North Central London
Medicines Optimisation Network

Joint Formulary Committee (JFC): Minutes

Minutes from the meeting held on 16th February 2023

		Present	Apologies
Members			
Prof A Hingorani	NCL JFC Chair		✓
Dr B Subel	NCL JFC Vice Chair	✓	
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; NCL ICS, Interim Chief Pharmacist	✓	
Dr R Urquhart	UCLH, Divisional Clinical Director	✓	
Dr K Tasopoulos	NMUH, DTC Chair	✓	
Ms S Stern	NMUH, 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)	✓	
Mr T Dean	Patient partner		✓
Attendees			
Ms S Amin	IPMO Programme Team, JFC Principal Pharmacist	✓	
Mr G Grewal	IPMO Programme Team, JFC Support Pharmacist	✓	
Ms S Maru	JFC Support Pharmacist	✓	
Ms P Varu	JFC Support 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	✓	
Ms H Weaver	NHSE, Specialised Commissioning Pharmacist	✓	
Ms A Blochberger	NHSE, Specialised Commissioning Pharmacist		✓
Ms A Fakoya	NCL ICB, Contracts & Commissioning Pharmacist	✓	
Dr A Hosin	UCLH, Clinical Pharmacology Registrar		✓
Ms EY Cheung	NCL ICB, Deputy Head of Medicines Management (Camden)		✓
Ms K Mistry	RNOH, Formulary Pharmacist	✓	
Ms S Ahmed	WH, Formulary Pharmacist		✓
Ms L Garubova	WH, Formulary Pharmacist	✓	
Mr J Flor	WH, Finance, Business and Performance Pharmacist	✓	
Ms M Thacker	RFL, Clinical Lead Pharmacist	✓	
Mr G Purohit	RNOH, Formulary Pharmacist		✓
Ms J Bloom	MEH, Associated Chief Pharmacist	✓	
Ms S Mahmoud	NHSE, Specialised Cancer Commissioning Pharmacist	✓	
Mr H Addada	CLCH, Medicines Management Pharmacist	✓	
Mr I Quarm	NCL ICB, Deputising for HoMM (Haringey)	✓	
Dr P Harrow	UCLH, Consultant Gastroenterologist	✓	
Ms J Toft	UCLH, Gastroenterology Pharmacist	✓	
Ms N Taherzadeh	RFL, Gastroenterology Pharmacist	✓	
Dr J O'Nions	UCLH, Consultant Haematologist	✓	

2. Meeting observers and members

Dr Subel welcomed members, applicants and observers 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 relevant to the agenda were declared by members.

4. Minutes of the last meeting

Draft minutes for the January 2023 meeting will be circulated via email for comments from the Committee.

5. Matters arising

5.1 Venetoclax with either low-or high-intensity chemotherapy regimes for relapsed/refractory acute myeloid leukaemia (Applicant: Dr J O'Nions, UCLH)

In January 2023, the Committee considered an application for venetoclax with either high-intensity or low-intensity chemotherapy for relapsed/refractory acute myeloid leukaemia (AML). The decision was deferred pending further clarification on the rationale for formulary approvals in other Trusts as well as the budget impact in NCL.

In terms of formulary approvals at other Trusts, Royal Marsden Hospitals had approved the use of venetoclax with low-dose cytarabine (LDAC) in relapsed/refractory patients, but it is currently restricted to privately funded patients only (i.e., not routinely available for NHS patients). South-East London APC have approved venetoclax with azacitidine (AZA) or LDAC in relapsed/refractory patients, as a bridge to haematopoietic stem-cell transplant (HSCT) or donor lymphocyte infusion with a maximum duration of 3 months treatment. The NCL application for low-intensity regime overlaps with these, however the applicants are seeking to treat for 12 months in patients who are ineligible for HSCT. The application for the use of venetoclax with FLA-IDA (i.e. a high-intensity chemotherapy) has not been approved elsewhere; it was clarified the request for use with FLA-IDA is in two patients per annum only, for patients who are eligible for HSCT but where treatment with AZA or LDAC would be inappropriate due to the adverse risk of disease (e.g., presence of genetic markers such as TP53 which are associated with poorer outcomes with low-intensity chemotherapy).

