North Central London Integrated Care System

NHS
North Central London
Medicines Optimisation Network

Joint Formulary Committee (JFC): Minutes

Minutes from the meeting held on 15th June 2023

		Present	Apologies
Members			
Prof A Hingorani	NCL JFC Chair	✓	
Dr B Subel	NCL JFC Vice Chair	✓	
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; NCL ICS, Interim Chief Pharmacist		✓
Dr R Urquhart	UCLH, Divisional Clinical Director	✓	
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		✓
Mr V Raman	RNOH, DTC Chair		✓
Mr A Shah	RNOH, Chief Pharmacist		✓
Prof A Tufail	MEH, DTC Chair		✓
Ms N Phul	MEH, Chief Pharmacist		✓
Ms K Delargy	BEH, Chief Pharmacist		✓
Ms L Reeves	C&I, Chief Pharmacist		✓
Dr L Waters	CNWL, Consultant Physician in HIV		✓
Ms R Clark	NCL ICB, Head of Medicines Management (Camden)	✓	
Mr P Gouldstone	NCL ICB, Head of Medicines Management (Enfield)	✓	
Ms E Mortty	NCL ICB, Interim Head of Medicines Management (Haringey)	✓	
Ms M Singh	NCL ICB, Head of Medicines Management (Barnet)	✓	
Mr A Dutt	NCL ICB, Head of Medicines Management (Islington)	✓	
Dr D Roberts	NCL ICB, Clinical Director (Islington)		✓
Attendees			
Ms S Amin	IPMO Programme Team, JFC Principal Pharmacist	✓	
Mr G Grewal	IPMO Programme Team, JFC Support Pharmacist	✓	
Ms S Maru	JFC Support Pharmacist	✓	
Ms P Varu	JFC Support Pharmacist	✓	
Ms I Samuel	RFL, Formulary Pharmacist	✓	
Mr H Shahbakhti	RFL, Formulary Pharmacist	✓	
Ms H Bouattia	RFL, Formulary Pharmacist	✓	
Mr A Barron	UCLH, Principal Pharmacist	✓	
Mr S O'Callaghan	UCLH, Formulary Pharmacist	✓	
Ms A Gabriela	UCLH, Formulary Pharmacist		✓
Ms A Sehmi	NMUH, Formulary Pharmacist	✓	
Ms H Thoong	GOSH, Formulary Pharmacist	✓	
Mr D Sergian	MEH, Formulary Pharmacist		✓
Ms H Weaver	NHSE, Specialised Commissioning Pharmacist	✓	
Ms A Blochberger	NHSE, Specialised Commissioning Pharmacist		✓

Ms A Fakoya	NCL ICB, Contracts & Commissioning Pharmacist		✓
Dr A Hosin	UCLH, Clinical Pharmacology Registrar		✓
Ms EY Cheung	NCL ICB, Deputy Head of Medicines Management (Camden)		✓
Ms K Mistry	RNOH, Formulary Pharmacist	✓	
Ms S Ahmed	WH, Formulary Pharmacist	✓	
Ms L Garubova	WH, Formulary Pharmacist		✓
Ms R Pointon	WH, Rotational Pharmacist	✓	
Mr J Flor	WH, Finance, Business and Performance Pharmacist		✓
Ms M Thacker	RFL, Clinical Lead Pharmacist	✓	
Mr G Purohit	RNOH, Formulary Pharmacist		✓
Ms J Bloom	MEH, Associate Chief Pharmacist	✓	
Ms C Weaver	Senior Prescribing Advisor, NCL ICB (Camden)	✓	
Ms N Patel	Prescribing Advisor, NCL ICB (Barnet)	✓	
Mr H Hafeez	RFL, Principal Pharmacist Women and Children's Services	✓	
Dr G Rotiroti	RNTNE, Consultant in Allergy Medicine	✓	
Ms E Gortari	UCLH, Specialist Pharmacist	✓	
Dr S Berkovitz	RLHIM, Consultant in Allergy Medicine	✓	
Ms A Lim	WH, Consultant Antimicrobial Pharmacist	✓	
Ms B Krishek	Direction of Medicines Optimisation, North East London (Observer)	✓	
Ms D Baker	North East London Formulary Team (Observer)	✓	
Ms A Vu	North East London Formulary Team (Observer)	✓	
Ms N Whitworth	North East London Formulary Team (Observer)	✓	

1. Meeting apologies

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

2. Meeting observers

Prof Hingorani welcomed observers to the meeting (see above).

