Joint Formulary Committee (JFC): Minutes

Minutes from the meeting held on 16th October 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	✓	
Dr A Scourfield	UCLH, DTC Chair	✓	
Mr J Harchowal	UCLH, Chief Pharmacist	✓	
Ms W Spicer	RFL, Chief Pharmacist	✓	
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 L Reeves	NLMHP, 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 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		✓

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		✓
Ms O Odejide	NCL ICB, Prescribing Advisor		✓
Ms C Weaver	NCL ICB, Senior Prescribing Advisor – Quality and Improvement	✓	
Mr S Mahal	GOSH, Lead Pharmacist – Clinical Services		✓
Ms A Coker	NLFT, Lead Pharmacist – Clinical Services		✓
Ms N Patel	RFL, Pharmacist Team Manager – Critical Care	✓	
Ms S Chauhan	NCL ICB, Prescribing Adviser - High Cost Drugs	✓	
Ms H Shah	NCL ICB, Senior Prescribing Adviser – Quality & Improvement	✓	
Ms A Farook	NCL ICB, Prescribing Support Pharmacist	✓	
Ms N Barrett	NCL ICB, Prescribing Adviser – Quality and Improvement	✓	
Ms N Patel	NCL ICB, Prescribing Support Pharmacist - Medicines Planning and Operations	✓	
Ms E Ward	IPMO Programme Team, Lead Pharmacist	✓	
Prof M Matharu	UCLH, Consultant Neurologist	✓	
Dr T Yates	UCLH, Consultant Neurologist	✓	
Dr B Athwal	RFL, Consultant Neurologist	✓	
Ms S Ladd	NCL ICB, Prescribing Advisor - Medicines Planning and Operations	✓	
Dr K Roy	UCLH, Respiratory Medicine Consultant	✓	
Mr L Nicholson	MEH, Consultant Ophthalmologist	✓	
Mr D Hanumunthadu	RFL, Consultant Ophthalmologist	✓	
Ms J Johnson	RNOH, Senior Clinical Pharmacist (Observer)	✓	
Mr L Hermiz	KRFT, Critical Care Pharmacist (Observer)	✓	
Ms H Yeoh	RFL, Principal Pharmacist – Multiple Sclerosis and Neurology (Observer)	✓	

2. Meeting attendees

Prof Hingorani welcomed members, observers, and applicants to the meeting (see above).

3. Members' declaration of interests

The Declarations of Interests register for Committee members was included for information. No further interests relevant to the agenda were declared by members or attendees present.

4. Minutes and abbreviated minutes of meetings on 18th September 2025

Minutes and abbreviated minutes of the 18th September 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
October 2022	Paromomycin for amoebiasis and giardiasis	**Reviewed by:** UCLH **Drug:** Paromomycin **Dose:** 500mg TDS for 7 days **Indication:** For amoebiasis and giardiasis	**To add to the NCL Joint Formulary**

		Decision: Approved **Prescribing status:** Restricted to secondary care only **Funding source:** In-tariff **Additional information:** Ratified according to the Hospital for Tropical Diseases guidelines 2022 **Fact sheet or Shared care required:** N/A	
October 2022	Tinidazole for amoebiasis and giardiasis	**Reviewed by**: UCLH **Drug**: Tinidazole **Dose**: • For Amoebiasis: 2g/day for 3-5 days (50-60mg/kg and in 3 divided doses for children) • For giardiasis: 2g STAT **Indication**: For amoebiasis and giardiasis **Decision**: Approved **Prescribing status**: Restricted to secondary care only **Funding source**: In-tariff **Additional information**: Ratified according to the Hospital for Tropical Diseases guidelines 2022 and UCLH guideline for Acute gastroenteritis and Traveller's diarrhoea **Fact sheet or Shared care required**: N/A	**To add to the NCL Joint Formulary**
September 2025	[FOC Scheme] Nivolumab and ipilimumab for advanced or metastatic angiosarcoma *†	**Reviewed by**: UCLH **Drug**: Nivolumab plus ipilimumab (off-label) **Dose**: • Adults (>18 yrs): Nivolumab 3mg/kg IV and ipilimumab 1mg/kg over IV every 21 days for 4 cycles. Followed by nivolumab monotherapy 480mg every 28 days or 240mg IV every 14 days. • Adolescents (≥13 to 18 yrs): Nivolumab 3mg/kg IV and ipilimumab 1mg/kg over IV every 21 days for 4 cycles. Followed by nivolumab monotherapy 6mg/kg every 28 days or 3mg/kg IV every 14 days **Indication**: Second line (and beyond) treatment option for patients aged ≥13 years with advanced or metastatic angiosarcoma, when there are no suitable clinical trials available. **Decision**: Approved **Prescribing status**: Restricted to secondary care only **Funding source**: Free of Charge Scheme **Additional information**: Nil **Fact sheet or Shared care required**: N/A	**Approved for UCLH only**
September 2025	[FOC Scheme] Nivolumab and ipilimumab for advanced of metastatic alveolar soft-part sarcoma *†	**Reviewed by**: UCLH **Drug**: Nivolumab plus ipilimumab (off-label) **Dose**: • Adults (>18 yrs): Nivolumab 3mg/kg IV and ipilimumab 1mg/kg over IV every 21 days for 4 cycles. Followed by nivolumab monotherapy 480mg every 28 days or 240mg IV every 14 days. • Adolescents (≥13 to 18 yrs): Nivolumab 3mg/kg IV and ipilimumab 1mg/kg over IV every 21 days for 4 cycles. Followed by nivolumab	**Approved for UCLH only**

