



# Joint Formulary Committee (JFC): Minutes Minutes from the meeting held on 20<sup>th</sup> March 2025

|                    |   | Present | Apologies |  |  |  |
|--------------------|---|---------|-----------|--|--|--|
|                    | Members   |         |           |  |  |  |
| Prof A Hingorani   | NCL JFC Chair   |         | ✓         |  |  |  |
| Dr B Subel (Chair) | 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         | · · · · · · · · · · · · · · · · · · ·                                 |         |           |  |  |  |
| Ms M Kaur-Singh    | NCL ICB, Head of Medicines Planning & Operations                      | ✓       |           |  |  |  |
| Dr D Roberts       | NCL ICB, Clinical Director (Islington)                                |         | ✓         |  |  |  |
| 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        |   |         |           |  |  |  |
| Ms M Butt          |   |         | ✓         |  |  |  |
| 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                                       | ✓       |           |  |  |  |
|                    | I .   |         | 1         |  |  |  |

| Ms A Bathia      | A Bathia RNOH, Formulary Pharmacist                           |   |   |
|------------------|---|---|---|
| Ms S Ahmed       | Is S Ahmed WH, Formulary Pharmacist                           |   |   |
| M A Sehmi        | A Sehmi NMUH, Formulary Pharmacist                            |   | ✓ |
| Ms Y Lam         | s 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 J Collins     | WH Rotational Pharmacist                                      |   | ✓ |
| Ms C Weaver      | NCL ICB, Senior Prescribing Advisor – Quality and Improvement |   | ✓ |
| Ms N Patel       | NCL ICB, Senior Prescribing Advisor – High Cost Drugs         | ✓ |   |
| Ms J Toft        | UCLH, IBD Specialist Pharmacist                               | ✓ |   |
| Dr M Kabir       | UCLH, Consultant Gastroenterologist                           | ✓ |   |
| Dr M Amran       | UCLH, Clinical Pharmacology Specialist Registrar              | ✓ |   |
| Dr N Meyer       | UCLH, Consultant Psychiatrist                                 | ✓ |   |
| Dr A Getz        | or A Getz NLFT, Consultant Psychiatrist                       |   |   |
| Ms L Anderson    | NCL ICB, Community Participant (Observer)                     | ✓ |   |
| Ms V Bovell      | NCL ICB, Community Participant (Observer)                     | ✓ |   |

## 2. Meeting attendees

Dr Subel 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 20th February 2025

Minutes and abbreviated minutes of the 20<sup>th</sup> February 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     |
|------------------|---|--|------------------------|
| February<br>2025 | [FOC Scheme]  Vorasidenib for IDH  mutant grade 2  oligodendroglioma or  astrocytoma *† | Reviewed by: UCLH Drug: Vorasidenib Indication: For IDH mutant grade 2 oligodendroglioma or astrocytoma Decision: Approved Prescribing status: Restricted to secondary only Funding source: Free of Charge Scheme Additional information: Follow up from November 2024 conditional approval. The Committee were satisfied that vorasidenib would now be managed within the established oncology processes for SACT and the conditions for approval had been met. The Committee did request confirmation on the pregnancy prevention process that would apply | Approved for UCLH only |

