Joint Formulary Committee (JFC): Minutes

Minutes from the meeting held on 21st September 2023

		Present	Apologies
Members			
Prof A Hingorani	NCL JFC Chair	✓	
Dr B Subel	NCL JFC Vice Chair	✓	
Ms L Coughlan	NCL ICB, Deputy Chief Clinical Officer & ICS Chief Pharmacist	✓	
Ms W Spicer	RFL, Chief Pharmacist	✓	
Dr P Jasani	RFL, DTC Chair		✓
Dr K Boleti	RFL, DTC Chair		✓
Dr A Scourfield	UCLH, DTC Chair	✓	
Mr J Harchowal	UCLH, Chief Pharmacist	✓	
Dr R Urquhart	UCLH, Divisional Clinical Director	✓	
Dr K Tasopoulos	NMUH, DTC Chair	✓	
Ms A Stein	NMUH, Interim Chief Pharmacist		✓
Dr M Kelsey	WH, DTC Chair		✓
Mr S Richardson	WH, Chief Pharmacist	✓	
Dr S Ishaq	WH, Consultant Anaesthetist		✓
Dr A Worth	GOSH, DTC Chair		✓
Ms J Ballinger	GOSH, Chief Pharmacist		✓
Mr V Raman	RNOH, DTC Chair		✓
Mr A Shah	RNOH, Chief Pharmacist	✓	
Prof A Tufail	MEH, DTC Chair		✓
Ms N Phul	MEH, Chief Pharmacist		✓
Ms K Delargy	BEH, Chief Pharmacist		✓
Ms L Reeves	C&I, Chief Pharmacist		✓
Dr L Waters	CNWL, Consultant Physician in HIV		✓
Ms R Clark	NCL ICB, Head of Medicines Management (Camden)		✓
Mr P Gouldstone	NCL ICB, Head of Medicines Management (Enfield)	✓	
Ms E Mortty	NCL ICB, Interim Head of Medicines Management (Haringey)	✓	
Ms M Singh	NCL ICB, Head of Medicines Management (Barnet)	✓	
Mr A Dutt	NCL ICB, Head of Medicines Management (Islington)		✓
Dr D Roberts	NCL ICB, Clinical Director (Islington)	✓	
Attendees			
Ms S Sanghvi	IPMO Programme Team, JFC Principal Pharmacist		✓
Ms S Amin	IPMO Programme Team, Lead Pharmacist	✓	
Ms S Maru	IPMO Programme Team, JFC Support Pharmacist	✓	
Ms P Varu	IPMO Programme Team, JFC Support Pharmacist	✓	
Mr G Grewal	RFL, Deputy Chief Pharmacist	✓	
Ms I Samuel	RFL, Formulary Pharmacist		✓
Mr H Shahbakhti	RFL, Formulary Pharmacist	✓	
Ms H Bouattia	RFL, Formulary Pharmacist		✓
Mr A Barron	UCLH, Principal Pharmacist	✓	
Mr S O'Callaghan	UCLH, Formulary Pharmacist	✓	
Ms A Sehmi	NMUH, Formulary Pharmacist	✓	
Ms H Thoong	GOSH, Formulary Pharmacist	✓	
Mr D Sergian	MEH, Formulary Pharmacist		✓

Mr G Purohit	RNOH, Formulary Pharmacist		✓
Ms K Mistry	RNOH, Formulary Pharmacist	✓	
Ms S Ahmed	WH, Formulary Pharmacist		✓
Ms R Pointon	WH, Rotational Pharmacist	✓	
Mr J Flor	WH, Finance, Business and Performance Pharmacist		✓
Ms M Thacker	GOSH, Deputy Chief Pharmacist	✓	
Ms J Bloom	MEH, Associate Chief Pharmacist	✓	
Ms H Weaver	NHSE, Specialised Commissioning Pharmacist (Observer)		✓
Ms A Fakoya	NCL ICB, Contracts & Commissioning Pharmacist		✓
Ms P Hayre	NHSE, Specialised Commissioning Pharmacist (Observer)	✓	
Ms M Patel	NCL ICB, Prescribing Advisor (Observer)	✓	
Dr P Harrow	UCLH, Gastroenterology Consultant	✓	
Ms J Toft	UCLH, Gastroenterology Pharmacist	✓	
Ms N Taherzadeh	RFL, Gastroenterology Pharmacist	✓	
Dr V Talaulikar	UCLH, Associate Specialist in Reproductive Medicine	✓	
Ms M Formica	WH, Lead Respiratory Pharmacist	✓	

