Joint Formulary Committee (JFC): Minutes

Minutes from the meeting held on 20th February 2025

		Present	Apologies
Members			
Prof A Hingorani (Chair)	NCL JFC Chair	✓	
Dr B Subel	NCL JFC Vice Chair	✓	
Ms L Coughlan	NCL ICB, Deputy Chief Clinical Officer & ICS Chief Pharmacist		✓
Ms W Spicer	RFL, Chief Pharmacist	✓	
Dr P Jasani	RFL, DTC Chair		✓
Dr K Boleti	RFL, DTC Chair		✓
Dr A Scourfield	UCLH, DTC Chair		✓
Mr J Harchowal	UCLH, Chief Pharmacist		✓
Dr K Tasopoulos	NMUH, DTC Chair	✓	
Ms S Stern	NMUH, Chief Pharmacist		✓
Dr M Kelsey	WH, DTC Chair	✓	
Mr S Richardson	WH, Chief Pharmacist		✓
Dr S Ishaq	WH, Consultant Anaesthetist	✓	
Dr A Worth	GOSH, DTC Chair		✓
Ms J Ballinger	GOSH, Chief Pharmacist		✓
Dr M Henley	RNOH, DTC Chair		✓
Mr A Shah	RNOH, Chief Pharmacist		✓
Prof A Tufail	MEH, DTC Chair	✓	
Ms N Phul	MEH, Chief Pharmacist		✓
Ms L Reeves	NLMHP, Chief Pharmacist		✓
Dr L Waters	CNWL, Consultant Physician in HIV		✓
Ms R Clark	NCL ICB, Assistant Director of Medicines Optimisation		✓
Ms M Kaur-Singh	NCL ICB, Head of Medicines Planning & Operations	✓	
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	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		✓
Ms J Peralta	RFL, Formulary Pharmacist		✓
Mr A Barron	UCLH, Principal Pharmacist	✓	
Mr S O'Callaghan	UCLH, Formulary Pharmacist		✓
Ms H Thoong	GOSH, Formulary Pharmacist		✓
Mr D Sergian	MEH, Formulary Pharmacist	✓	
Mr W Li	MEH, Formulary Pharmacist	✓	

Ms J Bloom	MEH, Associate Chief Pharmacist	✓	
Ms A Bathia	RNOH, Formulary Pharmacist	✓	
Ms S Ahmed	WH, Formulary Pharmacist		✓
M A Sehmi	NMUH, Formulary Pharmacist		✓
Ms Y Lam	UCLH, Formulary Pharmacist		✓
Ms M Thacker	GOSH, Deputy Chief Pharmacist		✓
Mr J Modha	NHSE, Specialised Commissioning Pharmacist		✓
Ms A Blochberger	NHSE, Chief Pharmacist – Specialised Commissioning	✓	
Mr J Flor	WH, Lead Pharmacist	✓	
Ms R Allen	UCLH, Commissioning Pharmacist		✓
Mr A Fazal	RFL, Principal Pharmacist		✓
Mr G Grewal	RFL, Deputy Chief Pharmacist	✓	
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	✓	
Dr J Bignall	NMUH, Sexual and Reproductive Health Consultant	✓	
Dr S McBride	RFL, Consultant Dermatologist	✓	
Ms S Wong	NCL ICB, Prescribing Advisor	✓	
Ms S Jalil	NCL ICB, Prescribing Advisor	✓	
Ms A Farook	NCL ICB, Prescribing Support Pharmacist (Observer)	✓	
Ms R Turner	RFL, Senior Specialist Pharmacist (Medical Specialities) (Observer)	✓	

2. Meeting attendees

Prof Hingorani welcomed members, observers, and applicants to the meeting (see above). Ms Weaver deputised for Ms EY Cheung at this meeting.

3. Members' declaration of interests

The Declarations of Interests register for Committee members was included for information. No further interests relevant to the agenda were declared by members or attendees present. Dr Bignall previously declared interests from the manufacturer for Slynd® (Exeltis).

