North Central London
Joint Formulary Committee

Free of charge (FOC) medicines schemes

Document management

Groups / Individuals who have overseen the development of this guidance:	'Free of charge (FOC) medicines schemes' Policy Working Group (membership from UCLH, RFL, NCL ICB, NHSE and NCL JFC) (2021) Updated by Sonali Sanghvi – JFC Principal Pharmacist (2024)
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Document control

Date	Version	Amendments
Nov 2020	1.0	New document
Feb 2021	1.1	Turned three PILs/Consent Forms into one
Dec 2021	1.2	Updated advice on patient consent and relevant information to relay to the patient
Mar 2025	2.0	Updated to include NHSE recommendations on FOC medicines schemes

1. Introduction

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[1(p1.1)]; this also includes very heavily discounted products so low they are effectively free of charge)[1(p1.4)]. Medicines in FOC schemes are generally, high cost, tariff excluded medicines commissioned by NHS Integrated Care Boards (ICBs) or NHS England Specialised Commissioning.

Currently, there is no standardisation in the type or terms of FOC medicine schemes being offered by pharmaceutical companies.[1(p3.2)] Outside of the voluntary MHRA Early Access to Medicines Scheme (EAMS) and European Medicine Agency (EMA) Compassionate Use schemes, there are no national frameworks to record, assess or monitor any FOC medicines schemes. This guidance specifically considers company-led FOC schemes outside of the MHRA/EMA frameworks.[1(p2.1)] Definitions of FOC schemes excluded from the scope of this guidance are outlined in Appendix 1.

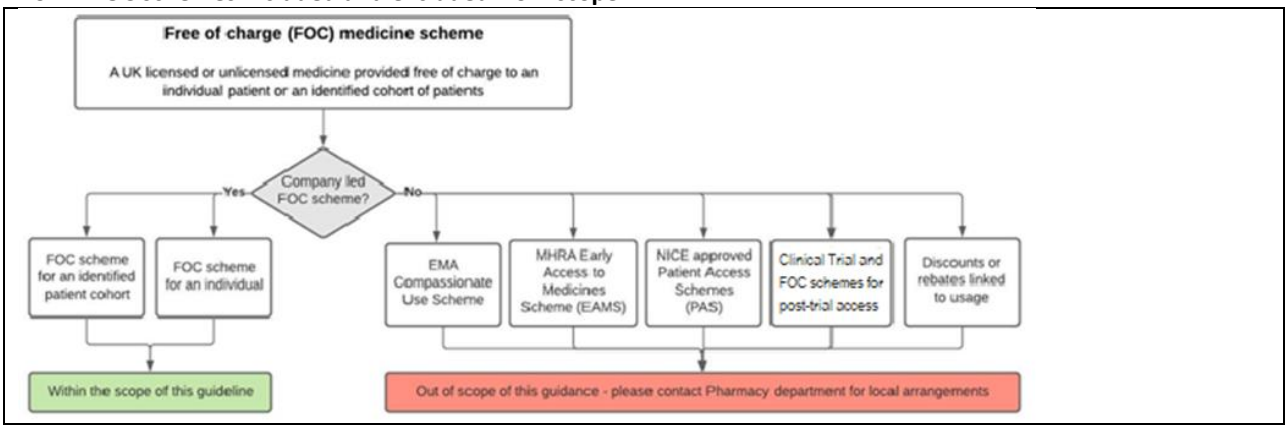
The motivation of pharmaceutical companies offering FOC schemes is often unclear, and there are concerns they are designed to build early product demand and 'seed the market' in advance of NICE or local commissioner decisions.[1(p3.1, 3.5),2] Whilst FOC schemes have the potential to enable patients access to promising treatments where there is an unmet need, they can also expose patients to unknown/uncertain risks of harm, particularly when investigational treatments are offered. They also risk undermining existing evidence-based treatment pathways made by NICE or local centres as well as potentially destabilising commissioning processes.[1(p3.1, 3.4),2] Therefore, all FOC medicines schemes should be appropriately managed to safeguard both patients and the NHS.[1(p4.1),2]

It is the responsibility of individual Trusts to assess the suitability of FOC medicine schemes for their own organisation. This guidance highlights the necessary principles when reviewing FOC medicine schemes for individual patients or before inclusion onto local/regional formularies for an identified cohort, to ensure a consistent and equitable approach.[1(p2.7),2]

2. Scope

Company led FOC schemes are included within scope, both for individual patients and defined patient cohorts. Other types of FOC scheme are excluded from scope, see Box 1 for details.

