North Central London
Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on 15 July 2019
Boardroom 1st Floor, Maple House, London, W1T 7NF

Present:	Dr M Kelsey	WH, DTC Chair	**(Chair)**
	Mr A Dutt	Islington CCG, Head of Medicines Management	
	Ms R Clark	Camden CCG, Head of Medicines Management	
	Dr K Tasopoulos	NMUH, DTC Chair	
	Mr S Richardson	WH, Chief Pharmacist	
	Ms W Spicer	RFL, Chief Pharmacist	
	Ms K Delargy	BEH, Deputy Chief Pharmacist	
	Dr A Sell	RNOH, DTC Chair	
	Mr S Semple	MEH, Chief Pharmacist	
	Dr R Urquhart	UCLH, Chief Pharmacist	
	Mr P Gouldstone	Enfield CCG, Head of Medicines Management	
In attendance:	Mr A Barron	NCL MEP, Lead Pharmacist	
	Ms M Kassam	NCL JFC, Support Pharmacist	
	Mr G Grewal	NCL JFC, Support Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Dr P Bodalia	UCLH, Principal Pharmacist	
	Ms S Sanghvi	UCLH, Formulary Pharmacist	
	Ms H Mehta	NMUH, Formulary Pharmacist	
	Ms Y Al-Hayali	MEH, Formulary Pharmacist	
	Dr C Leak	MEH, Ophthalmologist	
	Dr S Salman	NMUH, Consultant in acute medicine and renal medicine	(Via telephone)
	Dr W Townsend	ULCH, Consultant Haematologist	
Apologies:	Ms K Davies	NEL CSU, Deputy Director Medicines Management	
	Prof D Hughes	RFL, Consultant Haematologist	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Dr R Sofat	UCLH, DTC Chair (NCL JFC Vice Chair)	
	Prof L Smeeth	NCL JFC Vice-Chair	
	Mr G Kotey	NMUH, Chief Pharmacist	
	Dr A Bansal	Barnet CCG, GP Clinical Lead Medicines Management	
	Prof A Tufail	MEH, DTC Chair	
	Mr A Shah	RNOH, Chief Pharmacist	
	Dr T Rashid	NHS Haringey, GP Clinical Lead Medicines Management	
	Mr S Tomlin	GOSH, Chief Pharmacist	
	Dr S Yardley	CNWL, Consultant in palliative medicine	
	Dr A Stuart	Camden CCG, GP Clinical Lead Medicines Management	
	Ms L Reeves	C&I, Chief Pharmacist	
	Dr R MacAllister	NCL JFC Chair	
	Ms A Fakoya	NEL CSU, Senior Prescribing Advisor	
	Ms P Taylor	Haringey CCG, Head of Medicines Management	
	Mr C Daff	Barnet CCG, Head of Medicines Management	
	Mr T Dean	Patient Partner	

2. Meeting observers

Nil

3. Minutes of the last meeting

The minutes were accepted as an accurate reflection of the meeting

4. Matters arising

Ms Spicer requested JFC Support establish the status of the Commissioning Policy for anakinra for HLH submitted to NHS England.

5. JFC Work Plan & outstanding actions

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

6. Declarations of relevant conflicts of interest

No additional declarations were noted for the new medicine applications.

7. Local DTC recommendations / minutes

7.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
RNOH	Oct-18	Burosumab	'Post-NICE TA but pre-NHSE Commissioning' Free of charge Scheme: X-linked Hypophosphatemia in children and young people [Scheme now closed]	Decision: Approved Prescribing: RNOH + GOSH Tariff status: N/A Funding: FoC Fact sheet or shared care required: No
UCLH	June-19	Sapropterin (Kuvan®)	Post-Trial Free Access Scheme: Phenylketonuria	Decision: Approved Prescribing: UCLH only Tariff status: N/A Funding: FoC Fact sheet or shared care required: No
UCLH	June-19	Eculizumab	2nd line management of Delayed Haemolytic Transfusion Reactions (DHTRs) hyperhaemolysis in adult Sickle Cell and β-thalassaemia patients who have not responded to IVIG and steroids	Decision: Approved pending internal Trust funding approval Prescribing: Restricted to sickle cell treatment centres Tariff status: Not routinely commissioned Funding: Trust Fact sheet or shared care required: No Additional information: To be reviewed following publication of NHSE Commissioning Policy
UCLH	June-19	Spironolactone	Hirsutism in polycystic ovary syndrome	Decision: UCLH only Prescribing: Secondary care initiation, primary care continuation Tariff status: in tariff Funding: Trust/CCG Fact sheet or shared care required: No

