Joint Formulary Committee (JFC): Minutes

Minutes from the meeting held on 15th January 2026

		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	✓	
Dr A Scourfield	UCLH, DTC Chair	✓	
Mr J Harchowal	UCLH, Chief Pharmacist	✓	
Ms W Spicer	RFL, Chief Pharmacist	✓	
Dr J Cross	RFL, DTC Chair		✓
Dr P Jasani	RFL, DTC Deputy Chair		✓
Dr K Boleti	RFL, DTC Deputy Chair		✓
Dr K Tasopoulos	RFL, DTC Deputy Chair	✓	
Ms S Stern	RFL, Deputy 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 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 S Sanghvi	IPMO Programme Team, JFC Principal Pharmacist	✓	
Ms K Leung	IPMO Programme Team, JFC Senior Pharmacist	✓	
Ms S Maru	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 A Barron	UCLH, Deputy Chief 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		✓
Ms I Huda	WH, 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		✓
Ms O Odejide	NCL ICB, Prescribing Advisor		✓
Mr K Simpson	IPMO Programme Team, Principal Population health Analyst	✓	
Ms C Weaver	NCL ICB, Senior Prescribing Advisor – Quality and Improvement	✓	
Ms A Farook	NCL ICB, Prescribing Support Pharmacist	✓	
Ms S Chauhan	NCL ICB, Prescribing Advisor – High-Cost Drugs	✓	
Ms N Patel	RFL, Pharmacist Team Manager – Critical Care	✓	
Ms J Ihenyen	NLFT, CAHMS Specialist Pharmacist	✓	
Dr A Fikree	UCLH, Consultant Gastroenterologist	✓	
Dr P Harrow	UCLH, Consultant Gastroenterologist	✓	
Prof J Lee	RFL, Consultant Gastroenterologist	✓	
Ms J Toft	UCLH, Specialist Pharmacist Inflammatory Bowel Disease	✓	
Ms N Taherzadeh	RFL, Principal Pharmacist – Gastroenterology & Nutrition	✓	
Mr L Nicholson	MEH, Consultant Ophthalmologist	✓	
Mr D Hanumunthadu	RFL, Consultant Ophthalmologist	✓	
Dr D Masieh	UCLH, Clinical Pharmacology Specialist Registrar	✓	

2. Meeting attendees

Prof Hingorani welcomed members, observers, and applicants to the meeting (see above). The Committee welcomed back Ms Saloni Maru (IPMO Programme Team, JFC Senior Pharmacist), who has returned from maternity leave.

3. Members' declaration of interests

The Declarations of Interests register for Committee members was included for information. Prof Lee declared that he was an author on the PROFILE study which was reviewed as part of the application for earlier use of biologics in Crohn's disease. No further interests relevant to the agenda were declared by members or attendees present.

4. Minutes and abbreviated minutes of meetings on 20th November 2025

Minutes and abbreviated minutes of the 20th November 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 Sanghvi.

7. Local DTC recommendations/minutes

Date	Drug and Indication	DTC Decision and Details	JFC recommendation
March 2025	Temazepam for insomnia	**Reviewed by**: NLFT **Drug**: Temazepam **Indication**: Insomnia **Decision**: Approved **Prescribing status**: Red - Restricted to secondary care only **Funding source**: In-Tariff Additional information: As third line option (least preferred)	**To add to the NCL Joint Formulary**