		monotherapy 6mg/kg every 28 days or 3mg/kg IV every 14 days **Indication**: First line treatment option for patients aged ≥13 years with advanced or metastatic alveolar soft part sarcoma (ASPS), when there are no suitable clinical trials available. **Decision**: Approved **Prescribing status**: Restricted to secondary care only **Funding source**: Free of charge scheme **Additional information**: N/A	
September 2025	Sirolimus for epithelioid haemangioendothelioma (EHE)	**Reviewed by**: UCLH **Drug**: Sirolimus (off-label) **Indication**: Epithelioid haemangioendothelioma (EHE) **Decision**: Not Approved	**Not approved**

*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

Nil

9. Medicine Reviews

9.1. NCL High-cost Drug Migraine Prevention Pathway (Applicants: Prof M Matharu, UCLH; Dr T Yates, UCLH; Dr B Athwal, RFL)

The Committee reviewed the rationale and evidence underpinning the newly proposed NCL High-Cost Drug pathway for migraine prevention. Migraine is a debilitating headache disorder, characterised by unilateral, throbbing headaches that may be accompanied by symptoms such as fatigue, nausea, and increased sensitivity to light and sound. Depending on the frequency of attacks, migraine can be classified as episodic, headaches occurring on fewer than 15 days per month, or chronic, headache occurring on at least 15 days per month (with features of migraine present on at least 8 days per month) for more than 3 months.

In April 2021, in the absence of head-to-head data between calcitonin gene-related peptide (CGRP) therapies, the Committee agreed a prescribing approach that aligned with the NCL High-Cost Drug pathways commissioning principles. Patients initiating their first calcitonin gene-related peptide (CGRP) inhibitor therapy- should be initiated on the lowest cost option. At the time, erenumab was the treatment option with the lowest acquisition cost. For individuals already on treatment with a non-preferred CGRP inhibitor from a private clinic, the Committee recommended that a conversation takes place to encourage a switch to the preferred product when NHS treatment commences.

In October 2021, the Committee was informed that the Food and Drug Administration (USA) have amended the Prescribing Information for erenumab. The update highlights that patients should now be monitored for new-onset hypertension, or worsening of pre-existing hypertension, with consideration given to treatment discontinuation if an alternative cause is not identified. However, this warning was not mirrored by the UK Medicines and Healthcare products Regulatory Agency (MHRA). As a result, the Committee recommended that, a choice between erenumab and the second cheapest product with a NICE Technology Appraisal (TA) should be considered for patients who have controlled or poorly controlled hypertension.

To support an equitable and consistent approach for migraine prevention in NCL, the Committee were informed that a new High-Cost Drug pathway for the prevention of migraine has been developed. Alongside this, the NCL clinical pathway for primary care headache management was also updated in August 2025.

