North Central London Integrated Care System

NHS
North Central London
Medicines Optimisation Network

Joint Formulary Committee (JFC): Minutes

Minutes from the meeting held on 21st August 2025

		Present	Apologies
Members			
Prof A Hingorani (Chair)	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 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		✓
Dr M Henley	RNOH, DTC Chair		✓
Mr A Shah	RNOH, Chief Pharmacist		✓
Prof A Tufail	MEH, DTC Chair		✓
Ms N Phul	MEH, Chief Pharmacist		✓
Ms L Reeves	NLMHP, Chief Pharmacist		✓
Dr L Waters	CNWL, Consultant Physician in HIV	✓	
Ms R Clark	NCL ICB, Assistant Director of Medicines Optimisation		✓
Ms M Kaur-Singh	NCL ICB, Head of Medicines Planning & Operations	✓	
Ms EY Cheung	NCL ICB, Head of Quality and Improvement		✓
Ms K Petrou	NCL ICB, Community Pharmacy Clinical Lead	✓	
Dr S Ghosh	Enfield Unity PCN, Clinical Director; Enfield GP Federation, Co-Chair	✓	
Dr D Heaney	UCLH, Consultant Neurologist	✓	
Mr S Jenkinson	RFL, Lead Pharmacist Cancer Services	✓	
Attendees			
Ms C Tse	IPMO Programme Team, JFC Principal Pharmacist	✓	
Ms K Leung	IPMO Programme Team, JFC Senior Pharmacist	✓	
Ms M Darjee	IPMO Programme Team, JFC Senior Pharmacist	✓	
Ms M Butt	IPMO Programme Team, Director	✓	
Ms S Amin	IPMO Programme Team, Lead Pharmacist		✓
Ms I Samuel	RFL, Formulary Pharmacist	✓	
Mr H Shahbakhti	RFL, Formulary Pharmacist	✓	
Mr A Barron	UCLH, Principal Pharmacist	✓	
Mr S O'Callaghan	UCLH, Formulary Pharmacist	✓	
Ms H Thoong	GOSH, Formulary Pharmacist		✓
Mr D Sergian	MEH, Formulary Pharmacist	✓	
Mr W Li	MEH, Formulary Pharmacist	✓	
Ms J Bloom	MEH, Associate Chief Pharmacist	✓	
Ms A Bathia	RNOH, Formulary Pharmacist	✓	

Ms S Ahmed	WH, Formulary Pharmacist	✓	
M A Sehmi	NMUH, Formulary Pharmacist		✓
Ms Y Lam	UCLH, Formulary Pharmacist		✓
Ms M Thacker	GOSH, Deputy Chief Pharmacist		✓
Mr J Modha	NHSE, Specialised Commissioning Pharmacist	✓	
Ms A Blochberger	NHSE, Chief Pharmacist – Specialised Commissioning		✓
Mr J Flor	WH, Lead Pharmacist	✓	
Ms R Allen	UCLH, Commissioning Pharmacist		✓
Mr A Fazal	RFL, Principal Pharmacist	✓	
Mr G Grewal	RFL, Deputy Chief Pharmacist	✓	
Dr J Cross	RFL, DTC Chair	✓	
Dr E Troy-Barnes	UCLH, Haematology Consultant	✓	
Dr P Kumar	RFL, Consultant Haematologist	✓	
Dr A Saxena	RFL, Consultant Haematologist	✓	
Mr S Hassan	RFL, Lead Surgical Pharmacist (Surgery, Pain, and Anaesthetics)	✓	
Mr B O'Farrell	RFL, Lead Pharmacist (Intensive Care and Theatres)	✓	
Ms P Panesar	UCLH, Lead Antimicrobial Pharmacist	✓	
Ms M Lanzman	RFL, Consultant Pharmacist (Infection)	✓	
Ms M Pookolayil	WH, Senior Rotational Pharmacist	✓	
Mr K Simpson	IPMO Programme Team, Principal Population Health Analyst (Observer)	✓	

2. Meeting attendees

Prof Hingorani welcomed members, observers, and applicants to the meeting (see above). The Committee thanked Dr Laura Waters for her valuable contributions to the Committee over the years as she steps down from her role as a JFC member; the Committee wished her luck in her new role. Mr Flor deputised for Mr Richardson at this meeting.