		Fact sheet or Shared care required: N/A	
November 2025	Clonidine (oral/enteral) for drug-resistant dystonia	**Reviewed by**: UCLH **Drug**: Clonidine tablets (oral/enteral) **Dose**: Up to 1.2mg/daily **Indication**: Drug-resistant dystonia as a last-line treatment option after oral treatments and intramuscular injections of botulinum toxin have failed or not suitable **Decision**: Approved **Recommended prescribing status**: Amber 2 Specialist initiation with maintenance in primary care ***(Prescribing status will be reviewed at the next NCL ICB Medicines CRG meeting)*** **Funding source**: In tariff **Additional information**: Clonidine oral solution not approved	**To add to the NCL Joint Formulary**
November 2025	Chikungunya vaccine (Vimkunya®) for active immunisation for the prevention of disease caused by chikungunya virus	**Reviewed by**: UCLH **Drug**: Vimkunya® **Dose**: Single 0.8mL IM dose **Indication**: Individuals ≥12 years old in line with JCVI recommendations for those who are travelling to regions with active ChikV outbreaks, longterm, or frequent travellers to regions with chikungunya transmission in the past 5 years and laboratory staff working with ChikV. UCLH travel clinic only via private prescription. **Decision**: Approved **Prescribing status**: Red - Restricted to secondary care only **Funding source**: Privately funded **Additional information**: N/A	**Approved for UCLH only [Private patients only]**
November 2025	House dust mite allergen extract (Acaroid®) subcutaneous immunotherapy for allergic rhinitis and allergic asthma	**Reviewed by**: UCLH **Drug**: House dust mite allergen extract (Acaroid®) subcutaneous immunotherapy **Dose**: As per product treatment protocol **Indication**: Allergic rhinitis and allergic asthma in patients unable to tolerate sublingual immunotherapy **Decision**: Approved **Prescribing status**: Red – Restricted to secondary care only **Funding source**: In tariff **Additional information**: Initial supply of Acaroid SLIT should be limited to identify intolerances and avoid wastage	**To add to the NCL Joint Formulary**
November 2025	Benztropine mesylate for emergency management of drug-induced dystonic reactions	**Reviewed by**: UCLH **Drug**: Benztropine mesylate **Dose**: 1-2mg IV/IM **Indication**: Acute drug-induced dystonia as per TOXBASE **Decision**: Approved **Prescribing status**: Red – Restricted to secondary care only **Funding source**: In tariff **Additional information**: Nil	**To add to the NCL Joint Formulary**
December 2025	Baloxavir marboxil tablets for the	**Reviewed by**: UCLH **Drug**: Baloxavir marboxil tablets	**To add to the NCL Joint Formulary**

	management of influenza	**Indication**: Prophylaxis and treatment of influenza in line with UKHSA recommendations and Trust influenza guidelines **Decision**: Approved **Prescribing status**: Red – Restricted to secondary care prescribing only (on the advice of virology) **Funding source**: In-tariff **Additional information**: Decision was ratified for NCL via JFC Chair's action	
October 2025	Trastuzumab deruxtecan (Enhertu®) for HER2 low breast cancer [Private patients only]	**Reviewed by**: RFL **Drug**: Trastuzumab deruxtecan (Enhertu®) **Dose**: 5.4 mg/kg by intravenous infusion every 3 weeks (21-day cycle) **Indication**: HER2 low breast cancer **Decision**: Approved **Prescribing status**: Red – restricted to secondary care only **Funding source**: Private practice **Additional information**: Collection of audit data on treatment outcomes	**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. Matters arising

8.1. Strategic updates for NCL JFC

The Committee heard from the NCL JFC Chair, Prof Hingorani, that there are several important strategic changes happening at ICS- and national level with implications for JFC. These are scheduled for discussion at the February 2026 JFC meeting.

8.2. NCL Principles for Commissioning High-Cost Drug Pathways for ICB-commissioned Indications

The Committee reviewed and approved the updated 'Principles for Commissioning HCD Pathways for ICB-commissioned medicines' guideline subject to minor amendments.

8.3 Remifentanil as a sedative for mechanically ventilated ICU patients

In August 2023, the Committee considered an application from WH for remifentanil intravenous (IV) infusion, an opioid, for off-label use in the maintenance of sedation in mechanically ventilated adult patients in intensive care units (ICU). There was inconsistency in the use of and interest in remifentanil within NCL Trusts in an ICU setting as follows:

- NMUH use remifentanil in ICU with a local protocol.
- UCLH had remifentanil on formulary in 2008, but it was removed in 2010 and the clinical team did not wish to reinstate it.
- RFL were interested in using remifentanil for maintenance sedation in ventilated adult ICU patients.

Due to the variation across the sector, the Committee reviewed the evidence base and deferred a decision pending receipt of an NCL consensus on use, clear pathways, patient initiation criteria and risk mitigation steps.