JFC Support worked with the applicants to review the budget impact. Fundamental to this were three additional considerations following the previous review:

(i) In the previous JFC review, the Committee considered patients eligible for HSCT to receive high-intensity chemotherapy, and it was considered venetoclax would be added to this regime to increase its success

rate. However, the applicants highlighted that in future practice, a larger proportion of this cohort would be considered eligible for the combination of venetoclax with low-intensity chemotherapy (due to the claim of improved remission rate versus low-intensity chemotherapy alone, and reduced risk of adverse events versus high-intensity chemotherapy). Therefore, the comparators used in the initial review were not appropriate.

(ii) The original application stated the treatment dose of venetoclax would range from 50mg to 400mg. However, all relapsed/refractory AML patients would receive concomitant posaconazole and due to an interaction between posaconazole and venetoclax, the maximum allowed dose of venetoclax will be limited to 100mg (thereby reducing the maximum cost pressure).

(iii) The previous review did not consider the potential improvements in healthcare resource utilisation. High-intensity chemotherapy currently requires two six-week admissions. If a large majority of patients received venetoclax with low-intensity chemotherapy, it has the potential to offset inpatient admission time by 10 weeks per patient (although will increase day-case unit pressure of 2 weeks per patient due to azacitidine administration).

The total budget impact was re-calculated to be between £28,300 to £39,300 (dependent on whether 50mg or 100mg venetoclax was used in patients ineligible for HSCT). This cost pressure does not take into account any improvements in healthcare resource utilisation which could not be monetarily quantified.

JFC Support worked with the applicant to convey a series of clarifications around the data presented at the previous meeting, as it was considered by the applicant to potentially skew findings towards lower efficacy endpoints against venetoclax due to potential outliers in the retrospective studies (e.g., some studies included outcome data of patients using alternative venetoclax regimes, and some studies reviewed patients at much earlier timepoints than appropriate, etc). Whilst it would be ideal to have prospective data available, the Committee was informed that clinical trials investigating new AML treatments are using venetoclax with AZA or LDAC in their standard of care arm, which makes it very unlikely that new studies supporting these combinations will be undertaken in the future. An additional retrospective study (Shahswar et al, n=81) in relapsed/refractory AML patients who used venetoclax with FLA-IDA versus FLA-IDA alone was presented; a statistically significant improvement in composite remission rate (59% vs 30% [p=0.003]) and objective response rate (78% vs 47% [p=0.001]) was observed, although haematological treatment-related adverse events were in venetoclax patients only. Interpretation of the reported results are limited as this was only available as an abstract.

The Committee heard from Dr O'Nions that all patients would be genetically assessed prior to treatment as some markers are associated with improved outcomes (e.g., NPM1 or IDH1/2), whilst others tend to have poorer outcomes (e.g., patients with TP53 tend to be poor responders). In the case of the latter, patients requiring up to 12 cycles of treatment would be discontinued if no response is observed after cycle 4. Dr O'Nions highlighted results from the two largest retrospective studies and the pivotal trials in the treatment naïve AML population to demonstrate the benefits of adding venetoclax to the low-intensity chemotherapy regimen. Dr O'Nions raised the potential to improve on transfusion independence (reported as an overall 22% increase in transfusion independence); whilst data is only available from the treatment naïve cohort, it is seen as a potential opportunity to improve quality of life. Dr O'Nions informed the Committee that some patients are treated privately and tend to have good outcomes; patients that cannot afford the treatment are unable to access it via other means and this introduces health inequalities. The Committee enquired whether a Preliminary Policy Proposition was considered for submission to NHSE; Dr O'Nions is a member of the relapsed/refractory subgroup of the AML working party and it has been considered there, though it has not been formally submitted.

In camera, the Committee considered the proposal of each treatment regime. The Committee were supportive of the use of venetoclax with low-intensity chemotherapy due to the available evidence and additional information provided supporting formulary status and budget impact. The Committee considered the use of venetoclax with high-intensity chemotherapy, and whilst the available data was limited, findings were positive and the proposed use was limited to two patients per annum; therefore the Committee were supportive of the use in this cohort but advised caution due to the possible increase in adverse events. Lastly, the Committee acknowledged there is a need to ensure equity of access across the country and encouraged the applicants to proceed with submission of a Preliminary Policy Proposition at the earliest opportunity.