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 or attendees present.

4. Minutes and abbreviated minutes of meetings on 17th July 2025

Minutes and abbreviated minutes of the 17th July 2025 meeting were ratified.

5. Review of action tracker

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

6. JFC Outstanding items and workplan

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

7. Local DTC recommendations/minutes

Date	Drug and Indication	DTC Decision and Details	JFC recommendation
June 2024	Zoledronic acid for haemophilic arthropathy	**Reviewed by**: RFL **Drug**: Zoledronic Acid **Indication**: Haemophilic arthropathy **Decision**: Approved **Prescribing status**: Restricted to secondary care only **Funding source**: Divisional budget **Additional information**: • Development of a treatment algorithm which is to include schedule of administration • Ensure patients are consented and informed appropriately that Zoledronic acid for the treatment of haemophilic arthropathy is off label	**Approved for RFL only**

		use, and this is documented in the patient's medical notes • Collect audit data on the efficacy and safety of Zoledronic acid for the treatment of haemophilic arthropathy, which is to include any change in usage of factor concentrate pre and post treatment with Zoledronic acid • Confirm total annual numbers of patients who will be treated with Zoledronic acid **Fact sheet or Shared care required**: N/A	
June 2025	Nanocolloid human albumin (Nanoscan® or Nanotop®) for liver and spleen imaging*	**Reviewed by**: RFL **Drug**: Nanocolloid human albumin **Indication**: Liver and spleen imaging **Decision**: Approved **Prescribing status**: Restricted to secondary care only **Funding source**: Divisional budget, but no additional cost as the Nuclear Medicine department already procures nano-colloid kits for the sentinel lymph node and lymphoscintigraphy indications. The activity dose for liver spleen scans will be taken from the same vial. **Additional information**: N/A **Fact sheet or Shared care required**: N/A	**Approved for RFL only**
June 2025	Enfortumab vedotin (Padcev®) for metastatic urothelial bladder cancer) [Private patients only]	**Reviewed by**: RFL **Drug**: Enfortumab vedotin in combination with Pembrolizumab **Indication**: Metastatic urothelial bladder cancer **Decision**: Approved **Prescribing status**: Restricted to secondary care only **Funding source**: Private patient **Additional information**: N/A **Fact sheet or Shared care required**: N/A	**Approved for RFL only [Private patients only]**

*Subject to funding consideration; †The relevant commissioner should be notified in line with NCL Free of Charge scheme guidance. Approval is conditional on the provision of a free of charge scheme agreement and funding statement.

8.1 Melatonin for sleep deprivation in adult critical care

The Committee were informed that in May 2022 the UCLH Use of Medicines Committee (UMC) conducted a review of the historical off-label use of melatonin to manage sleep disturbance in adult ICU patients. While the UMC recognised that the supporting evidence was limited, it noted that the use of melatonin in this patient cohort was an established practice across NCL Trust ICUs. The potential benefit of reducing the need for hypnotic medicines such as zopiclone or zolpidem was also acknowledged. However, the UMC observed inconsistencies in how melatonin was being used across different ICUs. Consequently, a final decision was deferred to allow further engagement with the ICU teams focusing on the standardisation of dosing and treatment duration in line with current evidence. Additionally, the UMC recommended that clear mechanisms be put in place to prevent the inappropriate continuation of melatonin treatment during transitions of care, specifically at the point of ICU step-down to general wards, discharge, or transfer to other trusts.