Box 1: FOC schemes included and excluded from scope



3. Key considerations for FOC schemes

Governance

- Local medicines governance arrangements must continue to assess new treatments to ensure there is sufficient evidence supporting their effectiveness, appropriately balanced with the potential for harm, irrespective of whether a new treatment is being offered via an FOC scheme.[1(p6.1.4)]
- Only FOC schemes that address a clear unmet clinical need should be considered.[1(p1.3, 1.5)]
- FOC schemes should not undermine NICE or local treatment pathways and where approved treatments are available and appropriate, these should be utilised.[1(p5.3.2, 6.1.2),2]
- NHS England[2] also recommend that ICSs should not sign up to FOC schemes if:
    - it 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. [1(p1.5, 5.4.2)]
    - 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, FAD (i.e. post NICE TA).
    - 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.
- Clinicians requesting FOC scheme approval must outline intended clinical outcomes and clear stopping criteria if these are not achieved.[1(p5.4.1, 6.1.2)]
- A written agreement between the company supplying the FOC medicine and the Trust must be signed (see Section 5.0).[1(p5.1.4, 8.7.6),2]
- Local medicines governance processes must be followed to prevent introduction of inequity among patients of equal clinical need being treated differently. FOC schemes must provide equal access for all patients within the agreed indication in the written agreement.[1(p5.1.3, 6.1.1, 8.7.8),2]
- If offered via homecare, national and/or local governance arrangements must be followed.[1(p5.4.3)]
- A FOC scheme for an unlicensed/off-label medications should not undermine recruitment into a clinical trial where this is available, and patients are eligible.

Patient consent

- For consent to be valid, the patient must have capacity to make a decision on treatment, be acting voluntarily and free from undue pressure, and be made aware that they can refuse.
- Sufficient information should be provided for the patient to make an informed decision (such as characteristics of the medicine and how the FOC scheme will operate), including[1(p5.5.2, 5.5.3, 6.1.1),2]:
    - 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
    - Details of how the scheme operates and what will happen if the FOC scheme ends (including

any alternative treatment plan).
    - A reminder that this does not affect the patient's right to access NICE approved treatments.
- A signed patient consent form must be obtained; an example form is available in Appendix 2.
- 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.[2]

Financial and workforce impacts

- FOC medicine schemes can have financial and workforce impacts which have not been commissioned. Risks and hidden costs associated with FOC schemes include:[1(p5.2),2]
    - supporting costs for staff, equipment, concomitant medicines (particularly if not funded).
    - ongoing ordering, supply, and monitoring of the medicine. Failure of supply route could be an operational risk and therefore Trust(s) may want to discuss stock commitments within the FOC agreement to meet their needs.
    - ongoing management of the scheme.
    - data anonymisation and transfer risks and the associated administrative workload.
    - waste management.
    - cost of medicines after the end of the FOC scheme.
    - 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 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; this is more common in chemotherapy regimens.
- Trusts should consider whether there are any planned routes to commissioning for FOC schemes for a cohort (e.g. NICE TA, NHSE commissioning policy, CCG business case) as FOC access is unlikely to be indefinite as part of the application process (see Section 4.0).

4. Application process for a FOC scheme in North Central London

Requests for FOC schemes (either for cohorts, or individuals) are considered by the Trusts' MMC/DTC[1(p6.1.4)] or the North Central London Joint Formulary Committee (NCL JFC). The responsible Committee will assess unmet need[1(p1.3, 1.5)] and establish whether the overall benefits outweigh the overall risks, following a review of the evidence-based efficacy and safety profile[1(p5.2)]. The application process for North Central London is summarised in Appendix 1 of the NCL JFC Terms of Reference.

Clinicians must ensure the below application process is completed and approved **before** offering a FOC medication to any patient[1(p7.1)] or entering into a FOC agreement with a company.