Thereafter, the NCL Adult Critical Care Operational Delivery Network discussed this application to gain a consensus on use of remifentanil. The group reviewed the evidence base previously considered by the JFC, as well as a more recent systematic review by Lu et al (20 studies, n=3,422), which reported that remifentanil was not associated with a reduction in the duration of mechanical ventilation (MV) compared with fentanyl and morphine. Furthermore, the review reported that no regimen significantly shortened the ICU length of stay and improved the ICU mortality, efficacy, safety, and drug related adverse events.

The NCL Adult Critical Care Operational Delivery Network acknowledged the following concerns:

1. Remifentanil supply chain issues/intermittent shortages and the need to preserve stock for Total Intravenous Anaesthesia (TIVA) use in anaesthetics.
2. The risks of remifentanil use (bradycardia, hypotension) and the need for training.

3. The lack of Dose Error Reduction Software (DERS) functionality on infusion pumps at UCLH, Whittington and North Middlesex Hospital to help prevent administration errors.
4. The licensed duration of 3 days - and the risks of tachyphylaxis and hyperalgesia associated with prolonged use.
5. The difficulty in controlling usage in line with proposed restrictions if made available as a stock item across all ICUs.
6. The significant cost pressure of introducing and implementing the use of remifentanil in ICU in light of a lack of robust evidence.

The Network were therefore not supportive of using remifentanil for this indication across NCL ICUs. The Committee agreed that remifentanil for sedation in mechanically ventilated ICU patients across NCL Trusts should remain non-formulary and that NMUH should review the use of remifentanil for this indication in line with the NCL JFC and NCL Adult Critical Care Operational Delivery Network recommendations.

Drug: Remifentanil

Indication: Maintenance of sedation in mechanically ventilated adult patients in intensive care units

Decision: Not approved

Additional information: NMUH should review the use of remifentanil for this indication in line with NCL JFC and NCL Adult Critical Care Operational Delivery Network recommendations.

8.3. Semglee® (insulin glargine biosimilar) and Levemir® discontinuation

Ms Sanghvi informed the Committee that Levemir® (insulin determir) pre-filled pens and cartridges are being discontinued with stock anticipated to be exhausted by the end of 2026. The NCL Diabetes Network is supporting the implementation of insulin switches for existing Levemir® patients across NCL ICS in line with options available on the NCL Joint Formulary and national clinical guidance produced by the Association of British Clinical Diabetologists (ABCD) and Primary Care Diabetes and Obesity Society (PCDO).

In January 2020, the Committee reviewed Semglee® (biosimilar insulin glargine) as a treatment option for patients with T1 and T2 diabetes, which was not approved. With the discontinuation of Levemir® and instability in supply of insulins, the Committee were requested to review the decision for the inclusion of Semglee® in the NCL Joint Formulary. The NCL Diabetes Network would support safe implementation and switching to Semglee® where appropriate for individual patients, in line with the ABCD/ PCDO clinical guidelines. Short-term supply issues with Semglee® are anticipated to be resolved by end of January 2026.

In summary, the Committee approved the addition of Semglee® (biosimilar insulin glargine) to the NCL Joint Formulary. It was noted that Toujeo (ultralong acting insulin glargine) is an option in the ABCD/PCDO guidelines but remains non-formulary in NCL due to the potential for medication errors with the higher strength and availability of other formulary insulin options. An appeal form would be required for JFC to review this decision.

Drug: Semglee® (biosimilar insulin glargine)
Indication: Type 1 and Type 2 diabetes mellitus
Decision: Approved
Prescribing status: Suitable for initiation in primary and secondary care (Green)
Funding source: In tariff
Additional information: N/A

9. Medicine Reviews

9.1 Mirtazapine for function dyspepsia (Applicant: Dr A Fikree, UCLH)

The Committee considered an application for mirtazapine 15-45mg daily, a tetracyclic antidepressant, for off-label use as a fourth-line treatment option for functional dyspepsia in post-prandial distress syndrome patients with associated weight loss.

