Guidance for the management of free of charge/manufacturer discounted medicine schemes

Document history:

Version	Created by	Date	Main Changes/Comments
1	FM/GH	24.01.2022	First version
2	FM	28.01.22	Comments from GH – acute pharmacy working group and Sussex Dermatology
3	FM	22.02.22	Comments received from Joint Formulary Group
4	GH	7.06.22	FOC to include manufacturer discounted medicines schemes
5	GH	5.07.22	Pharmaceutical company commercial offers, including free of charge (FOC) and heavily discounted medicines schemes
6	JC/TO	02.10.23	Updated to reflect NHSE guidance

1. Introduction

- A pharmaceutical company commercial offer is defined as an arrangement where a medicine (licensed or unlicensed) is provided 'free of charge' (FOC) or at a heavily discounted price to an individual patient or an identified cohort of patients.
- There are established frameworks in place in England to enable access to medicines without charge. These are the MHRA Early Access to Medicines Scheme (EAMS) and, for compassionate use in certain scenarios, as defined by the European Medicines Agency
- Independent of this, there are an increasing number of schemes being made available by pharmaceutical companies that offer medicines 'free-of-charge' or provided at a heavily discounted price, to an identified cohort of patients, in advance of NICE approval.
- The aim of this guidance is to ensure a consistent and equitable approach is adopted when considering FOC schemes.
- This guidance reflects the "Free of charge (FOC) medicines schemes – National policy recommendations for local systems" published by NHS England (NHSE) on 3rd August 2023 which will be adopted nationally. Publication reference: PRN00297.

2. Purpose and Scope

- Company led FOC schemes are included within scope, for **defined patient cohorts**. The review of these schemes will follow the 'FOC Application Process Map' (Appendix 1). **Individual patient applications** will need to be managed at an organisational level. All applications are to follow the set of principles outlined in the 'FOC supply – Request for Approval Form' (Appendix 2).
- This guidance excludes European Medicines Agency (EMA) Compassionate use programmes, NICE approved Patient Access Schemes (PAS), MHRA Early Access to Medicines Schemes (EAMS) and clinical trial and post-trial FOC schemes.
- 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. Whilst FOC schemes have the potential to enable patients access to promising treatments where there is an unmet clinical 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. Therefore, all FOC medicines schemes should be appropriately managed to safeguard both patients and the NHS.
- This guidance highlights the necessary principles when reviewing FOC medicine schemes for an identified cohort, to ensure a consistent and equitable approach.

3. Recommendations

3.1 Recommendations for all FOC schemes

These recommendations have been made by NHSE as published in "Free of charge (FOC) medicines schemes – National policy recommendations for local systems". They apply to **all FOC schemes** regardless of whether a NICE TA or NICE highly specialised technology (HST) has been published or not:

1. Early discussion of potential FOC schemes (with an identified clinical need) should be undertaken with the relevant ICS stakeholders to allow robust suitability assessment of potential impact on currently commissioned pathways (locally or nationally commissioned through NHS England).
2. NHSE recommend that ICSs **should not** sign up to a FOC scheme if:

    - there is no unmet clinical need.
    - 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.
    - 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 FAD /Final Draft Guidance, a PAS, 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. As above any medicines commissioned by NHS England will need to be discussed with regional specialised commissioning leads prior to any FOC being implemented.
- ICSs should not sign up to FOC schemes that cap the number of patient numbers who are eligible for access as this leads to inequity.

3.2 Recommendations for FOC schemes for medicines following a positive NICE TA recommendation.

1. After NICE TA publication, ICSs should not sign up to a FOC scheme if it may result in patients receiving medicines that are not as efficacious as other treatments i.e. those treatments that are recommended earlier in the NICE treatment pathway.

2. Where NICE recommends the treatment and the patient meets the eligibility criteria (including NHS England criteria), the FOC scheme should specify that the free supply stops at the funding date and the commissioner is expected to fund ongoing treatment thereafter.

3.3 Recommendations for FOC schemes for medicines that have not yet received a positive NICE TA or following a negative NICE TA recommendation.

1. Where NICE does not recommend the treatment including non-submissions by companies, ongoing supply arrangements should be considered at the outset of the FOC scheme and exit provisions included in the written agreement where there is an ongoing patient benefit.

2. Where NICE approved eligibility criteria are not met, the pharmaceutical company is responsible to continue to supply treatment FOC until the clinician and the patient decide that the treatment should be stopped.

3.4 Exclusions to the recommendations

NHSE state these recommendations:

- do not preclude access to treatments which are considered exceptional and suitable for consideration through the commissioners IFR process.

- do not primarily focus on FOC schemes that allow access to treatments for rare conditions which would ordinarily be covered by a compassionate use scheme or a clinical trial.

- exclude those medicines approved by regulatory agencies where more defined frameworks are specified. These are compassionate use supplies, free of charge medicines as part of a NICE patient access scheme or the MHRA early access to medicines scheme. Please see “Free of charge (FOC) medicines schemes – National policy recommendations for local systems” for more information.