4. Minutes and abbreviated minutes of meetings on 21st November 2024 and 16th January 2025

Minutes and abbreviated minutes of the 21st November 2024 and 16th January 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
September 2014	Bupropion for depression	**Reviewed by**: NLFT **Drug**: Bupropion (off-label use) **Indication**: For depression- 3rd line monotherapy where NICE recommendations do not produce adequate response or are not tolerated. An alternative 4th line option as adjunctive therapy with an SSRI. Continuation therapy for patients whose symptoms are currently well managed on bupropion, where treatment was initiated overseas or by a private prescriber (where NICE	To add to the NCL Joint Formulary

		guidance has been followed but not produced adequate response or treatments not tolerated). **Decision**: Approved **Prescribing status**: Suitable for initiation in primary and secondary care **Funding source:** In tariff **Additional information**: Consultant psychiatrist must be consulted prior to initiation. **Fact sheet or Shared Care required**: N/A	
May and November 2024	Lurasidone for schizophrenia	**Reviewed by**: NLFT **Drug**: Lurasidone 37 to 148 mg once daily **Indication**: Treatment of schizophrenia - second line where there is: 1. QTc interval prolongation and/or an increased risk of cardiometabolic risks associated with weight gain 2. AND aripiprazole is deemed to be unsuitable **Decision**: Not approved	Not approved
July 2024	Carbamazepine for Mania (Bipolar)	**Reviewed by**: NLFT **Drug**: Carbamazepine **Indication**: Mania **Decision**: Not approved **Additional information**: The NICE guidance does not refer to carbamazepine. Carbamazepine is licensed for the prophylaxis of manic - depressive psychosis in patients unresponsive to lithium therapy. Carbamazepine is an established human teratogen. Evidence base supporting other strategies is stronger.	Not approved
July 2024	Semi-sodium valproate for manic episodes in bipolar disorder	**Reviewed by**: NLFT **Drug**: Semi-sodium valproate **Indication**: Treatment of manic episode in bipolar disorder only when there is no other effective or tolerated treatment. The continuation of treatment after a manic episode should be considered in patients who have responded to semi-sodium valproate for acute mania. **Decision**: Not approved **Additional information**: Sodium valproate MR tablets is the preferred preparation. Sodium valproate is a non-formulary medicine in patients less than 55 years due to MHRA requirements.	Not approved
July 2024	Risperidone depot injection for schizophrenia and other psychoses	**Reviewed by**: NLFT **Drug**: Risperidone depot injection (Consta®) **Indication**: Schizophrenia and other psychoses, if tolerant to oral risperidone – maintenance. Third line atypical antipsychotic depot option. **Decision**: Approved **Prescribing status**: Suitable for secondary care initiation, primacy care continuation. **Funding source**: In tariff **Additional information**: Nil **Fact sheet or Shared Care required**: N/A	To add to the NCL Joint Formulary
November 2024	Co-phenotrope for diarrhoea due to opioid withdrawal	**Reviewed by**: NLFT **Drug**: Co-phenotrope **Indication**: Management of diarrhoea due to opioid withdrawal **Decision**: Not approved	Not approved

December 2024	IM Olanzapine for rapid tranquilisation	**Reviewed by**: NLFT **Drug**: IM Olanzapine **Indication**: Rapid control of disturbed behaviours and agitation in patients with a manic episode, or schizophrenia, when oral therapy is deemed inappropriate (adults). **Decision**: Approved **Prescribing status**: Restricted to secondary care only **Funding source**: In tariff **Additional information**: Nil **Fact sheet or Shared Care required**: N/A	To add to the NCL Joint Formulary
December 2024	Activated Eptacog beta; Recombinant Factor VIIa) CEVENFACTA® for treatment of bleeding episodes	**Reviewed by**: RFL **Drug**: Activated Eptacog beta; Recombinant Factor VIIa **Indication**: Treatment of bleeding episodes **Decision**: Approved **Prescribing status**: Secondary care, hospital prescribing only **Funding source**: NHSE **Additional information**: Nil **Fact sheet or Shared Care required**: N/A	Approved for RFL only
December 2024	[FOC Scheme] Durvalumab (Imfinzi®) for Adjuvant Therapy for early-stage Small Cell Lung Cancer *†	**Reviewed by**: RFL **Drug**: Durvalumab - 1500mg every 4 weeks (Treatment duration of 24 months). **Indication**: Adjuvant therapy for early-stage small cell lung cancer after completion of concurrent platinum-based chemoradiotherapy with Carboplatin/ Etoposide chemotherapy/ radiotherapy **Decision**: Approved **Prescribing status**: Restricted to secondary only **Funding source**: Free of Charge Scheme **Additional information**: N/A **Fact sheet or Shared Care required**: N/A	To add to the NCL Joint Formulary
May 2015	Levobupivacaine for pain management and surgical anaesthesia	**Reviewed by**: UCLH **Drug**: Levobupivacaine **Indication**: For pain management (continuous epidural infusion, single or multiple bolus epidural administration for the management of pain, particularly post-operative pain, or labour analgesia) and surgical anaesthesia (major e.g. epidural [inc. Caesarean section], intrathecal, peripheral nerve block. Minor e.g. local infiltration, peribulbar block in ophthalmic surgery. **Decision**: Approved **Prescribing status**: Restricted to secondary only **Funding source**: In tariff **Additional information**: N/A **Fact sheet or Shared Care required**: N/A	To add to the NCL Joint Formulary
February 2025	[FOC Scheme] Retifanlimab for locally recurrent or metastatic anal squamous cell carcinoma *†	**Reviewed by**: UCLH **Drug**: Retifanlimab **Indication**: Locally recurrent or metastatic anal squamous cell carcinoma **Decision**: Approved **Prescribing status**: Restricted to secondary only **Funding source**: Free of charge scheme **Additional information**: N/A	To add to the NCL Joint Formulary