3. Members' declaration of interests

The Declarations of Interests register for Committee members was included for information.

4. Minutes of the last meeting

Minutes and abbreviated minutes were accepted as an accurate reflection of the May 2023 meeting. A minor change to the abbreviated minutes was noted for amendment.

5. Matters arising

Nil

6. Review of action tracker

Action tracker included for information.

7. JFC outstanding items & work plan

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

8. Local DTC recommendations / minutes

DTC site	Month	Drug	Indication	JFC outcome

UCLH	May 2023	FOC scheme: Daratumumab, lenalidomide and dexamethasone †	Relapsed or refractory plasmablastic lymphoma	**Decision**: Conditionally approved **Prescribing**: Secondary care only **Tariff status**: Not in tariff **Funding**: FOC scheme **Fact sheet or shared care required**: N/A **Additional information**: Conditions of the approval are: -Informed patient consent is obtained for each patient, highlighting the uncertainty of treatment efficacy, balanced with the established risks of daratumumab, lenalidomide and dexamethasone. -The clinical team commits to publication of cases treated (both responders and non-responders) to add to the published evidence base
UCLH	May 2023	FOC scheme: Sorafenib	Third line option for patients with unresectable desmoid type fibromatosis who have progressed and/or relapsed following previous treatment; only when clinical trials are not available or unsuitable.	**Decision**: Approved **Prescribing**: Secondary care only **Tariff status**: Not in tariff **Funding**: FOC scheme **Fact sheet or shared care required**: n/a
UCLH	May 2023	Paclitaxel albumin	Gynaecological cancer patients with documented taxane hypersensitivity to allow patients to complete taxane-based therapy.	**Decision**: Approved – subject to funding consideration **Prescribing**: Secondary care only **Tariff status**: In tariff **Funding**: Trust **Fact sheet or shared care required**: n/a **Additional information: Subject to funding consideration** (except for breast cancer – NHSE commissioned)

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9. New medicine reviews

9.1 COVID Medicines Delivery Unit medicines pathway

An overview of the pathway for medicines used via the COVID Medicines Delivery Unit was presented to the Committee. The pathway included Paxlovid® and sotrovimab for use in patients who are aged 12 or over and weighing at least 40kg and do not require supplemental oxygen. Both treatments were risk assessed for inclusion on the pathway. The model of care recommends Paxlovid® first-line, although certain patient cohorts (e.g., those unsuitable for Paxlovid® due to interactions) would be eligible for second-line sotrovimab.

Paxlovid® is licensed and approved by NICE for use in adults only, therefore use in patients aged 12-17 years is considered off-label. It was recognised that use of Paxlovid® in paediatrics is licensed by the FDA in USA and recommended by the US National Institute for Health using the same dose as recommended in adults. The data which informed this decision were (i) extrapolated from recommendations in adults with COVID-19, (ii) extrapolated from recommendations in children with other viral infections, and (iii) based on expert opinion. There was no known published comparative data for use of Paxlovid in paediatric patients (efficacy data was extrapolated from the EPIC-HR study conducted in adults). In terms of safety, data was also extrapolated from the adult population. comparative studies. Ritonavir has been extensively used in paediatric patients for HIV and hepatitis C infection with a tolerable adverse-effect profile. There was no pharmacokinetic or pharmacodynamic data available for use in children.

Sotrovimab is both licensed and approved by NICE in adults and paediatrics from the age of 12 and use in both populations was already considered for addition to the Joint Formulary for use by the CMDU in May 2023.

According to the pathway, patients would be triaged via the GP triage hub, and paediatric patients would be assessed by the North Thames Paediatric Network. The Committee largely agreed with the NCL CMDU medicines pathway, although recognised that paediatric patients prescribed Paxlovid® by their GP would be prescribing an off-label treatment ahead of licensed sotrovimab therapy based on recommendations made by the North Thames Paediatric Network. The Committee approved the CMDU pathway pending the addition of the following statements to clarify the role of the prescriber when prescribing Paxlovid in paediatric patients:

- Initiation of Paxlovid in paediatrics is decided on a case-by-case basis.
- Prescribers should be aware they are taking on additional responsibilities in prescribing an off-label treatment where another treatment already licensed in paediatrics (sotrovimab) exists.
- The rationale for initiating Paxlovid in the child should be documented and the prescriber should ensure they have a follow-up in place with the patient.