Camden CCG	Feb-18	Ulipristal acetate (EllaOne®)	Emergency contraception	Decision: Approved Prescribing: Primary and Secondary care Tariff status: In tariff Funding: CCG/Trust Fact sheet or shared care required: No
Camden CCG	Feb-18	Medroxyprogesterone acetate (Depo-Provera®) injection	First-choice parenteral progestogen-only contraceptive in patients unable to self-administer	Decision: Approved Prescribing: Primary and Secondary care Tariff status: In tariff Funding: CCG/Trust Fact sheet or shared care required: No
Camden CCG	Feb-18	Etonogestrel implant (Nexplanon®)	Second-choice parenteral progestogen-only contraceptive	Decision: Approved Prescribing: Primary and Secondary care Tariff status: In tariff Funding: CCG/Trust Fact sheet or shared care required: No

7.2 Not approved

DTC site	Month	Drug	Indication	JFC outcome
UCLH	June-19	Rivaroxaban, apixaban, dabigatran and edoxaban	Prevention of thromboembolic events in patients with antiphospholipid syndrome (APS)	Decision: Not approved (review existing patients whether continued treatment is appropriate, in particular high-risk patients [those who test positive for all three antiphospholipid tests – lupus anticoagulant, anti-cardiolipin antibodies and anti-beta 2 glycoprotein I antibodies], and consider switching to warfarin)
UCLH	June-19	Rituximab	Rituximab for the prevention of DHTR hyperhaemolysis not previously prevented by pre-transfusion IVIG/steroids or if multiple red cell alloantibodies are present where compatible blood is not available	Decision: Not approved
UCLH	June-19	Rituximab	3rd line management of Delayed Haemolytic Transfusion Reactions (DHTRs) hyperhaemolysis in adult Sickle Cell and β-thalassaemia patients who have not responded to IVIG, steroids and eculizumab.	Decision: Not approved

UCLH	June-19	Ciclosporin	4th line management of Delayed Haemolytic Transfusion Reactions (DHTRs) hyperhaemolysis in adult Sickle Cell and β-thalassaemia patients who have not responded to IVIG, steroids, eculizumab and rituximab.	Decision: Not approved

8. New Medicine Reviews

8.1 Ketotifen preservative-free eye drops (Ketofall®) for seasonal allergic conjunctivitis (Applicant: Miss J Hancox, MEH)

The Committee considered an application to use ketotifen preservative-free eye drops in patients with seasonal allergic conjunctivitis (SAC) who have an allergy to preservatives. Standard treatment of SAC includes the use of topical antihistamines, mast cell stabilisers, non-steroidal anti-inflammatory drugs, and corticosteroids which are reserved for severe symptoms unresponsive to other treatments.

A Cochrane review assessed the efficacy and safety of topical antihistamines and mast cell stabilisers for treating seasonal and perennial allergic conjunctivitis in children and adults. The primary outcome was participant-reported evaluation (by questionnaire) of severity of four ocular symptoms: itching, irritation, watering eye, and photophobia. The review found that all reported topical antihistamines and mast cell stabilisers reduce symptoms of seasonal allergic conjunctivitis in the short term when compared with placebo. Only two of the primary outcomes (itching and tearing) in one treatment comparison (olopatadine vs. ketotifen) could be meta-analysed due to the heterogeneity in outcome definition and time points between trials, and a lack of reported standard deviations. Results found olopatadine was more effective than ketotifen in improving the ocular itching scale (absolute difference reduction of 0.32; [95% CI: -0.59 to -0.06] n=182) but not tearing, after 14 days of treatment (absolute difference reduction of 0.06 [95% CI: -0.35 to 0.22] n=). Due to high statistical heterogeneity the results were recommended to be interpreted with caution. Overall, due to inconsistent reporting of outcomes, there was insufficient evidence to distinguish which topical antihistamines and mast cell stabilisers are the most effective.

The study by Mortemousque et al. was published after the Cochrane review and was a multi-centre, randomised, investigator-masked, clinical study to compare the efficacy and safety of preservative-free ketotifen 0.025% to olopatadine 0.1% in the treatment of SAC. Patients aged ≥ 18 years with a history of SAC, that presented with moderate to severe itching and conjunctival hyperaemia (n=75) were randomised 1:1 to receive ketotifen or olopatadine for 28 days. The primary outcome was the reduction in the composite score (itching, tearing, and conjunctival hyperemia) at 28 days. Safety evaluations included ocular and systemic adverse event reporting, and overall local tolerance assessed by the investigator and the patient. At day 28 there was a marked decrease in the ocular composite score in both arms from baseline (absolute difference reduction of -6.04 [95% CI: -6.40 to -5.68]) in the ketotifen group and −5.93 [95% CI: -6.29 to -5.57] in the olopatadine group), with no statistically significant difference between olopatadine and ketotifen (p = 0.67); both eye drops were reported to be well tolerated. The study was funded by Thea, and two authors were employed by Thea.

The Committee heard from Dr Leak (MEH, Ophthalmologist) that the MEH first-line option for the treatment of SAC is preserved olopatadine. For patients with preservative allergy currently sodium cromoglicate would be offered, as a preservative-free olopatadine formulation is not available. Sodium cromoglicate requires four times daily administration and has a long onset of action to provide relief of symptoms, therefore Dr Leak suggested it is better placed for long-term prophylactic use rather than treatment of SAC. Ketotifen is available as a preservative-free formulation, requires twice-daily administration, and is proposed to provide quicker relief of symptoms due to its dual action as a histamine antagonist and mast cell stabiliser. Effective management of SAC with ketotifen may reduce the use of steroid eye drops in children aged 3-16 years.

In terms of budget impact, preservative-free ketotifen is cost-minimising compared with preservative-free sodium cromoglicate (saving of approximately £25 per patient per three month period).

Primary care requested MEH support in producing an educational piece for GPs; supporting self-management of SAC for appropriate patients (using over-the-counter preparations) and establishing the place in therapy of olopatadine relative to sodium cromoglicate for routine prescribing in primary care.

In summary, despite the lack of comparative data between ketotifen and sodium cromoglicate, ketotifen was likely to be preferred owing to similar onset of action to olopatadine and a lower acquisition cost compared to preservative-free sodium cromoglicate. The Committee therefore agreed to add preservative-free ketotifen eye drops to the NCL Joint Formulary for the management of seasonal allergic conjunctivitis in patients allergic to preservative (within either sodium cromoglicate or olopatadine).

Decision: Approved
Prescribing: Primary and Secondary care
Tariff status: In tariff
Funding: Trust/CCG
Fact sheet or shared care required: No

8.2 Sodium hyaluronate and trehalose eye drops (Thealoz Duo®) for moderate to severe dry eye disease (Applicant: Mr H Jayaram, MEH)

The Committee considered an application to use combination sodium hyaluronate 0.15% and trehalose 3% preservative-free eye drops (Thealoz Duo) for the treatment of moderate and severe dry eye disease. The current NCL guidance for dry eye disease includes preservative-free sodium hyaluronate 0.1% (Hylo-Tear; moderate and severe) and 0.2% (Hylo-Forte; severe only).

One Phase-III single-blinded non-inferiority randomised controlled trial (n=105) compared Thealoz Duo to sodium hyaluronate 0.18% for the treatment of dry eye disease. The primary endpoint was non-inferiority of the Oxford grading score of the poorest scoring eye from baseline to the same eye at day 35 and day 84; non-inferiority margin was 2. Results identified that Thealoz Duo was non-inferior to sodium hyaluronate 0.18% at Day 35 (-2.5 ± 2.0 vs. -2.7 ± 1.7) and Day 84 (-4.0 ± 2.2 vs. -3.9 ± 2.3). Statistically significant differences in favour of Thealoz Duo were found for some secondary performance assessments (such as improvement in ocular surface disease index by day 84, and improvements in eye-stinging and eye-itching). The risk of adverse effects with Thealoz Duo was low.

In terms of budget impact, Thealoz Duo is expected to be cost-neutral for the management of severe dry eye disease but exert a cost-pressure if used for moderate dry eye.