To support consistent practice across the sector, the JFC secretariats partnered with the Lead Pharmacist for Intensive Care and Theatres at Royal Free London (RFL) to facilitate discussions within the NCL Adult Critical Care Operational Delivery Network (ODN) Group. These discussions led to a consensus document on the initiation and titration of melatonin in ICUs, in alignment with the UCLH guidance and the updated international Pain Agitation Delirium Immobility and Sleep (PADIS) guidelines published in March 2025. The Group also agreed on the preferred melatonin formulation and process for stopping treatment before ICU discharge or step-down to prevent inappropriate continuation in subsequent care settings.

The Committee agreed to approve the off-label use of melatonin for sleep deprivation in adult ICU patients, following consensus reached across all NCL ICU teams, summarised in the statement presented which was ratified by JFC.

Drug: Melatonin modified-release 2mg tablets (off-label historical review)
Indication: For sleep deprivation in adult critical care
Decision: Approved
Prescribing status: Restricted to secondary care only
Funding source: In-tariff
Fact sheet or shared care required: N/A
Additional information: N/A

8.2 Drospirenone for menstrual dysfunction and androgen excess in adolescents - PIL for final sign-off (Applicant: Dr H Learner, UCLH (in absentia))

In June 2025, the Committee requested improvements to the Patient Information Leaflet (PIL) to enhance clarity regarding the off-label use of drospirenone for adolescents for the treatment of menstrual dysfunction and androgen excess as a third-line alternative to Mirena® or depo-medroxyprogesterone for contraception; and as a second-line treatment option for androgen excess, replacing spironolactone. The Committee were informed that the revised PIL had been approved offline via Chairman's Action with the final version provided for information.

Drug: Drospirenone (Slynd®); off-label; 4mg daily
Indication:

1. Treatment of menstrual dysfunction in adolescents where treatment with desogestrel (DSG) or combined hormonal contraceptives (CHC) are ineffective or contraindicated.
2. Treatment of androgen excess where combined hormonal contraceptive (CHC) is contraindicated or not tolerated.

Decision: Approved
Prescribing status: Suitable for secondary care initiation, primary care continuation
Funding source: Divisional budget
Fact sheet or shared care required: N/A
Additional information: N/A

9 Medicine Reviews

9.1 Deferasirox for iron overload in transfusion-dependent low-risk myelodysplastic syndromes (Applicant: Dr P Kumar, RFL; Dr E Troy-Barnes, UCLH)

The Committee considered an off-label application for deferasirox, an oral iron chelator, for iron overload in transfusion-dependent low-risk myelodysplastic syndromes (MDS). Deferasirox is licensed for chronic iron overload due to frequent blood transfusions in patients with beta thalassaemia major and for the treatment of chronic iron overload due to blood transfusion when deferoxamine therapy is contraindicated or inadequate in adult and paediatric patients with other anaemias, aged 2 years and older. The licensed dose of deferasirox for transfusional iron overload is 14 to 28mg/kg/day, adjusted based on trends in serum ferritin. The Committee were informed that deferasirox is currently prescribed for iron overload in transfusion-dependent low-risk myelodysplastic syndromes at UCLH and WH, and that haematologists at RFL wish to begin prescribing it locally for the same indication to improve patient access.

The Committee were informed that NHS England (NHSE) currently commissions iron chelation therapy for the treatment of iron overload for transfused and non-transfused patients of all ages with chronic inherited anaemias (e.g., thalassaemia and sickle cell disease) according to NHSE Clinical Commissioning Policy 16070/P. However, patients with iron overload for other conditions, such as MDS, are excluded from these clinical commissioning policies and are not eligible for routine NHSE commissioning. The use of deferasirox for iron overload in transfusion-dependent low-risk myelodysplastic syndromes is endorsed by national and international guidelines such as the British Society for Haematology (BSH) guidelines for the management of adult MDS (2021, UK), the European Society of Medical Oncology (ESMO) guidance (2021), and the National Comprehensive Cancer Network (NCNN) MDS guideline (2025, USA).