- Ensure all formulary options have been exhausted.[1(p7.3)]
- Clearly specify the unmet health need of the patient (individual and/or cohort).[1(p1.3)]
- The FOC scheme has been approved by the following stakeholders:
    - Local MDT +/- regional consultation for cohort applications.[1(p7.4)]
    - Specialist/directorate pharmacist.[1(p7.3)]
    - MMC/DTC (or local equivalent), MMC/DTC chair or chief pharmacist.[1(p7.1, 7.4)]
    - Divisional/Trust funding approval for any additional costs not covered by FOC scheme.[1(p7.7, 7.10)]
    - Any other relevant stakeholders (where applicable).[1(p7.12)]

- A written agreement with the pharmaceutical company must be obtained and approved/signed by the above Trust bodies (see Section 5.0).[1(p7.12, 7.13)]
- Commissioners will be kept informed of any FOC cohort schemes considered at local DTCs and JFC.[2]
- FOC medicines are to be supplied through the appropriate channels in the pharmacy department.[1(p7.15)] This process should be facilitated by pharmacy procurement (and local Quality Assurance if unlicensed) once the FOC scheme is approved. **Under no circumstances should FOC medicines be supplied directly to patients, wards, clinics or medical staff.**[1(p7.15)]
- FOC schemes for medicines where the company has withdrawn their submission to commissioners should generally not be considered.[1(p5.1.2),2]
- Time or dose limited FOC schemes for chronic conditions should not generally be considered.
- For further information on roles/responsibilities see Section 8 of RMOC guidance and NHSE recommendations on FOC medicines schemes.[1(p8),2]

5. Pharmaceutical companies

- Pharmaceutical companies are expected to adhere to the RMOC recommendations[1] and NHSE recommendations.[2]
- Companies should clearly specify the unmet health needs addressed through introducing a FOC scheme, together with its duration and details of the relevant patient cohort.[1(p3.5)]
- Pharmaceutical companies should not request any patient identifiable information (e.g. initials or date of birth)
- A formal written agreement must be in place between the Company and Trust before commencement of any scheme.[1(p8.7.6)] The agreement should include a funding statement.[1(p5.1.1)] Recommended wording is provided in Box 2.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 in regard 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.

Box 2: Funding statement recommended wording

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 has been approved and implemented by the relevant health authority.

1. *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/after the date of commissioning implementation*
2. *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*

- Companies should not introduce FOC schemes that cap the number of patient numbers who are eligible for access as this leads to inequity.

References

1. Regional Medicines Optimisation Committee. Free of Charge (FOC) Medicines Schemes: Updated RMOC Advice for adoption as local policy. Specialist Pharmacy Service. Published 2020. https://www.sps.nhs.uk/articles/free-of-charge-foc-medicines-schemes-rmoc-advice-for-adoption-as-local-policy/
2. NHS England Free of charge (FOC) medicines schemes – national policy recommendations for local systems. November 2023. https://www.england.nhs.uk/long-read/free-of-charge-foc-medicines-schemes-national-policy-recommendations-for-local-systems/

Appendix 1 -Definitions of FOC schemes not considered within the scope of this guidance

European Medicines Agency (EMA) Compassionate use programmes

https://www.ema.europa.eu/en/human-regulatory/research-development/compassionate-use

Specific FOC schemes co-ordinated between pharmaceutical companies and the EMA to allow products in development be made available to groups of patients who have a disease with no satisfactory authorised therapies and who cannot enter clinical trials. EMA compassionate use programmes should not be confused with solely company-led FOC schemes that are referred to by the company as 'compassionate use' or 'compassionate access'.

EMA compassionate use programmes are not in the scope of this guidance.

NICE approved Patient Access Schemes (PAS)

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance

Refer to pricing agreements within the context of a NICE TA.

NICE PAS's are not in the scope of this guidance

MHRA Early Access to Medicines Schemes (EAMS)

https://www.gov.uk/government/collections/early-access-to-medicines-scheme-eams-scientific-opinions

Specific FOC schemes co-ordinated between pharmaceutical companies and the MHRA to allow products in development be made available to groups of patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need. Under the scheme, the MHRA will give a scientific opinion on the benefit/risk balance of the medicine, based on the data available when the EAMS submission was made.

MHRA EAMS are not in the scope of this guidance.

Clinical trial and post-trial FOC scheme

A clinical trial is a study performed to investigate the safety or efficacy of a medicine. The regulation of clinical trials aims to ensure that the rights, safety and well-being of trial subjects are protected and the results of clinical trials are credible. The European Medicines Agency relies on the results of clinical trials carried out by companies to reach its opinions on the authorisation of medicines.

Post- trial FOC scheme may be offered but these arrangements should be clear at the commencement of the trial. The principles in this guidance should be followed.

Appendix 2 – 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: Patient Signature: Date:	Name of Consultant: Signature of Consultant: Date: