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NHS
North East London

NEL Free of Charge (FOC) Schemes Guidance
– Applications, Checklist and Consent Template

NHS North East London

This guidance focuses on Pharmaceutically offered medicines at a free or discounted rate. It gives information about Free of Charge (FOC) Schemes and how to apply for such schemes across North East London. The document also provides examples consent templates and a checklist to support applications to the North East London Formulary and Pathways Group (NEL FPG).

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Contents

1. Background

1.1 A free of charge (FOC) medicine scheme is defined as an arrangement where a medicine (licensed or unlicensed) is provided free of charge by a pharmaceutical company to an individual patient or an identified cohort of patients. This also includes very heavily discounted products (for example £1 per pack or schemes offering money back).

1.2 In general, medicines offered through FOC schemes are high-cost, tariff-excluded medicines[1] that are typically used within services commissioned by NHS Integrated Care Boards (ICBs) or by NHS England (NHSE) Specialised Commissioning, although the medicines themselves may not always be formally commissioned

1.3 Apart from voluntary MHRA Early Access to Medicines Schemes and European Medicines Agency (EMA) Compassionate Use Schemes (which record and monitor the scheme), there is currently no standardisation of the type of FOC schemes that pharmaceutical companies offer.

1.4 This guidance focuses on Pharmaceutically offered medicines at a free or discounted rate.

1.5 FOC schemes, while having the potential to offer patient access to promising medicines, must be managed and assessed appropriately for the following reasons:

- They can lead to unwanted variation.
- They may open the patient up to risk of harm (especially if an investigational product is being offered).
- There are concerns that Pharmaceutical companies may offer FOC schemes prior to NICE or local commissioner approval in order to gain market share for their product.
- They risk undermining existing evidence-based treatment pathways made by NICE or local centres as well as potentially destabilising commissioning processes.
- They may lead to the Trust being left at financial risk if the scheme is then withdrawn.

1.6 In order to ensure a consistent and equitable approach across North East London (NEL), FOC schemes should be approved at the NEL Formulary and Pathways Group and System Prescribing and Medicines Optimisation (SyPMO) Board prior to being offered to patients.

1.7 In exceptional circumstances, where there is a life threatening or urgent clinical need for an individual patient (which cannot wait until the next NEL FPG), an FOC may be considered under a Chairs Action at the individual Trust. However, it should be noted that approval of medicinal product under Chairs action does not necessarily mean it will be approved for ongoing use at NEL FPG.

2. Scope

2.1 Pharmaceutical led FOC schemes (for a cohort or individual patient) are included in the scope of this document.

2.2 The following are outside the scope:

- EMA Compassionate Use Scheme

- MHRA Early Access to Medicines Scheme (EAMS)
- NICE approved Patient Access Schemes (PAS)
- Clinical Trial and FOC schemes for post-trial access
- Discounts or rebates linked to usage
- Individual funding requests (IFRs)
- Compassionate use – where the company agrees to offer a medicine free of charge at the request of a clinician when treating a life threatening condition for an individual patient (this should be reviewed by individual Trusts under Chairs actions)
- Cancer specific FOC schemes – these will be considered at the provider Trust, where the principles within this document should apply.

3. Key Considerations for FOC Schemes

3.1 Governance

3.1.1 The NEL FPG should continue to assess all new treatments and ensure evidence supporting the medicines effectiveness is appropriately balanced with the potential for harm, irrespective of whether a new treatment is being offered free of charge.

3.1.2 **FOC schemes should not undermine NICE or local treatment pathways**. Where approved treatments are available and appropriate these should be utilised.

3.1.2.1 Where NICE is due to imminently make a recommendation (for example within 6 months), an FOC should generally not be considered.

3.1.3 **Only FOC schemes that address a clear, unmet clinical need should be considered**.

3.1.4 NHSE also advises Integrated Care Systems (ICS)s should not sign up to FOC schemes if[1]:

- The company is solely offering a licensed medicine free of charge or at a lower cost for the purpose of market access in advance of a commissioning agreement.
- The pharmaceutical company has chosen not to make a submission on a topic that NICE has identified as requiring guidance. This includes medicine indications that the company has chosen not to submit to NICE, which has meant that NICE are unable to issue guidance. Such arrangements are therefore not generally supported because the clinical and cost effectiveness of the treatment is unknown.
- A positive NICE Final Draft Guidance (FAD), a patient access scheme (PAS), Early Access Medicines Scheme (EAMS) or other commercial arrangement is already in place, including any schemes offering medicines at a significantly discounted rate or at a lower cost than the current PAS price for indications as defined within the NICE guidance.
- If a PAS or commercial agreement is already in place and the scheme could potentially lead to an increase in inequity in access to medicines and will affect treatment pathways for that indication.

- The medicine or condition is currently commissioned by NHS England specialised commissioning.