		Fact sheet or Shared Care required: N/A	
November 2021	[FOC Scheme] Regorafenib for cholangiocarcinoma with no targeted mutations *†	**Reviewed by**: UCLH **Drug**: Regorafenib **Indication**: Cholangiocarcinoma with no targeted mutations where clinical trials and FOLFOX are not suitable. **Decision**: Approved **Prescribing status**: Restricted to secondary only **Funding source**: Free of charge scheme **Additional information**: Re-ratified to align with established FOC arrangement. **Fact sheet or Shared Care required**: N/A	To add to the NCL Joint Formulary
June 2003	SonoVue for stress echocardiography	**Reviewed by**: UCLH **Drug**: SonoVue **Indication**: Stress echocardiography **Decision**: Approved **Prescribing status**: Restricted to secondary only **Funding source**: In tariff **Additional information**: Historical decision, ratified for NCL use via Chairman's action as post-meeting action. **Fact sheet or Shared Care required**: N/A	To add to the NCL Joint Formulary

*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. Drospirenone (Slynd®) for contraception (Applicant: Dr J Bignall, NMUH)

In November 2024, the Committee considered an application for drospirenone, a fourth-generation progestin and spironolactone analogue, for contraception. Drospirenone was proposed as a second-line progestin-only contraceptive pill (POP), alongside levonorgestrel for women requiring POP contraception who do not have risk factors for potassium elevation. The Committee deferred its decision pending details on proposed place in therapy; definition of the eligible patient cohort; itemisation on operating procedure for initiation and monitoring; and clear itemisation of responsibilities (if any) to be placed on primary care for ongoing prescribing and monitoring.

Regarding the place in therapy, the Committee heard from Dr Bignall that all patients requesting contraceptive should be offered a discussion on long-acting reversible contraceptive (LARC) methods. For patients who decline a LARC or cannot use a combined oral contraceptive (COC), patients may be offered a POP. Currently, the first-line POP is desogestrel followed by levonorgestrel as the second-line option. This application seeks to place drospirenone ahead of levonorgestrel as the new second-line POP due to convenience benefits offered by drospirenone with its longer missed pill window (24 hours versus 3 hours for levonorgestrel). The Committee noted that drospirenone does not offer greater efficacy or safety compared to other POPs and that the theoretical advantage of the wider missed pill window was not supported by greater contraceptive efficacy in clinical trials. However, Dr Bignall explained that, anecdotally, greater convenience translates to greater efficacy in a real-world setting, as women are more reassured by a wider missed pill window. Dr Bignall also highlighted that there is a diverse population with varying levels of deprivation across NCL and women recruited to trials may not be reflective of all women accessing sexual and reproductive health (SRH) services. Dr Bignall explained that in practice, levenorgestrel would still be valuable on the formulary as an option for women who are over 50 years of age, those taking multiple medicines or those with co-morbidities where drospirenone initiation is unsuitable. Therefore, this application does not seek to have drospirenone displace levenorgestrel but to offer drospirenone as an alternative second-line treatment option to address the need of women who find the restrictive 3-hour missed pill window challenging.

