North Central London
Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) – MINUTES
Minutes from the meeting held on 21st April 2022

Present:	Dr B Subel	NCL JFC Vice Chair	(Chair)
	Dr K Tasopoulos	NMUH, DTC Chair	
	Dr G Smith	RFL, DTC Chair	
	Dr M Kelsey	WH, DTC Chair	
	Mr A Sell	RNOH, DTC Chair	
	Dr A Scourfield	UCLH, DTC Chair	
	Dr D Roberts	Islington Borough, Clinical Director	
	Dr R Urquhart	UCLH, Divisional Clinical Director	
	Ms K Delargy	BEH, Chief Pharmacist	
	Ms W Spicer	RFL, Chief Pharmacist	
	Mr A Shah	RNOH, Chief Pharmacist	
	Mr J Harchowal	UCLH, Chief Pharmacist	
	Mr S Richardson	WH, Chief Pharmacist	
	Ms M Singh	NCL CCG, Head of Medicines Management (Barnet)	
	Ms R Clark	NCL CCG, Head of Medicines Management (Camden)	
	Mr P Gouldstone	NCL CCG, Head of Medicines Management (Enfield)	
	Mr A Dutt	NCL CCG, Head of Medicines Management (Islington)	
	Ms E Mortty	NCL CCG, Deputy Head of Medicines Management (Haringey)	
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 H Thoong	GOSH, Formulary Pharmacist	
	Ms A Sehmi	NMUH, Formulary Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Mr H Shahbakhti	RFL, Formulary Pharmacist	
	Ms M Thacker	RFL, Clinical Lead Pharmacist	
	Mr A Barron	UCLH, Principal Pharmacist	
	Mr S O'Callaghan	UCLH, Formulary Pharmacist	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist	
	Mr J Flor	WH, Formulary Pharmacist	
	Ms A Fakoya	NHS London Shared Service, Contract & Commissioning Support Pharmacist	
	Ms S Y Tan	NHS London Shared Service, Contract & Commissioning Support Pharmacist	
	Ms H Weaver	NHSE, Specialised Commissioning Pharmacist	
	Dr S Sajid	NMUH, Consultant Physician and Nephrologist	
	Dr P Jasani	RFL, Consultant Haematologist	
	Dr S Gohil	UCLH, Consultant Haematologist	
	Dr P Harrow	UCLH, Consultant Gastroenterologist	
	Prof M Koepp	UCLH, Consultant Neurologist	
	Dr C Kortsalioudaki	UCLH, Consultant Neonatologist	
	Dr J Lambert	UCLH, Consultant Haematologist	
	Dr J Kimpton	UCLH, Clinical Pharmacology Registrar	
	Dr A Rismani	WH, Consultant Haematologist	
	Ms M Kassam	MEH, Senior Pharmacist	
	Ms I Ibrahim	NMUH, Senior Pharmacist	
	Ms S Maru	UCLH, Senior Pharmacist	

	Ms P Stepney	UCLH, Senior Specialist Neonatal Dietitian
	Ms J Toft	UCLH, Gastroenterology Pharmacist
Apologies:	Mr S Semple	NCL ICS, Interim Chief Pharmacist; GOSH, Interim Chief Pharmacist
	Dr A Worth	GOSH, DTC Chair
	Prof A Tufail	MEH, DTC Chair
	Dr S Ishaq	WH, Consultant Anaesthetist
	Dr D Burrage	WH, Consultant Clinical Pharmacologist
	Ms L Reeves	C&I, Chief Pharmacist
	Ms N Phul	MEH, Chief Pharmacist
	Ms S Stern	NMUH, Chief Pharmacist
	Ms J Bloom	MEH, Associate Chief Pharmacist

2. Meeting observers

Dr Subel welcomed observers to the meeting.

3. Members' declarations of conflicts of interest

Nil conflicts were declared. Ms Sanghvi asked all members and regular observers to complete a new form that has been circulated and a register of members' declarations of interest will be a standing item for future agendas.

4. Minutes of the last meeting

The minutes and abbreviated minutes were accepted as an accurate reflection of the March 2022 meeting.

5. Matters arising

5.1 Probiotics (ProPrems®): update on prevalence, surveillance and data collection form

In February 2022, the Committee could not recommend the use of probiotics (ProPrems®) for the prevention of necrotising enterocolitis based on limitations of the available evidence. The Committee deferred its decision and requested further information on baseline prevalence of NEC in interested Trusts, quality control data from the manufacturer, and details of the planned evaluation.

