

North Central London Joint Formulary Committee

Terms of Reference

1. Remit

The North Central London Joint Formulary Committee (NCL JFC) is responsible for advising Commissioners and Providers in NCL on the safe, appropriate, equitable, evidence-based and cost-effective use of medicines.

The JFC acts in a scientific and advisory capacity to take a strategic lead on the high-priority medicines optimisation issues affecting NCL. The JFC forms a collective clinical leadership committee, which aims to achieve consistency of robust decision-making across the area and oversee the development of robust care pathways within NCL. The Committee will review licensed medicines (including those being used for an off-label indication), unlicensed medicines, and Advanced Therapy Medicinal Products (ATMPs).

The scope of the JFC does not include the review of medicines that have received a positive NICE Technology Appraisal (TA) as there is a legal obligation for these medicines to be made available, therefore it can be accepted that positive NICE TA decisions are endorsed by the JFC. Where multiple medicines have NICE TAs for the same indication, JFC may review the evidence underpinning each NICE TAs to support safe and effective prescribing by generating a preference hierarchy.

The JFC may review applications for medicines that have received a negative TA, although there would need to be a strong level of clinical support for doing so, or for medicines used for indications that fall outside of that approved by a positive NICE TA. The JFC will review a decision for a medicine that is currently on the formulary, but subsequently receives a negative opinion by NICE.

The JFC prioritises applications for new medicines that are relevant to two or more Trusts, or where there is an impact for CCG commissioners, or where it is planned that prescribing will be transferred to primary care. Where only one Trust is affected, the application may be reviewed at the appropriate Drugs and Therapeutics Committee (DTC) and ratified by the JFC at the following meeting. JFC may review applications to decommission medicines (i.e. remove from the NCL Joint Formulary) where medicines are considered by the applicant, or NHS England, to be of low clinical value.

2. Accountability

The NCL JFC makes medicines related recommendations to the NCL Clinical Commissioning Group (CCG) and Provider Trusts DTCs within North Central London. These Committees in turn hold overall accountability of decisions made within their respective organisations.

The JFC submits its annual report and monthly abbreviated minutes to the Health & Care Cabinet of the North Central London Sustainability and Transformation Partnership (NCL STP).

3. Financial and Commissioning Impact

The NCL JFC will act as a single point of entry for new medicines or new indications for existing medicines in the following circumstances:

- Where there is a drive to use the technology in two or more Provider Trusts in NCL, in order to reduce the risk of inequality caused by different organisations arriving at different decisions (even where the drug cost is included in the national tariff)
- Where the proposed medicine will be prescribed in both primary and secondary care.
- Where the proposed medicine is excluded from the national tariff and will require additional funding from the CCG.
- Where adoption of a new medicine technology could lead to a major change in the care pathway.

A flow-diagram to identify which applications will be reviewed at NCL JFC is provided in <u>Appendix 1</u>.

The JFC is responsible for considering all relevant financial implications associated with introducing new medicines, including diagnostic tests, hospital appointments and GP time.

	Approved	Not Approved	
National tariff excluded	JFC makes recommendation to Trust DTCs that this medicine should be added to local formularies and to the CCG that this drug should be commissioned.	JFC makes recommendation to Trust DTCs that this medicine should not be prescribed.	
Within the national tariff	JFC makes recommendation to Trust DTCs and the CCG that this medicine should be added to local formularies/preferred prescribing lists where appropriate. Arrangements for prescribing across the interface should be clarified.	JFC makes recommendation to Trust DTCs that this medicine should not be included on local formularies for discussed indication. This may involve the hospital removing the medicine from the formulary.*	

* Where medicines are removed from a formulary, it is recommended that in most situations, patients will continue taking the medicine if there is perceived benefit, but no new patients will be started.

Where a CCG funded, national tariff excluded medicine is approved by the JFC, the Committee will make a recommendation to the NCL CCG that this treatment should be routinely commissioned. Where an 'in tariff' medicine is approved by JFC, the Committee will make a recommendation to provider Trusts and NCL CCG (where appropriate) that the treatment should be available to prescribe.

The NCL JFC will also act as a single point of exit for existing medicines considered to be of low clinical value.

4. Key Relationships

The JFC includes senior pharmacy and medical members from each member Provider Trust and NCL CCG. The JFC is funded by contributions from these member organisations.

Individual DTCs feed into the JFC by providing minutes for review in addition to DTC Chairs forming part of the JFC membership.

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NCL CCG is invited to nominate one pharmacist and one general practitioner from each NCL borough to join JFC membership. The Head of Medicines Management and Optimisation (or nominated deputy) at NHS London Shared Service is invited to advise on impact of commissioning decisions.