|          | <u> </u>                |   |               |
|----------|-------------------------|---|---------------|
|          |                         | given the teratogenic nature of vorasidenib and                                 |               |
|          |                         | requirement for non-hormonal effective  |               |
|          |                         | contraception.  |               |
|          |                         | Fact sheet or Shared Care required: N/A   |               |
| February | Gadopiclenol            | Drug: Gadopiclenol (Elucirem)   | Conditionally |
| 2025     | (Elucirem) for contrast | Indication: Contrast enhanced MRI in patients with                              | approved for  |
|          | enhanced MRI in         | Meniere's Disease   | UCLH only     |
|          | patients with           | Decision: Approved under evaluation   |               |
|          | Meniere's Disease and   | Prescribing status: Restricted to secondary care only Funding source: In tariff |               |
|          | contrast enhanced MRI   | Additional information: Applicants submit the                                   |               |
|          | across all tissue       | results of their experience using gadopiclenol                                  |               |
|          | types/subspecialties    | (Elucirem) in Meniere's disease one-year after                                  |               |
|          |                         | implementing (or after 200 patients whichever                                   |               |
|          |                         | sooner  |               |
|          |                         | Fact sheet or Shared Care required: N/A   |               |
|          |                         | race sheet or shared care required. 14/7.                                       |               |
|          |                         | Reviewed by: UCLH   | l <b>.</b>    |
|          |                         | Drug: Gadopiclenol (Elucirem)   | Not approved  |
|          |                         | Indication: Contrast enhanced MRI across all tissue                             |               |
|          |                         | types/subspecialties  |               |
|          |                         | Decision: Not approved  |               |
| February | Propranolol,            | Reviewed by: UCLH   | To add to the |
| 2025     | primidone,              | <b>Drug:</b> Propranolol 40 mg BD - TDS; titrated up to 80–                     | NCL Joint     |
|          | clonazepam, and         | 160 mg/day  | Formulary     |
|          | gabapentin for the      | Indication: Management of essential tremor                                      | •             |
|          | management of           | Decision: Approved  |               |
|          | essential tremor        | Prescribing status: Suitable for secondary care                                 |               |
|          | (off-label historical   | initiation, primary care continuation – referred to                             |               |
|          | review)                 | NCL JFC for review  |               |
|          |                         | Funding source: In tariff   |               |
|          |                         | Additional information: N/A   |               |
|          |                         | Fact sheet or Shared Care required: N/A   |               |
|          |                         | Reviewed by: UCLH   | To add to the |
|          |                         | <b>Drug:</b> Primidone 50 mg OD, titrated to up to 750                          | NCL Joint     |
|          |                         | mg/day  | Formulary     |
|          |                         | Indication: Management of essential tremor                                      |               |
|          |                         | Decision: Approved  |               |
|          |                         | Prescribing status: Suitable for secondary care                                 |               |
|          |                         | initiation, primary care continuation – referred to                             |               |
|          |                         | NCL JFC for review  |               |
|          |                         | Funding source: In tariff   |               |
|          |                         | Additional information: N/A   |               |
|          |                         | Fact sheet or Shared Care required: N/A   |               |
|          |                         | Reviewed by: UCLH   | To add to the |
|          |                         | Drug: Clonazepam 0.5–6 mg/day   | NCL Joint     |
|          |                         | Indication: Management of essential tremor                                      | Formulary     |
|          |                         | Decision: Approved  |               |
|          |                         | Prescribing status: Suitable for secondary care                                 |               |
|          |                         | initiation, primary care continuation – referred to                             |               |
|          |                         | NCL JFC for review  |               |
|          |                         |   | 1             |
|          |                         | Funding source: In tariff   |               |
|          |                         | Funding source: In tariff Additional information: N/A                           |               |
|          |                         | <u> </u>  |               |

