North Central London
Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on 19th November 2020

Present:	Prof R Sofat	NCL JFC Chair	(Chair)
	Dr P Taylor	NCL JFC Vice Chair	
	Dr M Kelsey	WH, DTC Chair	
	Ms W Spicer	RFL, Chief Pharmacist	
	Mr S Richardson	WH, Chief Pharmacist	
	Dr R Urquhart	UCLH, Chief Pharmacist	
	Mr S Tomlin	GOSH, Chief Pharmacist	
	Dr D Burrage	WH, Consultant in Emergency Medicine	
	Mr P Gouldstone	NCL CCG, Head of Medicines Management (Enfield)	
	Ms R Clark	NCL CCG, Head of Medicines Management (Camden)	
	Ms K Delargy	BEH, Deputy Chief Pharmacist	
	Ms S Lever	NCL CCG, Head of Medicines Management (Barnet)	
	Mr A Dutt	NCL CCG, Head of Medicines Management (Islington)	
	Mr T Dean	Patient Partner	
	Dr K Tasopoulos	NMUH, DTC Chair	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Mr A Stein	NMUH, Deputy Chief Pharmacist	
In attendance:	Dr P Bodalia	UCLH, Principal Pharmacist	
	Mr A Barron	North London Partners, MEP Project Lead	
	Mr G Grewal	North London Partners, JFC Support Pharmacist	
	Ms M Kassam	North London Partners, JFC Support Pharmacist	
	Ms H Thoong	GOSH, Formulary Pharmacist	
	Ms H Mehta	NMUH, Formulary Pharmacist	
	Mr V Soni	NHSE, Specialised Commissioning Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Mr F Master	RFL, Formulary Pharmacist	
	Ms K Davies	NEL CSU, Deputy Director Medicines Management	
	Mr J Kimpton	UCL, Clinical Research Fellow	
	Ms S Amin	UCLH, Formulary Pharmacist	
	Mr A Lambarth	UCL, Clinical Research Fellow	
	Dr M George	UCLH, Specialist Registrar Clinical Pharmacology	
	Dr A Hosin	UCLH, Specialist Registrar Clinical Pharmacology	
	Dr S Huq	UCLH, Consultant in Clinical Pharmacology	
	Ms SY Tan	NEL CSU, Contracting and Commissioning Pharmacist	
	Ms N Kubah	RFL, Formulary Pharmacist	
	Dr W Brownlee	UCLH, MS Consultant	
	Prof R Batterham	UCLH, Professor of Obesity, Diabetes & Endocrinology	
	Dr C Murray	RFL, Consultant Gastroenterologist	
	Dr P Harrow	UCLH, Consultant Gastroenterologist	
	Ms R Stennett	NCL Nutrition Group, Co-Chair	
	Ms C Biswas	WH, Consultant Obstetrician	
Apologies:	Ms P Taylor	NCL CCG, Head of Medicines Management (Haringey)	
	Ms L Reeves	C&I, Chief Pharmacist	

Mr A Shah	RNOH, Chief Pharmacist
Ms S Stern	NMUH, Chief Pharmacist
Mr S Semple	MEH, Chief Pharmacist
Mr A Tufail	MEH, DTC Chair
Ms G Smith	RFL, DTC Chair
Dr A Sell	RNOH, DTC Chair

2. Meeting observers

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

3. Minutes of the last meeting

The minutes and abbreviated minutes of the 21 October 2020 meeting were accepted as an accurate reflection of the meeting.

4. Matters arising

Nil

5. JFC Outstanding Items & Work Plan

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

6. Members declarations of conflicts of interest

Nil

7. Local DTC recommendations / minutes

7.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
UCLH	October 2020	Paracetamol	Patent ductus arteriosus (PDA)	Decision: Added to the NCL joint formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
UCLH	October 2020	Aspirin	VTE thromboprophylaxis following elective knee replacement in patients at low risk of VTE	Decision: Added to the NCL joint formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
UCLH	October 2020	Aspirin	VTE Thromboprophylaxis following periacetabular osteotomy	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
UCLH	October 2020	Bowel Preparation Protocol (Moviprep, Metoclopramide, Gastrografin, Phospho-soda, Bisacodyl)	Bowel cleansing protocol for Colon Capsule Endoscopy	Decision: Under evaluation at UCLH 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	October 2020	Glucose, insulin, potassium (GIK) infusion	Second-line therapy for low cardiac output in critical care	Decision: Not approved