There are a number of providers in NCL who may initiate or recommend prescribing for NCL patients, but that are not members of the JFC. These organisations should liaise with a current member organisation to make arrangements for bringing applications to the JFC. The JFC Support Pharmacists can help with this process.

The JFC is part of the NCL Medicines Optimisation Network (MON), which also comprises the Medicines Optimisation Committee, provider DTCs, the CCG Heads of Medicines Management Committee, and NHS London Shared Service commissioning support Team. When the JFC recommends a medicine be prescribed, it will refer to the Medicines Optimisation Committee if there is a need for additional guidance (e.g. Shared Care Guideline, treatment pathway). See Appendix 2 for details of the MON.

4.1. NHS England Regional Medicines Optimisation Committees

NHS England Regional Medicines Optimisation Committees (RMOCs) make recommendations, pursue actions and co-ordinate activities relating to medicines optimisation. Some recommendations from the RMOCs may require further scoping, discussion, action or implementation at area prescribing committee (APC) level. It is anticipated that for most output from the RMOCs, the NCL MOC will act as the initial point of contact, however, where the discussion required is to appraise of the evidence-base, the NCL JFC will be available to undertake this task.

The JFC Support Pharmacists will liaise with the Chair(s) of the NCL MOC to agree which Committee an RMOC output will be discussed at.

5. Decision Making

The NCL JFC is responsible for scientifically assessing medicines in terms of comparative efficacy, safety, convenience and cost-effectiveness. Applications to the Committee to appraise a medicine must be submitted to the JFC Support Pharmacists by either a consultant clinician or a GP/Head of Medicines Management in the CCG. The application will be reviewed by the JFC Support Pharmacist and an evaluation of the literature will be conducted. This review will form the basis of the discussion at the JFC meeting. The applicant will be invited to discuss the application at a JFC meeting. S/he will be welcome to nominate a deputy (Consultant/GP/SpR) if they are unable to attend the meeting in person. The applicant will be asked to leave the room to allow the Committee to discuss the application.

Each recommendation made by the JFC will be clearly documented in the minutes as below:

Decision: Approved / Not approved / Approved under evaluation / Deferred Prescribing: Hospital only / GP initiation / Secondary care initiation with continuation by GP Tariff status: Included / Excluded/ N/A – Free of charge Funding: Hospital budget only / Hospital and GP budgets / CCG / NHS-E/ N/A – Free of charge Fact sheet or shared care required: Yes (which) / No/ Deferred to NCL Shared Care Group Other notes: Include any relevant information i.e. dose if off-label, monitoring requirements

The Chair of the JFC may be asked to approve decisions outside the JFC meeting. This will occur only when it has been agreed by the Committee beforehand (e.g. when further information or amendments have been requested).

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Final decisions will be posted on the JFC website and will be sent to applicants within three weeks of the JFC meeting.

Recommendations made by the JFC will be incorporated into the NCL Joint Formulary platform using the colour rating described in <u>Figure 1</u>.

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Amber Approved for prescribing under defined circumstances. Can be prescribed in primary care following initiation in secondary care. Fact sheet or shared care may be required.	Green Approved for prescribing. Can be initiated by GP or in secondary care. Strong evidence of benefit and safety.				
Black Not approved for prescribing. Weak evidence of benefits and/or safety concerns.	Red Approved for prescribing in secondary care only.				

Figure 1: Colour coding used by the NCL Joint Formulary platform

5.1. Reviewing DTC minutes

DTC decisions relating to changes to the formulary are reviewed at JFC to confirm consistency with regional decision making. If JFC support the DTC decision, the medicine will be considered for addition to the NCL Joint Formulary (ratifying the DTC decision). In the event JFC have queries relating to the DTC decision, JFC Support will work with Trust Formulary pharmacists to resolve the Committee's concerns.

6. Members' Roles and Responsibilities

Each individual member has a responsibility for contributing to and participating in the activities of the JFC. Meetings will be held virtually via Microsoft Teams. Members should seek to attend each JFC meeting; the Chair will be asked to consider the membership of any member with attendance below 50% in any 12-month period. Individuals should ensure the clinical and operational perspectives of their organisation are considered within all decisions. JFC members will take a responsibility for any decision made at the committee meeting and will act as an advocate for these decisions within their own organisation. Deputies with delegated decision-making responsibility can be sent when it is not possible for a member to attend; the Chair should be advised of deputies at the start of the meeting.