9.2 Primary Care Adult Asthma Pathway

The risk assessments for the medicines included in the Adult Asthma Primary Care Pathway were presented to the Committee for consideration and approval as part of the JFC support for the pathways transformation work. The medicines in the pathway are currently align with the NCL prescribing recommendations and the NCL Adult Asthma Inhaler Choice guidance. The risk assessment undertaken involved a review of the place in the pathway and the evidence base for each medicine including safety, efficacy, costs and prescribing and formulary position. The medicines in the pathways were discussed with the JFC clinical pathways sub-group prior to the meeting with no issues identified.

In summary, the medicines-related elements in the Adult Asthma Primary Care Pathway were approved; other elements of the pathway (e.g., clinical and operational aspects) will be approved by other ICB groups as per the ICB primary care pathways' governance process.

9.3 Allergen Immunotherapies in NCL

The Committee considered a review for the use of allergen immunotherapies (AITs) across NCL in adults and children for the prevention of severe allergic reactions. It included subcutaneous immunotherapies (SCIT) and sublingual immunotherapies (SLIT) for tree pollen, grass pollen, house dust mite (HDM), cat, dog, bee, and wasp allergies. SCITs are already on formulary at several NCL Trust formularies due to historical use and there is increasing clinician interest in using SLITs across the sector. The JFC previously recommended the formation of an NCL immunotherapies working group to (i) review the NCL immunotherapies pathway, (ii) establish a minimal clinically important difference and (iii) establish a cost-effectiveness threshold for allergen immunotherapies.

Overall, the evidence quality for allergen immunotherapies was weaker than for other therapeutic areas that JFC have considered previously, with only 28% of the studies (total studies reviewed n=36) identified as randomised with optimal outcomes. Most of the studies included only surrogate endpoints and the observed treatment effect sizes were modest. Each immunotherapy product was reviewed individually for efficacy, safety, convenience, and cost and a summary was presented to the Committee for consideration. The evidence base for each allergen group is summarised below and illustrated in the Table below.

Tree pollen: There were 3 SCIT and 3 SLIT products reviewed.
SCIT: Pollinex® is the only SCIT product that is both licensed and currently on formulary. Allergovit® Mixed Tree and Allergovit® Birch are also on the formulary but are unlicensed. The efficacy, safety, and convenience for Allergovit® Mixed Tree and Pollinex® Trees are comparable, though Allergovit® Birch has a weaker efficacy profile.
SLIT: Itulazax® is licensed, whereas Oralvac® and Lais® are unlicensed. The efficacy for Lais® and Oralvac® is weaker compared to Itulzax®. Itulazax® covers birch tree allergen only, whereas Oralvac® can be formulated to cover any tree pollens. The cost for SLIT tree products would result in a significantly increased budget impact compared with SCIT. Oralvac® is slightly cheaper than Itulazax® and Lais®.

Grass pollen: There were 2 SCIT and 3 SLIT products reviewed.
SCIT: Pollinex® is the only SCIT product that is licensed and currently on the formulary. Allergovit® is also on the formulary but not licensed. The efficacy, safety and convenience are comparable across the products. However, for cost, Pollinex® is cheaper in comparison to Allergovit®.
SLIT: Grazax® is licensed, whereas Oralvac and Lais are unlicensed. The efficacy for Lais® is weaker compared to Grazax® and Oralvac®. As with Trees, the cost for all the SLIT tree products would result in a significantly increased budget impact. Oralvac® is slightly cheaper than Itulazax® and Lais®.

HDM: There was 1 SCIT product and 2 SLIT products reviewed.
SCIT: The SCIT product, Acaroid®, is currently on the formulary but it is unlicensed.
SLIT: Acarizax® is a licensed SLIT product with a better efficacy and marginally better cost profile compared to Acaroid®. Lais® is unlicensed and although the cost is lower than the other HDM AITs, it has a weaker efficacy profile compared to Acarizax®. Acaroid has a high injection burden (16 injections per year) requiring patients to come into hospital regularly which may be inconvenient for patients.