3.1.5 A written agreement or contract between the company and Trust must be signed (see section 5) which clearly states the exit strategy.

3.1.6 The requesting clinician must complete the FOC checklist (see Appendix 1) and a full formulary application, which must include the intended clinical outcome and clear stopping criteria if the clinical outcomes are not achieved.

3.1.7 When an FOC scheme is being reviewed, there should be consideration of the impact of equity across the Health System as well as capacity at individual Trusts.

3.1.8 Patients must be consented for any unlicensed or off label indications as per Trust Policy as well as completing a consent form (template in Appendix 2).

3.1.9 Where a patient would be eligible for a clinical trial, FOC schemes for an unlicensed/off-label medications should not undermine recruitment into said trial.

3.2 Workforce and Financial Impact

3.2.1 FOC schemes generally have a considerable impact on finance and workforce, despite the drug being “free”. These should be considered carefully and accounted for within the decision-making process.

- Cost of medicines after the end of the FOC scheme. The Trust should not be put at financial risk and so an exit strategy should be in place. The FPG should therefore consider if there are any planned routes to commissioning (and if this can be waited for).
- Ongoing ordering, supply, and monitoring of the medicine. Failure of supply route could also be an operational risk.
- Supporting costs for staff, equipment and concomitant medicines (particularly if not funded).
- Ongoing management of the scheme especially if it is then commissioned (leading to management of FOC and commissioned stock).
- Data anonymisation and transfer risks and the associated administrative workload.
- Waste management.
- Provider tariff activity costs that have not been commissioned for example admissions, outpatient appointments, follow up ratios, monitoring, treating adverse effects.
- Potential for harm and medical negligence claim should an adverse incident occur, plus the resulting reputational risk.
- Risk of undermining the NICE guidance as the funding mandate still applies to medicines approved by NICE, therefore any FOC scheme should not preclude patients from accessing a NICE approved treatment.
- Where the FOC drug could be given in combination with currently funded medicine(s), there is a risk that this could lead to increases in the costs of the currently funded

medicine(s) due to an increase in duration of treatment (more common in chemotherapy regimens).

- In general, FOC schemes added into combination with commissioned therapies/ regimens are *generally not supported* as these may mean the patient no longer meets commissioning criteria. Advice must be sought from the commissioner if unsure.

3.2.2 Where multiple schemes are in place, the above factors should be considered along with the cumulative burden of managing multiple schemes. Equity of access amongst patients should be central to this so all Trusts that are commissioned to treat the specific condition should first agree that they have capacity to offer the treatment before it comes to FPG/ SyPMO Board for a decision.

3.3 Patient Consent

3.3.1 Patients should have the capacity to make an informed decision about their treatment and be acting free from pressure.

3.3.2 If the FOC scheme is approved at NEL FPG, the patient should be consented as below:

- Ensure that they are aware that entry into an FOC scheme may mean that their treatment may stop if the scheme ends or the company withdraws access to the scheme. Any alternative treatment plan should be outlined at this stage.
- The purpose of and reasons for the recommended treatment.
- Options for treatment (including the option of no treatment).
- Likely benefits, risks, and potential adverse effects.
- Uncertainties regarding efficacy/safety data.
- A reminder that the patient can change their mind about having their treatment.
- How to take or use the medicine, how to obtain supply and how to report side effects.
- Permission to share non-identifiable information with the company where necessary.
- A reminder that this does not affect the patient's right to access NICE approved treatments.

3.3.3 A signed consent form must be obtained before entering the patient in the FOC scheme (see Appendix 2 for an example template)

3.3.4 When the FOC scheme involves some element of patient data collection, the scheme must have a non-disclosure agreement or the explicit consent from patients to share relevant, non-identifiable information. This protects patient data that would not be available if the patient had not entered a FOC scheme. Sharing of patient identifiable information is not acceptable.

3.3.5 Individual Trusts may also have additional Patient Consent Policies.

4. Free of Charge Applications to the NEL FPG

4.1 To apply for an FOC scheme to the NEL FPG, a full formulary application will be required along with a completed FOC checklist (found in Appendix 1).

4.2 The NEL FPG will also assess unmet need and whether the overall benefits outweigh the overall risks (including financial risk to the Trust). All decisions must then be ratified by the SyPMO Board.

4.3 The application should:

- Ensure all formulary options have been exhausted.
- Clearly specify the unmet health need of the patient(s)
- Ensure that the application has been approved by the following stakeholders:
    - Local Consultant/ clinician consultation for cohort application
    - Specialist/directorate pharmacist
    - Each Trusts Formulary Chair and/or Chief Pharmacist
    - Divisional/Trust funding approval for any additional costs not covered by FOC scheme
    - The Homecare team if applicable
    - Any other relevant stakeholders (where applicable)

4.4 Clinicians must ensure that the application has been approved by the NEL FPG and SyPMO Board (via the outcome letter that they will receive) before they offer the FOC medication to the patient or entering into an agreement with the company.