2. Meeting attendees

Prof Hingorani welcomed members, observers, and applicants to the meeting (see above).

3. Members' declaration of interests

The Declarations of Interests register for Committee members was included for information. No further interests were declared at the meeting.

4. Minutes of the last meeting

Minutes and abbreviated minutes will be circulated to the Committee via email for consultation prior to ratification post meeting.

5. Matters arising

5.1 Allergen immunotherapies for cat and dog

In June 2023, the Committee reviewed the use of allergen immunotherapies (AITs) across NCL. The approval for the use of AITs for cat/dog allergies was pending the following actions: i) clarification on whether a cat and dog AIT product is required, ii) development of strict criteria for use, and iii) identifying a single product to be made available on the formulary. The maximum number of patients eligible for treatment is approximately 5 per year. The criteria and product choice approved by the Committee are detailed below.

Eligibility criteria for use of cat/dog AIT (all must apply):

1. Significant symptoms and QoL impact
2. Unresponsive maximal medication (rescue or regular medication)
3. Unavoidable occupational exposure (e.g vet, carer, dog walker/groomer or hearing/seeing/emotional support animal)

Product choice: Clustek®– specialists confirmed a product is required for cat and dog allergies. As part of the original review, Lais® was reviewed for cat allergies only as Lais® is not available for dog allergies. Clustek® has a minimal cost difference compared to Lais®. Clustek® is a SCIT product and although a SLIT product would be more convenient, patient numbers are expected to be low, therefore the choice of SCIT vs. SLIT is less significant for this patient cohort.

In summary, the Committee approved the inclusion of Clustek® onto the NCL Joint Formulary for cat and/or dog allergies, where patients meet the eligibility criteria for treatment.

Medication: Clustek®
Decision: Added to the NCL Joint Formulary
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Additional information: Only approved for use with NCL JFC eligibility criteria

5.2 Bijuve HRT – Interim approval request

An interim approval request for the use of Bijuve®, an oral continuous combined hormonal replacement therapy (HRT) containing estradiol 1mg and body-identical progesterone 100mg, for use in postmenopausal women with an intact uterus and with at least 12 months since last menses, to reduce symptoms of oestrogen deficiency, was considered by the Committee. The Committee reviewed an application for Bijuve® for the same indication in October 2022, but this was not approved due lack of robust evidence of superior efficacy or safety in comparison to the available HRT products (Utrogestan® was available at the time). The new request for Bijuve was due to a national shortage of Utrogestan® (containing micronized progesterone 100mg); Bijuve would be an alternative option in women who are prescribed Utrogestan® as a separate component in their combination HRT regime but are unable to obtain supplies due to the ongoing shortage.

In terms of the evidence, since the previous JFC review, there was no new data on efficacy or safety to consider when comparing body-identical progesterone (contained in Bijuve®) vs. synthetic progestogens (e.g Kliovance®, Kliofem®). In terms of safety, some women choose not to take or are unable to tolerate synthetic progestogens due to side effects. Synthetic progestogens stimulate the androgen receptor and women can experience androgenic side effects (e.g acne, oily skin, hair on the body). Body-identical progesterone has no activity on the androgen receptor so fewer side effects are experienced. The applicant highlighted the significant safety concerns due to the shortage, as women are skipping or not taking their progesterone alongside their oestrogen, exposing them to increased risks of endometrial cancer. In practice, high numbers of GPs are seeking advice from secondary care on alternatives, and in addition high numbers of women are being referred from GPs to secondary care clinics due to breakthrough endometrial bleeding requiring costly interventions (i.e. pelvic scans, hysteroscopies) and GPs seeking advice on alternatives.