|                  |   | Reviewed by: UCLH Drug: Gabapentin 300 mg TDS, titrated up to 1200– 1800 mg/day Indication: Management of essential tremor Decision: Approved Prescribing status: Suitable for secondary care initiation, primary care continuation – referred to NCL JFC for review Funding source: In tariff Additional information: N/A Fact sheet or Shared Care required: N/A  | To add to the<br>NCL Joint<br>Formulary    |
|------------------|---|---|--|
| February<br>2025 | Topiramate for the management of essential tremor. (off-label historical review)                                  | Reviewed by: UCLH Drug: Topiramate 25–50 mg OD and titrated up to 400 mg/day Indication: Management of essential tremor Decision: Conditionally approved Prescribing status: Suitable for secondary care initiation, primary care continuation – referred to NCL JFC for review Funding source: In tariff Additional information: Pending clarification of positioning in the treatment pathway Fact sheet or Shared Care required: N/A   | Conditionally<br>approved for<br>UCLH only |
| February<br>2025 | Pregabalin, zonisamide, and trihexyphenidyl for the management of essential tremor. (off-label historical review) | Reviewed by: UCLH Indication: Pregabalin 50mg OD, titrated up to 600 mg/day Decision: Deferred Additional information: Pending supporting evidence submission within 6 months.  Reviewed by: UCLH Indication: Zonisamide 100 mg OD, titrated up to 200 mg/day Decision: Deferred  | Deferred  Deferred                         |
|                  |   | Additional information: Pending supporting evidence submission within 6 months.  Reviewed by: UCLH Indication: Trihexyphenidyl 1 mg OD, titrated up to 5–15 mg/day, max 20 mg/day Decision: Deferred Additional information: Pending supporting evidence submission within 6 months.  | Deferred                                   |
| February<br>2025 | Pylera® (bismuth subcitrate potassium, metronidazole and tetracycline) for H. pylori eradication                  | Reviewed by: UCLH  Drug: Bismuth subcitrate potassium, metronidazole, tetracycline hydrochloride (Pylera ®) 140mg/125mg/125mg capsules Indication: H.pylori eradication Decision: Approved Prescribing status: Suitable for secondary care initiation, or secondary care recommendation and primary care initiation – referred to NCL JFC for review Funding source: In tariff Additional information: As per UKHSA guidance and Trust H. pylori eradication guidelines Fact sheet or Shared Care required: N/A | To add to the<br>NCL Joint<br>Formulary    |

| February | Rifabutin for H.pylori | Reviewed by: UCLH  | To add to the    |
|----------|------------------------|--|------------------|
| 2025     | eradication            | Drug: Rifabutin capsules                                 | NCL Joint        |
|          |                        | Indication: H.pylori eradication                         | Formulary        |
|          |                        | Decision: Approved                                       | ,                |
|          |                        | Prescribing status: Suitable for secondary care          |                  |
|          |                        | initiation, or secondary care recommendation and         |                  |
|          |                        | primary care initiation – referred to NCL JFC for review |                  |
|          |                        | Funding source: In tariff                                |                  |
|          |                        | Additional information: As per UKHSA guidance and        |                  |
|          |                        | Trust H. pylori eradication guidelines                   |                  |
|          |                        | Fact sheet or Shared Care required: N/A                  |                  |
| January  | Sulphur hexafluoride   | Reviewed by: RFL   | To add to the    |
| 2025     | (SonoVue®) for         | <b>Drug:</b> Sulphur hexafluoride (SonoVue®)             | NCL Joint        |
|          | contrast enhanced      | Indication: Contrast enhanced renal and                  | Formulary        |
|          | renal and endocavitary | endocavitary ultrasound imaging                          | -                |
|          | ultrasound imaging     | Decision: Approved                                       |                  |
|          |                        | Prescribing status: Suitable for secondary care only     |                  |
|          |                        | Funding source: Divisional budget                        |                  |
|          |                        | Additional information: Provide covering document        |                  |
|          |                        | that lists all organs from the European guidelines       |                  |
|          |                        | that SonoVue® will be used in. Discuss and               |                  |
|          |                        | implement with Pharmacy and EPMA teams a                 |                  |
|          |                        | suitable prescribing process for SonoVue®.               |                  |
|          |                        | Fact sheet or Shared Care required: N/A                  |                  |
| January  | Tenofovir Alafenamide  | Reviewed by: RFL   | Approved for RFL |
| 2025     | (Vemlidy®) for Chronic | Drug: Tenofovir Alafenamide (Vemlidy®)                   | only             |
|          | Hepatitis B            | Indication: Chronic Hepatitis B                          |                  |
|          |                        | Decision: Approved                                       |                  |
|          |                        | Prescribing status: Suitable for secondary care only     |                  |
|          |                        | Funding source: Divisional budget                        |                  |
|          |                        | Additional information: N/A                              |                  |
|          |                        | Fact sheet or Shared Care required: N/A                  |                  |

