University Hospitals of Leicester NHS
NHS Trust

UHL Policy for the provision of medicines via Free of Charge (FOC) schemes.

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

No previous revisions as new policy

KEY WORDS

Free of charge

FOC

Early access to medicines scheme

EAMS

Compassionate use

Patient access scheme

Early access scheme

Early access programme

Expanded access programme

Post trial supply

Named patient supply

1 INTRODUCTION AND OVERVIEW

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for the provison of medicines procured by the trust on a free of charge (FOC) basis. This policy does not relate to medicines being exempt from from prescription charges for patients.

1.2 There are a variety of routes by which medicines can be accessed without charge. These include established frameworks such as the Medicines and Healthcare products Regulatory Agency (MHRA) Early Access to Medicines Scheme (EAMS) and formal compassionate use schemes as defined by the European Medicines Agency. Alongside this there are schemes made available by companies that offer medicines on a free of charge basis to an identified cohort of patients, in advance of potential NICE approval or licensing.

1.3 These less formal FOC schemes have the potential to override existing local pathways and existing NICE recommended treatment pathways and therefore require careful consideration before adoption locally.

1.4 Some FOC schemes aim to provide the treatment for a licensed indication that falls outside of NICE recommendations e.g. as a 1st line treatment when NICE only recommends after other treatment options have been tried.

1.5 Unlike medicines that are part of the EAMS, the safety and efficacy of medicines made available via FOC schemes may not yet have been fully considered by the MHRA.

1.6 Medicines sourced on a free of charge basis usually have increased governance requirements and carry additional resource and operational risks. They also have the potential to introduce inequality with regards to patients' access to treatment options.

1.7 The aim of this policy is to ensure that the introduction of new FOC medicines is managed in such a way to address potential risks and ensure there is a consistent and equitable approach through providing guidance when considering the use of FOC medicines schemes.

2 POLICY SCOPE

2.1 This policy is intended for use by all medical, nursing, pharmacy, management and other key UHL staff involved with the provison of medicines provided on a free of charge basis.

2.2 This policy does not cover the supply of medicines which are provided free of charge as part of a Patient Access Scheme (refer to definition in section 3) or commercial agreement as agreed by the Patient Access Scheme Liaison Unit (PASLU) in the context of a NICE technology appraisal. This includes medicines approved and commissioned via project ORBIS arrangements.

2.3 Investigational medicinal products which may be suppied FOC in the context of a clinical trial are outside the scope of this policy. However supplies for the continuation of treatment post trial completion do fall within the scope of this policy

2.4 Medicines supplied at neglible costs will be considered FOC medicines for the purposes of this policy.

3 DEFINITIONS AND ABBREVIATIONS

3.1 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.

3.2 **Compassionate use schemes** refer to schemes involving unlicensed medicines. The EMA defines compassionate use as "a treatment option that allows the use of an unauthorised medicine. Under strict conditions, products in development can be made available to groups of patients who have a disease with no satisfactory authorised therapies and who cannot enter clinical trials."

3.3 **Early Access to Medicines Scheme (EAMS)** aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation where there is a clear unmet medical need. It offers a way by which unlicensed medicines can be made available to patients. EAMS enable companies to gain additional knowledge and the NHS to gain experience of these medicines in clinical use. As part of the process the MHRA will give a scientific opinion on benefit / risk balance of the medicine, based on the available data when the EAMS submission was made. For an EAMS to be granted the medicinal product must offer promise i.e. benefit or significant advantage over and above existing treatment options. The medicine is provided free by the company during the scheme.

The MHRA EAMS is an example of a formal compassionate access to medicines programme.

3.4 **In-tariff/ Excluded from tariff** refers to the mechanism by which medicines are funded. In-tariff drugs are funded from within trust budgets whereas costs for excluded from tariff drugs are passed through to commissioners.

3.5 The **NICE Technology Appraisal (TA)** process is designed to appraise medicines based on the clinical and economic evidence for the medicine. The TA considers clinical and economic evidence principally provided by the company.
The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE technology appraisals. When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the implementation period (3 months from the date of publication unless otherwise

specified). Separate arrangements for funding are in place for cancer drugs, via the cancer drugs fund (CDF).

3.6 **Patient Access Schemes (PAS).** The Patient Access Scheme Liaison Unit (PASLU) has been set up by NICE to work with companies who are considering a patient access scheme for their treatment. The Patient Access Scheme Liaison Unit (PASLU) looks at the proposal made by the company to see if it is a scheme that would work in the NHS.

PAS proposals are made in the context of a NICE technology appraisal with the aim of enabling a positive NICE recommendation. The term 'patient access scheme' should only be used to refer to pricing agreements within the context of a NICE TA. More recently the term patient access scheme is being phased out and term "commercial agreement" is preferred to avoid confusion.

3.7 **Project Orbis** is a programme to review and approve promising cancer treatments. It aims to deliver faster patient access to innovative cancer treatments with potential benefits over existing therapies across the globe. Medicines approved via this process by be supplied at zero cost are considered formally commissioned by NHSE.

3.8 **Post trial supply** Following the completion of a clinical trial treatment may be made available by the trial sponsor on a free of charge basis for patients who were deriving benefit from treatment during the trial.