Representatives from Moorfields, who have been updating the NCL ocular lubricants guideline in collaboration with Islington CCG, agreed to pursue an application in the severe dry eye population only. The Committee heard from Dr Leak that ocular lubricants are not routinely prescribed at MEH unless the condition was severe. Thealoz Duo represents a treatment option for patients with few therapeutic options and experience with the product is that patients reported improvement. A recent trial suggested the pathophysiology of dry eye disease was a result of an inflammatory process, which trehalose is believed to be useful for. Over a third of attendances to A&E at Moorfields are a direct result of dry eye disease, and therefore there is a need to control the disease early in the disease process. Failure of current treatment options would lead to more intensive treatment (such as steroids or ciclosporin drops, or autologous serum transplant).

In camera, the Committee agreed that the addition of trehalose (a component of Thealoz Duo) as a new mechanism of action was useful in the management of severe dry-eye disease. It was asked whether Thealoz Duo should be restricted to secondary-care initiation only; the Committee heard from Dr Leak that it is not the drug but rather the condition that warrants specialist review therefore the Committee agreed this question should be resolved when developing the new NCL Ocular Lubricant pathway (noting that other existing therapies for severe dry-eye are not restricted to secondary-care initiation only). The Committee also suggested that MEH remove sodium hyaluronate 0.2% (Hylo-Forte) from the NCL Ocular Lubricant pathway as it was more logical to add a new mechanism of action (i.e. trehalose) rather than solely increasing the concentration of sodium hyaluronate when escalation from sodium hyaluronate 0.1% (Hylo-Tear) was required.

Decision: Approved subject to inclusion on the NCL Ocular Lubricant Pathway
Prescribing: To be determined on the NCL Ocular Lubricant Pathway
Tariff status: In tariff

Funding: Trust/CCG
Fact sheet or shared care required: No

8.3 Patiromer sorbitex calcium (Veltessa®) for hyperkalaemia (Applicant: Dr S Sajid, NMUH)

The committee considered an application for the use of patiromer in patients with hyperkalaemia (potassium level >5.5mmol/L) in the following indications:

- Patients with haemodialysis access failure (e.g. due to a blocked or infected line)
- Post-renal transplant
- Patients with acute kidney injury
- Those who require hospital transfer
- Patients on dialysis with spikes in potassium levels (in liaison with the parent dialysis team)
- CKD crash landers - to stabilise plasma potassium levels before inserting a tunnelled line

Cation exchange resin, calcium polystyrene sulfonate (Calcium Resonium®) is licensed for the treatment of hyperkalaemia however its use is limited by its efficacy, high frequency of administration and adverse effect profile (including constipation/intestinal necrosis). Patiromer is licensed for the treatment of hyperkalaemia in adults, administered once-daily and is proposed to minimise gastrointestinal side effects.

The pivotal clinical trial is a Phase III, 12 week, single-blind study that included people with chronic kidney disease stages 3 and 4 who were taking a renin-angiotensin-aldosterone inhibitor and had serum potassium levels of 5.1 to 6.5 mmol/litre. Part A of the study was a single-blind, dose-ranging, four week assessment and found serum potassium decreased for the total population by 1.01 mmol/litre. In part B of the study, patients who responded to patiromer in part A were randomised to placebo or patiromer thereby creating an enriched population within the trial. Part A found serum potassium was 0.72 mmol/litre higher in the placebo group, than for patients randomised to remain on patiromer after 8 weeks. Based on this evidence NICE published a negative appraisal consultation document for the use of patiromer in this patient population due to a lack of evidence to show that patiromer extends life or improves quality of life compared with standard care. The company did not submit evidence for the use of patiromer in the management of life-threatening hyperkalaemia or in dialysis therefore NICE have not reviewed it for these indications.

The Committee heard the evidence for the use of patiromer in haemodialysis patients. Bushinsky et al assessed the safety and efficacy of patiromer in patients undergoing haemodialysis, however the study was terminated early due to slow recruitment (n=6). Within this trial, patients with a serum potassium ≥5.5 mmol/L and adequately dialysed were admitted to a clinical research unit for 15 days (1 day run-in, 1 week pre-treatment and 1 week patiromer treatment). Patients received a controlled diet with identical meals on corresponding days of pre-treatment and treatment weeks. During treatment, patients received patiromer 12.6g daily (divided 4.2g three times a day with meals) for one week. One patient was enrolled in error with a screening potassium of 5.1 mmol/L but remained in the study. After Day 1 of patiromer the serum potassium level was 0.3 ± 0.3 mmol/L lower compared to the pre-treatment week. The maximum difference was achieved at Day 7 of patiromer (i.e. after a 3 day gap between haemodialysis sessions) where serum potassium was 0.6 ± 0.2 mmol/L lower (p=0.009). Results showed large day-to-day variability in serum potassium levels and large confidence intervals. The study had multiple limitations.