The eligible patient cohort will include women from menarche to 49 years of age who are unable to receive LARC or COCs. Drospirenone will be considered as second-line treatment following a 3-to-6-month trial of desogestrel (first-line POP), for women cannot tolerate other POPs. Dr Bignall explained the most common reasons for intolerance include unacceptable unscheduled bleeding, unacceptable androgenic side effects, and

compliance issues with the 12-hour pill-taking window. Dr Bignall also explained and provided rationale for the following exclusion criteria:

- Age 50 years and older – The upper age limit was included due to concerns about renal impairment, which may increase the risk of hyperkalaemia with drospirenone due to its mineralocorticoid effect. The Committee were informed that 4mg dose of drospirenone was equivalent to approximately 25mg of spironolactone.
- Individuals with known hyperkalaemia or hypoaldosteronism (e.g., Addison's disease) – In line with the Faculty of Sexual and Reproductive Healthcare (FSHRH) guidelines, additional medical eligibility considerations are required for drospirenone due to its potassium-sparing activity; this application proposes to exclude such women.
- Individuals currently taking potassium-sparing diuretics, aldosterone antagonists or potassium supplements (including over-the-counter medicines) – Patients will be reminded of the risk of drug interactions and the need to inform medical professionals if they are diagnosed with a condition or initiated any medication with potential interactions (including over-the-counter medicines, supplements, and herbal medicines).
- Known or suspected severe hepatic disease with deranged liver function values.
- Known renal impairment (all stages) or acute renal failure.
- Known or suspected sex-steroid sensitive malignancies.

With regards to venous thromboembolism (VTE) risk, the Committee were informed that there was no statistically significant increase in VTE risk for POPs other than drospirenone. Ethinylestradiol-containing COCs are associated with an increased risk of VTE; ethinylestradiol-containing COCs with drospirenone were associated with a greater risk of VTE than those that do not contain drospirenone. It was noted that no cases of VTE were reported in the licensing trials for drospirenone, however, these studies were not sufficiently powered to detect such events. The Committee were informed that ongoing post-authorisation safety studies focusing on incidence of VTE as an outcome of interest. Currently, the FSRH recommends that drospirenone should be considered to have similar VTE risk to other POPs such as levenorgestrel or desogestrel.

In terms of budget impact, drospirenone is more costly than other POPs and is expected to exert a cost pressure on the ICS. However, Dr Bignall explained that only a small group of women with limited options would be expected to be initiated on drospirenone. In the absence of alternative options, the costs associated with unplanned pregnancies could potentially increase.

In camera, the Committee discussed that the motivations for this application are based on real-world considerations outside of the context of clinical trials, such as improved convenience for women. The Committee were reassured that the cohort of women initiated on drospirenone are likely to be small given the preference for LARC, therefore, the overall budget impact is likely to be minimal. The Committee also addressed concerns regarding risk mitigation for potential hyperkalaemia and emphasised the importance of communication regarding treatment plans following the initiation of drospirenone at specialist secondary care services.

In summary, the Committee agreed to add drospirenone to the Joint Formulary as an alternative second-line POP, alongside levenorgestrel, subject to a review of an information leaflet for patients and general practitioners detailing the risks of hyperkalaemia and potential risks from future prescriptions (i.e., polypharmacy) and medical conditions that may affect the safety of the ongoing prescribing of drospirenone in primary care.

Drug: Drospirenone (Slynd®); as per licensed dose
Indication: Contraception for women deemed suitable for a POP, as an alternative second line therapy after desogestrel, alongside levonorgestrel.
Decision: Approved subject to a review of an information leaflet for patients and general practitioners with detailing the risks of hyperkalaemia and potential risks from future prescriptions (i.e., polypharmacy) and medical conditions that may affect the safety of the ongoing prescribing of drospirenone in primary care.
Prescribing status: Suitable for secondary care initiation, primary care continuation
Funding source: In tariff
Fact sheet or shared care required: N/A
Additional information: N/A

9 Medicine reviews

9.1 FOC Secukinumab dose escalation for Psoriasis (Applicant: Dr S McBride, RFL)

The Committee considered the addition of secukinumab dose escalation, available via a Free of Charge (FOC) scheme, to the psoriasis pathway. The standard maintenance dose of secukinumab for psoriasis is 300mg every 4 weeks. The proposed pathway suggests escalating the maintenance dose to 300mg every 2 weeks for patients weighing more than 90kg who have an inadequate primary response, achieving PASI 50 but still having significant disease burden. International and national guidelines such as the British Association of Dermatologists (BAD) endorses dose escalation prior to switching treatment. The proposed dose escalation is licensed for patients with a body weight≥ 90kg, as recommended in the SmPC for secukinumab. Patients with body weight <90kg will not be eligible for the proposed dose escalation as the FOC scheme is not available for this cohort and the evidence support the use of dose escalation in patients with obesity. For these patients, bimekizumab will be offered as an alternative treatment option. Treatment response will be assessed at 12 weeks, and if PASI 75 or PASI 50 and a 5-point reduction in DLQI are not achieved, the treatment will be stopped.