NB: Often companies will have their own nomenclature for schemes that provide medicines on a free of charge basis. This may include terms suchs as; compassionate access programme , early access programme, early access scheme, expanded access programme, named patient scheme, named patient supply and patient access scheme. Care should be taken to avoid confusing these terms with formal definitions outlined above.

3.9 **Abbreviations:**

MHRA	Medicines and Healthcare products Regulatory Agency
EMA	European Medicines Agency
EAMS	Early access to medicines scheme
NICE	National Institute for Health and Care Excellence
TA	Technology Appraisal
UHL	University Hospitals of Leicester NHS Trust
PASLU	Patient Access Scheme Liaison Unit
CMG	Clinical Management Group
TAS	Therapeutic advisory service
AWP	Antimicrobial Working Party

4 ROLES AND RESPONSIBILITIES

4.1 Trust Medical Director

4.1.1 The Medical Director is the executive lead responsible for the FOC medicines policy and ensures organisational adherence on behalf of the Trust board. This responsibility is delegated to the Chief Pharmacist.

4.1.2 The Medical Director is responsible for approving FOC schemes when a significant financial or clinical risk has been identified as escalated by the relevant clinical director.

4.1.3 The Medical Director will delegate authority for assuring monitoring of adherence to this procedure to the CMG Clinical Directors.

4.2 Chief Pharmacist (or person with delegated authority)

4.2.1 The Chief Pharmacist is responsible for ensuring that the FOC scheme does not contradict NICE recommendations, guidance or local commissioning arrangements.

4.2.2 The Chief Pharmacist is responsible for ensuring robust governance arrangements are in place for any FOC medicines scheme.

4.2.3 The Chief Pharmacist is responsible for ensuring there is sufficient pharmacy resource to manage the FOC scheme within pharmacy.

4.3 Chair of the Therapeutic Advisory Service (TAS)/ Local chemotherapy group/ Antimicrobial Working Part (AWP)

4.3.1 The Chair of the TAS committee/ local chemotherapy/AWP group is responsible for ensuring its decisions are clear as to whether a FOC medicine scheme is considered to have potential benefits that outweigh any harm and therefore is suitable to be offered and administered to a patient within UHL.

4.3.2 The TAS committee/local chemotherapy group/AWP is responsible for ensuring that the FOC medicine offers the patient additional benefit over and above existing treatment options.

4.4 CMG Clinical Directors, heads of service, and general managers

4.4.1 The clinical director (CD) is responsible for having an overview of FOC medicines schemes within their clinical management group (CMG) and ensuring the affected specialties comply with this policy.

4.4.2 The CD, or delegated manager and the head of the relevant service are responsible for planning any expenditure and resource issues that may be necessary if entering a FOC scheme. Particularly planning for if the FOC scheme is ended by the company, if the medicine becomes commissioned by the NHS and for the non-drug costs that may be incurred.

4.4.3 The clinical director must confirm if funding is available for any additional drug and non-drug costs incurred by the FOC scheme. Where there is a potential financial risk to the Trust this should be approved by the CMG finance lead.

4.4.4 The clinical director must consider the clinical and operational risks of the FOC scheme and escalate by exception to the Medical Director where necessary.

4.5 Consultants/ Non-medical prescribers (NMP)

4.5.1 The consultant/NMP requesting the use of FOC medicine is responsible for ensuring that TAS/ the local chemotherapy group/AWP has considered and supported a medicine available through a FOC scheme prior to offering it as option to patients.

4.5.2 They must liaise with the CMG lead pharmacist and specialist pharmacist as soon as possible and the trust's chief pharmacist should be informed of any proposed FOC scheme.

4.5.3 The consultant/NMP is responsible for providing information to the head of service and general manager to allow them to plan for the on-going management of patients on a FOC scheme and identify the potential financial risk the CMG may be exposed to.

4.5.4 Consultants/NMP are responsible for consenting patients as per the trust policy for consent to treatment and examination (Ref:A16/2002). This should include explicitly explaining that should a FOC scheme end without on-going NHS funding being identified the treatment will cease, even if it is being effective.

4.5.5 Consultants/NMP must ensure that the patient's General Practitioner is made aware of any FOC medicines prescribed. The responsibility for ongoing supply will remain with the secondary care consultant.

4.5.6 Consultants/NMP must not agree supply of medicines and associated contracts with a company directly. All FOC schemes must be referred to pharmacy for processing.

4.5.7 Consultants/NMP are responsible for the prescribing of the FOC treatment in accordance with the Leicestershire medicines code, ensuring that presriptions are generated and provided to pharmacy in a timely manner. As medicines used in FOC schemes are generally not stocked within the pharmacy department, it is the responsibility of the prescriber to liase with pharmacy to ensure stocks are available before a prescription is generated, particularly for patients receiving drug for the first time or undergoing dose adjustments.

4.5.8 Consultants/NMP are responsible for monitoring outcomes of treatment including any adverse events experienced by patients and report them via the the MHRA yellow card scheme.