5. Pharmaceutical Company Responsibilities

5.1 Pharmaceutical companies should adhere to NHSE guidance[1].

5.1.1 For post NICE TA publication FOC Schemes, pharmaceutical companies should review the current PAS or commercial arrangement with NHSE and NICE. New offers to local organisations in respect of FOC schemes or equivalent for post-NICE medicines should not be made.

5.1.2 If a FOC scheme is approved, companies should prepare a draft written agreement which sets out an overview and specific operational details of the proposed scheme for initial discussions with the trust clinical staff, chief pharmacist and other relevant NHS colleagues.

5.1.3 The written agreement must clearly set out:

- Clinical criteria/cohort and unmet clinical need.
- Patient information
- Any data collection requirements (non-identifiable only)
- Labelling, packaging, storage requirements and pack inserts of the necessary clarity and legibility to enable to the product to be safely administered in the NHS.
- The length and scope of the agreement, particularly with regards to continuity of supply until NICE or commissioning approval.
- Exit arrangements if treatment does not receive NICE approval or approval is delayed beyond length of the FOC scheme.

- If patients do not meet the treatment criteria set by NICE, NHS England or the relevant commissioner, the position regarding continuation on the FOC medicine and the management of the financial risk is to be specified in the agreement.
- In principle, all FOC supplies must continue until the medicine is commissioned and funding is in place. Any exceptions to this principle must be detailed in the formal written agreement outlined above.
- Companies should not introduce FOC schemes that cap the number of patient numbers who are eligible for access as this leads to inequity.

5.2 Contracts from Pharmaceutical Companies

5.2.1 Contracts should be signed by each organisation once there is agreement from the NEL FPG and SyPMO Board (via a written outcome letter). The Trust should assign a person to sign the contract. This may be the Formulary Chair, Head of Procurement or Chief/ Deputy Chief Pharmacist. **Contracts must not be signed by only the requesting clinician.**

5.3 Recommended wording for funding statement/ contract:

5.3.1 The medication will be provided free of charge by [company name] for as long as the patient(s) derive benefit (determined by the treating clinician) or until NHS commissioning/NICE TA has been approved and implemented by the relevant health authority.

- *If patients enrolled in the free of charge scheme, are eligible for treatment under NHS commissioning criteria, they will transition to ongoing NHS supply on the date of commissioning implementation.*
- *If patients are not eligible for treatment under NHS commissioning criteria, they will continue to receive free of charge supply provided the responsible clinician considers them to continue to benefit from treatment*

5.3.2 NHSE and ICS Responsibilities may be found in the NHSE FOC Guidance[1]

6. Appeals

6.1 Appeals will follow the normal NEL FPG appeals procedure (see NEL FPG Terms of Reference).

7. References

1. **NHSE Free of charge (FOC) medicines schemes – national policy recommendations for local systems. https://www.england.nhs.uk/long-read/free-of-charge-foc-medicines-schemes-national-policy-recommendations-for-local-systems/#appendix-1-suitability-assessment-of-foc-schemes Last updated 21st November 2023. Accessed 1st April 2026**

APPENDIX 1

Free of Charge (FOC) Schemes – Checklist

This form should be completed along with a full formulary application for all requests for approval of free of charge (FOC) schemes by the North East London Formulary and Pathways Group (NEL FPG).
It is based on the nationally recommended template. Further information around FOC schemes can be found via the document Free of charge (FOC) medicines schemes – national policy recommendations for local systems [1]
Approval of an FOC scheme should not create inequity across NEL. Therefore, the company must open the scheme to all Trusts who wish to adopt the scheme within NEL. Each Trust will be responsible for signing their own contracts.

	Applicant to complete	**For NEL FPG triage use**
Is this request is for an FOC scheme? If yes, please proceed. If this is for an EAMS, compassionate use or PAS scheme contact your formulary team.		
Requesting Trust		
1. Clinical and product details		
Drug name (and generic / biosimilar – if known)		
Preparation (strength and formulation)		
Pharmaceutical company		
UK license status		
Clinical indication		
Line in therapy and what this replaces (if any)		
Regimen (i.e. dose, route, duration and frequency, number of cycles. Include all anticancer drugs and supportive care medication used in combination with FOC drug)		
2. Risks and outcomes		
What are the existing treatment options for this condition?		
Detail how this medicine offers additional benefit over existing treatment options		
There are clear expected outcomes from the use of this treatment. (Yes or No please state these if yes)		
Are there any clinical risks with the product. (Yes or No – please state these if yes)		