Cat/Dog: Currently there are no cat or dog AITs on the formulary. The clinicians have stated that use is very rare and patient numbers would therefore be low. It would only be considered in exceptional cases, for example due to occupation related exposure.
SCIT: Clustek® is an unlicensed SCIT product for cat and dog allergies with a weak evidence profile.
SLIT: Lais ® is an unlicensed SLIT product, requested for use in cat allergies only, also with a weak efficacy profile. Clustek® and Lais® would result in a significantly increased budget impact, as use would require a new service to be set up.

Bee/Wasp: There was one SCIT product reviewed for bee and wasp allergen. Pharmalgen® was a NICE approved product but has been discontinued. Alutard SQ® is now the only licensed SCIT product available in the UK and is on the formulary.

Key limitations of the evidence base were that any meta-analyses included multiple products and compared across allergen groups as opposed to comparing specific products. There was large heterogeneity in outcome measures used; moreover due to the historical nature of many studies conducted, they often did not use optimal outcome measures as suggested by the EMA. There was limited use of validated scoring tools in most of the studies and very few studies included QoL measures. Many of the studies reported surrogate outcomes and therefore it was difficult to interpret clinically meaningful differences between treatment and comparators.

In terms of safety and risk, both SCIT and SLIT are generally well-tolerated with no significant safety concerns. Current guidance does not contraindicate SCIT or SLIT use in controlled asthmatic patients. For the uncontrolled asthmatic population, there is uncertainty on safety and risks of using immunotherapies. Adherence is expected to be better with SCIT due to increased patient contact during hospital administration, whereas adherence issues have been noted with SLIT daily tablets taken at home by the patient, although could be mitigated against by telephone follow up. SCIT can also cause injection site reactions are expected with SCIT. However, patients are administered SCIT in hospital with close monitoring to mitigate these safety concerns.

In terms of convenience, there is potentially increased convenience for patients with daily SLIT tablets which can be taken at home compared to SCIT where hospital attendance is required for administration. Patient groups that may benefit from SLIT include paediatric patients (who otherwise frequently need to miss school), needle phobic patients and HDM patients requiring weekly or fortnightly SCIT injections all-year round.

A proposed, rationalised evidence-guided immunotherapies formulary (as represented in the table below) was developed by rationalising all requested allergen immunotherapies based on efficacy, safety, cost and convenience, current formulary status and new product requests, whilst ensuring that a SCIT/SLIT product is available for each allergen, where relevant.

	Trees	Grass	House DustMite	Cat	Dog	Bee	Wasp
SCIT	Pollinex® Mixed Tree (L)(f)	Pollinex® Grass/Rye (L)(f)	Acaroid® (L)(f)			Alutard SQ® (L)(f)	Alutard SQ® (L)(f)
	E S Cn 6/yr C	E S Cn 6/yr C	E S Cn 16/yr C			E S Cn 21/yr C	E S Cn 21/yr C
SLIT	Itulazax® Birch (L)(f)	Grazax® (L)(f)	Acarizax® (L)(f)				
	E S Cn OD 7/12 C	E S Cn OD 7/12 C	E S Cn OD 12/12 C				
	Oralvac® (L)(f)						
	E S Cn OD 8/12 C						

An NCL budget impact was calculated based on the potential immunotherapies formulary and estimated patient numbers provided from UCLH, RFL and WH in both adult and children services. It was estimated that use of the potential allergen immunotherapies formulary would cost an additional £126,500 per annum (based on an estimated decrease in SCIT by £59,000 and increase in SLIT by £185,500). This also accounted for a greater number of patients receiving treatment if SLIT therapies were to be made available. The budget impact calculation did not account for a reduction in healthcare resource utilisation costs associated with SCIT administration in hospital such as day case appointments, nursing time and administration costs. It was noted that although the proposed immunotherapies formulary options would be considered as the first line options within NCL, there may be some exceptional circumstances where patients require the use of other immunotherapies (e.g., where an allergen is identified which is not covered by a product on the proposed formulary), and these should be assessed locally on a case-by-case basis.