Treatment options for migraine prevention with positive NICE recommendations include:

- For chronic and episodic migraine: galcanezumab (TA 659, 2020), erenumab (TA 682, 2021), fremanezumab (TA 764, 2022), eptinezumab (TA 871, 2023), and atogepant (TA 973, 2024)
- For chronic migraine only: botulinum toxin type A (TA 260, 2012) and occipital nerve stimulation (IPG 42, 2013)
- For episodic migraine only: rimegepant (TA 906, 2023)

The Committee was informed that while fremanezumab, eptinezumab, and rimegepant are available, they are not preferred due to their higher acquisition cost. Additionally, it was noted that rimegepant was only recommended for episodic migraine, and eptinezumab is considered to be less convenient as it is administered via IV infusion.

9.1.1 Injectable CGRP therapies

The Committee were informed that there was a lack of randomised controlled trials or head-to-head studies investigating migraine prevention. The existing literature comprises placebo-controlled trials. The Committee heard the following limitations of clinical trials investigating the efficacy of migraine prevention treatments:

- Large placebo effect has been reported in clinical trials. When this is taken into consideration, the true treatment effect of migraine prevention therapies appears considerably more modest.
- The effect of baseline monthly migraine days (MMDs) on the observed treatment effect, it was noted to be significant. The Committee heard that the treatment magnitude is positively correlated with the baseline number of MMDs. Patients with chronic migraine, characterised by higher baseline MMDs, experienced greater reductions in MMDs following treatment with CGRP therapies, compared to those with episodic migraine who have lower baseline MMDs. This confounding effect limits undermines the reliability of conclusions regarding comparative efficacy in meta-analyses that combine data from both chronic and episodic migraine populations.

The Committee considered the results of the following trials for erenumab, galcanezumab, and fremanezumab:

- Erenumab: Sun et al (2016), Goadsby et al (2017), Tepper et al (2017), Dodick et al (2018), Reuter et al (2018), Goadsby et al (2021), Hirata et al (2021), Takeshima et al (2021)
- Galcanezumab: Detke et al (2018), Skljarevski et al (2018), Skljarevski et al (2018), Stauffer et al (2018), Ailani et al (2020), Mulleners et al (2020),
- Fremanezumab: Bigal et al (2015), Dodick et al (2018), Silberstein et al (2017), Ashina et al (2021)

The reviewed studies suggest that overall, the three injectable CGRP therapies have similar treatment effects in both chronic and episodic patients. Notably, the trials were unselected and recruited a mix of treatment-naïve patients and those with prior treatment failure from one or more agents. The Committee were informed that only erenumab and galcanezumab have been specifically evaluated in patients who have failed previous treatments. Results from trials investigating treatment-resistant migraine suggest that treatment effects are broadly similar to those observed in unselected trials of these injectable CGRP therapies.

9.1.2 Oral CGRP therapies

In terms of efficacy of atogepant versus rimegepant, the Committee were informed that no head-to-head trials are currently available. The Committee reviewed studies on atogepant, including Goadsby et al (2020), Ailani et al (2021), Pozo-Rosich et al (2023), and Tassorelli et al (2024), as well as the results of Croop et al (2021) for rimegepant. The results indicated that atogepant was more effective than rimegepant in reducing the number of MMDs, particularly when the placebo-adjusted treatment effects and baseline migraine frequency were taken into account. Therefore, atogepant was designated as the preferred oral agent within the NCL migraine prevention pathway. Furthermore, atogepant offers the additional advantage of having been evaluated for both chronic and episodic migraine, as evidenced by positive NICE TAs for chronic and episodic migraine, whereas rimegepant has received a positive NICE TA only for the prevention of episodic migraine.

9.1.3 Botulinum toxin type A (Botox®)

Botulinum toxin type A, a purified neurotoxin complex, has neuromuscular transmitter blocking effects, thereby interrupting the pain transmission pathway. The Committee heard that botulinum toxin type A has a positive NICE TA for the treatment of chronic migraine only (NICE TA 260).

Botulinum toxin type A may be considered as a first-line option for patients with chronic migraine who are concerned about the side-effect profile of CGRP treatments, experience constipation or are unable to self-administer injections. Additionally, botulinum toxin type A may be used as a third-line treatment option for patients with chronic migraine, who have either not responded to, or have been unable to tolerate two previous lines of CGRP receptor therapies.