3.5 Risks with FOC schemes

FOC schemes may appear to offer the potential for a short-term saving in the cost of the medicine, however, other factors and hidden costs need to be considered:

- supporting costs for staff, equipment, concomitant medicines (particularly if 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.
- There is a 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.

Any additional costs outside of the FOC scheme should be discussed and agreed within the ICS before a decision to progress the scheme is made, particularly if new activity is involved. ICSs should confirm that the FOC scheme does not undermine the impact of local or national commissioning arrangements, including approved pathways and guidelines. It is important to keep a record of approved ICS FOC schemes and decisions to ensure a trail of accountability.

Before the formation of ICSs, where the commissioner did not agree to the FOC scheme, the entire financial risk remained with the trust, however with the formation of ICSs, and the joint funding pot, the risk now lies with the ICS.

Where multiple schemes are in place, the above factors should be considered along with the cumulative burden of managing multiple schemes.

3.6 Governance

- It is the responsibility of the trusts to review FOC schemes against the criteria before discussion at the High-cost drug working group, then High-cost drug working group to present to the Integrated Medicines optimisation steering group (IMOS) for decision making and if approved, then for ratification by Integrated medicines optimisation committee (IMOC).
- The High-cost drug working group 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 a FOC scheme. Please see request for approval template Appendix 2 which can be used internally for discussion at high-cost drug working group.

- Providers should consider whether there are any planned routes to commissioning for FOC schemes for a cohort (e.g., NICE TA, NHSE commissioning policy, PRGC commissioning policy, CCG business case) as part of the application process and should share their findings during the high-cost drug working group review of the scheme, as FOC access is unlikely to be indefinite.
- The financial impacts should be considered and assessed by the individual trust representatives/ provider representatives and raised to the High-cost drug working group for review before a decision is made at IMOS.
- Applicants requesting FOC scheme approval must outline intended clinical outcomes and clear stopping criteria if these are not achieved.
- Once approved a written agreement between the company supplying the FOC medicine and the individual Trust/ provider must be signed and should be submitted for noting through the Provider's governance arrangements.

3.6.1 Application process for a FOC scheme – please refer to appendix 1 for application process map.

- 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 cohort and to treat the indication in the written agreement.
- If offered via homecare, national and/or local governance arrangements must be followed.

3.6.2 Patient Information:

- Signed consent should be obtained and patients must be fully informed of the characteristics of the medicine and how the FOC scheme will operate including:
    1) Uncertainties regarding efficacy/safety data
    2) How to take or use the medicine, how to obtain supply and how to report side effects
    3) Permission to share non-identifiable information with the company where necessary.
    4) Details of what will happen if the FOC scheme ends.
- 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.

3.7 Responsibilities and accountabilities

3.7.1 Applicants must ensure the following is adhered to before a FOC application is submitted to the ICB:

- Ensure all formulary options have been exhausted.
- Clearly specify the unmet health need of the patient cohort.
- Ensure the FOC scheme has been approved by the following stakeholders:
    i) Local Trust consultant
    ii) Specialist/directorate pharmacist
    iii) Local trust chief pharmacist
    iv) Divisional/Trust finance team (for funding approval for any additional costs not covered by FOC scheme).
    v) Any other relevant stakeholders (where applicable).
- Ensure FOC medicines are to be supplied through the appropriate channels in the pharmacy department. 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.