8. New Medicine Reviews

8.1 FoC: Liraglutide 3.0 mg (Saxenda®) for maintaining suitability for bariatric surgery (Applicant: Prof Batterham, UCLH)

The Committee considered a free-of-charge (FOC) scheme for liraglutide 3.0 mg, a GLP-1RA receptor agonist, to maintain suitability for bariatric surgery whilst on the waiting list. Throughout the pandemic patients have gained weight whilst on waiting lists for bariatric surgery, where fewer procedures are taking place. Moreover, where surgical procedures are planned, the fact that patients have gained weight whilst waiting means that they are cancelled as patients are no longer suitable.

The evidence reviewed for the application was SCALE Obesity & Pre-diabetes; a 56-week, Phase III, placebo-controlled trial to assess the safety and efficacy of liraglutide 3.0 mg for in patients with stable body weight and BMI ≥30 Kg/m^2 or BMI ≥27 Kg/m^2 with risk factors (n=3,731). Key exclusion criteria were T1 or T2 diabetes and prior bariatric surgery. Results for the co-primary endpoints [weight change from baseline; proportion who lost ≥5% body weight from baseline; proportion who lost ≥10% body weight from baseline] were all in favour of liraglutide. The estimated treatment difference for liraglutide compared to placebo was a BMI/weight reduction of -5.4%. Subgroup analyses in higher risk patients and results from other trial support a consistent narrative of 4-5% weight-loss on average with liraglutide.

Liraglutide was safe with gastrointestinal disorders, although being very common, are usually transient and responsible for a small proportion (6%) of withdrawals from the trial. Risk of serious adverse events are low.

In terms of budget impact, liraglutide 3.0mg FOC is zero cost for 12 months only. The Committee heard from Prof Batterham that all surgeries would take place within this timeframe. The cost for refrigerated deliveries was estimated to be £10,000 per 200 patients.

The Committee agreed that the eligibility criteria and outcomes for 'SCALE Obesity & Pre-diabetes study' were not unequivocally aligned to the proposed context and the results should be considered with caution. The Committee heard from Prof Batterham that liraglutide would be used in addition to current best practice (including virtual support and very-low-calorie diet before surgery) and her clinic had experience of managing patient using GLP-1RAs remotely (via a clinical trial). Liraglutide would not replace surgery as surgery is much more effective. The Committee was made aware of the positive NICE Final Appraisal Determination for patients with BMI ≥ 35 Kg/m^2, pre-diabetes & high risk of developing cardiovascular disease; 49 of 60 (82%) of the patients proposed in the application would meet the TA criteria.

In camera, the Committee agreed that the liraglutide 3.0 mg was likely to reduce weight in the proposed population, were satisfied that weight gain during the current pandemic could be reduced, and that the desired outcome of 'maintaining eligibility for surgery' was likely.

In summary, the Committee agreed to add liraglutide 3.0mg FOC to the NCL Joint Formulary to maintain suitability for bariatric surgery whilst on the bariatric surgery waiting list. This approval was time limited for 1 year by which time it is anticipated that surgery waiting times will return to normal. All patients must consent to having treatment withdrawn after 1 year (irrespective of whether surgery had taken place or not), in line with the duration of the FOC scheme duration.

Decision: Approved
Prescribing: Secondary care only
Tariff status: NA – Free of charge
Funding: NA – Free of charge
Primary and secondary care Fact sheet or shared care required: No

8.2 High frequency vedolizumab for Ulcerative Colitis and Crohn's Disease (Applicant: Dr Murray, RFL)

The Committee considered an application for high frequency vedolizumab [intravenous every 4 weeks (q4w)] for patients with inflammatory bowel disease experiencing a secondary loss-of-response to standard frequency vedolizumab [intravenous every 8 weeks (q8w) or subcutaneous every 2 weeks (q2w)].

There were no randomised controlled trials identified comparing high frequency vedolizumab, to other possible interventions (e.g. biologic switching or surgical interventions) for the proposed population.

GEMINI Long Term Safety (LTS) study was a single-arm, open-label study investigating the safety of long-term vedolizumab q4w. The study population was heterogeneous however included a potentially relevant subgroup (11% of LTS study) who:

- responded to vedolizumab induction, then
- were randomised to vedolizumab q8w maintenance, then
- withdrew from the main efficacy studies [GEMINI I and II] due to
    - failure to achieve a clinical response by week 14, or
    - disease worsening, or
    - required rescue medication.