The Committee considered the pooled results of two phase 3 RCTs, PREEMPT 1 and PREEMPT 2 (2020, n= 1,384), which compared botulinum toxin type A with placebo in patients with chronic migraine. The pooled results reported a statistically significant reduction in headache days with botulinum toxin type A compared to placebo (-8.4 vs. -6.6 headache days; $p<0.001$).

The Committee heard that botulinum toxin type A is a resource intensive intervention, requiring specialist facilities for administration in secondary care settings, and that current waiting lists are long.

9.1.4 Switching following treatment failure

Patients with migraine are assessed at 12 weeks following treatment initiation. NICE defines treatment failure as less than 30% reduction in MMDs for chronic migraine, and less than 50% reduction in MMDs for episodic migraine. The Committee heard evidence for second-line agents in the NCL migraine prevention pathway. It was noted that there were no randomised controlled trials on switching and only observational studies were identified. There are several potential switches possible in the proposed NCL High-Cost Drug migraine prevention pathway:

- Botulinum toxin type A to CGRP therapies (for chronic migraine patients only)
- CGRP therapies to botulinum toxin type A (for chronic migraine patients only)
- Erenumab to galcanezumab (for chronic and episodic migraine patients)
- Atogepant to galcanezumab (for chronic and episodic migraine patients)

Regarding the switch from botulinum toxin type A to CGRP therapies, the Committee heard results from two studies. Singh et al (2020; n= 10) recruited patients with chronic migraine who received botulinum toxin type A for 1 year prior to a switch to galcanezumab. The authors reported that all patients saw a reduction in migraine headache days (MHDs) following treatment with galcanezumab (16.4 $\pm$ 1.2 MHDs with botulinum toxin type A versus 12.1 $\pm$ 1.5 MHDs with galcanezumab). Similarly, Iannone et al (2023, n= 78), a cohort study, recruited patients with chronic migraine first treated with botulinum toxin type A. Patients were then switched to receive either erenumab (n= 32), galcanezumab (n= 32), or fremanezumab (n= 14). The authors reported that following a switch to CGRP therapies, patients experienced a reduction in MHDs.

Regarding the switch from erenumab to galcanezumab, the Committee heard results from two studies. Zieglar et al (2020, n= 3) recruited patients who received erenumab 70mg for minimum of 3 months and those who had dose escalated to 140mg following 3 months of treatment with 70mg erenumab. The study reported that the switch to galcanezumab led to significant decrease in MHDs and intensity 3 months later. Overeem et al (2021, n= 25) recruited patients who received a minimum of 3 doses of erenumab; patients were started on 70mg erenumab before this was increased to 140mg. Patients were then switched to receive either galcanezumab (n= 12) or fremanezumab (n= 13). The authors reported that approximately 32% of erenumab non-responders showed a clinically meaningful reduction in headache days of more than 30% following the switch to CGRP monoclonal antibodies.

No published studies were identified regarding switches from CGRP therapies to botulinum toxin type A or from atogepant to galcanezumab.

In terms of safety, the Committee heard findings from three network meta-analyses, Wang et al (2022), Lampl et al (2023), and Damen et al (2025), which reported safety outcomes as secondary outcomes of interest. Overall, the meta-analyses reported that CGRP therapies were not associated with increased risk of treatment-emergent adverse events or serious adverse events. Lampl et al (2023) and Damen et al (2025) also found no convincing evidence that adverse events from CGRP therapies led to discontinuation of treatment. The Committee heard that the FDA had amended the Prescribing Information to highlight the risk of new-onset or worsening of pre-existing hypertension and constipation with serious complications. However, it was highlighted that no safety warnings regarding these adverse effects have been issued by the MHRA for erenumab.

In terms of convenience, the Committee acknowledged that oral CGRP therapies are more convenient than injectable alternatives. Botulinum toxin type A is a resource-intensive intervention requiring specialist facilities and trained personnel for administration resulting in long waiting lists at present.

In terms of budget impact, botulinum toxin type A has the lowest acquisition cost compared to other CGRP therapies. Among the CGRP therapies, erenumab remains the most cost-effective treatment, followed by rimegepant, atogepant, galcanezumab, fremanezumab, and eptinezumab. The inclusion of atogepant alongside erenumab as a first-line option in the pathway represents a cost pressure of approximately £340 per patient per year. However, the Committee recognised the importance of offering an oral treatment option for patients with migraine.