4.6 Pharmacy team

4.6.1 Appropriate specialist pharmacists are responsible for supporting consultants providing information to TAS/ local chemotherapy group/ AWP to help decide whether to support a FOC scheme.

4.6.2 All agreements and arrangements for FOC schemes must be reviewed by the Chief Pharmacist or their deputy, and the written agreement must signed by one of these individuals if supported by them and TAS/ local chemotherapy group/ AWP.

4.6.3 The pharmacy team is responsible for the ordering, receipt, stock management and supply of all FOC medicines.This should include referring to pharmacy SOPs 424, 501 and 704 (Pharmacy SOPs can be found at: http://insite.xuhl-tr.nhs.uk/homepage/clinical/medicines-information/pharmacy-staff-area/standard-operating-procedures-sops).

4.6.4 All FOC schemes involving the use of unlicensed medications should comply with the UHL unlicensed medicines policy (Ref:B29/2004).

5. POLICY IMPLEMENTATION

There are a number of factors that need to be considered prior to introducing a new FOC medicines scheme these include:

5.1 Governance risks and arrangements

5.1.1 FOC schemes should include provision for patients started on the FOC medicine where NICE do not recommend the treatment, or for situations where the NICE approved eligibility criteria are not met, such that the company will continue to supply it FOC until the clinician and the patient decide that the treatment should be stopped. In situations where NICE recommends the treatment and the patient meets the eligibility criteria, the FOC scheme should specify that the free supply stops at the implementation date and the commissioner is expected to fund ongoing treatment thereafter.

5.1.2 In principle, Trusts or commissioners should not sign up to a FOC scheme for a medicine indication 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 ofthe treatment is unknown.

5.1.3 Standard medicines governance processes must be followed to prevent the introduction of inequity with patients of equal clinical need being treated differently. The introduction of FOC schemes also carries the risk of undermining the NICE process and local commissioning decision making processes including pathways and guideline development.

5.1.4 A written agreement between the company supplying the FOC medicine and the trust must be signed. It is acknowledged that dependent on scheme specific processes the detail required within any written agreement may be spead across a number of individual documents or electronic resources provided by the company. Refer to section 5.7.11 for details.

5.1.5 The Government Master Indemnity Agreement Master indemnity agreement: approved suppliers - GOV.UK (www.gov.uk) states that the scope focuses on the free use of equipment; the NHS legal advice is that this definition does not relate to free of charge medicines. The absence of such indemnity cover should be noted by Trusts, and this situation is unlikely to be resolved by introducing payment of a very low nominal fee for such medicines.

5.2 Resource risks

5.2.1 Resource risk includes financial, workforce and operational risks. FOC schemes may appear to offer the potential for a short-term saving in the cost of the medicine, however, the need for supporting infrastructure and ongoing monitoring of the medicine could outweigh the resource benefits if the administrative burden is high.

5.2.2 Financial risks

- Provider tariff activity costs that have not been commissioned, e.g. admissions, outpatient appointments, follow up ratios, monitoring, treating adverse effects. These can be significant and should be brought to the attention of the relevant commissioner (via the UHL contracts team), particularly if new activity is involved.

- Staff costs, equipment costs, and concomitant medicines provision.
- Ongoing medicines costs following the end of the FOC scheme.
- Additional medicine costs if FOC medicine is used in combination with another (funded) treatment.
- If the commissioner (via the UHL contracts team) has not agreed the FOC scheme (including additional spend on funded medicines) then the entire financial risk lies with the Trust.
- Potential for harm and medical negligence claim should an untoward event occur, plus the resulting reputational risk

5.2.3 Workforce risks

- Staff time needed for assessment of the scheme, e.g. discussions with the company, reviewing the written agreement, producing the written agreement, following governance processes, obtaining legal advice where required, etc.
- Ongoing management of the FOC scheme.
- Procurement – FOC schemes often require individual patient ordering and more onerous stock management including the use of online stock management portals. ,

5.2.4 Operational risks

- Cumulative burden of managing multiple schemes.
- Failure of supply route.
- Waste management.
- Specific storage requirements
- New electronic protocol and prescription requirements

5.3 Inequity

5.3.1 It cannot be presumed that NICE will recommend a treatment. Patients started on a medicine via a FOC scheme prior to a decision from NICE are likely to continue to receive this medicine if supported by the company. However, new patients, for whom the FOC scheme may not be available, will not have the option. As such these FOC schemes have the potential to introduce inequity and postcode prescribing, and moreover, to undermine the evidence based recommendations made by NICE or local commissioning organisations.

5.3.2 FOC schemes that allow patients to access medicines that undermine existing NICE schemes or locally agreed pathways must not be endorsed.

5.3.3

Trusts jointly with commissioners, should confirm that the FOC does not undermine the impact of local or

national commissioning arrangements, including approved pathways and guidelines.

5.4 Clinical governance

5.4.1 Details of transparent arrangements for criteria for use and monitoring of the medicine should be included in the written agreement.

5.4.2 The FOC medicine should not replace an existing therapeutic option in an established pathway simply to reduce cost.

5.4.3 The appropriate route for the long-term supply of the medicine to the patient should be considered. When the company chooses to provide the medicine via homecare as one of the delivery routes, the national governance arrangements for company commissioned homecare must be followed and standards adhered to.