Augustin et al conducted a multicentre, double-blind, parallel-group trial, in patient with moderate-to-severe chronic plaque psoriasis weighing ≥ 90 kg (n=331). The patients were randomised to receive secukinumab 300 mg every 2 weeks or secukinumab 300 mg every 4 weeks. At 16 weeks, patients who did not achieve PASI 90 on the 4-weekly regimen were reallocated to either remain on the 4-weekly regimen or uptitrated to the 2-weekly regimen. The primary endpoint of the study was to achieve PASI 90 response at week 16 in patients treated with secukinumab 300mg every 2 weeks compared to secukinumab 300 mg every 4 weeks. The trial reported at week 16, 2 weekly dosing (n = 165) led to significantly higher PASI 90 responses compared to 4 weekly dosing [n = 166; 73.2% vs. 55.5%, one-sided P-value = 0.0003, odds ratio estimate (95% CI): 2.3 (1.4–3.8)]. At week 52, higher efficacy responses were maintained in the 2-weekly arm (n = 165) compared to the 4-weekly arm (n = 83); PASI 75: 88.9% vs. 74.8%; PASI 90: 76.4% vs. 52.4%; PASI 100: 46.7% vs. 27.3%. The PASI 90 non-responders who were up titrated at week 16 to 2 weekly (n = 31) showed higher efficacy responses at week 32 (16 weeks post-up titration, PASI 90: 38.7% vs. 16.5%) compared those who remained on 4 weekly (n = 40). The trial concluded that secukinumab 300mg every 2 weeks demonstrated superior and sustained efficacy compared with every 4 weeks in patients with moderate-to-severe plaque psoriasis weighing ≥ 90 kg.

In terms of safety, the trial conducted by Augustin et al reported no new or unexpected safety concerns in patients receiving secukinumab 300mg every 2 weeks. The incidence of adverse drug events remained consistent with its known safety profile, with the overall incidence of treatment-emergent adverse events remained similar between the secukinumab 300 mg 2 weekly group (77.0%) and the secukinumab 300 mg 4 weekly group (72.4%).

In terms of budget impact, the dose escalation is available on a FOC scheme therefore, there is no expected cost pressure, and it is estimated that 3 patient per annum will be eligible for the dose escalation regimen.

The FOC scheme is valid for 3 years and can be terminated earlier with a 30-day notice periods. However, the company has assured that all patients (i.e., those signed up prior to issuance of the notice of termination or prior to the expiry of the Term) with an adequate response will continue receiving the treatment free of charge should the scheme be terminated. This indicates there will be no financial risk with ongoing treatment when the FOC scheme terminated after 3 years. Considering secukinumab is one of the last line treatment options for patients with psoriasis, the FOC scheme addressed the clinical unmet need, allowing patients to exhaust all available dosing options prior to switching to an alternative treatment.

In summary, the Committee agreed to approve the addition of FOC secukinumab dose escalation to the psoriasis pathway.

Drug: Secukinumab subcutaneous injections (300mg every 2 weeks)
Indication: Moderate to severe psoriasis (body weigh ≥ 90kg and achieving PASI 50 but still having significant disease burden and inadequate primary response).
Decision: Approved
Prescribing status: Restricted to secondary care only
Funding source: Free of Charge Scheme
Additional information: Nil

9.2 High-impact psoriasis (Applicant: Dr S McBride, RFL)

High-impact psoriasis is a chronic inflammatory skin disorder, classified as high-impact (difficult to treat) when it affects areas such as the scalp, face, hands, feet and nails, genitals, and flexures. The condition is associated with significant functional impairment and high levels of distress due to its visibility. Body surface area (BSA) is a common way to determine the severity of psoriasis, with involvement of BSA 10% or more considered severe. While the quality of life generally mirrors disease severity, psoriasis on high-impact sites has a disproportionate effect, leading to depression and decreased participation in social roles and activities, regardless of total BSA. Many NICE TA for biologic or small molecule treatment require 10% or more BSA involvement for eligibility, leaving this cohort unsupported by NICE TAs.