The Committee heard from Prof Matharu, Dr Yates, and Dr Athwal that despite the modest effect of migraine prevention treatments reported in published studies, patients often experience benefits in real-world settings that far exceed those observed in clinical trials. Although trial data reported that patients did not experience higher rates of adverse events with any CGRP therapies, clinical experience suggests that patients treated with erenumab appear to experience more side effects than those on other CGRP therapies. It was noted that existing trials may not be sufficiently powered to detect this difference. The Committee also heard about the observed waning effect of erenumab over 6 to 12-month period. Prof Matharu, Dr Yates, and Dr Athwal cited

three observational studies; Andreou et al (2023, n= 160), Lambru et al (2020, n= 300), and Cullum et al (2022, n= 300); which reported that response rate to erenumab decreased over time. However, this phenomenon was not observed with other CGRP therapies. The Committee were informed that specialist services, such as those hosted at the National Hospital for Neurology and Neurosurgery (NHNN), often manage a more complex and treatment-refractory patient population who have been on migraine prevention therapies for extended periods. Therefore, the reported observations and treatment-emergent adverse events are not typically captured in clinical trials which generally have shorter follow-up period.

In camera, the Committee discussed the potential savings that could be achieved through the proposed NCL HCD migraine prevention pathway taking into account current prescribing practices at UCLH and RFL, the two major Headache Services in NCL. The Committee recognised that there was limited evidence base for switching from erenumab, a CGRP receptor antagonist, to galcanezumab, a CGRP ligand antagonist. However, the proposed pathway offered a pragmatic solution for patients who experience intolerable side effects, those who do not meet the NICE criteria for treatment response, and those who become non-responders to erenumab over time. The Committee discussed the importance of benchmarking and auditing prescribing following the implementation of the pathway to ensure clinical practice aligns with the agreed approach and expected savings are achieved. As such, the Committee requested greater clarity on the criteria for patients t to progress from first- to second-line CGRP therapy, as well as an agreed target proportion of patients (one that should not be exceeded) who are anticipated to switch to second-line treatment with galcanezumab.

In summary, the Committee agreed to clinically approve the proposed NCL High-Cost Drug migraine prevention pathway subject to audit standards specifying the proportion of patients who are expected to switch to second-line treatment with galcanezumab. These standards will ensure the pathway is used as intended and provide both clinical and financial assurance. The agreed audit standards for benchmarking should be agreed by the short-life working group and brought back to JFC for noting.

Post-meeting note: The JFC were informed that the migraine short-life working group agreed on audit standards, specifying that 20% of patients are expected to switch to second-line treatment with galcanezumab.

9.2. NCL High-cost Drug Retinal Vein Occlusion (RVO) Pathway (Applicants: Dr L Nicholson, MEH; Dr D Hanumunthadu)

The Committee reviewed the rationale and evidence underpinning the proposed changes to the NCL High-cost Drug treatment pathway for macular oedema secondary to retinal vein occlusion (RVO). RVO is a serious eye condition characterised by blockage of the retinal vein, typically presenting as sudden, painless, unilateral vision loss. Bilateral involvement is rare. Macular oedema (swelling and fluid leakage in the macula) is a common complication of RVO, leading to reduced central vision. RVO is classified into two main types: branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO). Treatment aims to alleviate macular oedema and minimise fluid leakage in the macula to optimise visual acuity.

The NCL RVO pathway include medications with a positive NICE Technology Appraisals (NICE TA), in line with statutory requirements and follows the principles for commissioning high-cost drug pathways for ICB commissioned indications. Previously, separate pathways existed for BRVO and CRVO, last updated in 2015 and 2016 respectively. The proposed unified pathway incorporates both conditions and reflects the updated NHSE commissioning guidance for macular oedema secondary to RVO, published in October 2025.

There are four main treatment options for RVO that are supported by positive NICE TAs: aflibercept biosimilar (NICE TA305 and TA409), dexamethasone intravitreal implant (NICE TA229), faricimab (NICE TA1004), and ranibizumab biosimilar (NICE TA283). The proposed NCL RVO treatment pathway recommends aflibercept biosimilar or dexamethasone implant as first-line options, with faricimab or dexamethasone intravitreal implant (if not previously used) recommended as second-line treatments.