REDUCE (NCT02933450) was an open-label pilot study which recruited patients from the Emergency Department with a serum potassium >6mmol/L, randomised to either 25.2g daily 'patiromer + standard-of-care' or 'standard-of-care' alone. The primary endpoint was a change in the serum potassium over 6 hours. Results showed a similar change in potassium levels in both arms (absolute difference from baseline: -0.36 vs -0.33 mmol/L).

PEARL-HD (NCT03781089) was a prospective, randomised, open-label trial, designed to determine whether 8.4g daily patiromer reduced the frequency of hyperkalaemic episodes in patients with end stage renal disease who were on conventional haemodialysis. Results are not expected until June 2021.

In terms of safety, the EMA pooled analysis identified the most common reported AEs as constipation (6.2%), hypomagnesaemia (5.3%) and chronic renal failure. Patiromer was discontinued in 9% of subjects.

The licensed starting dose of patiromer is 8.4g once-daily for 7 days although higher total daily doses were used in trials in the emergency setting. This lower administration frequency of patiromer equates to

a cost saving compared to Calcium Resonium of approximately £10-30 per patient per 5 day course. However, Calcium Resonium is infrequently used in clinical practice, therefore patiromer is more likely to be associated with a positive budget impact of £10,000 – £18,000 in NCL.

The applicant outlined that the main use will be in patients when haemodialysis is unavailable and to avoid an ICU admission or line insertion. The Committee heard that patiromer is not intended to be used in the management of life-threatening hyperkalaemia however, it may be used in mild-moderate hyperkalaemia. The Royal London has added patiromer to their formulary and have conducted an audit of its use in clinical practice.

In camera, the Committee agreed that the pivotal study was unsuitable for assessing the effectiveness of patiromer in the short-term and there were no studies comparing patiromer to Calcium Resonium. The REDUCE study (in patients with serum potassium >6 mmol/L) suggested that patiromer affords no improvement in serum potassium levels within 6 hours when compared to current best practice. The Committee agreed patients with haemodialysis access failure or requiring hospital transfer for dialysis who have non-life threatening but rising hyperkalaemia, might benefit from patiromer if it prevented severe life-threatening hyperkalaemia, however, the reviewed evidence did not support this claim. The Committee agreed to defer its decision until the results from the Royal London audit could be reviewed and it was better understood how the cohorts specified in the application are currently managed.

Action: JFC Support to request audit results of the Royal London

Action: Each Trust to provide information on how patients in each of the proposed indications are currently managed

Decision: Deferred

8.4 EAMS: Polatuzumab vedotin in combination with bendamustine + rituximab for relapsed/refractory Diffuse Large B-cell Lymphoma (DLBCL) ineligible for haematopoietic stem-cell transplant (Applicant: Dr W Townsend, UCLH)

The Committee considered an application for an EAMS to use polatuzumab in combination with bendamustine and rituximab in treating patients with relapsed and refractory Diffuse Large B-Cell Lymphoma (DLBCL) who are ineligible for stem-cell transplant. Polatuzumab is a CD79b monoclonal antibody.

An ongoing Phase-II trial in patient with DLBCL who are ineligible for autologous stem-cell transplant randomised participants to receive six 21-day cycles of bendamustine and rituximab with or without polatuzumab. The polatuzumab group were more likely to complete six cycles of treatment (19 versus 9), had higher median progression-free survival duration (6.7 months vs. 2.0 months; HR = 0.31 [95% CI: 0.18 to 0.55]) and higher median overall survival duration (11.8 months vs. 4.7 months; HR = 0.35 [95% CI: 0.19 to 0.67]). Similar trends of improvements in progression-free survival and overall survival were seen in refractory only and relapsed only subgroups. In terms of safety, higher grade 3-5 events were seen in the polatuzumab group, which may have been a consequence of the polatuzumab group completing more cycles of treatment.