In summary, the Committee agreed to clinically approve the addition of venetoclax to the NCL Joint Formulary for relapsed/refractory AML: (i) in combination with AZA or LDAC for up to 12 cycles in patients ineligible for

HSCT or for up to 3 cycles for patients eligible for HSCT, and (ii) in combination with FLA-IDA for up to 2 cycles in patients eligible for HSCT but ineligible for low-intensity chemotherapy due to presence of adverse disease risk. The approval is dependent on the production of a supportive protocol, divisional funding and Trust high-cost drugs panel approval. The Committee also strongly encouraged the applicants to complete a Preliminary Policy Proposition to NHSE at the earliest opportunity.

Decision: Approved
Prescribing: Secondary care only
Tariff status: Excluded from tariff
Funding: Trust
Fact sheet or shared care required: N/A
Additional information: Clinical approval; requires development of a supportive protocol, and requires divisional funding with Trust high-cost drugs panel approval. A Preliminary Policy Proposition should be submitted to NHSE at the earliest opportunity.

6. Review of action tracker

Action tracker included for information.

7. JFC Outstanding Items & Work Plan

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

8. Local DTC recommendations / minutes

8.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
NMUH	Nov 2022	Piperacillin/Tazobactam (Tazocin®)	Continuous 24-hour infusion in ICU (Excluding: neutropenic sepsis)	**Decision:** NMUH only **Prescribing:** Secondary care **Tariff status:** In tariff **Funding:** Trust **Factsheet or shared care required:** N/A **Additional information:** Should only be used if supported by a local guideline
BEH	Sep 2022	Quetiapine XL	Indications as per C+I (restricted to situations that addresses a patient-related issue precluding them from immediate release quetiapine	**Decision:** Added to the NCL Joint Formulary (JFC support will work with Trusts for Mental Health Formulary alignment) **Prescribing:** Primary and Secondary care **Tariff status:** In tariff **Funding:** Trust and ICB **Factsheet or shared care required:** N/A
BEH	Sep 2022	Escitalopram	Social anxiety (as per C+I)	**Decision:** Added to the NCL Joint Formulary (JFC support will work with Trusts for Mental Health Formulary alignment) **Prescribing:** Primary and Secondary care **Tariff status:** In tariff **Funding:** Trust and ICB **Factsheet or shared care required:** N/A

9. New Medicine Reviews

9.1 Bempedoic acid monotherapy for treating primary hypercholesterolaemia or mixed dyslipidaemia (Applicant: Dr C Lunken, UCLH and Dr D Nair, RFL)

The Committee considered an application in absentia for bempedoic acid tablets (180mg daily) as oral monotherapy, a first-in-class ATP citrate lyase inhibitor, licensed for primary hypercholesterolaemia and mixed dyslipidaemia, as an adjunct to diet, for statin intolerant patients in whom ezetimibe is i) not tolerated or ii) not effective (defined as no reduction or worsening of LDL-C).

A NICE TA is available for combination therapy of bempedoic acid with ezetimibe if statins are not tolerated or are contraindicated, or if ezetimibe alone does not control LDL-C well enough. The Committee heard that when seeking NICE approval, the manufacturers proposed a narrower position than the marketing authorisation for bempedoic acid as this was more reflective of current NHS practice (I.e. ezetimibe was unlikely to be used ahead of combination therapy).

The EMA conducted a meta-analysis of five phase 3, double-blind, placebo-controlled studies of 271 patients with elevated LDL-C and no lipid lowering background therapy. Patients were randomised to bempedoic acid monotherapy (n=180) or placebo (n=91). The primary endpoint, least squares (LS) mean % change from baseline in LDL-C was significantly greater for the combined data of bempedoic acid in patients with no lipid lowering background therapy compared to placebo (-22.2 vs. 0.4). Key limitations of the meta-analysis were that very small patient numbers were included in the pooled analysis from 5 studies.

The EMA also conducted a meta-analysis of six phase 2, double-blind, placebo-controlled RCTs in 121 patients with elevated LDL-C with/without statin intolerance. A naïve indirect comparison was made based on the combined data for patients on bempedoic acid monotherapy (n=99) and patients on bempedoic acid with ezetimibe (n=22). The primary endpoint, placebo-adjusted LS mean change from baseline to the end of study, was significantly greater than placebo in the bempedoic acid with ezetimibe arm compared to the bempedoic acid monotherapy arm (-50.1 [95% CI: -58.7 to -41.4] vs -32.4 [95% CI: -39.0 to -25.8]; p<0.0001). This supports the proposed place in therapy for bempedoic acid monotherapy. Key limitations of the meta-analysis were that indirect, naïve comparisons were made between both arms, small patient numbers were pooled from six phase 2 studies, there was a mixed population of statin intolerant and tolerant patients, patients may have been on low dose statins as background therapy and there is limited information on whether patients were appropriate to receive ezetimibe in the monotherapy arm.