The company's statements on antibiotic susceptibility in bacteria for human consumption and strain identification control documents were presented to the Committee. Dr Kortsalioudaki informed the Committee that the incidence of NEC at UCLH for 2 years (2020/2021) was 6-7% and shared the data collection form intended to record details and outcomes of the patients receiving ProPrems®. The Committee considered the data collection form to be appropriate. Dr Kortsalioudaki also informed the Committee that the Getting It Right First Time (GIRFT) Clinical Services Questionnaire includes the use of probiotics in pre-term neonates and that UCLH's neonatal unit is non-compliant with this GIRFT recommendation. The Committee noted that incidence of NEC across all NICUs is also 7% and that UCLH incidence currently sits within the middle 50% of providers despite probiotics not being used.

The Committee noted that there was no feedback on NEC incidence from other Trusts. Dr Kortsalioudaki informed the Committee that UCLH is the only Level 3 unit in NCL and that Level 2 units at other hospitals in NCL are likely to have a low requirement for probiotics in preterm babies. Although other probiotics are available in the UK, they do not consist of the recommended composition from the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN; March 2020). Dr Kortsalioudaki also explained that hospitals that used other brands of probiotics (Labinic®) such as Cambridge University Hospitals NHS Foundation Trust have switched to ProPrems®.

In camera, the Committee discussed concerns about limitations in the evidence to show efficacy and long-term safety of the use of probiotics as prophylaxis for NEC. The Cochrane review (2020) described the evidence as low-certainty due to potential bias from small trials with unreliable methods, and concluded that further large, high-quality trials are needed to inform policy and practice. The Committee questioned why GIRFT had set a standard despite these limitations, but noted that GIRFT focuses on benchmarking and not mandatory, evidence-based recommendations. Overall the Committee could not be assured that the low quality and limited evidence for efficacy and safety was sufficient to recommend the use of probiotics to prevent NEC.

Decision: Not approved

5.2 Sucroferric oxyhydroxide (Velphoro®): primary care prescribing

In March 2022, the Committee approved the use of sucroferric oxyhydroxide (Velphoro®) for adult CKD patients on dialysis in line with NICE guideline (NG203), for initiation in secondary care. Continuation of prescribing in primary care was considered appropriate clinically with development of a shared care protocol or fact sheet, however the Committee requested clarification on the funding mechanism for this NHSE commissioned drug. NHSE commissioners confirmed that there is currently no funding route available which allows recharging primary care cost to NHSE.

5.3 FOC scheme application update: Cladribine for highly-active relapsing-remitting multiple sclerosis in years 3 and 4

This agenda item was deferred to the May 2022 JFC meeting.

5.4 FOC scheme: olaparib as adjuvant therapy for high-risk BRCA-mutated HER-2 negative early breast cancer

At the February JFC meeting, the Committee considered a FOC scheme for olaparib for high-risk BRCA-mutated HER-2 negative early breast cancer. The Committee deferred the decision for the cohort of patients with triple-negative BRCA-mutated early breast cancer with residual disease following neoadjuvant chemotherapy, as these patients also had access to capecitabine (regardless of their BRCA-mutation status) and NCCN guidance stated there was no data on sequencing or to guide selection. The Committee had requested more information on comparative data from the applicant.

The Committee were informed that there is no comparative data available, and there is unlikely to be a comparative study. Patients within this cohort were eligible for olaparib therapy in the pivotal OlympiA trial. The applicant requests that patients with a BRCA-mutation therefore have access to either olaparib or capecitabine at the discretion of the consultant based on tolerability, toxicity and clinical response. JFC Support reviewed the pivotal trial for capecitabine and was unable to do an indirect comparison with olaparib owing to variations in the study design and the use of different comparators.

The Committee noted the lack of clarity regarding criteria for choosing olaparib over capecitabine (and vice versa). Therefore, the Committee's concerns of potentially replacing an established line of therapy with a FOC scheme medication remained. However, the Committee heard that specialists in other NCL Trusts who were part of the original study have also indicated support to use olaparib over capecitabine. The Committee requested more information from other NCL specialists to clarify why olaparib was preferred over capecitabine, and to determine whether other London specialist Trusts are currently using the FOC scheme.

