

North East London Formulary and 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
May 2024	2.2	Update to ToR
March 2026	3.0	Update to ToR

Document management

Produced	North East London Formulary and Pathways Group (FPG)
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1. Background

The North East London (NEL) Formulary and 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.

2. Purpose

The NEL FPG is a sub-group of the NEL System Prescribing and Medicines Optimisation (SyPMO) Board.

The Formulary and Pathways Group (FPG) operates as a clinical advisory group of the Integrated Care System, responsible for making clinically safe, evidence based decisions regarding formulary inclusion and medicines related pathways.

In line with its role, the FPG does not hold responsibility for commissioning, contracting, or determining prescribing responsibility. These accountabilities remain within the remit of the NEL System Prescribing and Medicines Optimisation (SyPMO) Board / NEL Integrated Care Board and Provider Trusts. This ensures a clear and appropriate separation between clinical judgement and contractual or financial accountability, with all decisions based on the available evidence and expert advice.

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, equitable 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/national NHS organisations to encourage rapid and consistent implementation.
 - To link in with the NEL Medicines Safety and Quality Group (MSQG) for any clinical risks identified with submissions to the FPG.
 - To link in with the NEL Medicines Value Group (MVG) for any submissions that have a significant financial impact on the ICS.

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, medical gases as appropriate).
- New indications for medicines.
- Medicines related pathways, guidelines and position statements.*
- Shared care and transfer of care guidelines / factsheets.

* 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.

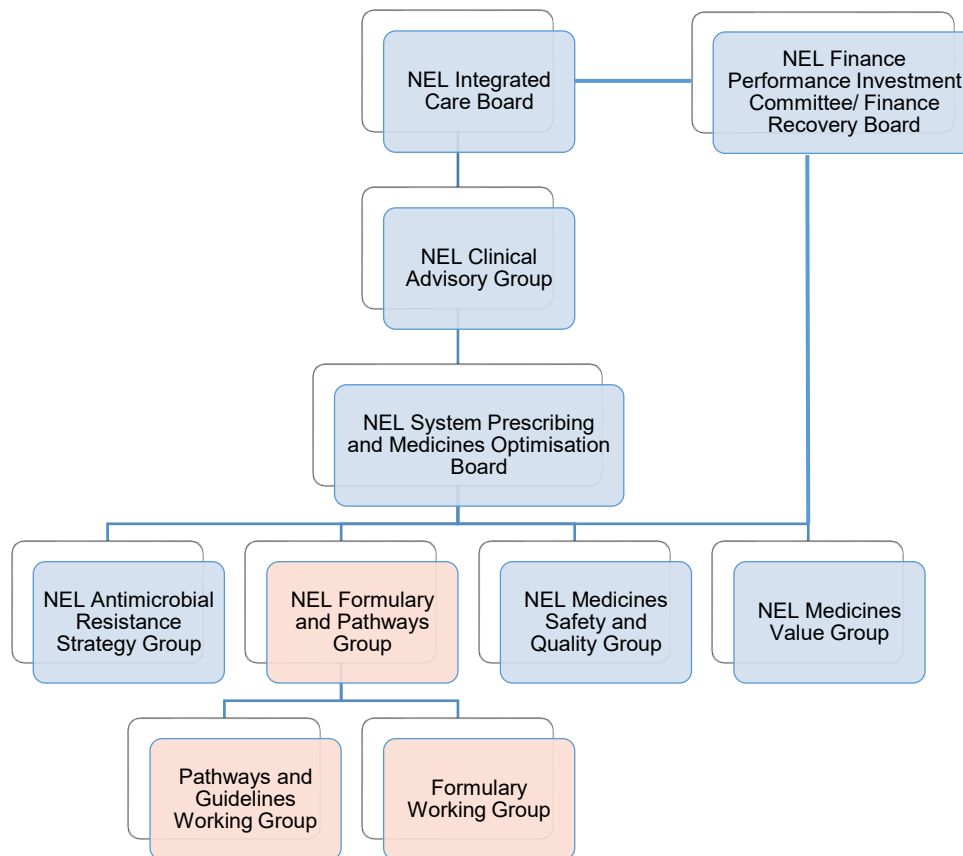
The FPG may, as agreed with SyPMO Board, convene specific working groups to take forward detailed work on appropriate topics as they arise. The groups should consist of nominated representatives from the relevant organisations and feedback progress against the set deadlines to the FPG. The Formulary & Pathways Group approval process is shown in Appendix A.