In terms of budget impact, the calculated cost of Bijuve® per patient per annum is lower than the cost of a combined HRT regime with Utrogestan® per patient per annum. In the previous review, the cost analysis for the combination therapy (Utrogestan® plus oestrogen product) was calculated using a weighted-average of all oral products. However, it has been recognised that Utrogestan® is more commonly prescribed with transdermal or gel oestrogen preparations which are more expensive. The updated cost analysis results in a cost-neutral and potentially cost-saving budget impact for the use of Bijuve® in the identified patient cohort.

The Committee heard from Dr Talaulikar regarding the practicalities of advising women on the alternatives to Utrogestan® and the limited options other than switching to synthetic progestogens (i.e Kliovance®, Kliofem®, Mirena® coil). Although the manufacturer advises stock is available, the experience in practice is that there are challenges in stock reaching all patients which is evident through the high number of referrals from GPs seeking advice on alternatives. The NICE guidance [NG23] on the management of menopause recommends transdermal HRT preferentially in those with a high VTE risk. It was clarified that patients who have a high VTE risk, and therefore receiving transdermal HRT for this reason, may not be considered for Bijuve® and would be offered an alternative e.g Mirena® coil. However, there are some patients with a moderate VTE risk, receiving transdermal HRT and Utrogestan®, who may temporarily be switched to Bijuve® until supply issues with Utrogestan® are stabilised.

In camera, the Committee agreed there would be benefit in evaluation of the evidence base to identify whether there is a clinical or safety difference between body-identical and synthetic progestogens. It was highlighted that a Serious Shortage Protocol has been issued for Utrogestan® which is valid until 29th September 2023. Therefore, patients may be able to obtain limited supplies. The Committee acknowledged that the supply appears to be variable which is causing issues across the primary and secondary care interface. An interim approval for 6 months is likely to help alleviate this issue.

In summary, given the challenges with prescribing HRT in primary and secondary care due to the unavailability of Utrogestan® and a cost-neutral budget impact for switching to Bijuve®, the Committee approved the use of Bijuve® for 6 months. The interim decision will be reviewed in 6 months.

Medication: Bijuve®
Decision: Interim approval – 6 months only
Prescribing: Primary and Secondary care
Tariff status: In tariff

Funding: Trusts/ICB
Fact sheet or shared care required: N/A
Additional information: The interim decision will be reviewed in 6 months.

6. Review of action tracker

Action tracker included for information. Closed actions have been updated on the tracker.

7. JFC outstanding items & work plan

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

7.1 Feraccru® Audit Evaluation: IBD patients with iron-deficiency anaemia

In December 2020, the Committee gave an interim approval for ferric maltol (Feraccru® 30mg BD for 3 months), an oral iron tablet, for patients who suffered from IBD and mild to moderate anaemia who were actively following Public Health England (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 in April 2022. The Committee approved a further 6-month extension to the evaluation period at UCLH to allow more time for data collection to: i) determine whether Feraccru® delayed an eventual requirement for IV iron, ii) quantify time and cost savings when using Feraccru compared to IV iron and, iii) outline criteria for patient selection for Feraccru®.

The patient selection criteria were outlined as inflammatory bowel disease (IBD) patients with iron deficiency anaemia with Hb in the range ≥80g/L but <120g/L in females, and ≥80g/L but <130g/L in males who have failed 2 previous oral iron products due to intolerance or inefficacy and are eligible for further oral iron treatment. Patients with Hb <80g/L continued to receive intravenous iron therapy.

Data from the evaluation period was presented as data from patients initiated on Feraccru® i) prior to April 2022 and ii) post-April 2022.