Decision: Deferred

Actions:

1) **To determine from NCL specialists why olaparib is preferred over capecitabine (and why clinicians remain unconvinced of capecitabine in this population)**
2) **JFC Support to determine use of the olaparib FOC scheme in other London specialist centres**

6. JFC Outstanding Items & Work Plan

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

7. Local DTC recommendations / minutes

DTC site	Month	Drug	Indication	JFC outcome
UCLH	Feb 2022	Hydroxoco-balamin (vitamin B12)	For patients with inherited intracellular disorders of cobalamin metabolism (cobalamin defects)	**Decision:** Added to the NCL Joint Formulary **Prescribing:** TBD (see below) **Tariff status:** In tariff **Funding:** Trust/CCG **Fact sheet or shared care required:** No **Additional information:** Suitability of transfer to primary care to be considered within JFC review of BIMDG formulary

UCLH	Feb 2022	Foetal analgesia (fentanyl, vecuronium and atropine)	Use in MMC, EXIT, FETO, shunts, feticide and intrahepatic in-utero transfusion procedures	**Decision:** UCLH only **Prescribing:** Secondary care **Tariff status:** In tariff **Funding:** Trust **Fact sheet or shared care required:** No
UCLH	Feb 2022	FOC scheme: Trametinib†	Refractory, multi-focal or high-risk Langerhans cell histocytosis	**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

† 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

8. New Medicine Reviews

8.1 Sodium zirconium cyclosilicate (Lokelma) for chronic hyperkalaemia (Applicant: Dr S Sajid)

The Committee considered an application for sodium zirconium cyclosilicate (Lokelma), a non-absorbable crystalline compound to remove potassium from the body, for six hyperkalaemia-related indications:

1. Patients with haemodialysis (HD) access failure (e.g. due to blocked or infected line)
2. Patients on dialysis with spikes in potassium levels (in liaison with parent dialysis team)
3. If hyperkalaemia precludes the use of renin angiotensin aldosterone system inhibitor (RAASi) therapy
4. Patients with acute kidney injury (AKI)
5. Post-renal transplant patients
6. Those who require hospital transfer

For indications 1 and 2, the Committee considered the evidence from the DIALIZE study. DIALIZE was a 4-week, Phase III, placebo-controlled, double-blind study to compare the efficacy and safety of Lokelma and placebo for patients with persistent hyperkalaemia despite adequate haemodialysis (pre-dialysis K+ >5.4mmol/L or higher after long interdialytic interval on day -7, as well as pre-dialysis K+ >5.0mmol/L after at least one short interdialytic interval on days -5 and -3) (n=196). Patients were randomised to Lokelma (5g to 15g on non-dialysis days using a titration regime) or placebo. The primary endpoint, proportion of responders (defined as pre-dialysis serum K+ following the long interdialytic interval of 4.0 to 5.0mmol/L), was significantly better with Lokelma compared to placebo (41% vs. 1% p<0.001]). In the other clinically important outcome of "rescue therapy" (defined as an intervention, such as dialysis, insulin plus glucose or other cation exchangers used given in severe hyperkalaemia of >6.0mmol/L) to urgently reduce serum potassium, events were infrequent in both groups (2.1% vs. 5.1%; statistical analysis not provided).

For indication 3, the Committee considered three pivotal studies previously considered by NICE for TA599. This includes two double-blind, randomised, placebo-controlled trials (a 48-hour RCT by Packham et al [ZS-003] and a 28-day RCT by Kosiborod et al [ZS-004]), which found statistically significant reductions in serum potassium compared to baseline when using licensed doses of Lokelma. The third study (Spinowitz et al [ZS-005]) was a multi-dose single-arm open-label study in patients with sustained hyperkalaemia at baseline (≥5.1mmol/L); after 12 months treatment of Lokelma 5g-15g daily, 88% of patients had a mean serum potassium of ≤5.1mmol/L during treatment.

The RCTs noted above also informed the use of Lokelma in indication 4, as these studies demonstrated an improved reduction in potassium level compared with placebo for acute treatment in patients with renal insufficiency. This was further supported by an additional phase 2 study by Ash et al (2015), which was a 2-day, double-blind, placebo-controlled dose-escalation study to compare the efficacy and safety of Lokelma and placebo in patients with stable stage 3 CKD hyperkalaemia 5.0-6.0mmol/L (n=90). In the group of patients that received Lokelma 10g TDS, mean maximal reduction in serum potassium was 0.92mmol/L. Compared to baseline, 24-hour urine collections demonstrated significantly better urinary potassium excretion with Lokelma 10g TDS compared with placebo (15.8mmol/24 hours vs 8.9mmol/24 hours [p<0.001]).