5.5 Patient consent

5.5.1 Discussions with the patient (or their parent/carer) must take place prior to commencing the treatment and they must be consented as per the trust policy for consent to treatment and examination (Ref:A16/2002).

The patient must be made aware and understand that treatment with the FOC medicine will be stopped if the company ends the provision of the FOC medicine prior to NHS funding being agreed, even if the patient perceives they have had benefit from treatment. This risk should be documented on the written consent form (Consent Form 1).

5.5.2 Any patients undergoing treatment with a medicine in a FOC scheme must be fully informed of the characteristics of the medicine and how the scheme will operate. The patient must therefore be provided with the following information as a minimum:

- How to take or use the medicine.
- What to do if they develop any side effects to the medicine.
- A written record of details of their treatment (including start date, dose, frequency and monitoring requirements), so it can be shared with other healthcare staff, particularly when not clearly within patient's health records.
- How to obtain supplies of the medicine.
- Details of what will happen if the treatment is stopped due to the end of FOC scheme.

5.5.3 Each patient receiving a medicine via the FOC scheme must sign a consent form which states that they have received the above information and that they understand that treatment might be stopped. A standard consent form (Consent form 1) must be used for this.

5.6 Principles

To minimise governance and resource risks the principles outlined below should be adhered to. The Royal Pharmaceutical Society (RPS) has published guidance and a framework for medicines optimisation. In this guidance there are three overarching global dimensions and four principles. The FOC scheme principles listed below have been mapped to the four RPS principles. However, when considering a FOC scheme the following two RPS global dimensions should be considered first:

- The scheme must have patient-centred approach.
- The scheme should have the aim of improving patient outcomes.

Free of charge scheme principle	Additional information

Aim to understand the patient's experience	
The FOC scheme must be for a medicine where there is an unmet clinical need.	The consideration should be for the benefit of a specified cohort of patients and not for the purpose of accessing the market prior to the medicine being commissioned for use in the NHS.
There is equal access for all patients with the agreed indication in the Trust or unit that has signed a written agreement for the scheme.	When a FOC scheme is implemented there should be consideration of equity across the local health economy. i.e. all providers of this therapeutic area of care. Commissioners should be consulted as part of an impact assessment in the approval of FOC schemes in order to plan for future developments.
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.
Any patients undergoing treatment with a medicine in a FOC scheme must be fully informed of the characteristics of the medicine and how the scheme will operate.	This will involve the patient in the process of informed consent and make an informed decision.
Full informed consent should 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.	As part of the consent process, patients who opt to start treatment with a FOC medicine must be made aware of, and agree to, the scenario that the medicine may not be available after the FOC period.
Evidence based choice of medicines	
The submission to Drugs & Therapeutics Committee (DTC), or equivalent, should be supported by all the published evidence for the effectiveness of the medicine.	When the medicine is waiting a NICE decision, and existing treatments already have a positive NICE TA, evidence of effectiveness compared with established treatment options should be provided.
Where an established treatment pathway exists, the evidence for the proposed place in treatment should be submitted.	The FOC scheme must not support the introduction of a medicine that circumvents an existing treatment pathway or increases the number of treatment options currently commissioned.
There should be clear expected outcomes from the use of this treatment.	Commissioning for outcomes should be included in any agreement to ensure that the appropriate patient cohort is targeted.
Ensure medicines use is as safe as possible	
The submission to the trust's DTC should be supported by information that identifies any clinical risks with the product.	As with all medicines the identified risks need a strategy in place to minimise risks and to monitor them.
Patients who are entered into the scheme must be monitored appropriately so that any adverse events or treatment failures can be identified and future incidents dealt with efficiently.	As clinical experience with most of the medicines available via FOC will be limited, a monitoring plan must be in place, particularly for the medicines with a black triangle status. All adverse events must be reported to the pharmaceutical company and the MHRA through the yellow card scheme.
Labelling of products must meet regulatory and quality standards.	Pharmacy Quality Assurance processes must ensure that product labelling is appropriate and does not introduce risk.