In the pre-April 2022 data, of a total of 47 patients, 24 were excluded from the efficacy data results (5 lost to follow-up, 5 failed to complete therapy, 3 never started and 11 suffered adverse effects and were unable to complete treatment). Of the remaining 23 patients, success (defined as ≥20g/L rise in haemoglobin) was observed in 6 patients (12.8%). Partial success (defined as 10 to 20g/L rise in haemoglobin) was observed in 9 patients (19.1%). Failure (defined as Hb still out of range or an increase of <10g/L) of treatment was observed in 5 (10.6%) 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 15 patients (31.9% in the intention-to-treat population). Within the 1-year follow-up period, 9 patients went on to receive an intravenous iron infusion; of which 2 had had a partial success with Feraccru®.

In the post-April 2022 data, of a total of 39 patients, 22 were excluded from the efficacy data results (5 lost to follow-up, 15 never started due to protocol or preference, and 2 suffered adverse effects and were unable to complete treatment). Of the remaining 17 patients, success was observed in 10 patients (25.6%). Partial success was observed in 2 patients (5.1%). Failure of treatment was observed in 5 (12.8%) patients. In total, success or partial success was observed in 12 patients (30.7% in the intention-to-treat population). Within the 1-year follow-up period, 5 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.

The success and partial success rate from the recent evaluation data is 12 out of 17 patients (71%). In terms of time savings, using Feraccru® instead of IV iron in these 12 patients was estimated to have saved 6 hours of prescribing and administration time in an infusion clinic (potentially rising to 20 hours if 2 cases were treated as a day-case). The Committee was also informed that there is an 8-week waiting list for IV iron and no waiting list to initiate Feraccru®.

In terms of cost savings, based on per-protocol Feraccru® patient numbers, £1800 of drug costs were saved if Feraccru® was used instead of IV iron. The Committee was informed that there would be no reduction in activity costs as the clinic time will be used to treat other patients such as patients that require biologics (for which there is also a waiting list).

In camera, the Committee agreed that although Feraccru® was inferior to IV iron in terms of efficacy, it can provide an alternative treatment option for patients that are not able to receive IV iron due to long waiting lists in some Trusts. From the results of the audit data, there was a signal that a proportion of patients achieved complete or partial success and the use of Feraccru® may mitigate against the need for iron infusions in patients with complete or partial success.

In summary, the Committee agreed to approve the use of Feraccru® inflammatory bowel disease (IBD) patients with iron deficiency anaemia (Hb≥80g/L to the lower limit of normal (i.e. <120g/L in females and <130g/L in males)) who have failed 2 previous oral iron products due to intolerance or inefficacy and are eligible for further oral iron treatment.

Medication: Feraccru®
Decision: Added to the NCL Joint Formulary
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

7.2 Feraccru® new proposal: IBD patients with iron deficiency without anaemia

The Committee considered a new proposal to expand the cohort of IBD patients with iron deficiency from those with anaemia (defined as patients with Hb≥80g/L to <120g/L in females and <130g/L in males) to those without anaemia (Hb≥120g/L in females and ≥130g/L in males and iron binding saturations < 10%).

The eligibility criteria of patients that would be initiated on this treatment includes IBD patients with iron deficiency (defined as Hb≥80g/L and iron-binding saturation <10%) and having trialled and failed, or are intolerant to at least two oral iron preparations. Patients are required to have good adherence to treatment (which will be confirmed during consultation) and should have a preference of using the oral formulation rather than the IV formulation. Response definitions were amended for the new proposed cohort. Success is defined as an increase in Hb by 20g/L or back in range or iron-binding saturations back in range (>20%). Partial success is defined as an Hb increase of at least 10g/L but still out of range or iron-binding saturations of 10-20% (if it was less than 10% when first starting). Failure is defined as an Hb still out of range or an increase of <10g/L or iron binding saturations <10%.

In terms of efficacy, the Committee was informed that there was no additional evidence for Feraccru® or other oral iron products to support this change in indication. The evidence previously reviewed by the JFC were the AEGIS-1 and -2 studies in IBD patients with iron-deficiency anaemia. Although the product is licensed for iron deficiency, the manufacturer also confirmed that there is no additional evidence to support the use of Feraccru® in iron-deficiency patients without anaemia.