Indication 5 was supported by two retrospective studies. The first by Swanson et al (2021) was a single-centre retrospective study in patients with kidney transplant and hyperkalaemia of >5.1mmol/L (n=28). The mean total dose given to patients was 31 ± 23g. The primary endpoint, the mean decrease in serum potassium at

48hr, was 0.8 ± 0.6mmol/L. The second study was by Winstead et al, who described a single-centre, retrospective review of medical records in adult patients with kidney, liver and heart transplants on calcineurin inhibitors before and after initiation with Lokela (n=35). The authors found a mean decrease in serum potassium of 1.3mmol/L. Both studies were limited by the retrospective nature, and the study by Winstead et al was in letter format.

Indication 6 was not supported by a specific study, but rather based on an issue of practicality; the applicant requested to use Lokelma in patients with a serum potassium ≥5.5mmol/L short-term to facilitate patient transfer to satellite wards, which otherwise do not have adequate medical cover to initiate and monitor treatment of hyperkalaemia.

In terms of safety, the most commonly reported adverse events with Lokelma are hypokalaemia and oedema related events due to high sodium content. Lokelma requires monitoring to avoid overcorrection in patients on chronic treatment.

In terms of budget impact, Lokelma is estimated to cost up to £11,000 per annum for NCL Trusts, and up to £227,000 to £455,000 for up to 120 patients per annum requiring chronic administration in primary care (noting that patients who fit NICE TA criteria for commissioning are within this cohort). The Committee heard that Lokelma may offset costs due to a reduction in inpatient bed days (including ICU beds), reduced hospital admissions for hyperkalaemia related events, and that Lokelma would help patients maintain treatment with RAAS inhibitors – which in turn would reduce hospital admissions related to heart failure and other complications.

The Committee heard from Dr Sajid that most patients would receive Lokelma short-term during their inpatient stay only. Those who do require longer treatment post-renal transplant or to enable continued use of their RAAS inhibitor therapy should continue Lokelma in primary care. Currently, patients are not able to access chronic treatment for hyperkalaemia in primary care.

In camera, the Committee discussed the clinical benefits of Lokelma, but noted the challenge of quantifying savings from these benefits and therefore the significant potential budget impact. The Committee acknowledged that funding for cohorts who fit NICE TA criteria should already be allocated, but sought clarity to understand which indications are outside of the scope of the NICE TA, the related budget impact and the potential number of patients under each indication likely to require longer-term prescribing via primary care.

Decision: Deferred

Actions:

1) JFC Support to work with applicant to clarify indications that are outside of scope of the NICE TA, whether these are for acute or chronic prescribing and the related budget impact.

2) London Shared Service to support with budget modelling for patients that fall within the NICE TA scope. JFC Support to calculate budget impact for patients that sit outside of NICE TA.

8.2 Free of Charge scheme: Pirtobrutinib for relapsed/refractory CLL/SLL, MCL, and WM (Applicants: Dr S Gohil, UCLH; Dr J Lambert, UCLH; Dr A Rismani, WH)

The Committee considered a pre-NICE free-of-charge (FOC) scheme for pirtobrutinib, a non-covalent Bruton's tyrosine kinase (BTK) inhibitor, for adult patients with relapsed/refractory chronic lymphocytic leukaemia (CLL)/small lymphatic lymphoma (SLL), mantle cell lymphoma (MCL), and Waldenstrom macroglobulinaemia (WM) under a free of charge (FOC) scheme (Eli Lilly and Company).

There are no published RCTs in this cohort of patients with pirtobrutinib. The Committee considered the BRUIN trial, a phase I/II, unblinded study with no control arm to assess the safety and efficacy of pirtobrutinib for patients with B-cell malignancies (n=323). In the dose-finding phase I (n=203), patients were randomised to seven dose levels (50-300mg) of pirtobrutinib OD as monotherapy. In phase II (n=120), participants received pirtobrutinib 200mg OD as monotherapy.