The Committee noted that there was limited evidence on the use of deferasirox in this cohort and were informed that a Cochrane review (2014) evaluated the use of oral deferasirox for patients with MDS did not identify any eligible studies for inclusion at the time.

TELESTO (2020, n= 225), a multicentre, double-blind RCT evaluated the efficacy and safety of deferasirox in iron-overloaded patients with low- or intermediate-1-risk MDS. Patients with serum ferritin levels >2247pmol/L and prior receipt of 15-75 packed red blood cell units with no severe cardiac, liver, or renal abnormalities were randomised to receive deferasirox or matching placebo. The primary outcome of interest was event-free survival (EFS) defined as time from date of randomisation to first documented non-fatal event (related to cardiac or liver dysfunction and transformation to acute myeloid leukaemia) or death, whichever occurred first; overall survival (OS) was a secondary end point. The study found median EFS was prolonged by approximately 1 year with deferasirox compared to placebo (3.9 years [95% CI 3.2 to 4.3 years] vs. 3.0 years [95% CI 2.2 to 3.7 years]) (HR 0.64 [95% CI 0.42 to 0.96]). However, patients randomised to deferasirox did not experience statistically significant prolonged median OS compared to those on placebo (5.2 years [95% CI 3.9 years to not evaluable] vs. 4.1 years [95% CI 3.0 to 4.9 years]) (HR 0.83 [95% CI 0.54 to 1.28]). Serum ferritin levels were reduced from by a median of 865 pmol/L (IQR, 2049 to 288 pmol/L) in patients randomised to deferasirox after 1 year but increased by a median of 1876 pmol/L (IQR, 155 to 5029 pmol/ in those randomised to placebo. Serum ferritin levels twice the baseline value at randomisation were observed in 17 (11.4%) deferasirox recipients and 30 (39.5%) placebo recipients (median follow-up, 1.7 years and 0.8 year, respectively). A limitation of the TELESTO trial was the amendment of the study protocol which downgraded the trial from a phase III trial to a phase II design with a reduction in the target sample size due to low patient enrolment. The Committee heard that other non-randomised, observational trials such as List et al (2012), Nolte et al (2013), and Gattermann et al (2012), reported that deferasirox were effective in reducing serum ferritin in transfusion-dependent, iron-overloaded patients with MDS.

In terms of safety, the TELESTO trial (2020, n= 225) reported similar adverse event profiles between the deferasirox and placebo groups except for raised serum creatinine. However, this may be attributable to the trial protocol that allowed for dose modifications to manage known side effects of deferasirox. The most common side effects reported were gastrointestinal upset and raised blood creatinine.

In terms of convenience, deferasirox is more convenient than desferrioxamine due to its oral administration, eliminating the need for slow subcutaneous or intravenous infusion that patients may find distressing and uncomfortable. Oral route also avoids concerns around needle disposal and infusion logistics.

In terms of budget impact, deferasirox is off-patent and is supplied to patients via homecare services. Despite its generic availability, drug acquisition costs can vary depending on the suppliers. Based on adult patients weighing 70kg, deferasirox is expected to cost approximately £32,000 to £53,000 per annum for 16 patients. This is significantly lower than the cost of desferrioxamine (Desferal®) which remain under patent. Additionally, the anticipated budget impact is expected to be minimal as deferasirox is already in use at acute Trusts in NCL.

The Committee heard from Dr Kumar and Dr Troy-Barnes that only a specific subset of MDS patients require iron chelation therapy; others are managed with active surveillance or erythropoiesis-stimulating agents (ESAs), and those with rapidly progressive disease will require chemotherapy.

In camera, the Committee were satisfied that deferasirox was an established treatment for iron overload in other forms of anaemia such as sickle cell anaemia. The Committee noted that deferasirox is preferred as a first-line treatment in this cohort, despite its off-label status, due to the parenteral route required for desferrioxamine. The Committee also acknowledged that deferasirox is a high-cost drug, and in view of the ongoing financial recovery plan, future commissioning decisions will require engagement with the NCL ICB high-cost drugs team.