Tack et al (2016; n=34) was an 8-week, placebo-controlled, double-blind study to assess the safety and efficacy of mirtazapine for functional dyspepsia patients with post-prandial distress syndrome and epigastric pain syndrome with weight loss and without depression or anxiety. Patients were randomised to mirtazapine 15mg daily or placebo. The primary endpoint, of a dyspepsia symptom score reduction from baseline to week 8, was not significantly better with mirtazapine compared to placebo (-2.6 ± 0.9 vs. -1.0 ± 0.8; p=0.55). The secondary outcomes of a difference in change for early satiation from baseline to week 8 and a difference in weight change from baseline to week 8 was significantly better (-0.77 ± 0.19 vs -0.24 ± 0.22; p=0.002 and 3.9 ± 0.7 vs -0.2 ± 0.4; p<0.001 respectively). Key limitations of the study were the small sample size, high drop-out rate, inability to perform subgroup analysis for PDS and EPS patient groups, failure to demonstrate an effect on the

primary endpoint, lack of representation of majority of the NCL population cohort due to majority of the patients enrolled in the study being female and exclusion of patients with comorbid depression/anxiety, short trial duration and the lack of clarity on if and how many previous lines of treatment were used.

Jiang et al (2016; n=60) was an 8-week, active comparator, randomised controlled study to compare the safety and efficacy of mirtazapine 30mg daily compared to paroxetine or conventional therapy (H2-receptor antagonists with a PPI/prokinetic). The primary endpoint of a reduction in the Nepean Dyspepsia Symptom Score Index from baseline to week 8 was significantly better for mirtazapine compared to paroxetine or the conventional arm ($p<0.05$). The secondary outcome of weight gain from baseline to week 8 was significantly better for mirtazapine compared to paroxetine and the conventional arm respectively (3.58 ± 1.57kg vs 0.53 ± 0.44kg vs 0.56 ± 0.45kg; $p<0.05$). Key limitations of the study were the small sample size, unclear blinding, exclusion of patients without comorbid depression/anxiety, short trial duration and the lack of clarity on if and how many previous lines of treatment were used.

Cao et al (2025; n=120) was an 8-week, active comparator, single-blinded, randomised controlled study to compare the safety and efficacy of mirtazapine 15mg daily compared to a conventional group (receiving cobizym three times daily with domperidone 10mg three times daily). The primary endpoint of a reduction in the dyspepsia symptom score from baseline to week 8 was significantly better for mirtazapine compared to the conventional arm (11.17 ± 2.14 vs 7.95 ± 1.86; $p<0.001$). The secondary outcome of a difference in weight change from baseline to week 8 was significantly better for mirtazapine compared to the conventional arm respectively (66.57 ± 5.18kg vs 60.49 ± 4.20kg; $p<0.001$). Key limitations of the study were single-blinding of patients only, different number and frequency of tablets in both arms risking unblinding, short trial duration, the use of cobizym as an active comparator that is not routinely used in the NHS and the use of conventional therapies for a 2-week period only prior to starting the trial.

In terms of safety, across the three studies, mirtazapine was associated with withdrawals or mild adverse drug reactions caused by fatigue (6%) or drowsiness (10%). No serious adverse drug reactions were reported. Additionally, mirtazapine has a known safety profile for its licensed indication.

In terms of budget impact, mirtazapine is expected to cost an additional £1200 per annum based on an estimated 100 eligible patients.

The Committee heard from Dr Fikree that the treatment goal is to improve symptoms, quality of life and obviate need for enteral nutrition. Mirtazapine was intended for fourth line use in patients where functional dyspepsia with post-prandial distress syndrome had not responded to routine therapies including *H. pylori* eradication therapy, PPIs, and prokinetics. Stopping criteria for mirtazapine treatment in this cohort are: (1) any weight loss, (2) no improvement or worsening of PAGI symptom scores, (3) adverse drug reaction or (4) excessive weight gain >10kg. In most patients, the functional dyspepsia symptoms resolve within 12 months of starting treatment. Most patients (~90%) have psychological comorbidities for which mirtazapine may be indicated and continued, even after resolution of functional dyspepsia symptoms. Use in this context would require discussion with the GP or community mental health team or UCLH neuro-gastro psychiatrist. In terms of polypharmacy, Dr Fikree explained that other treatments for functional dyspepsia (e.g. PPIs) should be stopped before initiating mirtazapine if ineffective, but would otherwise be continued alongside mirtazapine.