3.7.2 Pharmaceutical companies are expected to adhere to the NHSE guidance.

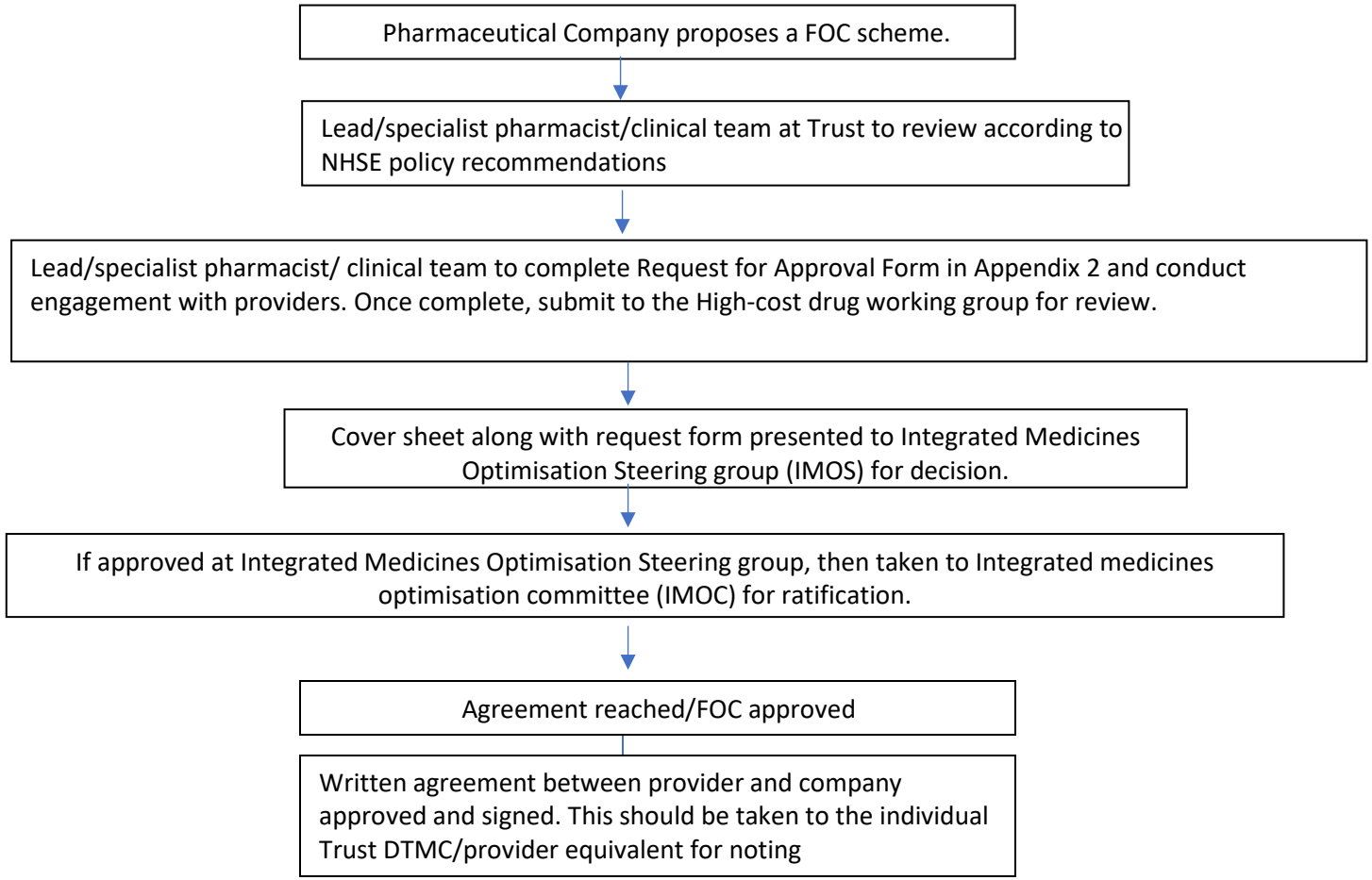
- Companies should clearly specify the unmet health needs addressed through introducing a FOC scheme, together with its duration and details of the relevant patient cohort.
- Pharmaceutical companies should not request any patient identifiable information (e.g., initials or date of birth).
- A formal written agreement must be in place between the Company and Trust before commencement of any scheme. The agreement should include a funding statement.

For further information on roles/responsibilities see Section 3.6 of NHS England guidance available below.

References

1. NHSE Publication reference: PRN00297 Free of charge (FOC) medicines schemes – National policy recommendations for local systems. Version 3 August 2023

Appendix 1 : FOC Application Process Map



Appendix 2 : Free of Charge/manufacturer discounted medicine (FOC) Supply – Request for Approval Form

Please complete all sections as thoroughly as possible

Provider requesting FOC Scheme	
Requesting Clinician (if applicable)	
Completed by	
Details for request	

Drug Information	
Drug Name- Approved (and generic/biosimilar if known)	
Current NICE status- Is guidance due, has an ACD or FAD been published ?	
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)	
Preparation (Strength and Formulation)	
Drug company offering the scheme	
UK License status	
Clinical Indication	
Line in therapy and will this replace a different therapy? (If any)	
Regimen – including dose, route, duration and frequency and number of cycles. Include all anticancer drugs and supportive care medication used in combination with FOC drug	
Is the medicine available via EAMS? (Yes or No)	
Does the medicine have a PAS in place? (Yes or No) If yes, see national policy recommendations.	

Funding Arrangements and Provider Activity	
Details of the Scheme being offered	
Estimated numbers of anticipated patients per financial year	
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	
Funding arrangements agreed with pharmaceutical company for existing patients if the drug does not gain marketing authorisation / NICE approval	
Funding arrangements agreed with pharmaceutical company for existing patients if NICE HTA is terminated	
Minimum dataset required by the company to administer the FOC scheme	

How long does the FOC last for?	
Provider activity – please detail number of attendances (outpatient, inpatient, follow-ups) required for the use of the drug	

Clinical and Practical Considerations	
Is there an unmet clinical need?	
Is this a 'me too' type treatment? (i.e. another option with similar indications, efficacy, cost and safety to its competitors)	
What administrative requirements are needed in order to obtain the medicine	
Will FOC scheme be available to all patients in Kent and Medway	

Contractual Considerations	
Is the offer legally binding? (e.g. assurance should be provided that the pharmaceutical company is able to meet their contractual obligations as the medicine provider, MOU should express clearly where financial responsibility lies)	
What is the arrangement for patient consent? (Patients be made aware of, and agree to, the scenario that the medicine may not be available after the FOC period)	

Additional information	
Any other information/supporting evidence (level of evidence, phase of trial, protocol etc.)	

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