Results for this subgroup show that upon enrolment into the LTS study and subsequent commencement of vedolizumab q4w, 4% and 6% of patients with CD (n=57) and UC (n=32) respectively were in remission. At after 100 weeks of vedolizumab q4w, this increased to 19% and 22% respectively. In terms of critique, it is not known how similar the subgroup was to the proposed population (baseline characteristics are not provided). The absence of a comparator means it is unknown whether dose-escalation per se caused the improvement in remission rates; something which is made less certain by similar 'mean change in disease activity scores' being reported for patients who entered into the LTS study having withdrawn from vedolizumab q4w arms of GEMINI (due to reasons i to iii) – suggesting the difference may not be related to the increase in dosing frequency.

A meta-analysis by Peyrin-biroulet et al., which included four observational studies (n=111), found vedolizumab q4w recaptured response for vedolizumab q8w secondary loss-of-responders in 53.8% (95% CI: 21.8% to 82.9%) of cases. A single-centre retrospective study in UC reported a recapture rate of 91% and separate study in UC and CD reported a recapture rate of 50%

In terms of safety, the LTS study shows vedolizumab q4w is well tolerated and there no new trends for infections, malignancies, infusion-related reactions, or hepatic events.

In terms of budget impact, the applicant suggests 5% of patients require dose-escalation which would cost an additional £210,000 in Year 1 rising to £280,000 in Year 2. A cost-sharing scheme is in place to effectively provide the additional vials required for dose escalation at zero-cost; the scheme however was not considered viable for NCL due to the proposed use of rebates, high data requirement and administrative burden.

High frequency vedolizumab is licensed for secondary loss-of-response however was not included in the manufacturers' submission to NICE and therefore does not form part of NICE TA342 or TA352. NCL patients experiencing secondary loss-of-response to vedolizumab q8w therefore switch to a new biologic or JAKi, are referred for surgery, or submit an IFR for vedolizumab q4w funding approval (although absolute numbers for each is unknown). Thresholds for therapeutic drug monitoring of vedolizumab remain unvalidated; dosing is proposed to be adjusted based upon objective measures of disease activity until further data is available.

The Committee heard from Dr Harrow and Dr Murray that there are no prospective studies assessing the efficacy-exposure relationship, however in clinical practice it has been observed that patients with a high weight or lower albumin are less likely to respond. It is known that 15% of patients at UCLH and RFL have a drug level of approximately 0, a proportion of whom will respond to dose escalation. Patients at both centres who have no alternative therapeutic options are being referred to centres outside of NCL to access treatment, which presumably is being funded by NCL CCG.

In camera, the Committee agreed the data to support vedolizumab q4w was limited and was more limited than the data reviewed for high-intensity infliximab for UC in January 2018. Assurance was taken

from the LTS study that vedolizumab q4w was safe. The annual treatment cost (including activity) of approximately £30,000 per patient per annum means vedolizumab q4w is not cost effective.

In summary, the Committee agreed that a subset of patients may benefit from dose optimisation however at list-price, doing so was not cost-effective (Vote on the application: Accept [4], Decline [6], Abstain [2]). The Committee agreed that if Trusts could identify a mechanism to offset the budget impact, then high-frequency vedolizumab would be approved

Decision: Deferred

8.3 Vedolizumab first-line for Ulcerative Colitis (Applicant: Dr Harrow, UCLH)

The Committee considered an application for vedolizumab, an integrin antagonist, for first line therapy of moderately to severely active ulcerative colitis in adults.

VARSITY is a 52-week, Phase 3b, double-blind, double-dummy, multicentre, active-controlled trial to compare the efficacy and safety of vedolizumab and adalimumab in patients with moderately to severely active ulcerative colitis (n=769). Patients were randomised 1:1 to intravenous vedolizumab q8w or subcutaneous adalimumab q2w; dose escalation was not permitted in either arm. The primary endpoint of 'clinical remission' at week 52 was higher with vedolizumab than for adalimumab (31.3% vs 22.5%; ETD 8.8% [95% CI: 2.5 to 15.0%]). 'Endoscopic improvement' was also higher with vedolizumab (39.7% vs 27.7%) however 'corticosteroid-free clinical remission' was not. Prespecified analyses of clinical response (55.1% vs 43%), patient reported remission (50.1 vs 40.4%), patient reported improvement (52.0% vs 42.2%) were also higher with vedolizumab. The incidence of hospitalisation (3.9% vs 5.2%) and UC-related procedures (1.8% vs 2.1%) were uncommon. There was no apparent advantage of vedolizumab for patients using steroids or immunomodulators at baseline in terms of 'clinical remission' or 'endoscopic improvement'.