In camera, the Committee expressed concerns about primary care prescribing of mirtazapine for an off-label indication in a patient cohort that required close clinical monitoring by the tertiary care provider. However, following 12 months of tertiary care follow-up and resolution of functional dyspepsia symptoms, a sub-group of patients may be appropriate for transition to primary care prescribing. This would be contingent upon the presence of a psychological comorbidity in this patient sub-group for which mirtazapine is a licensed treatment, alongside clear evidence of a sustained beneficial response to mirtazapine and the absence of significant adverse effects, thereby demonstrating safety and clinical stability to enable transition to primary care prescribing. The Committee also raised the concern that weight gain associated with mirtazapine reflects a pharmacological side effect rather than true nutritional improvement. In a minority of patients, mirtazapine was intended to delay or prevent progression to total parenteral nutrition and associated hospitalisation; however, there is currently no direct evidence to support this outcome. Despite the limited evidence base, the Committee acknowledged that mirtazapine may have a role as a fourth-line treatment option for this cohort of difficult-to-treat patients within a tertiary care setting.

In summary, the Committee agreed to add mirtazapine to the NCL Joint Formulary as a fourth-line treatment option in functional dyspepsia patients with post-prandial distress syndrome and associated weight loss.

Drug: Mirtazapine tablets 15 -45mg daily for 12 months followed by a weaning period

Indication: Fourth-line treatment option in functional dyspepsia patients with post-prandial distress syndrome and associated weight loss

Decision: Approved

Prescribing status:

- Restricted to secondary care only (Red) for the treatment of functional dyspepsia alone
- In patients with psychological comorbidities for which mirtazapine has a licensed indication, mirtazapine prescribing can be transferred to primary care following resolution of dyspepsia symptoms in line with its licensed use

Funding source: In tariff

9.1. NCL Crohn's Disease Pathway Update - Earlier use of biologics (Applicants: Dr P Harrow, UCLH; Prof J Lee, RFL; Dr C Murray, RFL (in absentia))

The Committee considered an application for the earlier use of first-line biologics (adalimumab, infliximab, and ustekinumab) for moderate to severely active Crohn's Disease. Under the existing pathway, in line with NICE recommendations (TA 187 and TA 456), patients with "*moderate-to-severely active Crohn's Disease, with lack or loss of response, intolerance or contraindication to conventional therapy (steroids and/or immunosuppressant) are eligible for treatment [with biologic therapy]*". The application proposes access to treatment with first-line biologics without previous treatment with steroids and/ or immunosuppressants, which is considered off-label use of these medicines. The proposal seeks to prevent delays in accessing biologics which the applicants claim will result in better treatment outcomes for patients and more cost-effective outcomes for the healthcare system.

The PROFILE study (2024, n= 225), a multi-centre, open-label randomised control trial, compared 'top-down' versus 'accelerated step-up' strategies for adults with newly diagnosed active severe Crohn's Disease (Harvey Bradshaw Index (HBI) ≥7). Patients recruited to the trial were started on an 8-week course of oral steroids, and at 2 weeks, they were then randomised 1:1 to either:

- Top-down therapy: infliximab plus immunomodulator (e.g., azathioprine). Patients who developed anti-infliximab antibodies or were intolerant of infliximab were switched to adalimumab. Patients could have an accelerated steroid wean after commencing treatment with a biologic plus immunomodulator.
- Accelerated step-up therapy: Patients completed steroid wean and therapy was escalated progressively following disease flare. Firstly, to steroid plus immunomodulator, and then addition of infliximab for a subsequent flare.

The PROFILE study found 79% of patients randomised to 'top-down therapy' achieved sustained steroid-free and surgery-free remission up to 48 weeks (primary outcome) compared to 15% of patients in the 'accelerated step-up therapy' group (absolute difference 64%, p< 0.0001). Endoscopic remission rates were also higher in 'top-down therapy' group compared to 'accelerated step-up therapy' (67% versus 44%, p= 0.0001). Regarding secondary outcomes, the PROFILE study reported that patients in 'top-down therapy' experienced fewer flares (-1.29 [95% CI -1.42 to -1.16], p< 0.0001), received fewer steroid courses (-0.87 [95% CI -0.97 to -0.76], p< 0.0001), and had fewer hospital admissions and surgeries (-0.12 [95% CI -0.23 to -0.02], p= 0.023) compared to 'accelerated step-up therapy'. Hospitalisation for Crohn's disease flare was less frequent in the top-down group (2% vs 6%) and there were also fewer surgeries for disease complications (1% vs 5%). A limitation of the PROFILE study was its relatively short study duration of 48 weeks (given the chronic nature of Crohn's disease). However, a longer follow-up study is currently underway.