In terms of safety, the adverse events profile of bempedoic acid is well-established and it is used routinely in practice by clinicians in combination with ezetimibe for its licensed indication.

In terms of budget impact, bempedoic acid tablets cost the same as the combination product with ezetimibe and therefore there is no cost difference anticipated per annum, compared to the combination therapy (bempedoic acid and ezetimibe tablets).

The Committee noted that there is very limited long-term cardiovascular outcome data available for bempedoic acid and the primary outcome, reduction in LDL-C, was being used as a surrogate marker. The Committee were also informed that bempedoic acid monotherapy was not included in the original lipid management pathway as the number of patients anticipated to require it were deemed to be very low. However, following concerns from GPs due to the use of bempedoic acid monotherapy outside of the approved NCL Lipid pathway in primary care, a JFC review was required to ensure governance oversight and for formal inclusion into the pathway.

In summary, the Committee agreed to add bempedoic acid monotherapy to the NCL Joint Formulary for primary hypercholesterolaemia and mixed dyslipidaemia, as an adjunct to diet in adults who are statin intolerant and in whom ezetimibe is i) not tolerated or ii) not effective.

Decision: Added to the NCL Joint Formulary pending NCL Lipid Management pathway review and update
Prescribing: Secondary care initiation, primary care continuation
Tariff status: In tariff
Funding: Trust and ICB
Fact sheet or shared care required: N/A

9.2 FOC Scheme: Upadacitinib for Crohn's disease (Applicant: Dr P Harrow and Ms J Toft, UCLH)

The Committee considered a pre-NICE free-of-charge (FOC) scheme for upadacitinib 15-45mg daily, an oral JAK inhibitor, for previously treated moderate to severe active Crohn's disease. At the time of application, upadacitinib was off label in Crohn's disease but has recently been granted a marketing authorisation.

U-EXCEED (n=495) and U-EXCEL (n=526) were two 12-week, phase III, placebo-controlled, double-blind induction studies to assess the safety and efficacy of upadacitinib for adult patients with previously treated moderate to severe active Crohn's disease. U-EXCEED included patients who had an inadequate response or intolerance to any biologic therapy. U-EXCEL included patients who had an inadequate response or intolerance to ≥1 conventional (oral locally acting steroids, IV or oral corticosteroids, and immunosuppressants) and/or biologic therapies.

Patients were randomised to upadacitinib 45mg daily or placebo. Co-primary endpoints differed based on regulatory conditions by the EMA or FDA; for the purposes of the evaluation, clinical remission reported as Crohn's disease activity index (CDAI) scores were used based on current NCL guidance and other NICE technology appraisals. In the first co-primary endpoint, clinical remission at week 12 (defined by CDAI score <150) was significantly better with upadacitinib compared to placebo in both U-EXCEED (39% vs 21% [p<0.0001]) and U-EXCEL (49.5 vs 29.1% [p<0.0001]). In the second co-primary endpoint, endoscopic response (defined by decrease in SES-CD [Simple Endoscopic Score Crohn's disease] >50% from baseline, or ≥2-point reduction from baseline if SES-CD score of 4 at baseline) was significantly better with upadacitinib compared to placebo in U-EXCEED (35% vs 4% [p<0.0001]) and U-EXCEL (45.5% vs 13.1% [p<0.0001]). In secondary outcomes, a significantly higher proportion of patients who received corticosteroids at baseline achieved corticosteroid-free clinical remission at week 12 with upadacitinib compared to placebo in U-EXCEED (34% vs 12% [p<0.0001]) and U-EXCEL (42.9 vs 15.7% [p<0.0001]). Limitations of the trials include that they have not been published in a peer-reviewed journal and active comparators were not used in the studies.