3. Accountability

The FPG will provide regular reports to the SyPMO Board:

- Monthly highlight reports and decisions for ratification by SyPMO Board
- Annual report

4. Governance



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

5. Scope

Introduction, review and update, or development of NEL wide:

- Entry of new medicines
- New indications for medicines
- Medicines related pathways
- Pharmacogenomics
- Prescribing guidelines
- NEL formulary
- Shared care/transfer of care guidelines / factsheets
- Prescribable treatments (e.g. appliances/devices closely associated with medicines, contrast medias, oral nutritional supplements/feeds, dressings, continence products, medical gases as appropriate)
- 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. MHRA, Accelerated Access Collaborative, NHSE).

The group will review outputs from regional/national organisations and advise SyPMO Board 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 and Therapeutics Committee
 - Individual Provider Trusts' Medicines Optimisation Groups:
 - ELFT Medicines Committee
 - NELFT Medicines Optimisation Group
 - BHRUT Medicines Optimisation Group
 - Homerton Medicines Committee

7. Financial impact consideration

Individual Provider 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 per 12 month period for NEL health economy (circa £500K), this would need to be discussed at ICB Finance (via NEL MVG) prior to submission to FPG.

8. Urgent clinical decisions

Any item considered to be of urgent clinical need will be considered by individual Provider Trusts via their internal processes (i.e. via Provider 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 Provider 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 Provider Trust.

NICE TAs due to be implemented outside of the FPG meeting timeframe should be considered and approved by individual Provider Trusts and noted at the next FPG meeting.

A summary of Chair's actions (approved by individual Provider Trusts and FPG Chairs) will be reported to the FPG at the next meeting or at least quarterly

9. Membership

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

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

The group will be supported by formulary pharmacists (or equivalent) in member Provider 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)	<ul style="list-style-type: none"> Deputy Director of Medicines Optimisation, Medicines Pathways and Commissioning/ equivalent role Commissioning & Contracting Pharmacist Commissioning & Contracting Senior Pharmacy Technician Formulary Pharmacist(s)
Barts Health NHS Trust	<ul style="list-style-type: none"> Medical/Surgical Consultant Formulary & Pathways Lead Pharmacist Lead Medicines Commissioning & Pathways Pharmacist
Barking, Havering and Redbridge University Hospitals NHS Trust	<ul style="list-style-type: none"> Medical/Surgical Consultant Lead/Senior Pharmacist
Homerton Healthcare NHS Foundation Trust	<ul style="list-style-type: none"> Medical/Surgical Consultant Lead/Senior Pharmacist
East London NHS Foundation Trust	<ul style="list-style-type: none"> Medical Consultant Lead/Formulary Pharmacist
North East London NHS Foundation Trust	<ul style="list-style-type: none"> Medical Consultant Lead/Formulary Pharmacist
NEL Local Pharmaceutical Committee (LPC)	<ul style="list-style-type: none"> Chief Executive or nominated deputy
NEL Local Medical Committee (LMC)	<ul style="list-style-type: none"> 1 GP representative from Londonwide LMC and 1 GP representative from Barking, Dagenham and Havering LMC
Primary Care Prescribing Leads	<ul style="list-style-type: none"> 3 Prescribing Leads (one of which should be a GP)
Paediatric representative	<ul style="list-style-type: none"> 1 Representative (optional)
Lay representation (optional)	<ul style="list-style-type: none"> 1 Representative (optional)
Non-medical prescribing representative	<ul style="list-style-type: none"> 1 Primary Care representative 1 Secondary Care representative
NICE Associate	<ul style="list-style-type: none"> 1 NICE Associate
NHSE Specialised Commissioning – London region	<ul style="list-style-type: none"> 1 Pharmacist

** Members who are subject matter experts may be co-opted for specific agenda items according to the agenda (e.g. Public Health, medical gases, pharmacogenomics).

10. Chair

Meeting Chairs:

- Consultant Provider Trust Lead (Co-chair)
- GP Prescribing Lead/Clinical lead/Clinical Director (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 Provider Trust Medical/Surgical Consultants
- 2 Provider Trust Formulary/Lead Pharmacists from separate Provider Trusts – at least 1 from acute provider
- 1 NHS NEL ICB Formulary / Place Delivery Pharmacist
- 1 Primary Care GP or nominated Deputy

If the meeting is inquorate, to seek agreement from the relevant representation(s) outside of the meeting (via email).

12. Running of the meeting

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

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

All submitted items will be considered at triage and placed in the next available meeting based on priority.

