

North East London Formulary & Pathways Group Terms of Reference

Document control

Date	Version	Amendments
September 2022	1.0	New document
June 2023	2.0	Update to ToR
December 2023	2.1	Update to ToR

Document management

Original authors	Tase Oputu, Lead Pharmacist Medicines Commissioning &	
	Pathways, Barts Health NHS Trust	
	Belinda Krishek, Director of Medicines Optimisation, NHS NEL	
Version updated by	Belinda Krishek, Director of Medicines Optimisation, NHS NEL	
	Anh Vu, Formulary Pharmacist, NHS NEL	
Version	2.1	
Approved by	North East London Formulary & Pathways Group	
Date approved	05/12/2023	
Ratified by	North East London Integrated Medicines Optimisation &	
	Prescribing Committee	
Date ratified	19/12/2023	
Review date	19/12/2024	

1. Background

The North East London (NEL) Formulary & Pathways Group (FPG) provides a single joint forum for the assessment and approval of new medicines and medicines related pathways, with the aim to decrease duplication, improve equity of access, improve health outcomes and help decrease health inequalities for patients across NEL.

The formation of the NEL Integrated Care System (ICS) and component parts from 1st July 2022 meant that the existing decision-making primary care medicines management groups that serve across NEL were disbanded.

There are multiple formularies in use across NEL as shown in Appendix A.

2. Purpose

The NEL FPG is a sub group of the NEL Integrated Medicines Optimisation & Prescribing Committee (IMOC).

The areas of responsibility are:

 To provide a collective clinical leadership group to ensure co-operation and consistency of approach to medicines optimisation across NEL.

- To enable local clinicians to work together across the ICS to ensure that patients have safe and consistent access to cost-effective medicines in the context of care pathways which cross multiple providers.
- To advise on implementation of best practice around medicines, including NICE guidelines and technology appraisals, and advice from Regional Medicines Optimisation Committees (RMOC) to encourage rapid and consistent implementation.
- To link in with the NEL Medicines Safety & Quality Group (MSQG) for any clinical risks identified with submissions to the FPG.

The FPG provides a forum for discussion and decisions on the following:

- Entry of new medicines including prescribable treatments (e.g. appliances/devices closely associated with medicines, contrast medias, oral nutritional supplements/feeds, dressings).
- New indications for medicines.
- Medicines related pathways, guidelines and position statements.*
- Shared care and transfer of care guidelines.
- * The FPG may, on occasions (where appropriate), approve the inclusion of drugs/prescribable treatments onto the formulary as part of a guideline/pathway approval. During these circumstances, the formulary approvals would be specified in the FPG outcome letter and minutes.

Alongside routine business regarding entry of medicines, the group will develop a work plan with specific objectives which will be reviewed regularly and formally on a 12-month basis.

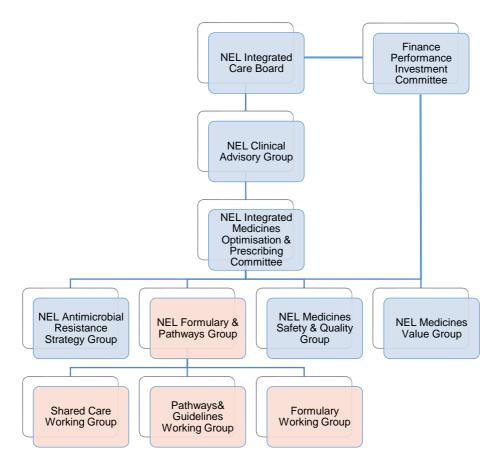
The FPG may, as agreed with IMOC, convene specific working groups to take forward detailed work on appropriate topics as they arise. The groups should consist of nominated representatives from the relevant organisations and feedback progress against the set deadlines to the FPG.

3. Accountability

The FPG will provide regular reports to the IMOC:

- Monthly highlight reports and decisions for ratification by IMOC
- Annual report

4. Governance



N.B. Governance structure correct at time of publication.

5. Scope

Introduction, review and update, or development of:

- · Entry of new medicines
- New indications for medicines
- Medicines related pathways
- Pharmacogenomics
- Prescribing guidelines
- NEL formulary
- Formularies for any Providers
- Shared care/transfer of care guidelines
- Prescribable treatments (e.g. appliances/devices closely associated with medicines, contrast medias, oral nutritional supplements/feeds, dressings, continence products)
- Hospital Only List medicines
- NICE guidelines & Technology Appraisals
- Messaging to be included into prescribing decision-making software (e.g. OptimiseRx) where FPG decisions relate to new medicinal products, indications and medicines-related guidelines and pathways
- Free of charge/discount schemes

The group will take into account recommendations from other national bodies (e.g. RMOC, MHRA, Accelerated Access Collaborative, NHSEI).