<sup>\*</sup>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. Psoriasis pathway – Bimekizumab update

In January and February 2025, the Committee considered the NCL psoriasis high-cost drug pathway. The proposal at the time was to include bimekizumab (IL-17 A&F receptor inhibitor) in the psoriasis pathway, considering it as an alternative mechanism of action to other IL-17 inhibitors, which target the IL-17 A receptor inhibitors. Based on evidence of superior efficacy over the alternative IL-17 inhibitors, the Committee agreed that patients with primary or secondary loss of efficacy with secukinumab, ixekizumab or brodalumab, could access treatment with bimekizumab. Due to cost considerations, the Committee recommended using bimekizumab as first line treatment for all new patients, as it was of lower cost (amber cost band) compared to the other IL-17 inhibitors (red cost band).

Since then, the psoriasis short-life working group were informed that St John's Institute of Dermatology at Guy's and St Thomas' NHS Foundation Trust had moved away from bimekizumab as their preferred IL-17 inhibitor due to the higher risk of candidal infections. Results from the BE VIVID (2021; n= 567) and BE RADIANT (2021; n= 743) trials indicate that candidiasis is more common with bimekizumab compared to secukinumab and ustekinumab. However, despite the increased risk, most cases of candidiasis associated with IL-17 inhibitors, including bimekizumab, are mild to moderate and can be effectively managed with antifungal treatments whilst patients are continued on therapy. Therefore, the psoriasis short-life working group proposed assigning bimekizumab a red RAG rating for cost, aligning it with other IL-17 inhibitors due to the higher risk of candidal infections and the relatively small cost difference among all IL-17 inhibitors.

In summary, the Committee agreed to remove the preference for bimekizumab as the IL-17 inhibitor of choice for new patients and to reclassify bimekizumab as a red RAG rating for cost. This allows clinicians to select an alternative IL-17 inhibitor with a lower risk of candidal infections when clinically appropriate.

#### 9. Medicines Review

## 9.1. Adalimumab for Microscopic Colitis (Applicant: Ms J Toft, Dr E Seward and Dr M Kabir, UCLH)

The Committee considered an application for the off-label use of adalimumab biosimilar (Yuflyma®) for treatment of microscopic colitis. Adalimumab is a licensed pharmacological treatment commonly used for rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. Microscopic colitis (MC) is a chronic inflammatory disease that affects the colon, characterised by persistent non-bloody diarrhoea with a sense of urgency, abdominal pain, nausea, weight loss and other symptoms that can significantly impact a patient's quality of life. The condition is more prevalent in individuals aged 50 and above, predominantly in females, and smoking increases the risk. MC is classified into three subtypes: collagenous colitis (CC), lymphocytic colitis (LC), and incomplete colitis (IC). Diagnosis is typically confirmed through histological results obtained from a biopsy during a colonoscopy.

Following dietary and lifestyle changes, pharmacological treatment begins with an anti-diarrhoeal drug such as loperamide. If this fails to control bowel movements and symptoms, patients proceed to a course of steroids. Typically, if symptoms are under control, corticosteroids are gradually weaned off after three months of treatment. Patients can have up to four courses of corticosteroids for multiple flares within a year. A disease-modifying antirheumatic drug (DMARD) such as azathioprine is considered if a patient experiences more than two flares within six months. Azathioprine should be used cautiously and avoided in patients over 65 due to the risk of adverse events and insufficient evidence. Bile acid sequestrants are added as a fourth-line treatment for patients' intolerant to or unsuitable for DMARDs. The applicant identified an unmet clinical need due to the increased risk of side effects from repeated steroid courses. With limited treatment options, an alternative is needed to avoid these side effects; otherwise, surgical intervention may be necessary.