Participants will be expected to represent the views of their peers or organisation and must ensure they maintain a communication network that allows them to discharge this duty. Members are expected to challenge and probe views expressed by other Committee members and those of clinicians presenting medicines at JFC. The tenure of membership for members representing a Trust or CCG is not time-limited, but requires ongoing employment with the organisation in question.

Members must complete a Declaration of Interests on an annual basis and update this as required. Members are expected to act within the corporate policies of the organisation they represent, of UCL Partners and those specific to the JFC (e.g. Equal Opportunities, Data Protection).

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6.1. Chair and Vice-Chair

The Chair and Vice-Chair(s) are key members of the JFC, taking responsibility for its effective functioning.

The position of Chair is subject to an application process and carries a 3-year initial term. At the end of the first term, the Committee may vote to extend the tenure for one additional term otherwise the position will be re-advertised. At the end of the second term, the position of Chair will be re-advertised; if no-one suitable is identified the Committee may vote to allow the incumbent to continue for up to one additional term whilst a suitable candidate is appointed.

The Chair and Vice-Chair should give minimum 3 month notice of their intention to terminate their tenure except in circumstances of ill health. In exceptional circumstances, the Committee may vote to terminate the tenure of the Chair or Vice-Chair; this will be communicated in writing and if necessary the employing organisation's HR department would be informed.

The Committee will appoint up to two Vice-Chairs from within the membership to act as alternates in the Chair's absence, ideally one from primary care and one from secondary care. The roles and responsibilities described in Section 6.1.1 for a Chair apply to the Vice-Chair for meetings they are responsible for.

6.1.1. Roles and responsibilities

The Chair has a number of roles that they must perform to allow the committee to achieve its objectives. These include:

- Spokesperson sharing and summarising the views of others
- Organiser help to ensure the right people are in the right place discussing the right things
- Communicator ensures that everyone knows what is going on before, during and after a meeting
- Action person makes sure actions are generated appropriately and followed up
- Mediator finds compromise between two people in a way that does not let their own feelings get in the way

The Chair may delegate some of these roles to others (particularly to the Vice Chair and the committee's secretariat), but must maintain overall responsibility for them.

The Chair and Vice Chair must work closely together, therefore need to respect each other and agree respective roles.

The Chair is responsible for meeting with the JFC secretariat two weeks before each meeting to plan the agenda. The Chair's contribution at this meeting will be to highlight potential issues with documentation to provide the secretariat with the opportunity to rectify this before the meeting. The Chair will provide support with progress on action points from the previous meeting, where necessary.

At the JFC meeting, the Chair is responsible for ensuring the agenda runs to time, encouraging discussion, helping the committee reach an agreement and clarifying action points to be achieved by the next meeting. To support effective committee decision making, the Chair may need to act as a negotiator, influencer or diplomat.

The Chair must be able to handle disagreements in the meeting and to deal with all of the stakeholders around the table, whilst ensuring they do not become the source of the disagreement.

After the meeting, the Chair is responsible for ensuring the secretariat produces the minutes in a timely manner. The minutes must be accurate and provide sufficient detail for the committee to follow up

actions and hold each other to account. The Chair may need to approve certain documents by Chair's action where minor amendments have been suggested during the meeting.

6.2. Membership List

See "JFC Membership" for a full list of members. Current members should inform the Chair and JFC Support Pharmacists if they wish to stand down from the Committee so an appropriate replacement can be found.

Organisations wishing to propose new members should approach the Chair and JFC Support Pharmacists.

6.3. Joint Formulary Committee Support Pharmacists

JFC Support Pharmacists are responsible for collating new drug applications and liaising with Formulary Pharmacists and the Chair of the JFC to set agendas. New drug applications will be shared with CCG Heads of Medicines Management and Provider Formulary Pharmacists within one week of receipt, to allow adequate time for consultation. JFC Support Pharmacists will complete the formulary review for new drug applications according to agreed local standards. JFC Support Pharmacists are responsible for writing the draft meeting minutes in a timely manner and agreeing these with the Chair of the JFC. Communicating meeting decisions will be completed by the JFC Support Pharmacist.

6.4. Provider Trust Formulary Pharmacists

Formulary Pharmacists within each organisation have a responsibility for forwarding JFC new drug applications to the JFC Support Pharmacists in a timely manner. Formulary Pharmacists are expected to consult with specialists within their own organisation when applications for use of medicines are received from other organisations to ensure a consistent response across NCL. Formulary Pharmacists are responsible for disseminating the outcomes of JFC meetings with the relevant committees and individuals within their organisation. Formulary Pharmacists will make the minutes of DTC/formulary meetings held in their organisation available to the JFC Support Pharmacists at least two weeks before the next JFC meeting.