The Committee noted two key differences between the PROFILE study protocol and the proposed use of early biologic therapies in NCL. In the 'top down arm' of the PROFILE study: (1) all patients received initial steroid treatment whereas the NCL protocol aims to limit the initial use of steroids to patients where there are delays to accessing biologics or a specific patient need; infliximab or adalimumab were used with an immunomodulator, however, infliximab with an immunomodulator, or monotherapy with adalimumab or ustekinumab are the options proposed in the NCL protocol.

In terms of safety, the PROFILE study was not sufficiently powered to show a difference in safety endpoints. However, the study reported there was no difference in risk of serious infection between trial arms and no reported malignancies or deaths during the trial. The long-term safety profile of the biologic drugs is well established from their licensed use.

The anticipated budget impact is estimated to be between £100K to £150K per annum for 190 patients based on the applicants' estimate of biologics being initiated 2-3 months earlier on average than at present at a 1:1:1 ratio for adalimumab, infliximab, and ustekinumab. Estimated costs increase to £300K if biologics are initiated on average 6 months earlier than at present, and to £900K if initiation of biologics occurs on average 18 months earlier than at present. The Committee also reviewed a cost-effectiveness analysis which used clinical data from the PROFILE study and NHS comparable drug costs. The study found that 'top-down' therapy resulted in

lower healthcare resource use and better clinical outcomes and was cost saving overall with an incremental gain of 0.17 QALYs per patient over a 5-year time period.

The following commissioning considerations were discussed:

- The *drug* cost of the Crohns' disease pathway would likely increase, but but costs from treatment of disease complications including hospitalisations and surgeries could decrease. This was considered within the PROFILE cost-effectiveness study, but the offset savings have not been quantified locally.
- For 2025/2026 financial year, NCL ICB is not funding high-cost drug business cases that fall outside of NICE TA recommendations. This is predicted to continue into 2026/27. There remains uncertainty about the commissioning position under the new West & North London (WNL) ICB following the merger.
- There is a national proposal (not yet confirmed) to remove adalimumab, infliximab, and ustekinumab from the high-cost drugs list from 2026/27, and move to in-tariff funding. If this occurs, it will be more challenging to provide assurance that prescribing is aligned to the criteria in the proposal.
- Any variability in individual Trust decisions regarding affordability of the proposal and funding may risk inequitable access across NCL. Furthermore, an NCL decision raises questions of equity of access across London providers and nationally.
- Earlier use of biologics could have an impact on Provider activity with additional demand being placed on infusion clinics.

The Committee heard from Prof Lee and Dr Harrow, who emphasised that the substantial treatment effect seen in the PROFILE study demonstrates clinical- and cost-effectiveness of the earlier initiation of biologics. The applicants highlighted that the current standard of care differs from the 'accelerated step-up' arm of the PROFILE study, as patients in NCL who have a flare are initiated on steroids, and if there is any evidence of inflammation (detected via faecal calprotectin or ultrasound) at the end of the course of steroids, they are initiated on a biologic. On average, patients start a biologic within 2-3 months. Current practice is therefore closer to the intervention arm of the PROFILE study, and hence the longer-term treatment costs are not anticipated to be significant, particularly with the falling costs of biosimilars. The proposal would remove the requirement to assess patients' response to steroids prior to starting biologics, and the applicants noted that minimising delays to starting biologic results in better response rates, maintenance of treatment effect and fewer disease complications including surgeries.

The applicants acknowledged that the direct evidence is for anti-TNF therapy but requested inclusion of ustekinumab in this approach based on equivalent efficacy between anti-TNFs and ustekinumab and similar costs (when using best value biosimilars). The applicants reported that this proposal has already been adopted into clinical practice in several hospitals across London and England and that the PROFILE study authors are in discussion with NICE regarding national review of the new evidence.