Adalimumab is proposed as a fifth-line therapy after loperamide, azathioprine, a bile sequestrant, and repeated corticosteroids. The dosing regimen starts with 160 mg subcutaneously, followed by 80 mg after 2 weeks, then 40 mg every 2 weeks for maintenance, with an option to escalate to 40 mg weekly if needed. Prescreening tests include a chest X-ray and blood tests (full blood count, urea and electrolytes, kidney and liver function, virology). Monthly blood monitoring is required for the first 3 months, then every 3 months. Treatment response is assessed at 3, 6, and 12 months, aiming for a 50% reduction in stool frequency. Colonoscopies at 6 and 12 months will evaluate histological improvement. Treatment will be discontinued if a 50% reduction in stool frequency is not achieved after 6 months or if severe adverse events or allergies occur.

The European guideline on MC recommends thiopurines, anti-TNF drugs or vedolizumab for selected patients who do not respond to budesonide for inducing and maintaining clinical remission. The American Gastroenterological Association Institute Guideline also supports anti-TNF treatment for patients with MC.

There are no randomised clinical trials comparing the efficacy of adalimumab against placebo or other active comparators in patients with MC. A meta-analysis conducted by Taneja et al highlighted several case series and reports on anti- TNFs such as adalimumab, infliximab and vedolizumab. Daferera et al (n=18) reported a single-centre experience with anti-TNF treatment in budesonide-refractory MC patients. This retrospective study included adults aged 18 and above with histological diagnosis of MC, CC, or LC, who had active disease despite maintenance treatment with 6–9 mg budesonide for at least eight weeks. Patients received adalimumab (160mg, 80mg, 40mg then 40 mg every other week) or infliximab (5mg/kg at weeks 0, 2 and 6 and maintenance at 5 mg/kg every eight weeks). Symptoms were assessed using the Hjortswang criteria, defining clinical remission as < 3 stools per day and < 1 watery stool per day during a week. In this study 10 patients received adalimumab as first line therapy. At 12 weeks, four patients achieved remission (40%), four were responders (40%) and two were non-responders (20%). In the infliximab group (n=8), five patients were switched to adalimumab. At 12 weeks, three (60%) had achieved remission and two (40%) were responders. The authors concluded that anti-TNF treatment is effective and safe for budesonide-refractory MC, improving quality of life and potentially avoiding surgery.

Esteve et al reported a case series involving four adult patients with a subtype of MC, characterised by more than 8 daily bowel movements. Three patients were initially treated with infliximab however due to either loss of response or adverse drug event or allergy, treatment was stopped and switched to adalimumab. Following treatment with adalimumab, three patients achieved more than 70% reduction in daily bowel movement and sustaining this response for at least 12 months. One patient loss response after 3 months and was recommended for colectomy.

In terms of safety, a multicentre retrospective cohort study conducted by Boivineau et al (n=7) reported no new adverse drug events or fatalities. In the adalimumab group four patients experienced mild to moderate adverse event including sinusitis, mild psoriasis, and pain. Two patients discontinued treatment due to side effects.

In terms of budget impact, patients may concurrently use all four classes of treatments, with up to four courses of corticosteroids per year to control severe symptoms. This could cost a maximum of approximately £2,200 per patient per annum in secondary care and £1,500 per patient per annum in primary care. This cost will vary depending on treatment with colestyramine or colesevelam. The estimated cost of adalimumab biosimilar is approximately £780 for a standard dose or £1,300 for a course of dose escalation per patient per annum, with up to a potential of 13 patients eligible for adalimumab within NCL as indicated by the Trusts.