In summary, the Committee agreed to add deferasirox to the Joint Formulary for iron overload in transfusion-dependent low-risk MDS.

Drug: Deferasirox tablets (as per licensed dose)
Indication: For iron overload in transfusion-dependent low-risk myelodysplastic syndromes (MDS)
Decision: Approved
Prescribing status: Restricted to secondary care only
Funding source: Divisional budget
Fact sheet or shared care required: N/A
Additional information: N/A

9.2 Appeal: Methoxyflurane for prostate biopsy, insertion/ removal of surgical drains, incision, and drainage of cutaneous abscesses (Appellants: Dr A Saxena, RFL)

The Committee considered an appeal for the off-label use of Methoxyflurane (Penthrox®) for prostate biopsy, insertion/ removal of surgical drains, incision, and drainage of cutaneous abscesses. Methoxyflurane is currently licensed for emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain.

The Committee had previously reviewed methoxyflurane for these off-label indications in May 2021. At that time, the application was not approved due to insufficient supporting evidence. Key concerns included: (i) the off-label nature of the indication, (ii) challenges with interpreting observational data on efficacy, particularly regarding generalisability, (iii) the absence of RCT data against a relevant comparator, and (iv) the less clearly defined patient benefits in elective surgery compared to its use in the A&E setting, where methoxyflurane has demonstrated faster resolution of moderate to severe trauma-associated pain, and reduced discharge times. At the time, the Committee were unable to support the use of methoxyflurane in theatres for minor procedures. It was agreed that, in the absence of supporting evidence from RCTs, it would not be appropriate to recommend its use outside of a clinical trial setting. The Committee noted data from such trials would be necessary to inform more definitive guidance in the future.

The appeal was made on the grounds that new evidence had become available since the May 2021 review, warranting reconsideration. The appellant proposed that methoxyflurane would be used in addition to local anaesthetic. Despite the absence of RCTs comparing methoxyflurane with IV sedation or general anaesthesia, a phase 3 double-blind placebo-controlled randomised trial published in July 2021 investigated its use with periprostatic local anaesthesia to reduce discomfort during transrectal ultrasonography-guided prostate biopsy.

The appeal proposed that methoxyflurane may serve as a convenient analgesic option; offer rapid pain relief for minor procedures in theatres; enhance procedural pain management; improves patient experience and reduce reliance on IV sedations and opioids. Furthermore, the appellant outlined potential service-level benefits linked to methoxyflurane, including simplified administration under minimal supervision, reduced need for prolonged post-procedure monitoring, and increased theatre throughout.

Hayne et al (2021, n=388) reported a multicentre, phase 3 double-blind placebo RCT evaluated the use of methoxyflurane with periprostatic infiltration of local anaesthesia (PILA) to reduce discomfort during transrectal ultrasonography-guided prostate biopsy (TRUSB). The primary outcome was the pain score reported by patients 15 minutes after the biopsy, rated on a scale from 0 (no trouble at all) to 10 (worst pain imaginable). The mean (SE) pain score (on a scale where 0= no trouble at all, and 10= worse pain imaginable) 15 minutes after TRUSB were 2.51 (0.22) in those assigned methoxyflurane vs 2.82 (0.22) for placebo (difference = 0.31, 95% confidence interval [CI] −0.75 to 0.14; P = 0.18). The overall experience score (on a scale where 0= much better, and 10= much worse) was 2.15 with methoxyflurane and 2.65 with placebo ((difference −0.50, 95% CI −0.92 to −0.08; P = 0.021, adj. P = 0.053). There was no significant difference in the number of ≥ grade 3 adverse events: (2.6%) in the methoxyflurane group and 4.1% in the placebo group (difference = 1.5%, 95% CI −2.1 to 5.1; P = 0.4). The authors concluded that the primary endpoint was not met, as there was no significant difference between the methoxyflurane group and the placebo group in the primary end point of 15 minutes after TRUSB despite the placebo rather than an active comparator such as iv sedation, opioids, or general anaesthesia. Additionally, 15% of patients used another analgesic within 24 hours prior to the procedure., which may have influenced the pain outcomes.