7. Stakeholder Engagement

The JFC agenda and relevant supporting papers will be sent to all identified stakeholders at least one week in advance of the meeting. Stakeholders will be encouraged to provide any pertinent comments that should be brought to the attention of the JFC. For complicated agenda items, additional stakeholders may be invited to the meeting to help participate in discussions.

CCG Heads of Medicines Management and Provider Formulary Pharmacists will be informed of new medicine applications within one week of them being received by the JFC Support Pharmacists to allow organisations to perform their own internal stakeholder consultation.

8. Horizon Scanning

The London Medicines Evaluation Network, on behalf of the London UK Medicines Information (UKMi) service and Specialist Pharmacy Services (SPS), undertakes a horizon scanning activity of all newly licensed medicines in the UK. This activity log identifies which medicines will be allocated for review by NHSE or NICE, and therefore which should be prioritised for local APC / DTC. Any reviews allocated to the NCL JFC should be applicable to the NCL services and will be identified on the JFC work plan.

9. Public Communications

The JFC Patient Partners are included in all communications of JFC agendas and are included in discussions at JFC meetings.

Minutes of previous meetings and decisions are accessible through the public JFC website.

10. Appeals Process

The JFC will only reconsider a decision if one of four scenarios occurs:

- 1. Significant new information is available requiring reconsideration of the evidence. This may include evidence of the safety or efficacy of comparator medicines
- 2. The original decision was based on inaccurate or incomplete information
- 3. The Committee did not follow its agreed process
- 4. A perverse decision was made based on the evidence considered by the Committee

The applicant or another clinician must submit an appeal letter to the Chair and JFC Secretariat, detailing which appeal criteria applies. Additional relevant information must be presented by the appellant at this stage. The first appeal will be reviewed by the JFC Chair and secretariat, and presented to the NCL JFC. If a second appeal is received, this will be forwarded to the South East London Joint Formulary Committee for a review of the process followed. A third line appeal of the process should be sent to the NCL Health and Care Cabinet.

11. Register of Interests

All members of the JFC, meeting attendees and observers should ensure that all relevant personal and non-personal interests have been declared to the Chair of the Committee.

11.1. Examples of Personal Interests

Regular or commissioned work for a consultancy or directorship, position or work for the pharmaceutical industry which attracts regular or occasional payments. Where shares or held in a company, or the member otherwise benefits from the activity of shares in a company (excluding shares held through unit trusts or similar, where the member has no influence on the financial management of these shares).

11.2. Examples of Non-Personal Interests

This relates to payments related to the department for which a person is responsible, but where the payment does not personally benefit the member. This can include fellowships, grants or other support funded by the pharmaceutical industry.

11.3. Declaring Interests

On appointment to the JFC, members should inform the Committee in writing of their current (in the last two years) personal and non-personal interests (name of company and nature of interests). Each year, members will be asked to complete a Declaration of Interests form to include all personal and non-personal interests. Any relevant change to interests must be declared at the time of the change.

Any personal gift individually valued at £25 (or multiple gifts from same or related source individually costing less than £25, but collectively more than £100) must be declared.

11.4. Declaring Interests at Committee Meetings

A member must declare any personal interest specific to a product if s/he has worked on the product under consideration and has personally received payment for that work from the pharmaceutical industry in the last two years. In addition to making a verbal declaration of interest at the meeting, applicants must declare any interests on the application form.

Clinicians sponsoring a drug application at the JFC will be asked to declare any personal and nonpersonal interests they have. Applicants will need to be prepared to provide the Committee with a detailed statement of their income from relevant pharmaceutical companies when they present at the meeting.

12. Quoracy

The JFC meeting will be considered quorate if the Chair (or Vice Chair), plus four primary care and four secondary care members are present.

13. Meeting Frequency

JFC meetings will be held on a monthly basis on the 3rd Thursday of each month between 1630 and 1830. The Committee takes a planned break in December. The JFC Support Pharmacists will meet with the JFC Chair at least monthly to agree meeting agendas.

14. Review of the Terms of Reference

The Terms of Reference will be reviewed annually by the JFC.

15. Annual Report

The JFC Support Pharmacists will submit a report to member organisations every year in July (to allow April to March reporting).