The Committee heard from Ms Toft and Dr Kabir that although the cohort of affected patients is small, the condition significantly impacts their quality of life. The treatment is proven safe and effective for inflammatory bowel disease, but there is little data on the use of anti-TNFs in MC. Ms Toft informed the Committee that they plan to collaborate with other specialist centres to collect data to support evidence base and present it at a future JFC meeting. Dr Kabir emphasised the severe social and psychological effects of MC on patients. Ms Toft mentioned that infliximab was initially considered a second-line biologic treatment. However, due to its higher cost compared to adalimumab, this option is no longer being explored. Request for alternative biologic treatment would be considered via the individual funding request (IFR) route. In the past, three one-off requests for adalimumab were considered and approved by the UCLH's UMC but they were not commenced due to funding issue. Dr Kabir explained that assessing treatment response in this cohort of patients is challenging, as the tools used for ulcerative colitis are not validated for MC.

In camera, the Committee discussed the unmet need despite the lack of evidence. The Committee emphasised that the cost implications are minimal, as the cost of adalimumab biosimilar is comparable to the alternative medications currently available. In relation to safety, repeated courses of corticosteroids pose a higher risk for steroid induced side effects such diabetes and fractures caused by osteoporosis which also have cost implication. The Committee highlighted the need for further clarity on the initiation criteria for commencing biologic treatment, similar to the criteria for patients with inflammatory bowel disease.

In summary, the Committee agreed that adalimumab is a suitable and safe treatment option to address the unmet clinical need. The Committee conditionally approved the use of adalimumab for microscopic colitis, requiring applicants to provide clear initiation criteria for adalimumab and to present the cohort study data in 12 months. The application will need to be submitted to the NCL Medicines, Finance and Value Group for financial consideration.

Drug: Adalimumab biosimilar pre-filled pen (Yuflyma®), by subcutaneous injection

Adult: Initially 160 mg, then 80 mg after 2 weeks; maintenance 40 mg every 2 weeks, if necessary increased to 40 mg once weekly.

Indication: For Microscopic colitis (off-label use)

**Decision:** Conditionally approved pending documentation of clear initiation criteria for adalimumab in the treatment pathway.

**Prescribing status:** Restricted to secondary care only **Funding source:** ICB-commissioned High-Cost Drug

**Additional information:** The applicants are requested to present cohort data to the Committee in 12 months. Financial approval needs to be sought from the NCL Medicines, Finance and Value Group.

## 9.2. Prazosin for PTSD-related and idiopathic nightmares (Applicant: Dr N Meyer, UCLH)

The Committee considered an application for the off-label use of prazosin, an alpha-1 adrenergic receptor antagonist, for:

- PTSD-associated nightmare disorder, and
- Idiopathic nightmare disorder.

This application seeks to use prazosin alongside trauma-focused psychological therapy (such as imagery rehearsal therapy), which is the first-line treatment for both PTSD-associated and idiopathic nightmare disorder. The proposed dose for prazosin is 0.5mg every night, increasing in 0.5mg increments every 3 days, up to a maximum dose of 15mg nightly. Presently, there is no licensed treatments for PTSD-associated nightmare disorder; other pharmacological options such as trazodone, clonidine, olanzapine, and quetiapine are used off-license for insomnia.

#### PTSD-associated nightmare disorder

Raskind et al (2018; n= 304), a phase 3, multicentre, double-blind, placebo-controlled RCT evaluated the efficacy of prazosin in veterans with chronic combat-related PTSD with frequent nightmares. The primary outcomes were reduction in nightmare frequency (as per Clinician-Administered PTSD Scale (CAPS) item B2 score) and improvement in sleep quality (as per Pittsburgh Sleep Quality Index (PSQI)) at 10 weeks. The study reported no significant differences between prazosin and the placebo group in the mean change from baseline in nightmare frequency (between-group difference, 0.2; 95% CI: –0.3 to 0.8, p=0.38) and in the mean change in PSQI score (between-group difference, 0.1; 95% CI: –0.9 to 1.1, p=0.80) at 10 weeks. Similarly, at 26 weeks (secondary outcome), there were no significant differences in both outcomes. The authors concluded that prazosin did not alleviate distressing dreams or improve sleep quality.