The severity of high-impact psoriasis is measured using the Physician's Global Assessment (PGA) score instead of Psoriasis Area and Severity Index (PASI) score. The PGA score is measure on a scale of 0-5 with 0 being clear and 5 being very severe and it is based on plaque thickness/ induration, erythema, and scaling. The DLQI score, ranging from 0-30, assesses the effect on a patient's quality of life. The higher the DLQI score, the greater the effect on the patient's quality of life and it is utilised in conjunction with the PGA score. Biologic treatment aims to achieve a 50% reduction in the DLQI and a PGA score of 0 (clear) or 1(nearly clear).

The updated pathway proposes to change the eligibility criteria from DLQI>15 (PGA 4 or 5, severe to very severe) to DLQI >10 with psoriasis (PGA 3 or 4, moderate to severe). This proposal aligns with the recommendations by BAD guidelines which suggests biologics in psoriasis patients with DLQI >10 and severe localised sites associated with significant functional impairment and/or high levels of distress.

The current psoriasis pathway approved in 2019 includes treatment for high-impact psoriasis, patients are only eligible to commence one line of therapy either adalimumab (preferred) or apremilast or dimethyl fumarate (DMF). If a patient fails to respond, no alternative options are available. The proposal includes adding ustekinumab biosimilar and deucravacitinib as alternative treatment options. While adalimumab remains the preferred biologic, patients could use ustekinumab biosimilar, apremilast, DMF or deucravacitinib first line if an anti TNF therapy is contraindicated. In patients failing to achieve an adequate response, defined as a 50% reduction in DLQI from baseline and a PGA of clear, nearly clear, or mild disease, will be eligible to switch to an alternative lowest cost therapy (taking into consideration comorbidities) with a different mechanism of action, up to 4 lines of treatment. National and international guidelines support the use of biologics in patients with high-impact psoriasis.

There are no studies compare different lines of treatment in high-impact psoriasis, nor do they show the efficacy of ustekinumab and deucravacitinib specifically in high-impact psoriasis.

Blauvelt et al (POETYK PSO 1 & 2 trial) conducted a phase 3, 52-week, double-blinded trials in adults with moderate to severe psoriasis (n=1084) and conducted a sub analysis in patients with scalp psoriasis. Patients were randomised 1:2:1 to oral placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily. The eligible patients were ≥18 years old and had stable plaque psoriasis for ≥6 months, with moderate to severe psoriasis (PASI ≥12, scalp specific PGA ≥3, and body surface area involvement ≥10%) at screening and baseline visits. Scalp psoriasis was graded using the scalp specific-PGA and the Psoriasis Scalp Severity Index (PSSI) score. The secondary endpoints of the studies were to achieve a ss PGA score of 0 or 1 (clear or nearly clear) with a ≥2-point improvement from baseline and ≥90% reduction from baseline in PSSI (PSSI 90). The pooled trial data reported that efficacy with deucravacitinib was observed as early as week 1 versus placebo (n=19[3.7%] vs 3[1.0%]; P = 0.025) and by week 8 versus apremilast (n=256[49.8%] vs 96 [34.8%]; P<0.0001). Additionally, the trial reported a greater PSSI 90 response rate with deucravacitinib were observed by week 1 versus placebo (n=16 [3.1%] vs 2 [0.7%]; P = 0.024) and by week 8 versus APR (n=168[32.7%] vs 55 [19.9%]; P = 0.0001). The trial concluded that patients with moderate to severe scalp psoriasis, deucravacitinib was significantly more efficacious than placebo or apremilast with results being maintained through to week 52.

There are three non-randomised observational studies which support the use of ustekinumab and deucravacitinib in psoriasis. Hagino et al (n=70) conducted a 24-week retrospective observational study explored the use of deucravacitinib in patients with genital, nail, or scalp psoriasis. The study assessed the efficacy using the site-specific PGA scores. This study concluded that deucravacitinib improved genital, nail, and scalp symptoms of psoriasis. Burlando et al (n=25) conducted a 26-week retrospective observational study in patient which compared the use of ustekinumab, ixekizumab, adalimumab, secukinumab, etanercept and certolizumab with genital psoriasis. The study used the PGA score to measure effectiveness and reported that the most beneficial treatment was in patients receiving IL-17 inhibitors and ustekinumab. Foriadou et al (n=145) conducted a 48-week retrospective cohort study comparing ustekinumab, adalimumab, etanercept and infliximab in patient with scalp psoriasis. The primary endpoint of the study was a 75% reduction in the

PSSI score. The study report that infliximab exhibits the fastest reduction in PSSI score however ustekinumab achieved the greatest reduction over a 48-week period.