The Committee was informed that the change in indication will increase patient numbers by approximately 20% and that a treatment pathway has also been developed to support this change of indication.

The Committee heard from Ms Toft that IBD patients generally have difficulty absorbing iron from food or supplements and tend to be iron deficient but is unsure if treating iron-deficiency patients without anaemia will help prevent them from becoming anaemic. The aim for treating this cohort of patients would be to avoid waiting for these patients to become anaemic before treating them.

In camera, the Committee discussed the lack of evidence to support the use of Feraccru® for patients without anaemia. Concerns were also highlighted regarding the significant increase in patient numbers and associated cost.

In summary, given the lack of evidence, the Committee did not approve the use of Feraccru® for use in IBD patients with iron-deficiency without anaemia.

Decision: Not approved

8. Local DTC recommendations/minutes

DTC site	Month	Drug	Indication	JFC outcome
BEH	January 2023	Paliperidone long-acting injection (Byannli)	Maintenance treatment of schizophrenia, in patients who are clinically stable on paliperidone 1- or 3-monthly injections.	**Decision**: Approved - BEH only **Prescribing**: Secondary care only **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: N/A
RFL	July 2023	Budesonide (oral)	IgA nephropathy for renal transplant patients	**Decision**: Approved under evaluation - RFL only **Prescribing**: Secondary care only **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: N/A

RFL	July 2023	Bevacizumab (Vegzelma)	Biosimilar switch from bevacizumab (Alymsys)	**Decision**: Added to the NCL Joint Formulary **Prescribing**: Secondary care only **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: N/A
UCLH	July 2023	Intraventricular daptomycin	CSF infection with vancomycin-resistant Gram-positive organisms	**Decision**: UCLH only **Prescribing**: Secondary care only **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: N/A **Additional information:** Approved pending guideline update and completion of risk assessment
UCLH	July 2023	Amantadine Modafinil	Management of fatigue in MS	**Decision**: Added to the NCL Joint Formulary **Prescribing**: Secondary care initiation, primary care continuation **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: N/A
UCLH	July 2023	Gabapentin	Management of spasticity in MS as a second-line option after baclofen, or as a third-line option in combination with baclofen	**Decision**: Added to the NCL Joint Formulary **Prescribing**: Secondary care initiation, primary care continuation **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: N/A
UCLH	July 2023	Diazepam	Management of spasticity in MS	**Decision**: Added to the NCL Joint Formulary **Prescribing**: Secondary care initiation, primary care continuation **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: N/A
UCLH	July 2023	Gabapentin Memantine	Management of oscillopsia in MS	**Decision**: Added to the NCL Joint Formulary **Prescribing**: Secondary care initiation, primary care continuation **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: N/A
UCLH	July 2023	Amlodipine Fluoxetine	Management of Raynaud's Phenomenon	**Decision**: Added to the NCL Joint Formulary **Prescribing**: Secondary care initiation, primary care continuation **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: N/A **Additional information:** Approved pending development of treatment pathway

9. New medicine reviews

9.1 Dienogest for endometriosis

Deferred.

9.2 Appeal: Budesonide Multimatrix tablets (Cortiment®) for Ulcerative Colitis

The Committee considered an appeal for budesonide multimatrix tablets (Cortiment®) (dose of 9mg daily for 8 weeks), a corticosteroid, licensed for the induction of remission of mild-to-moderate ulcerative colitis in patients where mesalazine treatment is not sufficient.

In March 2019, the Committee considered Cortiment® for induction of remission in mild-to-moderate ulcerative colitis where mesalazine is not sufficient and patients have an intolerance or contraindication to prednisolone. This application was not approved as the Committee agreed that Cortiment® is less effective and more expensive than oral prednisolone. Additionally, there was no direct or indirect evidence available to suggest Cortiment® would be associated with a lower risk of steroid-related side effects.