Gabriel et al (2025, n=226) reported a non-randomised study as an abstract involving man undergoing prostate biopsies under standard-of-care local anaesthesia. Participants received either local anaesthesia with placebo (n=167) or local anaesthesia with methoxyflurane (n=59). Participants were asked to rate their pain using a 10-point numeric scale at various stages of the procedure, including the initial local anaesthetic injection to the perineal skin, the periprostatic block, the biopsy overall, and recovery immediately after the procedure. Satisfaction with pain control and the overall biopsy experience was also recorded. The study showed that pain during the second periprostatic local anaesthetic block was significantly lower in the methoxyflurane group when compared to the non-methoxyflurane group (3.07±2.20 and 3.60±2.03 (p=0.0374). Satisfaction with the overall biopsy experience was slightly higher in the methoxyflurane group (mean 9.73±0.64 compared to 9.49±1.30 (p=0.191)) in the non-methoxyflurane group, although this difference was not statistically significant.

Carney et al (2024, n=130) reported a prospective observational study as an abstract where adults with ‘simple’ abscesses were enrolled over a 12-month period and given inhaled methoxyflurane for ward-based incision

and drainage. The outcomes of the study were to determine a difference in length of admission and outcomes at 1week, 1 month and 3 months post procedure were compared to simple abscess drainage in theatre to determine safety, efficacy, and cost-savings. The study found that patients taken to theatre spent on average 34.5 hours in hospital compared to 1.65 hours for those performed using Methoxyflurane (Penthrox®) and 93.8% (122/130) had successful drainage with a mean admission time of 99 minutes. Although the study concluded that the use of methoxyflurane reduced the burden on emergency theatre, key limitations included the lack of comparative data and insufficient detail in the observational study.

A systematic reviewed conducted by Sairally et al (2025) assessed whether methoxyflurane (Penthrox®) provides better pain relief for elective, outpatient interventional procedures compared with other methods of pain control. The review highlighted a lack of large high-quality RCTs and concluded that the available evidence suggests that the relative benefits of methoxyflurane may vary depending on the type of intervention and the comparator pain control measure; and that it was difficult to draw meaningful conclusions regarding the use of methoxyflurane for any specific indications in outpatient and ambulatory settings.

In terms of safety, Hayne et al reported the frequencies of dizziness (51% vs 30%; difference 22%, 95% CI 12–35%; P < 0.001) and somnolence (44% vs 26%; difference 18%, 95% CI 8.9–28%; P < 0.001) were higher in the methoxyflurane group compared to placebo. The systematic review also noted that, with the potential increase in the use of low dose methoxyflurane, concerns regarding potential hepatic and renal toxicity may require further investigation.

In terms of convenience, inhaled methoxyflurane offers an element of patient-controlled analgesia and does not require specialist administration. However, its use may be limited by side effects such as dizziness and somnolence, and the lack of robust comparative data raises questions about its suitability across all outpatient settings.

In terms of budget impact, the cost of one methoxyflurane inhaler is £22.18. Depending on the length of the procedure, a maximum of 2 inhalers may be used within 24 hours. It is estimated that approximately 400 patients will be eligible for methoxyflurane in NCL, resulting in a projected cost pressure of approximately £9000 per annum.

The Committee heard from Mr Hassan that the use of methoxyflurane is routine at the Royal Surrey Hospital, supported by a local audit, though detailed data were not available to review. Dr Saxena reported that the Royal Free Hospital has implemented Entonox as an alternative to IV sedation and opioids. However, he noted that methoxyflurane, being short-acting, is particularly suited for use during local anaesthesia and biopsy procedures. He also referenced indirect treatment comparisons suggesting potential benefits of methoxyflurane over IV sedations, opioids, and placebo. However, these comparisons involve non-equivalent patient populations, which limits the reliability and generalisability of the conclusions.