Reist et al (2020; n= 6) was a systematic review and meta-analysis that investigated the pooled effect of prazosin versus placebo on sleep disturbances in patients with PTSD. The meta-analysis included six studies (n= 429) with prazosin dosage ranging from 8.9 to 15.6mg per day. The meta-analyses showed that treatment with prazosin resulted in a small, but statistically significant decrease in nightmare frequency (standardised mean difference= -0.75; 95% CI: -1.24 to -0.27), and improvement in sleep quality (standardised mean difference= -0.57; 95% CI: -1.02 to -0.13). The authors noted the negative results of the Raskind et al (2018) trial, however, its inclusion did not negate the statistically significant pooled overall effect of prazosin compared to placebo. Key limitations include the small number of trials included, with all but one having small patient cohorts of fewer than 100 patients (potential for small study bias).

The Committee were also informed that the Maudsley Prescribing Guidelines in Psychiatry (2022), recommends prazosin as second-line treatment for PTSD-associated nightmares and sleep disturbances. The American Academy of Sleep Medicine (AASM) Position Paper (2018) also states that prazosin may be used for the treatment of PTSD-associated nightmares.

#### Idiopathic nightmare disorder

In terms of efficacy of prazosin in idiopathic nightmare disorders, no relevant trials were identified. The Committee were informed that there was no relevant NICE guidance, however, the AASM Position Paper (2018) states prazosin may be used for the treatment of idiopathic nightmare disorder.

In terms of safety, common side effects of prazosin include dizziness, syncope, and hypotension due its vasodilatory effect. However, patients should be initiated on a low dose before gradually uptitrating it and should be counselled to take the daily dose at night to reduce the risk of hypotension and falls.

In terms of budget impact, the anticipated spend for prazosin is approximately £7,000 per annum for 14 patients per annum across NCL. Due to low patient numbers, the budget impact is expected to be minimal. The Committee also noted the price disparity between the UK-licensed 500 micrograms prazosin tablets and the imported 2 mg and 5 mg strengths. While the imported version may help reduce pill burden, the long-term cost implications must also be taken into consideration.

The Committee heard from Dr Meyer and Dr Getz that there is trial and anecdotal evidence suggesting prazosin addresses the nightmare element of PTSD. Prazosin would not be used as a first-line treatment and would be offered alongside psychological therapies for patients with nightmares without exhibiting symptoms of insomnia. Dr Meyer elaborated that many patients with significant nightmares often have experienced trauma, whether it be a one-off event or chronic traumas that cause nightmare. Therefore, prazosin represents a valuable treatment option for a cohort of patients with limited alternatives available. Dr Meyer and Dr Getz emphasised the challenges with uniformity of treatment in PTSD patients due to the numerous factors that may affect patients' recovery and success of treatment such as other presenting PTSD symptoms, type of trauma, and patient's psychological mindedness. As a result, it is difficult to predict how long patients will

remain on prazosin, but patients, will trial a gradual weaning down of prazosin dose whilst the benefits of other psychological therapies (such as image rehearsal therapy) are realised.

In camera, the Committee were unconvinced about the addition of prazosin to the NCL Joint Formulary for idiopathic nightmares. For PTSD-associated nightmares, the Committee expressed concerns around the small effect size and the generalisability of the trial results, since most of the trials were conducted in American veterans. It was noted that there are no licensed treatment options for this patient cohort and prazosin is a relatively safe pharmacological therapy used for many years for other conditions such as hypertension, congestive heart failure, and benign prostatic hyperplasia. However, Committee members questioned the increased risk of hypotension and falls with higher doses of prazosin, and the required ongoing monitoring following transfer of prescribing to primary care. The committee discussed interface prescribing issues such as continued prescribing, compliance (i.e., high pill burden as only 500 micrograms tablets are licensed in the UK), dose titration (e.g., weaning down), and monitoring of efficacy in primary care were discussed. The Committee deliberated whether retaining prazosin in secondary care would mitigate concerns, however, capacity within secondary care services remained a consideration.