In camera, the Committee acknowledged the compelling clinical evidence to support the earlier use of biologics in this patient cohort. The treatment effects reported in PROFILE were substantial and the cost-effectiveness was considered favourable overall. The Committee discussed the following points:

- The PROFILE study examined the earlier use of infliximab and adalimumab (anti-TNFs) in newly diagnosed Crohn's disease. However, the Committee noted there is real-world indirect comparative evidence supporting parity of effect among the three agents. In addition, the costs amongst these agents are similar when the best value biosimilar is used. Therefore, it was considered reasonable to accept the extrapolation of the results from the PROFILE study to ustekinumab, provided the best value ustekinumab biosimilar was prescribed.
- As the acquisition costs of biosimilar biologic agents continue to decline, these reductions may off-set the use of more expensive medicines elsewhere in the pathway.
- Given the potential transition of these biologic agents to in-tariff funding in the 2026/2027 financial year, the current capacity of individual Trusts to fund this proposal remains uncertain. Regardless of the funding arrangements for adalimumab, infliximab, and ustekinumab, this will require a coordinated approach across NCL to ensure equitable implementation. The Committee emphasised that NCL Trusts should not arrange or approve divisional funding independently, as a collective approach across NCL would be most appropriate.
- To support equity of access nationally, the Committee agreed to write formally to NICE to seek a national position (acknowledging that the proposed use is currently off-label).

In summary, the Committee agreed to clinically approve the earlier use of biologics (adalimumab, infliximab, and ustekinumab) without previous treatment of steroids and/or immunosuppressant in moderate to severely active newly diagnosed Crohn's disease subject to an NCL-wide business case to assess affordability and

support equitable implementation across NCL. Inclusion of ustekinumab was subject to implementation of best value ustekinumab biosimilar across NCL Trusts. The Committee highlighted that the requirement for patients "to have received prior treatment with corticosteroids and/or immunosuppressant" should not be removed from the pathway until the funding arrangements across NCL have been confirmed. Commissioning implications of the merger to WNL ICB should also be taken into consideration where relevant. Additionally, NCL JFC will write to NICE requesting review of the NICE TA criteria in light of the new evidence, to support a national position and equitable implementation.

Drug: Adalimumab, infliximab, and ustekinumab
Dose: As per NCL HCD Crohn's disease pathway
Indication: Newly diagnosed moderate to severely active Crohn's disease (Harvey Bradshaw Index ≥6) without previous treatment with corticosteroids and/or immunosuppressants
Decision: Clinically approved subject to an NCL-wide business case to assess affordability and support equitable implementation across NCL and subject to implementation of best value biosimilar ustekinumab.
Prescribing status: Restricted to secondary care only (Red)
Funding source: To be confirmed
Fact sheet or shared care required: N/A
Additional information: NCL Trusts should co-ordinate a collective business case to seek funding approval. Commissioning implications of the merger to WNL ICB should also be taken into consideration where relevant.

9.3 NCL Diabetic Macular Oedema (DMO) High-Cost Drug Pathway (Applicants: Mr L Nicholson, MEH; Mr D Hanumunthadu, RFL)

The Committee reviewed the rationale underpinning the proposed changes to the NCL Macular Oedema High-Cost Drug Pathway which was updated in line with the High-Cost Drug Commissioning Principles. The updated pathway reflected the new NICE TAs, the NHSE DMO pathway (October 2025) and the NICE Diabetic Retinopathy guidance (August 2024).

In summary, the Committee approved the following changes to the NCL DMO pathway:

- Inclusion of the new NICE Tas for faricimab and brolucizumab
- Inclusion of aflibercept 8mg
- Inclusion of aflibercept 2mg biosimilar
- Removal of unlicensed triamcinolone acetonide
- Inclusion of ranibizumab and brolucizumab as options for consideration in the NCL pathways
- Switchback from fluocinolone to anti-VEGFs are subject to individual consideration via a Blueteq form
- Switchback from faricimab to aflibercept 2mg biosimilar if patients experience an adverse drug reaction or no added clinical benefit
- Treatment interval < 6 months for intravitreal dexamethasone implants
- > 7 intravitreal dexamethasone implants in one eye
- The use of faricimab in patients previously treated with aflibercept

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. Interface Prescribing Group Updates

Nil

12. Next meeting

Thursday 19th February 2026

13. Any other business

Nil