9.2.1 Intravitreal dexamethasone implant administered at intervals less than six months

The proposed NCL RVO pathway permits the administration of intravitreal dexamethasone implant at intervals less than six months for patients requiring retreatment following the initial dose. According to NICE TA 229, clinicians may consider re-treatment at 4 months in clinical practice. However, more frequent dosing is not advised due to the increased risk of adverse events associated with the accumulation of dexamethasone in the eye. Furthermore, the Summary of Product Characteristic (SmPC) for the dexamethasone intravitreal implant highlights that there is only very limited information regarding repeat dosing intervals less than 6 months.

The COBALT study (2018, n=71) was a prospective, observational, non-comparative, open-label, multicentre study that evaluated the efficacy of intravitreal dexamethasone implant in treating macular oedema (MO) secondary to branch retinal vein occlusion (BRVO) in adult patients aged 18 and above. Retreatment with intravitreal dexamethasone implant was allowed if more than 4 months had passed since the last injection. The primary endpoint of this study was the mean change from baseline in Best Corrected Visual Acuity (BCVA) at 6 months. At this time point, patients demonstrated a significant improvement in BCVA from baseline (n = 62; mean gain of 18.6 ± 12.9 letters; p < 0.0001; 95% CI 15.4–21.8). The mean retreatment interval was 20.0 ± 5.0 weeks.

In terms of safety, the most commonly reported adverse events were increased intraocular pressure (35%), cataract (16%), and vitreous detachment (6%). The study concluded that intravitreal dexamethasone administered at interval of ≥ 4 months resulted in rapid and significant improvement in BCVA. However, a limitation of this study was that it did not compare the primary endpoint of BCVA improvement between patients who were retreated at ≥6 months and those treated earlier.

Pina et al (2016, n=18 eyes) conducted a multicentre observational study to evaluate the efficacy and safety of repeated intravitreal dexamethasone implant in eyes with macular oedema secondary to RVO. Patients received three consecutive dexamethasone implants on an 'as needed' basis, with the primary endpoint investigating the mean change in BCVA from baseline to two months following each of the three doses. The mean treatment interval was 5±1.3 months. At baseline, the mean (±SE) logarithm of the minimum angle of resolution (LogMAR) BCVA was 0.74 ± 0.08, improving to 0.45 ± 0.04 2 months after the -third implant, yielding an overall mean increase of 0.30 (95% CI, −0.50 to −0.08, P = 0.009).

In terms of safety, intraocular pressure (IOP) elevation was observed in 9 eyes (50%); all of which were managed medically. Cataract progression necessitating surgery occurred in 69% of phakic eyes (9 out of 13 eyes), while no cases of retinal detachment, vitreous haemorrhage, or endophthalmitis were reported. A limitation of this study was the absence of a direct comparison with patients receiving retreatment at fixed 6-month intervals. However, the author referenced a comparison to the GENEVA study, a pivotal clinical trial that recommended retreatment 6 months after the first dose, as a point of reference.

In support of the safety profile, the Committee heard that, in addition to the COBALT study, the SAFODEX study (2017, n=361, 421 eyes) provided further reassurance. An analysis of the 77 cases that underwent early retreatment (defined as receiving a subsequent injection between 3–4 months after the previous dose) showed no increased risk of intraocular pressure elevation (defined as an increase ≥6 mmHg) compared with retreatment intervals more than 4 months (p = 0.87). These findings suggest that earlier retreatment with dexamethasone implants does not confer additional risk in terms of IOP elevation.

9.2.2 Efficacy of faricimab in patients previously treated with aflibercept

Hafner et al (2025, n=19), conducted a retrospective observational study investigated patients who were switched to Faricimab due to an inadequate response or adverse events related to prior intravitreal therapies, including ranibizumab, aflibercept, or the intravitreal dexamethasone implant (Ozurdex®). The primary outcome of the study was the change in best-corrected visual acuity (BCVA), measured in logMAR, from baseline to month 3. The study reported a significant improvement in BCVA, from 0.20 logMAR at baseline to 0.00 logMAR at month 3 (p < 0.01). the authors concluded that faricimab provided meaningful short-term improvement in BCVA, as well as in other parameters such as central subfield thickness (CST) and the presence of intraretinal fluid (IRF) on optical coherence tomography (OCT).