Dr Townsend informed the Committee that around two-thirds of patients diagnosed with DLBCL respond well to the standard first-line chemotherapy regimen. However, relapsed or refractory patients are difficult to treat and have poor outcomes. The most serious adverse events (e.g. neuropathy, neutropaenia etc.) are well known and managed by the haematology unit. As UCLH is a tertiary referral centre it is expected that a number of patients will be referred here who would benefit from this treatment. On consideration of the absolute difference in months of overall survival that this treatment adds, it was proposed that the [median] 6 months would mean a great deal to those patients with the poorest outcomes. It was noted that the pharmaceutical company are also making the combination drugs (bendamustine and rituximab) available free of charge.

In camera, the Committee agreed the early data for polatuzumab was encouraging given the improvement in overall survival verses current standard of care and is likely to be a useful treatment option for a difficult to treat population with few therapeutic options available. In summary, the Committee approved the application for polatuzumab EAMS in combination with bendamustine and rituximab in treating relapsed and refractory Diffuse Large B-Cell Lymphoma (DLBCL) who are ineligible for stem-cell transplant.

Decision: Approved
Prescribing: Secondary care only
Tariff status: N/A
Funding: FoC (EAMS)
Fact sheet or shared care required: No

9. Pre-NICE application: Andexanet alfa (Ondexxya®) for reversal of anticoagulation due to life-threatening or uncontrolled bleeding in patients treated with a factor Xa inhibitor

The Committee were presented with information on a pre-NICE application submitted to JfC Support for andexanet alfa, a reversal agent to the direct factor Xa inhibitors rivaroxaban and apixaban in life-threatening or uncontrolled bleeding. The application suggested the possible use in two patients per month at UCLH, which would cost between £400,000 to £720,000 per annum. Evidence underpinning the application came from a Phase-III single-arm study which investigated two co-primary efficacy outcomes; anti-factor Xa activity and a rating of haemostatic efficacy both of which are surrogates for mortality and morbidity. The significant cost impact will also affect the cost-effectiveness of the factor Xa inhibitors in their licensed indications, which NICE will need to consider as part of their technology appraisal (due in March 2020). The Committee were asked, in line with the JfC terms of reference, if it would be appropriate to review this pre-NICE application at JfC in advance of the NICE technology appraisal, or if it should be deferred until discussions at NICE have concluded.

JfC has previously reviewed and approved a dabigatran reversal agent (idarucizumab; Praxbind®) however idarucizumab was not scheduled for reviewed by NICE (i.e. not a pre-NICE application) and the acquisition cost was substantially less. The Committee agreed that this application should be reviewed at the national level, notwithstanding exceptional requests, after which point the JfC would consider regional implications. The Committee requested further information from each Trust on how patients admitted for DOAC-related major bleeds are treated to better understand the baseline protocols and standard of care; this information would be used to inform the decision on whether there is exceptionality for JfC to review in advance of NICE. Information gathered by JfC would be submitted to NICE in support of its Technology Appraisal update.

Actions:

- ***Determine the current standard of care for the treatment of DOAC related bleeds at each NCL Trust***
- ***Determine the formulary position of andexanet alfa from other Area Prescribing Committees***

10. JFC declarations of interest form for members and applicants [update]

Approved

11. Carbocisteine formulary position

UCLH has received multiple requests for the use of carbocisteine, currently non-formulary. Carbocisteine is available without restriction at NMUH, WH and RFL which has introduced variation across the region. No DTC minutes were available from the time of adding carbocisteine to respective formularies ; this was avoidable or unwarranted variation.

JFC Support and UCLH Formulary teams have drafted a proposed restriction to the use of carbocisteine, based on national/international guidance for COPD, Motor Neurone Disease and bronchiectasis. These proposals were circulated for review by NCL CCGs and Formulary Pharmacists; although the volume of response was low, comments received were generally supportive of the restricted place in therapy. Additional indications have been requested for use by UCLH Specialist Pharmacists in other treatment areas (e.g. intensive care, critical care and interventional bronchoscopy) and are not included within national guidance.

The Committee agreed that because the proposed uses of carbocisteine were numerous and included off-label indications, all Trusts should submit an inclusive list of indications where carbocisteine is currently used (including duration of therapy and timelines for review of effectiveness). The possibility of a JFC review for each indication could not be ruled out due to the limited efficacy of carbocisteine, the propensity for patients to remain on long-term treatment without review and the risk of gastrointestinal bleeds.

Action:

- ***Trusts to submit a complete list of carbocisteine indications (inc. licensed and off-label indications, rationale for treatment, treatment durations and timelines for review)***

12. Next meeting

Monday 19th August 2019.

13. Any other business

Nil