In terms of safety, Blauvelt et al reported that the overall incidence of adverse effects in the deucravacitinib group (up to week 16) was lower compared to apremilast, but higher than placebo. Nasopharyngitis and upper respiratory tract infection were the most common adverse drug events in the deucravacitinib group which were mild to moderate in severity, and the incidence of serious adverse drug events were low across groups. Adverse drug events leading to discontinuation of treatment occurred less frequently with deucravacitinib in comparison to placebo or apremilast. There is a rare risk of exfoliative dermatitis when treatment is initiated with ustekinumab as report by MHRA.

In terms of budget impact, within the last 12 months (Dec 23-Dec 24) 24 new patients have been initiated on either adalimumab or apremilast for high-impact psoriasis. It is predicted that an additional 10 patients would commence treatment within year 1 resulting in a total number of 34 patients treated for high impact psoriasis in year 1. Maintaining the current pathway position by only having one line of treatment available incurs no additional cost. However, the proposed changes to the high-impact psoriasis pathway estimates a cost pressure of approximately £8119 in year 1. This cost will be offset by the availability of adalimumab and ustekinumab biosimilar dose escalation as part of the psoriasis pathway.

The Committee heard from Dr McBride that clinical practice has evolved, and ciclosporin is no longer used due to its extensive monitoring requirements. Furthermore, the prevalence of psoriasis has increased with obesity and patient are becoming less tolerant to high dose topical steroids.

The Committee agreed to approve the proposed changes to the eligibility criteria, setting it to a PGA of moderate to severe and a DLQL of 10 or more. The Committee also approved the addition of ustekinumab and deucravacitinib as alternative treatment options, providing different mode of action available for this cohort of patients.

Drug: Deucravacitinib tablets (6mg once daily)
Indication: Moderate to severe high-impact psoriasis with a PGA of moderate to severe and a DLQL of 10 or more.
Decision: Approved
Prescribing status: Restricted to secondary care only
Funding source: ICB
Additional information: Nil

Drug: Ustekinumab subcutaneous injections (body weight ≤ 100kg: An initial dose of 45 mg administered subcutaneously, followed by a 45 mg dose 4 weeks later, and then every 12 weeks thereafter; body weight ≥ 100kg: An initial dose of 90 mg administered subcutaneously, followed by a 90 mg dose 4 weeks later, and then every 12 weeks thereafter)
Indication: Moderate to severe high-impact psoriasis (body weigh ≥ 90kg and achieving PASI 50 but still having significant disease burden and inadequate primary response).
Decision: Approved
Prescribing status: Restricted to secondary care only
Funding source: ICB
Additional information: Nil

10 Position Statements and Guidelines

10.1 Intranasal dexmedetomidine for sedation in paediatrics as premedication to general anaesthesia

In August 2022, the NCL JFC approved the use of intranasal dexmedetomidine (IND) for pre-medication in children undergoing general anaesthesia pending submission of guidelines with risk mitigation details aligned across the interested Trusts.

The JFC secretariats undertook a comparison exercise between existing guidelines from GOSH, WH, and UCLH focusing on anaesthetic agents, respective place in therapy, and risk mitigation details. There were notable differences between guidelines and criteria for use of anaesthetic agents. The JFC secretariats facilitated discussions with consultant anaesthetists from numerous NCL Trusts to reach a consensus guideline across NCL. However, delivering uniformity of practice for the paediatric population across NCL presents numerous challenges. Key factors such as physiological and psychological differences, intended surgical procedure, and previous experience with anaesthesia affect the choice of anaesthetic agents.

Given the multifactorial approach required for selecting appropriate anaesthetic agents, this necessitates greater autonomy for anaesthetists in formulating individual treatment plans. The JFC secretariats were also informed that NCL Trusts may treat different paediatric conditions, therefore, it may be more appropriate for paediatric sedation guidelines to be formulated and implemented at Trust-level to better address the specific needs of their patient population. This allows flexibility of treatment choice by anaesthetists to ensure safer, and more effective care for each child taking into account patients' preferences and individual needs.

