed to continue treatment under specialist diabetologist supervision only, subject to a consultant review to establish that (1) the patient falls within previous NICE TA criteria and is deriving benefit (stop if there is no sustained improvement in glycaemic control; a fall in HbA1c level of 0.3% or 3 mmol/mol) (2) patient has good understanding of risk of DKA and how to manage this risk, including ketone monitoring requirements, (3) patient is aware of withdrawal of licence and off-label status, (4) prescribing of dapagliflozin for T1DM is from secondary care specialists only.

Decision: Removed from NCL Joint Formulary.
Existing patients stabilised on dapagliflozin for T1DM may continue treatment under specialist supervision, subject to review from consultant to check:

- Patient is still deriving benefit from treatment in accordance with NICE TA stopping criteria
- Patient has good understanding of risk of DKA and how to manage this risk, including ketone monitoring requirements.
- Patient is aware of withdrawal of licence and off-label status

Prescribing: Secondary care only for existing patients
Tariff status: In Tariff
Funding: Trust
Fact sheet or shared care required: No

9. MHRA Drug Safety Update: Adrenaline auto-injectors (AAIs)

The Committee were informed that Emerade 300micrograms and 500micrograms had been reintroduced to the market, alongside publication of an MHRA public assessment report with recommendations for effective and safe use of AAIs. JFC Support ran a stakeholder consultation to assess whether there was support for a preferential order of AAIs in NCL, and for further feedback on the recommendations from the MHRA. There was consensus that all AAIs should be available on the NCL formulary without a preferential order, to ensure resilience to supply shortages. The Committee and stakeholder feedback also supported development of NCL guidance to highlight and clarify key recommendations from the JFC and the MHRA. This action will be deferred to the NCL Shared Care Group.

10. Increased risk of death with pregabalin in Northern Ireland

The Committee reviewed the evidence related to a decision in Northern Ireland to remove pregabalin from their formulary in 2021 due to an increased risk of death. The Committee were informed that the incidence rate for pregabalin-related death within England and Wales was significantly lower than in Northern Ireland (0.58 per 100,000 versus 4.08 per 100,000). There were several limitations in the data, including lack of data on the total number of prescriptions for pregabalin in relation to the incidence of death, the country-wide data may have been skewed by higher rates in certain parts of the UK and lack of comparison data on incidence of deaths related to other drugs in the same class (e.g. gabapentin). The Committee were also informed that the MHRA are not currently considering regulatory action on this issue. The Committee noted additional concerns in relation to this class of drugs such as risk of diversion and over-prescribing. However, overall the Committee did not consider the available evidence sufficient to preclude the use of pregabalin in NCL when initiated and prescribed responsibly.

11. Position statement – infliximab for immune checkpoint inhibitor-induced colitis

The Committee were presented with a position statement to support the use of infliximab for immune checkpoint-inhibitor induced colitis, which was reviewed and approved by JFC in April 2021. The Committee approved the guidance.

Intervention: Infliximab for immune checkpoint inhibitor-induced colitis
Decision: Approved
Prescribing: Secondary care only
Tariff status: Excluded from tariff
Funding: CCG
Fact sheet or shared care required: No
Additional information: Approved in line with NCL guidance for infliximab for immune checkpoint inhibitor-induced colitis

12. Position statement – Ensure Plus Advance

The Committee reviewed and approved an updated position statement for Ensure Plus Advance.

13. NCL antiplatelets guideline and flow diagram for initiation of rivaroxaban and aspirin in PAD/CAD

The Committee reviewed an updated NCL guideline on antiplatelet options for cardiovascular disease, and a flow diagram for the initiation of rivaroxaban and aspirin for PAD/CAD in Acute Trusts. The Committee agreed the antiplatelets guideline could be approved via Chairs action pending minor amendments. The pathway was approved for use in NCL Acute Trusts.

14. Any Other Business

14.1 Anifrolumab for systemic lupus erythematosus

The Committee considered a request to review a free of charge scheme for anifrolumab, a type-1 interferon receptor blocker, for systemic lupus erythematosus (SLE). The request was made to allow access to the medication in advance of the NICE TA (estimated for publication in April 2022). The Committee did not consider it appropriate to review the FOC scheme for a cohort of patients due to the imminent publication of the NICE TA; however, the Committee agreed that individual cases could be considered by Trust DTCs in advance of the NICE TA in cases of exceptionality.

15. Next meeting

Thursday 17th February 2022