The appeal was made on grounds that the original decision was based on inaccurate or incomplete information. In terms of the treatment pathway, licensed, colonic-release Cortiment® was intended to be used in a second-line setting after mesalazine and in place of off-label, ileal-release budesonide capsules (Budenofalk®), in patients intolerant or contraindicated to prednisolone or patients at a higher risk of developing steroid-related side effects (e.g. diabetes, osteoporosis, hypertension, obesity, major psychiatric disorder, cardiovascular disease, stroke or previous steroid side effects).

In terms of efficacy, there is no direct head-to-head data comparing Cortiment® to prednisolone in ulcerative colitis patients. Travis et al (2014, n=410), conducted a phase 3, double-blind, placebo-controlled randomised trial to compare the safety and efficacy of Cortiment® to placebo. A non-powered arm of Entocort® (ileal-release budesonide capsules licensed for induction of remission in mild-to-moderate Crohn's disease) was also included as an active-control. This study was reviewed as Budenofalk® is also an ileal-release formulation. No statistically significant difference was found for the primary endpoint of combined clinical and endoscopic remission between Cortiment® and Entocort® (17% vs 13%; RR: 1.38, [95% CI: 0.72 – 2.65]). The main limitation of this study was that it was not sufficiently powered for this comparison.

With respect to the appeal, four pieces of evidence had been submitted focussing on: i) the mechanism of action and pharmacokinetic profile, ii) cortisol level suppression relative to prednisolone, iii) indirect corticosteroid-related adverse effect profile compared to prednisolone and iv) inclusion in the British Society of Gastroenterology (BSG) 2019 guidelines.

The Committee was informed that the mechanism of action of Cortiment® was included as part of the evaluation in 2019 but was not focussed on during the Committee meeting. The SPC states that Cortiment® is metabolised in the liver to metabolites of low glucocorticoid activity and that Cortiment® has a local action in the colon due to the multi-matrix formulation. This results in controlled topical release of budesonide with minimal systemic absorption. The manufacturer therefore claims that at similar doses to prednisolone, Cortiment® gives significantly less hypothalamic-pituitary-adrenal (HPA) axis suppression. During the 2019 evaluation, the manufacturers were contacted for comment and stated that these claims were supported by a study which used a standard oral budesonide formulation. This study was included in the Cochrane review. The Cochrane review also reported that no patients in the budesonide arm compared to 76% of prednisolone patients had a cortisol level below the lower reference limit. However, this was deemed as very low-quality evidence due to sparse data and unclear risk of bias.

The second piece of evidence submitted for the appeal was not previously considered by the Committee and compared the cortisol level suppression of prednisolone to Entocort®. Cortisol level suppression is an indicator of the bioavailability of systemic steroids and therefore used as an indicator of the steroid adverse effect profile. Studies by Rutgeerts et al (1994, n=176) and Campieri et al (1997, n-178) conducted double-blind, randomised, active-controlled studies in Crohn's disease patients comparing the efficacy and safety of Entocort® to prednisolone over a 10 and 12-week period, respectively. Both studies reported that serum cortisol levels fell below the lower reference limit for prednisolone but not Entocort®, suggesting a lower corticosteroid-related adverse effect profile for Entocort® compared to prednisolone.

The third piece of evidence was also not previously considered by the Committee and indirectly compared the corticosteroid-related adverse effects of various corticosteroids in inflammatory bowel disease (IBD) patients. Bonovas et al (2017; n=4819) conducted a network meta-analysis of 31 randomised controlled trials in patients with IBD (either Crohn's disease or ulcerative colitis) and reported that Cortiment® had significantly fewer corticosteroid-related adverse effects compared to prednisolone (OR: 0.25 [95%CI: 0.13 – 0.49]). There was no significant statistical difference between Cortiment® and prednisolone for serious adverse effects or discontinuation rates due to adverse effects. The main limitations of this study were that this was an indirect comparison of treatments based on a mixed IBD population and different doses were treated as the same intervention.

The final piece of evidence that had not previously been considered by the Committee is the inclusion of Cortiment® as a recommended treatment option for mild-to-moderate ulcerative colitis in the BSG guidelines (2019). The Committee acknowledged that the evidence reviewed in the guideline was the same evidence reviewed by JFC in 2019.