16. References

- NICE Code of Practice for Declaring and Dealing with Conflicts of Interest Issue date: April 2007 Review date: December 2009.
- Local formulary development (2012 updated 2015) NICE medicines practice guideline 1
- National Institute for Health and Care Excellence. Good Practice in Chairing: Guidelines Best Practice.
- National Institute for Health and Care Excellence. Guideline Committees: A guide for members

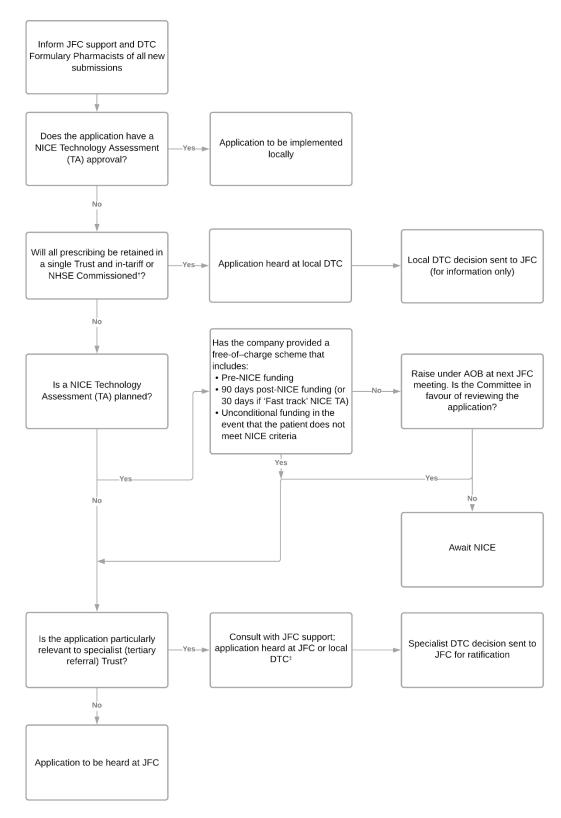
17. Document control

Date	Version	Amendments
29 February 2016	1	
10 March 2016	1.1	Section 5 Decision making: "Grey" medicines changed to "Black" when referring to medicines rejected by the formulary due to weak evidence.
11 July 2016	1.2	Reference to "NCL JFC Appeals Process" removed from section 10
12 Jan 2017	1.3	Update to role of Chair and committee members based on documents from NICE
18 September 2017	1.4	Link to Health & Care Cabinet; Secondary Care Co-Vice Chair; Appeals process updated
20 August 2018	1.5	Clarification on JFC remit, accountability and Chair / Vice Chair tenure Role as Area Prescribing Committee with regards to RMOC decisions specified Update on horizon scanning process Declarations of interests from consultants presenting medicine Decommissioning medicines Addition of 'New medicine submissions flow diagram'
12 November 2021	2.0	Review and interim update of Terms of Reference

Document management

Groups / Individuals who have overseen the development of this guidance:	Prof Reecha Sofat, JFC Chair Sonali Sanghvi, Gurpal Grewal, Royce Rajan (JFC Secretariat)
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Equality impact assessment:	Not completed
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Review date:	+ 1 year

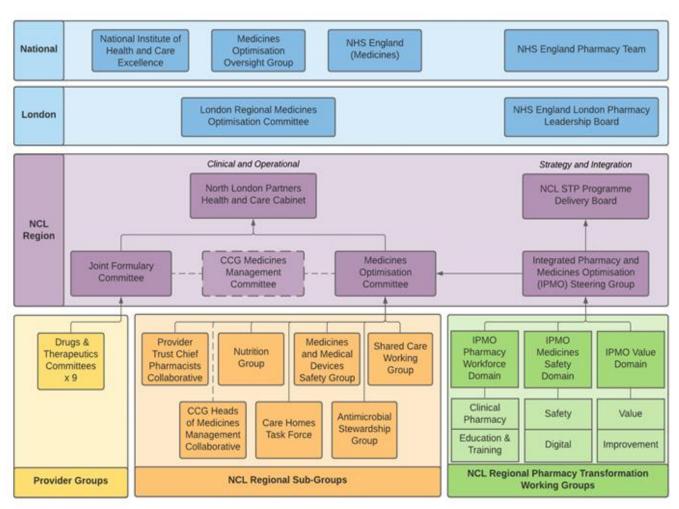
Appendix 1: New medicine submissions flow diagram



⁺ Established collaboratively between DTC formulary pharmacists and either JFC support or by the submitting Trust

[‡] A local DTC may be chosen based on local expertise and capacity. For example, the JFC may approach MEH to consider a new ophthalmologic preparation, even if the application originated from a different Trust (e.g. RFL).

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Appendix 2: NCL Medicines Optimisation Network