U-ENDURE (n=502) was a 52-week, phase III, placebo-controlled, double-blind study to assess the safety and efficacy of upadacitinib 15mg and 30mg daily as maintenance therapy for adult patients with moderate to severe active Crohn's disease who achieved clinical response to upadacitinib 45mg daily in the induction studies (U-EXCEED and U-EXCEL) for up to 52 weeks. Responders from the induction studies were re-randomised to upadacitinib 15mg, upadacitinib 30mg or placebo. The first co-primary endpoint, clinical remission as per CDAI score at week 52, was significantly better with upadacitinib compared with placebo for both upadacitinib 15mg (37.3% vs 15.1% [p<0.0001]) and 30mg (47.6% vs 15.1% [p<0.0001]) respectively. The second co-primary endpoint, endoscopic response as per SES-CD score at week 52, was significantly better with upadacitinib compared to placebo for both upadacitinib 15mg (27.6% vs 7.3% [p<0.0001]) and 30mg (40.1% vs 7.3% [p<0.0001]) respectively. Similarly, a key limitation of this study was that it had not been published in a peer-reviewed journal and no active comparators were used in the study. In terms of safety, data from the studies confirm that the safety profile of upadacitinib 15-45mg daily was consistent with the known safety profile of upadacitinib in other indications and no new safety risks observed.

In terms of budget impact, upadacitinib is available via either a FOC scheme or a commercial agreement. A NICE TA for the use of upadacitinib in Crohn's disease is expected in June 2023 and is expected to be a Fast-Tracked Appraisal (FTA) with a 30-day implementation period. It was noted that the terms of the FOC scheme complies with NCL guidance.

The Committee heard from Dr Harrow and Ms Toft that upadacitinib is an effective, first in class JAK inhibitor for use in Crohn's disease, which will address a significant unmet need in this cohort. It was highlighted that managing patients with active disease can be costly and should be considered in any future potential budget impact. Other medications for Crohn's disease have been approved for use by NICE which are available in other areas of London but are currently inaccessible for patients within NCL as the IBD pathway for high-cost medications requires updating. The current FOC application places upadacitinib after all available therapies in the pathway, however post publication of the NICE TA it is hoped that it can be placed as a second-choice option (alongside ustekinumab and vedolizumab). It was clarified that upadacitinib is a modified-release formulation with absorption taking place in the proximal gut and is suitable for use in patients who have had a small bowel resection. Increased risk of VTE was highlighted as the main risk with some precautions for elderly patients, however the median age of the intended patient cohort is 30 years.

In camera, the Committee agreed that there was sufficient evidence for efficacy and safety to support the use of upadacitinib as a last-line option for the treatment of moderate to severe active Crohn's disease. The place in therapy via the FOC scheme was discussed; in line with NCL FOC guidance, such schemes can only be approved for use where there is a clinical unmet need, in this case placing upadacitinib last line (i.e., in line

with the original application). The place in therapy once the NICE TA has been published would need to be reviewed, noting that a shorter 30-day implementation is likely compared to the usual 90 days.

In summary, the Committee agreed to add upadacitinib to the NCL Joint Formulary for previously treated adult patients with moderate to severe active Crohn's disease as a last-line option with access via either the FOC scheme or commercial agreement. The existing NCL IBD pathway will require review once the NICE TA has been published.

Decision: Approved
Prescribing: Secondary care
Tariff status: N/A – FOC scheme
Funding: FOC scheme or Trust-funded commercial agreement
Fact sheet or shared care required: N/A

9.3 Rapid review: Duloxetine for Stress Urinary Incontinence (SUI)

The Committee reviewed the use of duloxetine capsules (40mg BD) licensed for stress urinary incontinence. Duloxetine was reviewed to be used in line with NICE guidance, as a second-line therapy if women prefer pharmacological to surgical treatment or are not suitable for surgical treatment.

Evidence of duloxetine as an established standard of care for the treatment of stress urinary incontinence was identified in standard resources including the BNF, NICE, NICE CKS, EAU guidelines, UpToDate, Martindale and Micromedex. A Cochrane review concluded that duloxetine can improve quality of life of patients with SUI. The Committee were informed that duloxetine was on the NMUH and South-East London formulary for this indication and is routinely prescribed in primary care in line with NCL primary care guidelines. The Committee were informed that an MHRA Drug Safety Update recommends monitoring for signs of suicidal ideation and behaviour in patients on duloxetine. The Committee were reassured that duloxetine has an established safety profile, was already routinely used in practice for stress urinary incontinence and the cost pressure of introducing this indication was minimal.