In terms of cost, Cortiment® is more expensive than prednisolone and marginally more expensive than Budenofalk® capsules per patient per treatment course. It had come to light ahead of the meeting that the way in which Cortiment® would be used varies in different Trusts across NCL and therefore, a consensus was required to estimate patient numbers and calculate the budget impact on NCL. The Committee noted that Budenofalk® enemas (approved for use by the JFC in 2018 for ulcerative proctosigmoiditis patients) was more expensive per treatment course than Cortiment® and therefore it's place in therapy relative to Cortiment® could be considered for this cohort of patients.

The Committee heard from Dr Harrow that the use of Cortiment® is based on the favourable safety profile rather than on improved efficacy compared to prednisolone. Licensed Cortiment® is preferred to be used instead of off-label Budenofalk® due to the colonic-release profile to treat a disease that affects the colon. The use of Cortiment® has potential to reduce the number of patients that may proceed to receive biologics which are costlier for the system.

In camera, the Committee discussed that it would be useful to consider the corticosteroid-related adverse effect profile over an 8-week period as opposed to a protracted course. The Committee agreed that further alignment across the Trusts on the proposed place in therapy of Cortiment® is required prior to making a decision on this application.

In summary, the Committee deferred the application for the use of Cortiment® in the proposed cohort until a consensus on place in therapy was reached by NCL gastroenterologists across all interested NCL Trusts.

Decision: Deferred pending consensus of place in therapy of Cortiment® among NCL gastroenterologists

10. Guidelines, Pathways and Position statements

10.1 Valproate Risk Minimisation Guideline Update

The Committee reviewed and approved updates made to the NCL Valproate Risk Minimisation Guideline, aimed at minimising the teratogenic risk of valproate to patients of childbearing potential in NCL, following feedback from the project pilot. All amendments were made in collaboration with the NCL valproate risk minimisation group. The rollout of these guidelines will be presented at upcoming DTC meetings at each Trust that initiates valproate.

10.2 NCL COPD Guideline Update

In March 2023 the Committee reviewed the lack of consistency amongst definitions for COPD patients who may demonstrate "steroid responsiveness". NICE defines asthmatic features/features suggesting steroid responsiveness as "any previous secure diagnosis of asthma or atopy, a higher blood eosinophil count, substantial variation in FEV1 over time (at least 400ml) or substantial diurnal variation in peak expiratory flow (at least 20%)". GOLD criteria of steroid responsiveness are defined by those who have eosinophils ≥300 cells/microlitre. Further research into the exact features of inhaled corticosteroid responsiveness is required. It was agreed that there was a need for NCL COPD guidance which included the recommendations from both NICE COPD guidelines (2019) and GOLD standards (2022). The updated NCL guidance for the acute and chronic management of COPD was presented to the Committee. It was highlighted that this would be an interim guidance and therefore subject to further update/discussion with respiratory clinicians with regards to ownership of the guidance (for future reviews), and official publication of the Pan-London COPD pathway.

In summary, the Committee approved the NCL treatment guidelines for the acute and chronic management of COPD as an interim measure, pending publication of the Pan-London COPD pathway.

10.3 Biosimilars update

The Committee were presented with recommendations on changes to biosimilar drug evaluations, biosimilar to biosimilar switching and the available patient information for biosimilars. It was agreed that:

1. Biosimilars which are being considered for adoption in NCL will not require submission of a full application, however, a brief review will be brought to JFC for consideration regarding addition to the formulary. This will consider any key differences (compared to originator or existing biosimilars) in:

- Licensing
- Device/formulation
- Evidence for efficacy, safety and immunogenicity
- Budget impact

2. Switching between biosimilar-to-biosimilar products is acceptable based on the MHRA guidance on the licensing of biosimilar products and EMA statement on interchangeability of biosimilars.
3. The current section on the NCL-MON website for biosimilars will be retired, and instead, links will be provided to generic information on biosimilars to support patients and healthcare professionals.

10.4 Next meeting

Thursday 19th October 2023

10.5Any other business

Nil