The group will review outputs from the London Medicines & Pathways Group (LMPG) and advise IMOC on adoption of any recommendations.

6. Reports received by the FPG

The FPG will receive updates (as needed) from the following groups from NEL:

- Barts Health Cancer Drugs & Therapeutic Committee
- Individual Trusts' Medicines Optimisation Groups:
 - o ELFT Medicines Committee
 - o NELFT Medicines Optimisation Group
 - o BHRUT Medicines Optimisation Group
 - Homerton Medicines Committee
- NEL Sub Regional Immunoglobulin Assessment Panel

The FPG will receive updates from the LMPG and associated working groups (e.g. Hospital Only List, Respiratory, Ophthalmology).

Decisions/output from the NEL FPG will be shared with the other London Integrated Care Systems via the LMPG (North Central London, North West London, South East London, South West London) and vice versa.

7. Financial impact consideration

Individual Trusts are expected to approve financial expenditure at the point of decision making via their own internal procedures.

For the NEL Integrated Care Board (ICB) submissions, where the medicines and activity cost impact is likely to be above a threshold of >£25K per 100,000 population for NEL health economy (circa £500K), this would need to be discussed at ICB Finance prior to submission to FPG.

8. Urgent clinical decisions

Any item considered to be of urgent clinical need will be considered by individual Trusts via their internal processes (i.e. via Trust Chair's action) until such a time it can be presented for full discussion and recommendation. Chair's action requests are reviewed to help inform submissions to the FPG.

Where a Trust makes the decision to initiate a medicine for a patient or group of patients outside of the approval process, this will be at the clinical and financial risk of the Trust.

FPG Chair's action may need to be sought for NICE TAs with short implementation date (e.g. 30 days) to enable implementation deadlines to be met whilst awaiting ratification from IMOC.

A summary of Chair's actions (approved by individual Trusts and FPG Chairs) will be reported to the FPG on a regular basis.

9. Membership

The FPG is a multidisciplinary working group that is supported at a senior strategic level by IMOC.

Resources and leadership required across partner organisations will be reviewed on a regular basis with IMOC retaining oversight.

The group will be supported by formulary pharmacists (or equivalent) in member Acute and Mental Health Trusts and NHS NEL Pharmacy and Medicines Optimisation team.

Nominated representatives are responsible for ensuring two-way reporting, implementation and feedback to the FPG via relevant committees/groups in member organisations.

Organisation/representation**	Title/post
NEL Integrated Care Board (NHS NEL)	 Deputy Director of Medicines Optimisation, Medicines Pathways and Commissioning Commissioning & Contracting Pharmacist Commissioning & Contracting Senior Pharmacy Technician Formulary Pharmacist
Barts Health NHS Trust	 Senior Medical Lead Formulary & Pathways Lead Pharmacist Lead Medicines Commissioning & Pathways Pharmacist
Barking, Havering and Redbridge University Hospitals NHS Trust	Senior Medical LeadLead/Senior Pharmacist
Homerton Healthcare NHS Foundation Trust	Senior Medical LeadLead/Senior Pharmacist
East London NHS Foundation Trust	Senior Medical LeadLead/Formulary Pharmacist
North East London NHS Foundation Trust	Senior Medical LeadLead/Formulary Pharmacist
NEL Local Pharmaceutical Committee (LPC)	Chief Executive or nominated deputy
Primary Care Prescribing Leads	3 Prescribing Leads (one of which should be a GP)
Paediatric representative	1 Representative
Lay representation (optional)	1 Representative (optional)
Non-medical prescribing	1 Primary Care representative
representative	1 Secondary Care representative
NICE Associate	1 NICE Associate
NHSE Specialised Commissioning – London region	1 Pharmacist

^{**} Members who are subject matter experts may be co-opted for specific agenda items according to the agenda (e.g. Public Health).

10. Chair

Meeting Chairs:

• Consultant Trust Lead (Co-chair)

- GP Prescribing Lead (Co-chair)
- Nominated Deputy/Vice Chair in case of absence or conflict of interest for a specific item.

Chairs will have a 2-year tenure.

11. Quorum for decision making

Meeting quorate with the below representation:

- Chair/Deputy
- 2 Trust Senior Medical Leads
- 2 Trust Formulary/Lead Pharmacists from separate Trusts at least 1 from acute provider
- 1 NHS NEL Place Based Partnerships/ICB Lead Pharmacist
- 1 NHS NEL Place Based Partnership/ICB Formulary Pharmacist
- 1 Primary Care Prescribing Lead or nominated Deputy
- 1 Non-Medical Prescribing Representative

If the meeting is inquorate, Chair's action may be taken.

12. Running of the meeting

The meeting will be held monthly. No meetings will be held in August and December (agenda and attendance permitting).

Running of the meeting will involve quoracy check and members declaring conflicts of interests prior to commencement of discussions.