Make medicines optimisation part of routine practice	
All proposals for a FOC medicine scheme must be reviewed and supported by the trust's DTC. The trust must approve the use of the medicine prior to agreeing the FOC.	The same medicines governance arrangements should be in place for FOC schemes as for other medicines introduced into an organisation.
Details of each FOC scheme must be shared with local commissioners and agreement reached when there are financial implications.	Commissioners must be aware of all FOC schemes approved in the local health economy to assure preparedness for future financial and resource implications and planning for future service development. Commissioning support organisations must be aware of all FOC schemes in order to monitor high cost data efficiently. Where applicable Blueteq forms can be made available to support monitoring.
Each organisation should have a transparent process for considering FOC schemes to ensure a planned and efficient response.	Consultants and specialist pharmacists will communicate potential FOC schemes to the Trust Chief Pharmacist as early as possible and in line with this advice.
Consideration should be made to any potential burden for pharmacy departments that might be related to ordering and storage requirements.	All FOC schemes must be agreed with the directorate pharmacist and pharmacy procurement team.
Medicines in a FOC scheme may only be purchased or acquired by a pharmacist or member of pharmacy staff acting under delegated authority.	Under no circumstances should medicines be supplied directly to wards, clinics or medical staff. If a FOC medicine is available via homecare, the pharmacy must be involved in the process as per national homecare standards.
The FOC scheme must only be undertaken after a written agreement has been signed with the pharmaceutical company.	This provides assurance that the company can meet their contractual obligations as the medicine provider.
There should be consideration of the local health economy impact of adopting a FOC scheme.	FOC schemes offer the potential for a short-term saving in the cost of the medicine but there might be risks associated with the supporting infrastructure plus an ongoing use of the medicine after a NICE decision. These risks may outweigh the benefits. These include financial, resource and operational risks.
The FOC scheme should be clear about funding responsibilities once the NICE TA or local commissioning agreement has been decided, depending on whether the outcome is positive or negative.	The written agreement should express clearly where financial responsibility lies following the end of the FOC scheme. This could be a mutual responsibility. This should include medicine costs and associated on-going care of the patient.
There should be mechanisms put in place to monitor the FOC schemes and to ensure that written agreements are adhered to.	There is a risk to an organisation if FOC schemes are not administered according to the agreements with the company.

5.7 Procedure for new FOC scheme medicine introduction.

5.7.1 When approached by a company with a proposal of FOC scheme, the clinical teams must liaise with their lead or specialist pharmacist as soon as possible, in order that the Chief Pharmacist (or pharmacist with delegated authority) is informed of a proposed FOC scheme before offering to patients.

5.7.2 The principles outlined in 5.6 should be applied to the application process. Appendix A provides a framework of questions to ensure that any newly proposed FOC is considered in light of the risks and principles described above.

5.7.3 The responsible consultant should liaise directly with the lead pharmacist for the specialist area who must review the medicine as clinically appropriate. Using a multi-disciplinary approach, the team should ensure all existing formulary options have been optimised.

5.7.4 If the medicine is for a cohort of patients, and is not already used for the proposed indication, the responsible consultant should first submit a new drug request form to the Therapeutic Advisory Service (TAS). In the case of a cancer medicine, requests should be directed to the local chemotherapy group for consideration. Requests for medicines containing antimicrobials, antivirals or antibiotics should be refered to the Antimicrobial Working Party (AWP).

5.7.5 The medicine, for the specified indication, must be approved by TAS, local chemotherapy group or AWP before (or at the same time as) the FOC application is made.

The lead pharmacist should determine the nature of scheme to facilitate the appropriate level of scrutiny. Appendix B summarises the various types of schemes offered.

5.7.6 A written agreement between the company supplying the medicine free of charge and the trust must be obtained and signed once it the scheme been agreed through TAS/ local chemotherapy group/AWP.

5.7.7 The application must include confirmation from the relevant CMG that funding is available for any additional drug and non-drug costs incurred by the FOC scheme. Where there is a potential financial risk to the Trust this should be approved by the CMG finance lead.

5.7.8 The agreement is to be in place until the point at which commissioning of the medicine for the identified patient or patient groups is funded. 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.

5.7.9 The application must meet the commissioners' prior notification requirements, and any potential financial risk to the commissioner is to be identified and agreed prior to the FOC scheme being started.

5.7.10 In the context of section 5.7.9 above, some FOC schemes require the FOC medicine to be used in combination with an existing commissioned medicine. This can change how the existing commissioned medicine is used, particularly in cancer where the addition of a FOC medicine can extend usage of the existing medicine where the combination is considered to be more effective than the existing medicine alone, thus increasing the budget impact.

5.7.11 The written agreement should be approved by :

- Lead clinician
- Chief Pharmacist (or person with delegated authority)
- TAS committee/ chemo group/ AWP chair (as applicable)

- Trust Medical Director (or person with delegated authority) where potential financial or clinical risk
- Lead commissioner (when financial risk to commissioner)
- UHL legal team (where applicable)
- Caldicott Guardian (when data sharing considered)

5.7.12 The written agreement must be signed by:

- A representative of the pharmaceutical company
- The lead clinician
- The Chief Pharmacist (or person with delegated authority)

5.7.13 An electronic copy of the signed written agreement must be retained on the pharmacy purchasing network drive.

5.7.14 FOC medicines are to be supplied through Pharmacy. Under no circumstances should FOC medicines be supplied directly to wards, clinics or medical staff. Free samples offered by representatives of pharmaceutical companies must not be accepted as per the trust policy for managing company representatives (Ref: B40/2016).

5.7.15 Once the new FOC medicine has been approved by the relevant committee the relevant CMG Lead Pharmacist (or senior pharmacist) will be informed. The relevant pharmacist needs to ensure that a new product request form is completed and sent to the pharmacy electronic systems mailbox so the product can be set up on the relevant systems (refer to pharmacy SOP 501).

All systemic anti-cancer therapy (SACT) should be prescribed on Chemocare. A new ChemoCare protocol will need to be built and validated to enable the drug to be prescribed (refer to chemocare governance document)

5.7.16 If the FOC medicine is unlicensed the lead pharmacist should liase with the Chief Pharmacy Technician-Unlicensed Medicines to discuss whether a specification and risk assessment for the unlicensed medicine is requireed.