The pooled overall response rate (ORR) of phase I and II was 63%, 52% and 68% in CLL/SLL (n=139), MCL (n=56) and WM (n=19), respectively. The ORR were similar for the sub-group analysis of patients who were pre-treated with a BTK. The primary endpoint of phase II, ORR, was 51% (CLL/SLL; n=37), 41% (MCL; n=17), and 50% (WM; n=2).

Key limitations of the study were that progression-free and overall survivals are not reported and that there was no comparator arm. The efficacy results were pooled from all dose ranges. The trial reports a short follow-up period and is therefore limited in assessing long term response and safety as the study is ongoing.

In terms of safety, results were pooled from all dose ranges and indications. The most common grade 1 or 2 adverse events reported were fatigue (20%), diarrhoea (17%), and contusion (13%). Neutropenia (4%) and febrile neutropenia (1%) were reported as grade 4. The trial noted that pirtobrutinib did not have adverse events, such as haemorrhages and atrial arrhythmias, associated with covalent BTK inhibitors.

In terms of budget impact, pirtobrutinib is free of charge with each patient requiring an individual contract with the company. The company will continue FOC supply until NICE reimbursement or clinician decision to stop treatment by treating physician, whichever comes first.

The Committee heard from Dr Gohil that the use of pirtobrutinib in CLL/SLL will be in line with the FOC scheme to use four lines of therapy (including a BTK inhibitor and chemotherapy) prior to starting patients on pirtobrutinib. Dr Rismani clarified that pirtobrutinib will be a fourth-line treatment for WM patients, after two lines of chemotherapy/immunotherapy and a BTK inhibitor.

In camera, Dr Jasani supported pirtobrutinib's use in B-cell malignancies due to the poor outcomes associated with this condition and promising early data. The Committee noted the early efficacy results particularly in patients who had failed prior BTK-inhibitors, albeit with limitations in the evidence, and the proposed use as an option for refractory patients after all other available lines of therapy had failed. The Committee discussed whether FOC pirtobrutinib may preclude eligibility of patients with MCL to receive CAR T-cell therapy and requested further clarification from the NHSE London Regional Team and NHSE cancer commissioning pharmacists.

In summary, the Committee agreed to add pirtobrutinib to the NCL Joint Formulary for relapsed/refractory CLL/SLL and WM as per the FOC scheme. The Committee requested clarification on commissioning for CAR T-cell therapy prior to approval for use in MCL.

Decision: Approved for relapsed/refractory CLL/SLL and WM. NHSE/I should be notified in line with NCL Free of Charge scheme guidance. Deferred – MCL
Prescribing: Secondary care only
Tariff status: N/A – Free of charge scheme
Funding: N/A – Free of charge scheme
Fact sheet or shared care required: No

9. Reviews of previous decisions

9.1 Brivaracetam – review of evaluation data

In 2016, the Committee reviewed an application for brivaracetam, an anti-seizure medication, as an adjunct for partial onset seizures. Despite the lack of comparative data between brivaracetam and levetiracetam, the Committee approved brivaracetam under evaluation for patients who had previously responded to levetiracetam but had to stop due to off-target effects (due to a perceived reduced risk of adverse effects with brivaracetam). In 2018, the Committee considered results of the ongoing evaluation; the Committee recommended that brivaracetam may hold value for a specific cohort of patients and requested that the selection criteria and evaluation process continue.

The Committee were presented with the final results of the brivaracetam evaluation. 161 patients with pharmacoresistant epilepsy were initiated on brivaracetam (39 patients with generalised epilepsy and 122 with partial onset epilepsy), and were followed up over a mean of 707 days. 94% had previously discontinued levetiracetam due to inefficacy or adverse effects. Following brivaracetam, 6.5% achieved seizure freedom for a minimum of 6 months, 23% achieved ≥50% reduction in seizure frequency for ≥6 months, and 51% experienced any reduction in seizure frequency. 22% of patients discontinued due to a lack of efficacy or worsening of seizures.

57% of patients had adverse effects with brivaracetam (most commonly low mood, fatigue and aggressive behaviour), and 23% discontinued due to adverse effects. In patients who had previously discontinued levetiracetam, 79% experienced similar adverse effects with brivaracetam, and 39% also discontinued brivaracetam.

The Committee heard from Prof Koepp that the evaluation is limited in reporting on efficacy as the switch to brivaracetam is due to issues in tolerance. There was a high proportion of patients who suffered similar adverse effects with both levetiracetam and brivaracetam, and this was not surprising due to both drugs having the same mechanism of action.