In summary, the Committee agreed to add duloxetine to the NCL Joint Formulary for stress urinary incontinence in line with NICE guidance, as a second-line therapy if women prefer pharmacological treatment to surgical treatment or are not suitable for surgical treatment.

Decision: Added to the NCL Joint Formulary
Prescribing: Primary and Secondary care
Tariff status: In tariff
Funding: Trust and ICB
Fact sheet or shared care required: N/A

9.4 Rapid review: Hydromorphone for cancer pain

The Committee reviewed the oral use of hydromorphone immediate-release and modified-release tablets for cancer pain after traditional opioids are used.

Evidence of hydromorphone as a standard of care treatment option for cancer pain was identified in the following standard resources:

i. Severe cancer pain: BNF, SPC and SIGN guidelines (although unclear if SIGN guidelines are updated as they have been taken down from the SIGN website but are uploaded on palliativedrugs.com)
ii. Moderate to severe cancer pain: ESMO, NCCN, Micromedex and Scottish Palliative Care guidelines (as a fourth line opioid in patients responsive to opioids and unable to tolerate oral morphine/oxycodone, subcutaneous diamorphine/morphine or oxycodone due to persistent side effects)
iii. Moderate to severe pain (cancer pain not specified): UpToDate and Martindale

A Cochrane review concluded that there is little difference in analgesic efficacy of hydromorphone compared to other opioids. The Committee were informed that in NCL hydromorphone is only on the NMUH formulary for sickle cell pain and is on the South-East London formulary without an indication specified and restricted to KCH only.

In terms of safety, hydromorphone has an established safety profile. The Committee were informed that an MHRA Drug Safety Update describes the risk of dependence and addiction when using opioids for non-cancer pain.

In terms of budget impact, although estimated patient numbers expected to be initiated on hydromorphone in NCL were not known, the total cost per annum of hydromorphone was cheaper than for an equivalent dose of oxycodone.

The Committee discussed that further clarification was required on the rationale for addition of another opioid to the formulary when there were already several options available. The Committee also discussed that evidence would be needed that patients unable to tolerate one opioid will be able to tolerate another opioid. The Committee noted that further clarification on which specialty will initiate prescribing is required and that there is a risk of prescribing creep across primary and secondary care.

In summary, the Committee could not recommend hydromorphone due to concerns about rationale for use, the availability of several opioids already on the formulary, the risk of prescribing creep and that other centres in NCL do not use hydromorphone for cancer pain currently. Any future requests should be submitted via a full application.

Decision: Not approved

10. Semaglutide and Dulaglutide Shortage

The Committee were informed about the ongoing national shortage for semaglutide (1mg and 0.5mg) and dulaglutide (0.75mg, 1.5mg, 3mg and 4.5mg) subcutaneous injections with estimated resupply dates of April 2023 and January 2024 respectively. Advice was provided about the shortage in line with the SPS Medicines Supply Notification.

11. Octasa® (mesalazine) 1600mg MR tablets

The Committee considered a request to add Octasa 1600mg MR tablets to the NCL Joint Formulary for use in induction of UC only (not for use in maintenance as the usual desired dose of 2400mg cannot be achieved). Octasa remains the most cost-effective and hence preferred brand of mesalazine in NCL; although; historically it has been available in 400mg and 800mg tablets only. The purported benefits of Octasa® 1600mg tablets are that (i) it can be taken as a single-daily dose with a lower tablet burden versus other presentations of Octasa® to improve compliance; and (ii) it can be switched to lower strengths of Octasa® for maintenance, maintaining the large majority of mesalazine prescribing using the preferred brand. It does carry a higher budget impact in induction (at maximum duration of 12 weeks, it will cost £26 extra versus Octasa® 800mg tablets and £12 extra versus Mezavant® 1200mg tablets) and requires a patient to have their medication switched to the lower strength Octasa® after successfully completing induction therapy. The Committee were supportive of using a therapy which carries a minimal budget impact to improve upon known issues in compliance. The Committee advised effective communication between the specialist and GP with regards to switching product strength in maintenance therapy.

Drug: Octasa® 1600mg MR tablets
Indication: Induction treatment in mild to moderate ulcerative colitis
Decision: Approved
Prescribing: Primary and secondary care
Tariff status: In tariff
Funding: Trust and ICB
Fact sheet or shared care required: N/A

12. Next meeting

Thursday 16th March 2023

13. Any other business

Nil