If a specification and risk assessment is required this will then be presented at the Pharmacy Quality and Safety Board for approval.

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 There are no specific education and training requirements to implement this policy. For further advice or clarification regarding the introduction of a new FOC medication to the trust, please contact:

TAS Professional Secretary- Medicines information 0116 2586491

7 PROCESS FOR MONITORING COMPLIANCE

7.1 Adherance to this policy will be monitored through audits. Results will be reported annually to the committee of the therapeutic advisory service and UHL Medicines Optimisation Committee. The audit criteria for this policy and the process to be used for monitoring compliance are given in the table below:

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
All FOC medicines schemes will be recorded on a local FOC scheme database	TAS secretary	Report run from JAC to cross match any new FOC drugs set up with FOC scheme database.	Annual	TAS MEDOC

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES AND RELATED POLICIES

9.1 Royal pharmaceutical Society. Medicines Optimisation: Helping patients to make the most of medicines. 2013 Available from: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy/helping-patients-make-the-most-of-their-medicines.pdf

9.2 Regional Medicines Optimisation Committee. Free of Charge (FOC) Medicines Schemes: RMOC Advice for adoption as local policy. 2020. Available from: https://www.sps.nhs.uk/articles/free-of-charge-foc-medicines-schemes-rmoc-advice-for-adoption-as-local-policy/

9.3 Related policies:

- Policy for the introduction of new medicines into Leicester, Leicestershire and Rutland (LLR)-B28/2011
- Unlicensed medicines (ULM) policy-B29/2004
- Policy for managing company representatives (Reps Policy)- B40/2016
- Policy for consent to examination or treatment-A16/2002

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 This policy will be reviewed every 3 years. The updated version of the Policy will be sent for approval, uploaded and made available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system. All relevant personnel will be notified, in writing, of any changes to the Policy and/or Procedures

10.2 The policy will be disseminated via an awareness, dissemination and implementation strategy as advised by the Policy and Guidance Committee

10.3 A link to the policy will be located in the Therapeutic Advisory Service (TAS) section on the intranet and available for all staff.

10.4 Monitoring compliance of the document will be the responsibility of the Medical Director and will be carried out as outlined in section 7.

Appendix A: Framework of questions and notes for consideration of FOC schemes

Questions	Notes or considerations	Answer
1. Is the medicine offered FOC as part of a formal MHRA endorsed Early Access to Medicines Scheme (EAMS)?	EAMS aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation where there is a clear unmet medical need. The risks and benefits of medication supplied via EAMS will have been reviewed by the MHRA and deemed to offer significant advantage over and above existing treatment options. List of current EAMS available at: https://www.gov.uk/government/collections/early-access-to-medicines-scheme-eams-scientific-opinions	If yes Skip to Q17
2. Is the medicine being offered FOC to continue treatment for patients post completion of a clinical trial?	There is an ethical responsibility to provide post-trial access free of charge to patients who participate in clinical trials until the product is commercially available and accessible locally if: • There is evidence of continued clinical benefit for the patient and the patient consents to continue with treatment, and • There are no comparable or satisfactory alternative treatment options available or a change in treatment poses a risk to the patient The need for post-trial supply should be identified and highlighted to the relevant parties as part of the pharmacy review process for all new studies. Discussions with lead pharmacists and TAS applications should be completed sufficiently in advance of the first patient requiring a supply.	If yes Skip to Q11
3. Is the medicine being offered on a compassionate use basis?	The scheme would qualify as compassionate use if either: 1) It is listed on the EMA database of compassionate use opinions, or 2) The scheme meets the following criteria a. The patients' clinical needs cannot be met by any other available treatments or through enrolment in clinical trials b. The medicine offered is being used to help patients with life-threatening, long-lasting or seriously debilitating illnesses. c. The treatment should not be purely experimental or unproven and there should be data to suggest that patients would receive benefit.	If yes Skip to Q11
Questions if answered NO to Q1-3 above		
4. Have NICE published a Final Appraisal Determination (FAD) or Appraisal consultation document (ACD)	Caution is advised if an ACD has been published in which the preliminary recommendations are substantially more restrictive than the terms of the marketing authorisation or do not recommend use of the technology.	

with regards to the medicines being offered?	If NICE produces an ACD, then NICE invites consultees, commentators and the public to comment on the ACD. After considering these comments, the Committee finalises its recommendations and submits them to NICE in the form of a FAD. The FAD forms the basis of the guidance that NICE issues to the NHS in England. NICE TAs are usually more restrictive than licensed indications listed within SPCs	
5. Is there an unmet clinical need?	The consideration should be for the benefit of a specified cohort of patients and not for the purpose of accessing the market prior the medicine being commissioned for use in the NHS. Also the FOC medicine should not replace an existing therapeutic option in an established pathway simply to reduce cost.	
6. FOC medicine, but at what cost?	The true cost to the NHS must be considered and not the drug in isolation this includes: • Admissions • Outpatient appointments • Monitoring • Treating adverse events caused by the FOC medicine • Equipment costs • Staff costs • Cost of consumables If the relevant commissioner has not agreed the scheme then the entire financial risk sits with the trust.	
7. Is this a ‘me too’ type treatment?	‘me too’ type products offer another option with similar indications, efficacy, cost and safety to its competitors. A FOC medicine that is a ‘me too’ type product should not generally be accepted as it will not offer a significant advantage over currently commissioned treatment options.	
8. Does this offer a significant step change in clinical practice	As a general rule these types of schemes will not be accepted. It is envisaged that such schemes require a significant amount of input and resource from clinicians and pharmacists.	
9. Does the offer restrict clinician	No schemes that impose restrictions on a clinician’s choice will be accepted. Where there is	