The Committee heard from Dr Berkovitz and Dr Rotiroti who agreed with the overall limited evidence base for allergen immunotherapies. It was highlighted that the availability of a SLIT product will not necessarily result in a large increase in patient numbers as clinicians apply strict eligibility criteria to allergen immunotherapy. Patients who do not respond to immunotherapy treatment will not routinely be offered another product as there is no evidence to show efficacy where one product has failed. The clinicians acknowledged the variability in measuring patient response in the studies; in their view, the main outcome for assessing response to immunotherapy treatment is the patient's QoL. Although the evidence for long term benefits is limited, there is some indication that the treatment effect lasts 3-years post discontinuation and many patients who remain

in the service rarely require a second course of treatment. Overall, the clinicians accepted the rationalised immunotherapies formulary presented and the products included.

In *camera*, the Committee acknowledged the weak evidence base for allergen immunotherapies but noted that this is a service that has been long standing in NCL. The committee also highlighted that SLIT therapies often had a comparable efficacy profile to SCIT products which are already on formulary. Although a full cost-effectiveness analysis had not been undertaken, the Committee agreed of the potential cost savings related to reduction in day case appointments, clinic visits and staff time from increased use of SLIT. The Committee agreed that due to unfamiliarity with the treatments involved and the level of ongoing support required, the prescribing of allergen immunotherapies should be retained in secondary care only. The Committee approved the proposed, rationalised, evidence-guided immunotherapies formulary (see Tabular summary) and products presented for tree, grass, HDM, bee and wasp allergen immunotherapies. The Committee requested eligibility criteria to outline the use cat and dog allergen immunotherapies, and agreement on a single product (SCIT or SLIT) being made available on the NCL Joint Formulary.

In summary, the Committee approved the rationalised immunotherapies formulary presented for tree, grass, HDM, bee and wasp allergen immunotherapies, and requested further information for cat and dog allergen immunotherapies to determine eligibility criteria and a suitable product for inclusion on the NCL Joint Formulary. The rationalised immunotherapies formulary will include the following products according to allergen group:

- Tree Pollen:
    - SCIT: Pollinex® Mixed Tree
    - SLIT: Itulazax®
- Grass pollen:
    - SCIT: Pollinex® Grasses & Rye
    - SLIT: Grazax®
- HDM:
    - SLIT: Acarizax®
- Cat/Dog:
    - Product to be confirmed (SCIT: Clustek® or SLIT: LAIS®)
- Bees/Wasp:
    - SCIT: Alutard SQ®

<u>Tree pollen:</u>

Medicine: Pollinex® Mixed Tree
Decision: Approved pending financial approval and local implementation at each provider Trust
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Medicine: Allergovit® Mixed Tree
Decision: Not approved/removed from formulary
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Medicine: Allergovit® Birch
Decision: Not approved/removed from formulary
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Medicine: Itulazax®

Decision: Approved pending financial approval and local implementation at each provider Trust
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Grass pollen:

Medicine: Pollinex® Grasses & Rye
Decision: Approved pending financial approval and local implementation at each provider Trust
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Medicine: Allergovit® Grasses
Decision: Not approved/removed from formulary
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Medicine: Grazax®
Decision: Approved pending financial approval and local implementation at each provider Trust
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Tree and Grass pollen:

Medicine: Oralvac®
Decision: Not approved
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Medicine: Lais®
Decision: Not approved
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

HDM:

Medicine: Acaroid®
Decision: Not approved/removed from formulary
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Medicine: Acarizax®
Decision: Approved pending financial approval and local implementation at each provider Trust
Prescribing: Secondary care only
Tariff status: In tariff

Funding: Trust
Fact sheet or shared care required: N/A

Medicine: Lais®
Decision: Not approved
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

Cat/Dog

Medicine: Clustek®
Decision: Deferred – pending the development of criteria/identifying a single product choice
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A
Additional information: Subject to the development of strict criteria for use and identifying a single product to be made available on the formulary

Medicine: Lais®
Decision: Deferred – pending the development of criteria/identifying a single product choice
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A
Additional information: Subject to the development of strict criteria for use and identifying a single product to be made available on the formulary

Bees/Wasp

Medicine: Alutard SQ®
Decision: Approved pending financial approval and local implementation at each provider Trust
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trust
Fact sheet or shared care required: N/A

10. Next meeting

Thursday 20th July 2023

11. Any other business

The Committee were informed that NICE had published a negative technology appraisal for Evusheld®; the NCL position statement, which similarly recommended against the use of Evusheld®, will now be removed.