In the prespecified subgroup of patients using vedolizumab as their first-line treatment for UC [the population of interest], 'clinical remission' at week 52 remained higher with vedolizumab than for adalimumab (34.2% vs 24.3%; NNT = 10; ETD: 10.1% [95% CI: 2.8 to 17.1%]). 'Endoscopic improvement' was also higher with vedolizumab (43.1% vs 29.5%; NNT = 8) however 'corticosteroid-free clinical remission' was not.

In terms of adverse effects, vedolizumab had a similar risk of serious adverse events compared to adalimumab (7.3% vs 7.0%, excluding UC exacerbations). The incidence of infection was lower in the vedolizumab arm (23 vs. 35 events per 100 patient-years), however the incidence of serious infection was similar (1.6 vs. 2.2 events per 100 patient-years). There was no comparative safety data beyond 52 weeks.

Annual treatment costs for vedolizumab are substantially more than for biosimilar adalimumab (q2w or q1w). Preferential use of vedolizumab in the first-line setting would increase use of vedolizumab in this setting [from 36% to 60% of eligible patients], with an estimated budget impact of £480 000 in year 1. Some of this cost-pressure would be offset in the long term as patient treated with first-line vedolizumab would transition to cheaper agents (e.g. adalimumab and infliximab) as subsequent line therapy.

The Committee heard from Dr Harrow that the VARSITY study indicates superiority of vedolizumab in the first-line setting. Furthermore, when looking at the whole patient pathway, vedolizumab → TNF-inhibitors may be preferred to TNF-inhibitors → vedolizumab because whilst the effectiveness of anti-TNF is similar irrespective of place in therapy [EVOLVE study], the effectiveness of vedolizumab is greater when used 1st line [VARSITY; theoretical rationale for finding is that TNF-inhibitors reduce the efficacy of vedolizumab due to effects on leucocyte trafficking]. Greater exposure to TNF-inhibitors is thought to result in an increase in the rate of infections. It was proposed that first-year treatment costs should account for the fact that patients who fail to achieve an initial response will discontinue treatment and start an alternative; assuming discontinuation rates of 40% for both treatments, the effective average cost-pressure for "1st line vedolizumab and if no response, initiate adalimumab" was only £5,345 compared to "1st line adalimumab and if no response, initiate vedolizumab" [see post-meeting note].

In camera, the Committee acknowledged VARSITY found vedolizumab to be modestly superior to adalimumab, however confidence in this finding was reduced by inconsistent findings in some subgroups (concurrent immunosuppressants and corticosteroids) and a key secondary outcome (corticosteroid-free clinical-remission [for those using corticosteroids at baseline]). Additionally, the treatment effect may be an over-estimate in comparison to NCL practice, as adalimumab dose escalation was not permitted in

VARSITY. Balancing the uncertain and limited treatment benefit with the incremental cost and high budget impact, the Committee concluded it was unlikely that vedolizumab was cost-effective compared to adalimumab in the first-line setting. The recommendation to use low-cost biosimilars as the first-line drug would also be consistent with other high-cost drug pathways in NCL, including rheumatoid arthritis, psoriasis and psoriatic arthritis.

In summary, based on the perceived cost-effectiveness the Committee did not recommend the use of vedolizumab for the first-line management of ulcerative colitis (Vote on the application: Accept [4], Decline [6], Abstain [3]).

Decision: Not approved

Post meeting note: JFC Support reviewed the annual treatment cost presented by the applicant and confirmed it was correct assuming (i) no activity costs for intravenous infusions, (ii) vedolizumab SC used for maintenance and (iii) treatment discontinuation rates of 40% for both treatments due to lack of response. Modifying these assumptions and using VARSITY 'clinical response at week 14' rates returns an incremental cost of and £5,411 for "1st line vedolizumab SC and if no response, initiate adalimumab" (£6,616 for vedolizumab IV). It is the opinion of JFC Support that the approach suggested by Dr Harrow is superior to that used in the JFC evaluation. However, by assuming primary non-responders transition to the next treatment after 14 weeks (rather than staying on an ineffective treatment), the effectiveness gap between 1st line vedolizumab and 1st line adalimumab shrinks therefore the NNT increases. Subsequently the cost-per-endoscopic improvement would be in excess of £43,000 [NNT>8 x £5,411]. A cost-effectiveness analysis is required to estimate the £/QALY of competing treatment sequences, however in the absence of this, a drug which costs many times more than adalimumab but is at most 40% more effective ('clinical response at week 14' [70.1%-49.5%]/49.5%), is unlikely to be cost-effective. The budget impact assessment presented is expected to be accurate as it describes a shift in overall market share (rather than modelling treatment pathways for individual patients).