In camera, the Committee concluded new evidence indicated clearly that methoxyflurane does not demonstrate superior pain management, faster relief or recovery, meaningfully enhanced patient experience, or a reduction in IV sedation, opioid use, or theatre resource burden compared to current practice for any of the proposed off-label indications. The Committee noted that in September 2024, the UMC conditionally approved methoxyflurane for pain management during colonoscopy in patients who prefer IV sedation but who are unable to arrange an escort. This decision was supported by evidence comparing methoxyflurane to an appropriate active comparator (IV fentanyl) within the relevant patient cohort. Approval was contingent upon the development of a local SOP and submission of a follow-up report after six months or 20 patients (whichever occurred first), capturing data on pain scores, colonoscopy success rates, and inpatient bed avoidance.

In contrast, the current appeal differs significantly in both scope and quality of evidence. The submitted data lacks a direct comparison with a suitable active comparator and pertains to a different patient population. Consequently, the Committee was not satisfied that methoxyflurane addresses an unmet clinical need, nor did the evidence demonstrate clear patient benefit or improvements in service delivery, including theatre efficiency, across any of the proposed off-label uses.

The Committee agreed to not approved the use of methoxyflurane for prostate biopsy, insertion/ removal of surgical drains, incision, and drainage of cutaneous abscesses.

Drug: Methoxyflurane (Penthrox®)
Indication: For prostate biopsy, insertion/ removal of surgical drains, incision, and drainage of cutaneous abscesses
Decision: Not approved

9.3 COVID-19 algorithm for treating persistent SARS-CoV-2 infection in severely immunocompromised patients (Applicants: Mr S O'Callaghan, UCLH; Dr M Brown, UCLH (in absentia); Dr E Sanchez, UCLH (in absentia); Ms P Panesar, UCLH (in absentia))

In June 2025, the Committee agreed to defer the decision on the proposed treatment algorithm for severely immunocompromised patients with recurrent SARS-CoV-2 infection and requested that UCLH engaged with other Trusts and relevant stakeholders and work together to collaboratively reach a consensus and produce a treatment algorithm that could then be adopted by other Trusts across NCL.

In addition to the approved NICE technology appraisals (TA 878 and TA 971), the Committee has previously approved the use of Paxlovid in children and in severe renal impairment and expanded the use of antiviral (Paxlovid and remdesivir) plus sotrovimab in severely immunosuppressed patient irrespective of O2 requirements or days of symptom onset. The Committee were informed that there are a small cohort of patients with persistent infection within the UCLH Haematology. RFL Transplant and other services (e.g. primary immunodeficiency, rheumatology patients on rituximab) which can have persistent SARS-CoV-2 infection and may require extended treatment.

Each approach was further informed by input from the ID and Virology MDT teams. The proposed treatment options were:

1. For inpatients with COVID pneumonitis and an oxygen requirement: Upfront treatment with high dose sotrovimab (1g) and extended course of either remdesivir or Paxlovid (initially 5 days, if symptoms persist a further 5 days may be considered); total: 10-day course).
2. For inpatients with non-COVID pneumonitis: continue to offer standard combination sotrovimab (500mg) plus antiviral (either remdesivir for 5-10 days or Paxlovid for 5 days). Where patients had a prior history of failure to standard combination therapy, there was an option to offer high dose sotrovimab (1g) plus extended course antiviral with either remdesivir or Paxlovid (initially 5 days, if symptoms persist a further 5 days may be considered; total: 10-day course). Patients who were peri-transplant/CAR-T therapy could be offered upfront intensified treatment.
3. For outpatients with refractory chronic SARS-CoV-2 infection with no oxygen requirement who met the following criteria:
    - persistent respiratory symptoms > 2 months with no new onset of symptoms, and
    - persistent positive SARS-CoV-2 PCR for over 2 months, and
    - significant underlying immunosuppression (B or T cell depletion), and
    - alternative causes of persistent symptoms considered unlikely.