choice?	more than one option with no obvious advantage a preference may be stated but the final decision rests with the treating clinician.	
10. Is the company providing any added value not already considered?	For example • Formulations that improve patient concordance • Training for healthcare professionals • Patient resources to better manage their condition	
Questions for all non EAMS		
11. How long does the FOC apply?	A FOC scheme should apply up until NHS funding is in place. Company schemes should continue to fund until the date the responsible commissioner agrees to fund.	
12. What happens in the event of the company withdrawing from the scheme prematurely before funding has been agreed with commissioners?	A positive NICE appraisal is no guarantee of funding as the commissioning criteria may differ from the eligibility criteria of the FOC scheme. Ensure that written agreements are clear that the company will continue to fund for patients already on treatment who are considered to be gaining benefit. Note- NICE have a generic statement in their publications "People whose treatment with 'x' is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue 'x' until they and their NHS clinician consider it appropriate to stop'. This clause should not be used by pharma to relinquish its responsibilities and as a get out clause in any written agreements.	
13. Patient consent	As part of the consent process, patients who opt to start treatment with a FOC medicine must be made aware of, and agree to, the scenario that the medicine may not be available after the FOC period. It is a requirement to gain written consent from the patient & to ensure this is filed within the medical records. Patients should also receive a copy of this information.	
14. Does the scheme have any impact on commissioners?	Does the FOC medicine have the potential to increase spend on existing commissioned drugs (e.g. if required to be used in combination)?	

Appendix A: Framework of questions and notes for consideration of FOC schemes

	Any potential financial risk to the commissioner is to be identified and agreed prior to the FOC scheme being started. In the event of a negative NICE TA commissioners will not pay providers for <u>any associated activity unless explicitly agreed prior to initiation of the scheme</u>. Provider trusts must provide commissioners with assurance of splitting commissioned activity from activity associated with the FOC medicine. For all schemes where NHSE specialised commissioning would be the responsible commissioner the *Free of Charge (FOC) Supply – Request for approval* form (Appendix D) must be Completed and sent to england.scpharmacymidlands@nhs.net	
15. Does taking part in this scheme have the potential to introduce inequity?	Patients of equal clinical need should not be treated differently as a result of participation in the FOC scheme.	
16. What is the relationship with the company providing the FOC medicine and information governance?	Only minimal pseudo anonymised patient level data should be shared with the company to confirm use and for ordering. If any patient identifiable data is required to be shared as part of the scheme this should be discussed with the trusts privacy team.	
Questions for all schemes		
17. How is the supply of medication obtained?	What is the proposed ordering mechanism for the FOC scheme? Who will be responsible for placing initial and subsequent orders for the FOC medicine? Under no circumstances should medicines be supplied directly to wards, clinics or medical staff. If a FOC medicine is available via homecare, the pharmacy must be involved in the process as per national homecare standards.	
18. Anticipated patient numbers	Please state the anticipated patient number for this scheme.	
19. Have the associated costs and any additional activity been agreed locally.	Has the CMG director/finance lead or their deputy approved any additional activity and costs associated with the scheme?	
20. Is there a significant administrative burden to manage the scheme	It will remain the responsibility of the trust to give commissioners assurance that drug costs will not be passed through to them. Commissioners expect that any administrative burden to administer the schemes is absorbed by the trust.	

Appendix A: Framework of questions and notes for consideration of FOC schemes

	Is there a large administrative burden on the Trust to manage this scheme and ensure that costs are not inappropriately passed through to commissioners?	
21. What is the proposed route of supply for the FOC medication?	Inpatient pharmacy, Outpatient pharmacy, Aseptic lab, Homecare?	
22. Does the scheme have a significant impact on the pharmacy service?	Does FOC stock need to be segregated from regular pharmacy stocks of the same medication? Does the medicine have any special storage requirements and can these be met with current pharmacy resource? How is the FOC medication delivered? Does the dispensing of the FOC medication involve any additional steps over and above a standard medication?	
23. Is the FOC medicine supplied a licensed product?	If the product supplied does not have a marketing authorisation then unlicensed medicine governance processes should be followed. The product should be referred to the chief pharmacy technician –unlicensed medicines to draw up a specification and be added to the trusts unlicensed medicines risk register.	
24. Has the FOC medicine been approved by the Therapeutic Advisory Service (TAS) or local chemotherapy group?	The submission to TAS or local chemotherapy group, should be supported by all the published evidence for the effectiveness of the medicine.	