Hikichi et al (2025, n=42), conducted a retrospective observational study involved patients who were switched from aflibercept to faricimab following recurrence of macular oedema secondary to RVO. The primary endpoints of the study were changes in BCVA, central foveal thickness (CFT), and intravitreal injection intervals over six months. The study reported that BCVA (logMAR) improved significantly from 0.16 ± 0.03 to (LogMAR) 0.04 ± 0.03 at one month (p < 0.01) and remained stable at 0.02 ± 0.02 at the final visit. Additionally, mean CFT (± standard error) decreased significantly from 356 ± 23µm to 214 ± 3µm at one month (p < 0.01) and remained stable at the final visit (205 ± 4µm) at the final visit. The mean injection interval was also significantly extended from 12.3 ± 0.4 weeks to 16.2 ± 0.5 weeks (p < 0.01).

In terms of safety, Hafner et al reported that intraocular pressure remained stable throughout the study period, suggesting that faricimab does not pose a risk for pressure-related complications. However, both studies emphasised the need for further research to evaluate the long-term efficacy and safety of faricimab.

The Committee were presented with the NHSE commissioning guidance on medical retinal treatment pathway for macular oedema secondary to RVO, published in October 2025. The NCL RVO pathway broadly reflects the NHSE guidance, retaining its core elements and principles. However, the NCL RVO pathway has been simplified to facilitate implementation within NCL. The Committee was informed of the specific deviations and omissions in the NCL pathway compared to the NHSE recommendations.

In terms of cost, aflibercept is currently the most cost-effective treatment within the pathway, with a biosimilar expected to become available in due course. Although the 4 monthly intravitreal dexamethasone implant regimen incurs higher cost, it is prescribed to a significantly smaller patient population, with anti – VEGF therapies remain the mainstay of treatment for this condition. The Committee were informed that the cost modelling reflects the approach used in the NHSE commissioning guidance and is based on clinical trials evidence. The estimated cost pressure in NCL is expected to range between £5000 - £8500 over a two-year period.

The Committee heard from Mr Hanumunthadu that the number of patients receiving steroid monotherapy is low, with only a very small proportion remaining on steroid monotherapy on a four monthly basis. This will remain as mainstay within practice in London with treatment at intervals less than three months will not be considered.

The Committee heard from Mr Nicholson, who provided further insight into the proposed treatment pathway. He explained that while some patients may initiate treatment with steroids, particularly those unable to tolerate monthly injections or have a history of stroke, alternative treatments may be considered if response is inadequate. The pathway is designed to promote appropriate use of faricimab, with limited reliance on intravitreal dexamethasone. He referenced published data suggesting that approximately 30% of patients may require treatment beyond five years, while nearly 50% may discontinue within two to three years.

Mr Nicholson also discussed the potential for switching from faricimab back to aflibercept in selected cases, particularly where clinical benefits is insufficient or when inflammation occurs. This approach is consistent with the NHSE RVO pathway.

The Committee acknowledged that the NHSE pathway supports a treat-and-extend approach following initial treatment, consistent with current practice. A subset of patients with sustained response may transition to a ‘as required (PRN)’ regimen with treatment resumed if symptoms return. The approach is intended to reduce appointment burden and enhance service efficiency. The proposed NCL RVO pathway remains non-prescriptive regarding follow-up strategies, allowing clinicians to exercise their professional judgment in selecting either a treat-and-extend or PRN model based on individual patient needs.

In camera, the Committee agreed that the simplified pathway provides a clear and structured approach to managing this patient cohort.

In summary, the Committee agreed to clinically approve the NCL High-cost Drug pathway for the treatment of macular oedema secondary to retinal vein occlusion (RVO).

10. Position statements and guidelines

10.1. NCL chronic obstructive pulmonary disease (COPD) guideline updates (Applicants: Dr K Roy, UCLH; Ms S Ladd, NCL ICB)

The Committee heard from Ms Ladd regarding the NCL chronic obstructive pulmonary disease (COPD) guideline, which was approved by the NCL Medicines Clinical Reference Group (MCRG) in September 2025.

In September 2023, the Committee approved the NCL treatment guidelines for the acute and chronic management of COPD as an interim measure, pending publication of the anticipated Pan-London COPD pathway. The interim guideline covers diagnosis, treatment, and local inhaler formulary options for COPD.