A stepwise intensification of treatment of single agent rechallenge with Paxlovid (if suitable), standard combination (sotrovimab 500mg plus either remdesivir for 5-10 days or Paxlovid for 5 days), then high dose sotrovimab (1g) plus extended course antiviral with either remdesivir or Paxlovid (initially 5 days, if symptoms persist a further 5 days may be considered; total: 10-day course). Patients who were peri-transplant/CAR-T therapy could be offered upfront intensified treatment.

The Committee reviewed data from a pre-print publication of the RECOVERY study (n=720), a multicentre randomised, controlled, open-label, adaptive platform study. Patients with a high blood SARS-COV2 antigen concentration were randomised to receive either sotrovimab 1g plus usual care or usual care alone (defined as oxygen, steroids, antivirals, anti-IL6 and/or JAK inhibitor). All cause mortality at day 28 (primary endpoint) was lower in the sotrovimab treated group (23%) than the control group (29%; rate ratio 0.75 [95% CI 0.59 to 0.99; p=0.046]). No significant differences in other key secondary endpoints were reported. No difference in any endpoint was detected in an additional low-antigen study group. A 'severely immunocompromised' subgroup did not suggest that these patients were more likely to benefit, however, this subgroup was not defined and based on clinician opinion. It was noted that the viral nucleocapsid antigen test was not routinely available outside of a research setting, however, specialists from both UCLH and RFL agreed that there was a high level of clinical confidence that the 'proposed' population (B or T cell depleted) would have a high antigen level aligned with the primary population in the RECOVERY results.

Results from a UCLH retrospective observational audit (n=15) were also presented for severely immunocompromised patients with chronic SARS-COV2 infection who were refractory to first line therapy. Results highlighted that a proportion of patients responded to a further rechallenge of single agent Paxlovid (25%), while others required standard (25%) or high intensity (25%) combination therapy in order to clear the virus.

The Committee discussed that, within an inpatient setting, remdesivir would be preferred over Paxlovid. In contrast, Paxlovid was considered the preferred option in outpatient settings due to its oral formulation, which offered greater convenience for this patient cohort.

In terms of cost, the Committee were informed that the estimated additional cost pressure for the proposed pathway across NCL would be approximately £35,000 per year. Within the current financial year, the NCL ICB has paused new funding of high-cost drugs prescribed outside NICE recommendations. However, the Committee noted that sotrovimab remained available at zero cost until January/February 2026. Commissioning arrangements for future financial years would require further discussion and consideration with the ICB.

Overall, the Committee supported and approved the extended use of sotrovimab, remdesivir and Paxlovid for the three proposed cohorts of severely immunocompromised patients in line with the updated pathway.

Drug: High dose Sotrovimab (1g)
Indication: For COVID-19 in severely immunocompromised patients
Decision: Approved
Prescribing status: Restricted to secondary care only
Funding source: Divisional budget for 2025/2026. For 2026/2027, funding arrangement to be reviewed by the ICB High-Cost Drug team.
Fact sheet or shared care required: N/A

Drug: Paxlovid tablets (nirmatrelvir/ ritonavir) (10-day course)
Indication: For COVID-19 in severely immunocompromised patients
Decision: Approved
Prescribing status: Restricted to secondary care only
Funding source: Divisional budget for 2025/2026. For 2026/2027, funding arrangement to be reviewed by the ICB High-Cost Drug team.
Fact sheet or shared care required: N/A

10 Position statements and guidelines

Nil

11 Sub-Group Updates

11.1 NICE TA Implementation Group Report

Nil

11.2 NCL Pathways Group

Nil

11.3 Shared Care Group Updates

Nil

12 Next meeting

Thursday 18th September 2025

13 Any other business

Nil