EVOLVE is a retrospective study of UC and CD participants who initiated first or second line vedolizumab or TNF-inhibitor. Limitations include: results were presented at the American college of Gastroenterology Annual Meeting and have not been published, reasons for vedolizumab discontinuation were not reported, infliximab represented the majority of TNF-inhibitor use, and the inherent biases associated with non-randomised, observational trials which can result in apparent effects which could be attributed to unmeasured or residual confounding alone.

8.4 Ensure Plus Advance for frail elderly people at risk of undernutrition

The Committee considered the evidence for Ensure Plus Advance, an oral nutritional supplement for frail elderly people at risk of undernutrition.

The NOURISH trial was a 90-day, Phase III, placebo-controlled study to assess the safety and efficacy of Ensure Plus Advance for hospitalised inpatients aged 65 years or older (n=652). Patient with congestive heart failure, chronic obstructive pulmonary disease, myocardial infarction or pneumonia were included. Exclusion criteria were extensive and included people with diabetes and those who reside in nursing homes. Patients were randomised to Ensure Plus Advance (350kcal, 20g protein, 11g fat and 45g carbohydrates in 237mL) or placebo (48kcal, no protein, no fat and 12g carbohydrates in 237mL) twice daily. The primary composite endpoint, 90-day post-discharge incidence of 'death or non-elective readmission', was not lower with Ensure Plus Advance compared to placebo (26.8% vs. 31.1%). Key limitations of the study were the lack of active comparator, lack of control of baseline nutrition throughout the study period, extensive exclusion criteria, extensive loss to follow-up, and the lack of generalisability as initiation was in hospitalised patients only. The study reports mortality was significantly lower with Ensure Plus Advance, however the study was not powered to detect this difference and therefore any incidental finding is hypothesis generating which requires testing in a larger study.

Current standard of care options used in NCL include oral nutritional supplements available on prescription (e.g., Aymes Shake) or non-prescription alternatives (fortified Horlicks). In terms of budget impact, Ensure Plus Advance is expected to cost up to an additional £1,149 per patient per annum compared to Aymes Shake, or an additional £1,478.40 per patient per annum compared to fortified Horlicks.

The Committee considered the evidence and agreed that results do not support any claim that Ensure Plus Advance is a superior product versus placebo, and by extension, to alternative recommendations for oral nutritional supplementation. The Committee also discussed the ethical approach to the study, and the environmental impact from the addition of another ready-to-drink formulation where each dose in individually sealed in a plastic container.

In summary, based on the evidence available, the Committee could not recommend the use of Ensure Plus Advance in place of alternative recommended oral nutritional supplements used in NCL.

Decision: Not approved

9. Uterotonic pathway for caesarean section

In July 2020, the Committee considered an application to use carbetocin for prevention of post-partum haemorrhage in patients undergoing Caesarean section and requested that an NCL uterotonic pathway be created. A pathway was presented to the Committee which was agreed between clinicians; oxytocin was not included on the pathway as carbetocin has a similar mechanism with a long duration of action. Carboprost was retained as a treatment option but positioned lower down the treatment pathway.

Ms Biswas stated that WH began using carbetocin in April 2020 and a comparison against data from 2019 demonstrated a modest reduction in major obstetric haemorrhage after introduction of carbetocin (3.3% vs 1.8%). Other additional benefits include improved experience for mothers, and reduced time required on labour ward recovery which has improved patient flow.

In camera, the Committee recapitulated the concerns from the original evidence review; in particular, the use of two separate pathways for vaginal and Caesarean delivery, and the order of uterotonics used in patients who switch from vaginal to Caesarean delivery. A suggestion to incorporate the pathway into local Trust guidance was not viable as the Committee heard NMUH have recently updated their treatment pathway with more treatment options. The Committee concluded that a subgroup should be formed to ensure a standardised treatment pathway is used across the sector.