In September 2024, the Committee considered an appeal for Trixeo Aerosphere® (budesonide, glycopyrronium bromide, formoterol fumarate dihydrate) for maintenance treatment in adult patients with moderate to severe COPD, alongside a proposed update to the interim NCL treatment guidelines for the acute and chronic

management of COPD. Following the Committee's decision to reject the Trixeo Aersophere® appeal, the authors were requested to revise and provide an updated guideline.

In September 2025, it was noted that the work on the Pan-London COPD guideline has been discontinued, with no further updates anticipated. In response, the authors updated the interim NCL COPD guidelines, which were presented to the NCL MCRG. The Committee were informed that the treatment options remained unchanged.

The key changes made to the NCL COPD guidelines include:

- Addition of fractional exhaled nitric oxide (FeNo) testing if clinical history suggests a diagnosis of asthma.
- Consider spirometry screening with handheld device or clinicians may progress straight to quality assured diagnostic testing (as per recent GOLD guidance).
- Quality assured diagnostic spirometry should be performed > 6 weeks post any exacerbation and as per ARTP (Association of Respiratory Technology and Physiology) standards and the NCL Respiratory diagnostic Hub SOP. If baseline spirometry indicates obstruction, (or mixed restriction and obstruction), reversibility testing should be performed.
- SNOMED codes have also been provided to support appropriately coding.
- If patient shows asthma symptoms *plus* eosinophils levels > 0.4 *and/or* FeNO > 50. This supports an asthma diagnosis. In such cases, patients should be coded and managed as per NICE asthma guidelines 2024 or the recently published NCL adult asthma guidelines.
- Contact details for all the smoking cessation services and pulmonary rehab services have been updated
- The information on when to issue steroid cards and how they should be used has been updated.

In summary, the Committee were informed that the NCL COPD guideline was approved by the NCL MCRG in September 2025 and the update was brought to NCL JFC for noting.

10.2. NCL direct oral anticoagulants (DOAC) prescribing guideline updates

The Committee heard from Ms Ward regarding the NCL DOAC prescribing guideline, which has been shared across the system for consultation and presented at the General Practice Provider Alliance (GPPA) group for comments prior to approval at the Medicines Clinical Reference Group (mCRG) in September 2025.

The key changes made to the NCL DOAC prescribing guidance are as follows:

- Section 5 - Update of DOAC preference across NCL to reflect the use of generic apixaban and rivaroxaban and deprioritising the use of edoxaban,
- Section 9 – update to renal impairment section including new advice for DOAC initiation (AF) with CrCL 25-30ml/min and DOAC management advice for patients with CrCL < 25ml/min,
- Section 11- Update of monitoring frequency for patients who are age ≥75/ frail. This is in line with the NICE clinical knowledge summaries,
- And addition of a new template for general anticoagulation enquiries.

Ms Ward informed the Committee that an updated NCL DOAC counselling checklist and referral template are expected to be presented for sign-off in the coming months.

In summary, the Committee were informed that the NCL DOAC prescribing guideline was signed off at NCL MCRG in September 2025 and the update was brought to NCL JFC for noting.

11. Sub-Group Updates

11.1. NICE TA Implementation Group Report

The Committee were informed that the October NICE TA Implementation Group meeting was cancelled, and the next meeting is scheduled for November 2025.

11.2. NCL Pathways Group

Nil

11.3. Interface Prescribing Group Updates

The Committee were informed that changes to the Interface prescribing and governance process are being driven by the London Procurement Programme's RAG classification, which further subdivides amber drugs into amber 1, 2, and 3 categories. This classification is based on the level of specialist input required for ongoing

prescribing and the additional responsibilities placed on primary care. As part of the future process, a Short Life Working Group will be established to determine the appropriate amber sub-classification. Membership will be condition- and drug-specific to ensure relevant expertise is represented.

All related documents are currently being reviewed and input is being gathered from representatives across all care sectors to ensure updates are inclusive and reflect diverse perspectives. Once the paperwork and governance structure are finalised, and training has been delivered to support awareness, the Interface Working Group will proceed with communications about the new system.

12. Next meeting

Thursday 20th November 2025

13. Any other business

Nil