All final submissions must have undergone consultation with the relevant stakeholders. Where there is not a relevant clinical network or equivalent group, the Pathways and Guidelines Working Group meeting must be used to ensure submissions have enabled relevant stakeholders (including nominated representatives) sufficient consultation time to enable robust submissions to be presented at each FPG meeting. Any submissions not meeting this requirement will be rejected at triage.

Important dates:

- Deadline for submissions – at least 4 weeks before FPG meeting
- Triage – 2 weeks before FPG meeting
- Chairs pre-meet – 2 weeks 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 SyPMO Board meeting

13. Secretariat

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

Clinical and pharmaceutical input will be primarily provided by Pharmacy Teams in member Acute and Mental Health Provider Trusts and NHS NEL. Medical and primary care input will be provided by Consultants, GP and primary care representatives

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

14. Decision making

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

All decisions are subject to final ratification by SyPMO Board.

15. Appeals Process

Appeal requests must be submitted in writing to the Secretariat of the SyPMO Board within 30 days of the date of issue of the decision. The appeals process gives applicants the right to appeal a decision if they feel that the process leading to the decision being made was not followed correctly.

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

- In reaching the original decision, the FPG did not follow its 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
- If new evidence has come to light following the original decision made by the FPG, the application can be resubmitted for reconsideration of the decision by the FPG/ SyPMO Board.

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
- Full application form to request the addition of a new medicinal product to the NEL formulary
- Short application form for formulary harmonisation, change/ addition of a formulation (for the same indication) or Formulary status change to the NEL formulary
- Position statement
- Primary Care prescribing support factsheet
- Declaration of interests form
- Triage process
- RAG definitions for responsibility of prescribing
- Monthly highlight report to SyPMO Board with decisions for ratification
- End of financial year report to SyPMO Board

17. Publications

- Publication of redacted minutes
- Publication of FPG decision log
- Individual Provider 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 netFormulary and NEL Primary Care Information Portal

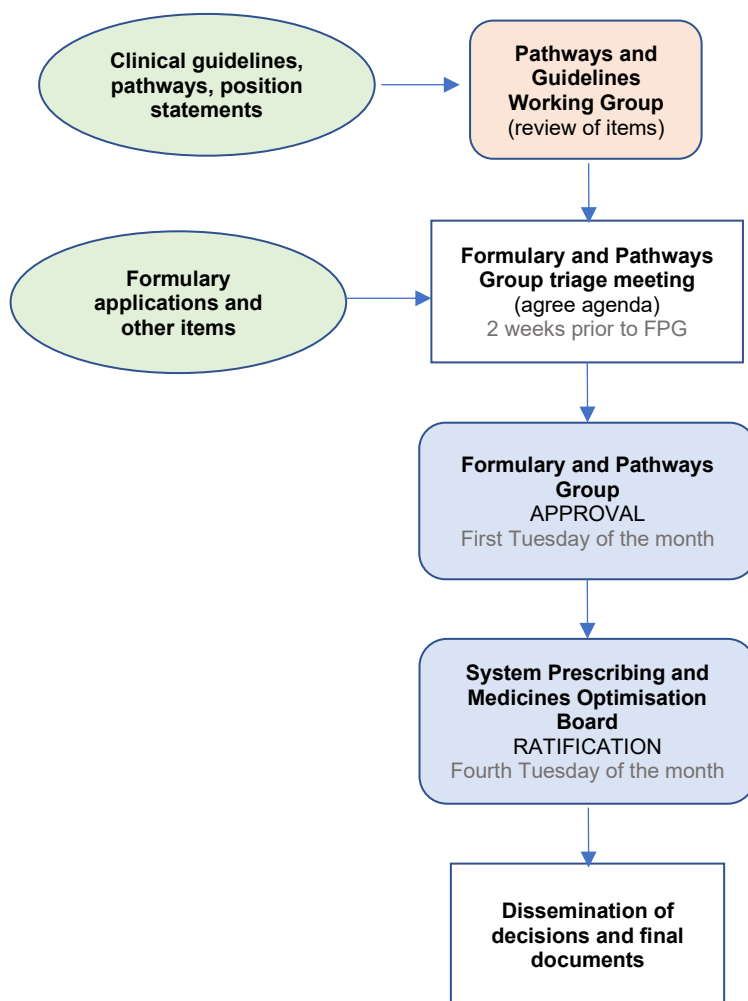
18. Prescribing support

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 SyPMO Board.

Appendix A – Formulary & Pathways Group approval process



N.B. Approval process correct at time of publication