The Committee could not recommend the use of prazosin for idiopathic nightmare disorder due to a lack of clinical efficacy. For PTSD-associated nightmare disorder, the Committee deferred the decision, requiring applicants to clarify the proposed place in therapy (relative to the other off-license treatment options) and the prescribing and monitoring arrangements for retaining prazosin in secondary care.

Drug: Prazosin

Indication: Idiopathic nightmare disorder

**Decision:** Not approved

Drug: Prazosin

**Indication:** PTSD-associated nightmare disorder

**Decision:** Deferred, pending clarity on the proposed place in therapy (relative to the other off-license treatment options) and the prescribing and monitoring arrangements for retaining prazosin in secondary care.

## 9.3. Sucralfate for bile reflex (Ms S Ahmed, Formulary Pharmacist WH)

Deferred

## 10. Position Statements and Guidelines

## 10.1. NCL Free of Charge Medicines Schemes Guidance (Final sign off)

The Committee approved the updated NCL Free of Charge (FOC) Medicines Schemes Guidance following a 2-week consultation period with NCL stakeholders.

## 11 Sub-Group Updates

## 11.1 NICE TA Implementation Group Report

The Committee heard from Ms Weaver who provided a summary of updates from the NICE TA Implementation Group. The Committee noted the current workplan, which was included in the agenda pack for information.

The following updates on NICE TAs with interface considerations were provided to support formulary teams and Trust DTCs with implementation:

- Atogepant (Aquipta®) for preventing migraines (NICE TA973): Implementation within secondary care is
  underway through inclusion in the headache pathway. While it is not yet part of the primary care headache
  pathway, the governance process will ensure a smooth transition once secondary care initiates treatment
  and primary care takes over the prescribing and monitoring.
- Vibegron for treating symptoms of overactive bladder syndrome (NICE TA999): A green prescribing status
  (primary or specialist care initiation) has been assigned for this NICE TA in line with NICE recommendation.
  Vibegron is as effective and safe as mirabegron. Consultation with NCL Trusts is underway as there is a
  potential to use as vibegron as first line options over mirabegron due to cost saving. In terms of efficacy
  and safety they are equivalent.
- Tirzepatide for managing overweight and obesity (NICE TA1026): The NICE TA implementation group is
  awaiting NHSE prioritisation and their commissioning policy framework to establish which cohort of
  patients will have access to the medication first.

• SQ-HDM SLIT; Acarizax for treating allergic rhinitis and allergic asthma caused by house dust mites (NICE TA1045): An amber prescribing status (specialist initiation and primary care continuation) has been assigned for this NICE TA in line with NICE recommendation. The JFC Committee has previously reviewed acarizax as part of the immunotherapy treatment pathway for allergies. Therefore, the NCL JFC formulary position needs updating to reflect NICE recommendation.

## 11.2 NCL Pathways Group

Nil

## 11.3 Shared Care Group Updates

The Committee was informed that Ms Coughlan (NCL ICB Chief Pharmacist) stepped in as interim chair for the Shared Care Group.

The Committee were informed that the next shared care group meeting will be held on Tuesday 8<sup>th</sup> April 2025. This meeting will focus on the post workshop action which was held in January 2025. The priority actions will focus on enhancing resources and deliverables, revising interface documents, and managing new requests.

## 12 Next meeting

Thursday 24th April 2025

## 13 Any other business

Following a recent Committee vote, Dr Subel announced that Professor Hingorani will continue as Chair for NCL JFC for a second term, extending his tenure for three more years until May 2028.

The April 2025 JFC meeting will be postponed to Thursday 24<sup>th</sup> April 2025 to avoid a clash with Good Friday and the Easter Bank Holiday weekend.