Clinicians would be keen to retain brivaracetam as a treatment option after levetiracetam to ensure patients who demonstrate an intolerance have a treatment option available to them; however, Professor Koepp noted that the mean of seven previous anti-seizure medications prescribed for patients in the audit does not reflect clinical practice. Levetiracetam is used early in the treatment pathway, and he therefore recommended against the restriction to use brivaracetam in patients with highly refractory partial onset epilepsy only.

In camera, the Committee considered the results of the audit and agreed that despite results of a slightly improved adverse effect profile, the data does not support the routine use of brivaracetam in patients who suffer off-target effects with levetiracetam, particularly given that a high percentage of patients experienced the same off-target effects with both levetiracetam and brivaracetam.

In summary, based on the evidence from the evaluation, the Committee could not recommend the use of brivaracetam for the treatment of partial onset seizures in highly refractory patients who suffered off-target effects with levetiracetam.

Decision: Not approved

Additional information: Patients who were initiated and established on brivaracetam during the evaluation period to continue on treatment; brivaracetam not to be initiated in new patients.

9.2 Feraccru – review of evaluation data

In December 2020, the Committee gave an interim approval for ferric maltol (Feraccru®), an oral iron tablet, for patients who suffered from IBD and mild to moderate anaemia who were actively following PHE advice to shield during the COVID-19 pandemic. Data from patients who were provided with Feraccru at UCLH were presented back to the Committee.

Of a total of 47 patients, 23 were excluded from the efficacy data results (5 lost to follow-up, 4 failed to complete therapy, 3 never started and 11 suffered adverse effects and were unable to complete treatment). Of the remaining 24 patients, success (defined as ≥2 g/dL rise in haemoglobin) was observed in 6 patients (12.8%). Partial success (defined as 1 to 2 g/dL rise in haemoglobin) was observed in 10 patients (21.3%). Failure of treatment was observed in 5 (10.6%) of patients, and an increase in iron (but not haemoglobin) was observed in 3 patients (6.4%).

In total, success or partial success was observed in 16 patients (34% in the intention-to-treat population). 9 patients went on to receive an intravenous iron infusion; however, none of the patients who had a complete or partial success with Feraccru required an iron infusion within the 3-month follow up. The applicants requested to continue use of Feraccru with defined criteria for eligibility, which would exclude patients who are poorly compliant with treatments and for the initial supply to be provided by the hospital to allow for a tolerability and compliance check.

The Committee heard from Dr Harrow and Ms Toft that patients who tolerated and responded to Feraccru were able to avoid an iron infusion, which has led to a decrease in treatment time and costs related to infusion clinic administration. Infusion clinic capacity remains challenging. A majority of patients in this audit had failed previous iron products, therefore the efficacy rate of 34% was considered substantial. Patient feedback indicated that patients who were used to coming in for infusions were initially reluctant to trial an oral product again, however the feedback improved and was positive from those who demonstrated a good response. There was mixed feedback from patients regarding tolerability.

The Committee recognised that the efficacy data presented did not suggest that Ferracru was more effective than intravenous iron and that due to the short follow-up period, the data could not demonstrate whether the use of Feraccru was delaying an eventual requirement for an intravenous iron infusion. The data found that the use of Feraccru led to the avoidance of 16 patients requiring intravenous iron, and it was difficult to quantify the savings in time and money that this provides. The Committee further noted that patient selection is challenging and relies on individual expertise within the UCLH clinical team rather than objective criteria. This would be challenging if the drug was adopted across NCL. The Committee requested additional data to understand how many patients require an iron infusion after initial response to Feraccru and the criteria for

patient selection, and therefore approved a 6-month extension to the approval at UCLH only to allow more time for data collection.

Decision: Approved under evaluation for further 6 months
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: No
Additional information: Approved for 6 months to allow for further data collection and consideration of patient selection criteria; applicant to return with follow-up data on patients who have an initial response to Feraccru but eventually require intravenous iron

10. For approval

10.1 Rheumatoid arthritis pathway

The Committee approved the updated rheumatoid arthritis high cost drug pathway.

10.2 Daily tadalafil position statement

The Committee approved the updated daily tadalafil position statement.

11. Next meeting

Thursday 19th May 2022

12. Any other business

The Committee was informed that Prof Aroon Hingorani was successfully appointed to the position of JFC Chair. Prof Hingorani will assume post from the May 2022 JFC meeting.