Patients who are entered into the scheme will be monitored appropriately so that any adverse events or treatment failures can be identified and future incidents dealt with efficiently. (Yes or No)		
Labelling of products meets regulatory and quality standards. (Yes or No)		
3. Current or future access to the medicine		
Is the medicine available via an MHRA Early Access to Medicines Scheme? EAMS [2]or an EMA access for compassionate use scheme[3]? (Yes or No)		
Has the company made a submission to NICE (or NHSE)?		If no, an FOC should not be considered
Is the medicine due to be assessed by NICE? If yes, when are NICE due to publish an assessment?		If less than 6 months, an FOC **may** not be suitable
Does the medicine have a positive NICE FAD? (Yes or No)		
If the medicine has a positive NICE FAD, does the indication, dose, frequency described in the FOC scheme fall outside of NICE criteria? (Yes or No)		
Does the medicine already have a Patient Access Scheme (PAS)[4] in place? (Yes or No)		
4. Financial impact		
Estimated number of anticipated patients per financial year across NEL		
Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval		
Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval but the patient does not fit the funding criteria		The provider must not be at financial risk for treatment in the event there is a negative TA or the patient falls outside of NICE criteria
Funding arrangements agreed with pharmaceutical company for existing patients if the drug does not gain marketing authorisation / NICE approval		The provider must not be at financial risk for treatment in the event there is a negative TA or the

		patient falls outside of NICE criteria
Trust activity – please detail number of attendances (outpatient, inpatient, follow-ups) and procedures required for the use of the drug		
The contract has been attached to the application (Yes or No)		The contract must be checked to ensure there is equity of access across NEL and the provider is not put at financial risk when the patient exits the scheme
5. Additional governance		
Any other information/supporting evidence (level of evidence, phase of trial, protocol etc.)		
The scheme has a non-disclosure agreement or the explicit consent from patients to share relevant, non-identifiable information. (Yes or No)		
Patients undergoing treatment with a medicine in a FOC scheme will be fully informed of the characteristics of the medicine and how the scheme will operate. (Yes or No)		
Fully informed consent will be documented according to local procedures for each patient who opts to use a medicine supplied through a FOC scheme, including any restrictions on duration of treatment. (Yes or No)		
Mechanisms are in place to monitor the FOC scheme to ensure the written agreement will be adhered to. (Yes or No)		
Other Trusts in NEL have been consulted (Yes or No). If no, please explain why		
6. Signatories		
Requesting clinician:		
Supporting Specialist/directorate pharmacist:		
Checklist completed by:		

Date completed:		

The checklist, company contract, and completed formulary application should be sent to the Lead Formulary Pharmacist for your organisation for review prior to submission at NEL FPG

APPENDIX 2

Sample Consent Form

Consent for access to medicines under a free of charge agreement

Name of Medicine:_____

Treatment for:_____

The above medicine is recommended by your Consultant. Currently, this medicine is not available under the NHS, however the company has agreed to provide this free of charge. The hospital has given special permission for this free of charge medicine to be offered to you.

The medicine is (tick one):

□ Approved to treat your condition (a 'licensed medicine')

□ Approved to treat a different condition (an 'off-label use of the medicine')

□ Not yet approved to treat any condition (an 'unlicensed medicine')

This medicine is being prescribed for you because (tick all that apply):

□ There is no suitable alternative approved to treat your condition

□ The medicine has shown promising results in a clinical trial but is not yet available to the NHS

□ The medicine is still under investigation within a clinical trial, with early data showing benefit in rare or difficult to treat conditions

□ The medicine is still under investigation within a clinical trial however you are unable to be part of the trial

Please be reassured that your Consultant and pharmacist have thought very carefully about selecting the best medicine for you. If you have any concerns regarding this medicine please contact your Consultant or the pharmacy department. You retain the right to opt out of treatment at any point.

Please note:

• This medicine is being provided for your personal use only

• The company supplying this medicine may stop providing it free of charge at any time. If this happens, your hospital will not be able to continue your treatment, even if you are benefitting.

Your Consultants responsibilities:

• Discuss the characteristics of both the treatment and free of charge scheme prior to initiation

• Supply and/or administer the medicine whilst the medicine is made available to you from the company

• Monitor how well you respond to the treatment and make changes to your treatment if the medicine is not benefitting you

• Keep you and your GP updated on response to treatment

• Discuss with you any changes to treatment if necessary

Your responsibilities:

• Ensure that we have your correct contact details
• Attend the hospital for your regular appointments
• If you cannot attend an appointment please re-book it with the relevant department
• In the event of being unable to comply with the above, we will remind you by telephone/SMS to attend your appointment. If problems persist, we will send a letter, which will also be copied to your GP. Where we cannot safely monitor the treatment, your supply of medicine may have to be discontinued.

If you agree to the above please fill in your details below and sign to confirm consent. A copy of this form will be held in your medical records.

Patient Name:_____ Name of Consultant:_____

Patient Signature:_____ Signature of Consultant:_____

Date:_____ Date:_____