10. Pre-NICE FoC: Siponimod for secondary progressive multiple sclerosis

In June 2020 the committee considered an application for siponimod (pre-NICE FoC scheme) for the treatment of secondary progressive multiple sclerosis (SPMS). The decision was deferred by the committee pending the outcome of a NICE review and to establish clearer eligibility criteria for the FoC scheme. A NICE TA published in November 2020 recommended siponimod an option for treating SPMS within its licensing for SPMS patients with active disease. The eligibility criteria of the FoC scheme matches the NICE TA, and the scheme is still being offering until commissioning is in place.

In summary, the committee were satisfied that all the deferred points had been addressed and therefore approved access to the FoC scheme.

Decision: Approved

11. JFC publication: Opicapone in Parkinson's Disease audit

The Committee was made aware of an JFC evaluation that had been accepted for publication.

12. Summary of antibiotic treatment options for proven or suspected infections due to MDR aerobic, carbapenem-resistant gram-negative pathogens

NCL Consultant Microbiologists, NCL Antimicrobial Pharmacists and JFC Support had produced a summary of the options available for the treatment of resistant gram-negative infections. The summary was approved and would be uploaded to the website and NetFormulary.

Cefiderocol for the treatment of Ambler class B beta-lactamase producing (aka metaloenzyme producing) pathogens with proven susceptibility to cefiderocol with no other suitable treatment options (including ceftazidime + avibactam, ceftolozane + tazobactam and meropenem + vaborbactam)

Decision: Approved in line with the NCL summary of options available for treatment of resistant gram-negative infections
Prescribing: Secondary care, microbiologist approval only
Tariff status: In tariff
Funding: Hospital
Primary and secondary care Fact sheet or shared care required: No

Meropenem/vaborbactam for treatment of infections due to proven or suspected multi-drug resistant aerobic, gram negative pathogens that have susceptibility to meropenem/vaborbactam and other agents cannot be used due to intolerability, contraindication, allergy or interactions; these would usually be KPC producing pathogens.

Decision: Approved in line with the NCL summary of options available for treatment of resistant gram-negative infections
Prescribing: Secondary care, microbiologist approval only
Tariff status: In tariff
Funding: Hospital
Primary and secondary care Fact sheet or shared care required: No

13. COVID-19 vaccination programme update

This item was deferred to December JFC meeting

14. Alternative H2-antagonists for pre-medication in chemotherapy protocols

The Committee considered the use of famotidine or nizatidine (H2 receptor antagonists) within chemotherapy or desensitisation protocols for prophylaxis of histaminergic reactions, where ranitidine is unavailable. Both medicines are listed as potential options in the British Oncology Pharmacists Association; there is more evidence for use of famotidine, though use is dependent on availability which has proven unreliable over the past year. The Committee agreed that both medicines should be added to the NCL Joint Formulary as an option for Trusts whilst ranitidine is unavailable.

15. Next meeting

Tuesday 8th December 2020

16. Any other business

16.1 Dapagliflozin

The Committee agreed dapagliflozin was effective for patients with HFrEF NHYA II to IV. Further, dapagliflozin was potentially more convenient than sacubitril valsartan (NICE TA388) as dose-titration is not necessary. It was noted that NICE did not prioritise this TA during the COVID pandemic "this appraisal has not been defined as therapeutically critical" therefore the Committee agreed to wait for the TA guidance (anticipated publication 3rd Feb 2021). As an alternative, and in line with RFL DTC processes, the application may be reviewed locally. In the interim, the Committee encouraged the applicant to support the development of a HFrEF pathway for the sector (making clear the place in therapy) and to develop any local supporting information for GPs (who will eventually take on prescribing).

16.2 Evaluation of dietetic products

In relation to Ensure Plus Advance (item 8.4), it was noted that JFC Support had progressed with an appeal received from the manufacturer rather than an NCL clinician. The Committee agreed this was not aligned with established practice or the Committee's Terms of Reference. The Committee heard that on this occasion it was necessary to consider the appeal from the manufacturer, as the Committee had previously not reviewed the underlying evidence, but rather had accepted the recommendation of the NCL Dietetics Committee. It was agreed that going forward, dietetic critical evaluations would be written by NCL dieticians and presented to NCL JFC alongside any future position statements to support informed decision making. No further appeals from the manufacturer would be accepted for dietetics or medicines.