The Committee agreed to guideline development and implementation to Trust DTCs with risk mitigation details in place to address the additional risks of hypotension and bradycardia associated with the use of IND.

10.2 NCL H2-receptor antagonist position statement – Update

In October 2024, the NCL proton-pump inhibitor (PPI)/ H2-receptor antagonist (H2RA) position statement was updated and approved by JFC pending clarification of preferred PPI suspension products for use in enteral tube administration in adults. The Committee heard from Ms Jalil regarding a proposal to add Mezzopram® (dispersible gastro-resistant omeprazole) to the NCL Joint Formulary as the second-line option for enteral tube administration in adults. This recommendation was proposed to support crucial primary care medicines optimisation workstreams in 2025/26. The Committee discussed the challenges associated with procuring brand-specific generic products in the secondary care, noting that procurement is constrained by existing contract agreements.

In summary, the inclusion of Mezzopram® in the NCL PPI/H2RA position statement has been deferred pending offline discussions regarding procurement arrangements in secondary care. Input from the NCL Formulary Group will be sought to the development of a NCL position statement on branded generics.

10.3 NCL Glaucoma Guidelines

The Committee reviewed the updated NCL Pathway for the Treatment and Management of Open Angle Glaucoma, which was approved by the NCL ICB Medicines Clinical Reference Group (MCRG). The key updates include:

- Inclusion of latanoprost-netarsudil (Roclanda®) following the publication of NICE TA1009, and
- NCL preferred choices for multidose bottle (MDB) alternatives to single dose use (SDU) preservative free eye drops.

The Committee heard from Ms Wong that extensive work was undertaken in collaboration with secondary care stakeholders to coordinate the move away from SDUs to MDBs, including a comprehensive safety review of products. It has been agreed that MDBs will be prescribed generically in secondary care, and patients will be switched to the NCL preferred choice for MDBs (listed in Appendix 1) when they are discharged to primary care (i.e., prescribed by brand). Where individual patient circumstances prevent the switch to MDBs, the need for SDU eye drops must be stipulated in the discharge letter from secondary care. Additionally, any other eye drops that are not available as MDBs will be the exception to this rule. This initiative will improve sustainability in line with NHSE Green Agenda and deliver cost efficiencies across the ICS. A working group has been established to monitor the implementation of this initiative across NCL.

In summary, the Committee ratified the updated NCL Pathway for the Treatment and Management of Open Angle Glaucoma and Ocular Hypertension.

10.4 NCL Free of Charge Terms of Reference (Draft)

The Committee were informed that the NCL Free of Charge (FOC) Medicines Schemes Guidance was updated. The key updates include:

- Reference to the NHS England FOC medicines schemes recommendations, and
- Incorporating legal input from the legal counsel at UCLH to ensure FOC medicines schemes and consent form are appropriate.

The Committee heard from Ms Tse that the legal counsel at UCLH confirmed the guidance met legal requirements. However, it is crucial that clinical teams involved in recruiting patients to FOC medicine schemes must ensure patient expectations are managed and processes are thoroughly documented to avoid reputational or ethical issues arising.

In summary, The Committee reviewed changes made to the NCL FOC Medicines Scheme Guidance and agreed to send any comments back to the JFC secretariats within 2 weeks.

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:

- 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 first implementation date is 23 March 2025, for specialist weight management patients, followed by a second phase implementation for general patients with BMI >35 and weight related co-morbidities starting 26 June 2025. This introduction is in line with the funding variation proposed by NHSE. The group is still awaiting the NHSE commissioning policy to be published.

11.2 NCL Pathways Group

Nil

11.3 Shared Care Group Updates

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

The Committee was provided with an update from Ms Tse regarding the shared care process review workshop which was held on Wednesday 22nd January 2025. The workshop highlighted the key areas which require improvement through the feedback received from the ICB, secondary care and primary care representatives. The result of the workshop has initiated development of short-, medium- and long-term improvement plan. These plans primarily focus on system change, better governance and enhancing interface engagement and addressing out of area challenges. The subgroup will brief the MRCG on these discussions and potentially involve them in the overall shared care governance.

12 Next meeting

Thursday 20th March 2025

13 Any other business

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