Important dates:

- Deadline for submissions at least 4 weeks before FPG meeting
- Triage 2 weeks before FPG meeting
- Chairs pre-meet 1 week before FPG meeting
- Circulation of agenda (and papers) minimum 5 working days before FPG meeting
- Publication of outcomes will follow ratification of FPG decisions at each IMOC meeting

13. Secretariat

Administration resource and co-ordination will be provided via the NHS NEL Pharmacy and Medicines Optimisation Team with support from Trust Formulary Teams.

Clinical and pharmaceutical input will be primarily provided by Pharmacy Teams in member Acute and Mental Health Trusts NHS NEL Pharmacy and Medicines Optimisation Team.

All correspondence for the FPG should be directed to: nelondonicb.nelfpg@nhs.net

14. Decision making

Decisions will be reached by consensus in the group based on the available evidence and expert advice. Appropriate decision-making framework will be employed.

All approved decisions will be ratified by IMOC.

15. Appeals Process

Appeal requests must be submitted in writing to the Secretariat of the IMOC within 30 days of the date of issue of the decision. The appeals process gives applicants the right to appeal an FPG decision if they feel that the process leading to the decision being made was not followed correctly. The IMOC Secretariat will not consider whether the decision was clinically right or wrong and cannot change the assessment criteria agreed by FPG.

The Grounds for an appeal against decisions made by the FPG are:

- In reaching the original decision, the FPG did not follow it's agreed decision making process as outlined in the Terms of Reference.
- The applicant can demonstrate that not all relevant evidence available at the time of review was taken into consideration at the time of the decision for whatever reason.

Notes:

- The applicant cannot appeal against a decision just because they do not agree with the decision or because new evidence has come to light since the original decision was made. If new evidence is provided following a decision made by the FPG, the correct procedure is to resubmit for reconsideration of the decision by the FPG/IMOC.
- The applicant cannot appeal against a decision because a neighbouring FPG/IMOC (or equivalent Committee) came to a different decision.
- The applicant will not be able to lodge an appeal if they did not attend the meeting where the application was considered.

The appeal panel will assess if the FPG has followed its own processes accurately. The results of this appeal will be communicated directly to the appealing clinician and the FPG, who will review the decision if required. All appeals will be reported and reviewed annually by the FPG to help inform if updates are required to FPG processes.

16. Documentation

- Cover sheet
- Application form to request the addition of a new medicinal product to the NEL formulary
- Declaration of interests form
- Chair's action form
- Triage process
- RAG definitions for responsibility of prescribing
- Monthly highlight report to IMOC with decisions for ratification
- End of financial year report to IMOC

17. Publications

- Publication of redacted minutes
- Individual Trusts to update their own formulary pages (a NEL-wide process will be considered as part of the workplan)
- NEL ICB to disseminate information to primary care and update formulary accordingly

18. Prescribing support

Updating of OptimiseRx prescribing support software will be done by the NHS NEL Pharmacy and Medicines Optimisation Team.

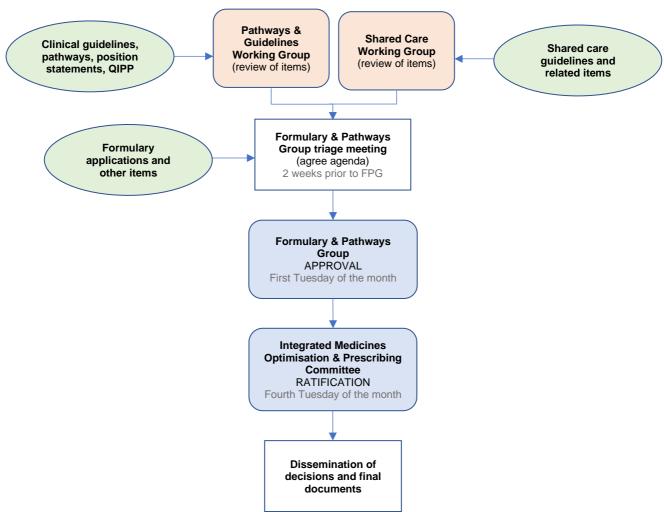
19. Monitoring of outcomes

To be specified as part of the approval criteria and included in reports to IMOC.

Appendix A - Formularies in use across NEL as of 1st July 2022

- Barts Health Formulary
- Barking, Havering, Redbridge University Trust Formulary
- ELFT Psychiatric Medicines formulary
- NELFT Psychotropic Drugs Formulary
- NELFT Prescribable medical devices and appliances formularies e.g. Dressings formulary
- City & Hackney/Homerton Healthcare
- Tower Hamlets Formulary
- Waltham Forest/Newham Formulary

Appendix B – Formulary & Pathways Group approval process



N.B. Approval process correct at time of publication