Recommendation of the review pharmacists (if accepted this may include recommendations of whole acceptance or adopting a concessionary prior approval process)		

Appendix B: Summary of FOC schemes by type

The mechanisms by which medications may be offered on a free of charge basis are summarised below:

	EAMS	Post-trial supply	Compassionate use	All other schemes
Definition	Formal MHRA initiative to give patients access to medicines that do not yet have a marketing authorisation. This is intended as an interim arrangement and happens when the MHRA designate the scientific opinion on the benefits and risks of a new medicine. The on-going use of the medicine depends upon the outcome of the full review / licensing decision. If no marketing authorisation is granted to the company for the drug, the company will agree a clear exit strategy with the relevant bodies which should include continuing to meet the cost of medicines for patients already initiated on the treatment. Only if the EAMS ends in NICE approval and national commissioning would the Trust have to pay for the medication, including for on-going patients.	Where medication is provided free of charge to trial participants to continue treatment following completion of the clinical trial. There is an ethical responsibility to provide post-trial access free-of charge to patients who participate in clinical trials until the product is commercially available and accessible locally if: • There is evidence of continued clinical benefit for the patient and the patient consents to continue with treatment, and • There are no comparable or satisfactory alternative treatment options available or a change in treatment poses a risk to the patient	Either: Medicines with a formal compassionate use opinion from the Committee for Medicinal Products for Human Use (CHMP) as listed on the EMA database of compassionate use opinions Or Medicines meeting the following criteria: a) The patients' clinical needs cannot be met by any other available treatments or through enrolment in clinical trials b) The medicine offered is being used to help patients with life-threatening, long-lasting or seriously debilitating illnesses. c) The treatment should not be purely experimental or unproven and there should be data to suggest that patients would receive benefit.	All schemes which do not meet the definitions of EAMS, Post-trial supply or compassionate use these may include: Where doctors may approach a manufacturer directly to request the supply of a new medicine that does not have a UK product licence, to be used for a patient under their direct responsibility. Where companies choose to run schemes that allow early access to their medicine on a free of charge basis to an identified cohort of patients in advance of potential NICE approval or licensing.

Level of scrutiny required

Less formal schemes particularly those which have not been reviewed centrally by the relevant authorities (MHRA/ EMEA) will require a greater degree of scrutiny locally to ensure governance requirements are met, potential risks are managed and that a consistent approach is taken by the trust to ensure equity.

Appendix C: NHSE FOC Supply – Request for approval form

Free of Charge (FOC) Supply – Request for approval sent to NHS England

Send completed form to england.scpharmacymidlands@nhs.net

Medicines made available via pharmaceutical FOC schemes which have not yet been identified by the NHS England Early Access to Medicines Scheme (EAMS) must have this form completed for specialised medicines, and shared with the commissioner in order to obtain agreement to proceed with the scheme.
Completion of this form **does not** ensure future commissioning arrangements.

Trust Name	
Drug Name – Approved (and generic / biosimilar – if known)	
Preparation (strength and formulation)	
Drug 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)	
Estimated number 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	

Appendix C: NHSE FOC Supply – Request for approval form

Funding arrangements agreed with pharmaceutical company for existing patients if the drug does not gain marketing authorisation / NICE approval			
Trust activity – please detail number of attendances (outpatient, inpatient, follow-ups) required for the use of the drug			
Any other information/supporting evidence (level of evidence, phase of trial, protocol etc.)			
Requesting clinician			
Completed by:	**Name**	**email**	**Date**

Reference: https://www.sps.nhs.uk/wp-content/uploads/2018/07/FOC-medicine-scheme-policy-v-3.0-Final.pdf

Please note:

1. **NHS England does not generally commission the use of other medicines in combination with Free of Charge medicines. It is anticipated additional information and agreement may be required for any combination therapy.**
2. **A positive National Institute for Health Care Excellence Technology Appraisal (NICE TA) does not automatically mean that the responsible commissioner will pick up funding for patients already established on treatment. This would need discussion and agreement between pharmaceutical company and the responsible commissioner.**
3. **This form does not apply where a drug is used under a compassionate use scheme. For information the European Medicines Agency definition of a compassionate use scheme is: "Compassionate use is a treatment option that allows the use of an unauthorised medicine. Under strict conditions, products in development can be made available to groups of patients who have a disease with no satisfactory authorised therapies and who cannot enter clinical trials." This would normally apply to small numbers of patients and the medicine used would be unlicensed for the indication intended.**
4. **The criteria that NHSE Local Leadership Team (LLT) will use to decide on whether or not to approve the FOC scheme application are as follows:**
   a. **Licensed status of treatment**
   b. **Treatment part of the NICE appraisal process**
   c. **Treatment is not likely to affect a currently commissioned pathway**
   d. **Route of administration is the same as the currently commissioned alternative treatment**
   e. **Significant change in activity owing to the introduction of the FOC drug is not likely.**
   f. **Patient numbers will not have an impact on activity and service capacity.**
   g. **There is a clear plan for continuation of treatment of patients on the FOC scheme when NICE guidance / marketing authorisation is issued.**