The Royal Wolverhampton NHS Trust

MP- 08
Policy for Free of Charge Medicines Schemes

Contents

Appendices:

1.0 Policy Statement (Purpose / Objectives of the policy)

A free of charge medicine scheme is defined as an arrangement where a UK licensed or unlicensed medicine is provided free of charge by a pharmaceutical company to an individual patient or an identified cohort of patients.

This policy covers the principles which must be met when a medicine is supplied as free of charge. It details the different situations which may lead to a supply being made available and provides standardisation of how such schemes are to be managed within the Trust thus ensuring patient safety is not compromised. This policy should be read in conjunction with the Regional Medicines Optimisation Committee (RMOC) 'Free of charge medicines schemes' policy.[1]

2.0 Definitions

European Medicines Agency (EMA) Compassionate Use Schemes refer to schemes involving unlicensed medicines assessed by the EMA. 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."

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.

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 (TA) 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.

A **clinical trial** is a study performed to investigate the safety or efficacy of a medicine.

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.

A **licensed medicine** is one that has been granted a UK marketing authorisation for one or more indications.

An **unlicensed medicine** is a medicine that currently does not have a UK marketing authorisation.

Blueteq is a high-cost drug management system. Clinicians are required to complete a Blueteq form for any patient who is prescribed a high-cost drug. This, in turn, enables NHS England and Clinical Commissioning Groups to monitor the use of expensive treatments, so that only treatments prescribed in line with local policy and National Institute for Health and Care Excellence guidelines are reimbursed.

3.0 Accountabilities

Trust Chief Medical Officer (CMO)

- The CMO is the lead director responsible for the FOC medicines policy and ensures organisational adherence on behalf of the Trust board. This responsibility is delegated to the Clinical Director of Pharmacy.
- The CMO is responsible for approving FOC schemes when a significant financial or clinical risk has been identified.

Chair of the Trust Medicines Management Group (MMG)

- The Chair of the MMG 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 the Trust.
- The MMG is responsible for ensuring that the FOC medicine offers the patient additional benefit over and above existing treatment options.

Clinical Directors and Group Managers

- The relevant service Clinical Director and Group Manager are responsible for having an overview of FOC medicines schemes operational in the service and ensuring the affected specialties comply with this policy.
- The Clinical Director and Group Manager 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.

Consultants

- The consultant is responsible for ensuring that the MMG has considered and approved a medicine available through a FOC scheme prior to offering it as an option to patients.
- The consultant must liaise with the lead / specialist pharmacist as soon as possible and the Trust's Clinical Director of Pharmacy should be informed of any proposed FOC scheme.
- Consultants are responsible for providing information to the Directorate/Group Manager to allow them to plan for the on-going management of patients on a FOC scheme and identify the potential financial risk the Directorate may be exposed to.
- The relevant service Directorate/Group Manager must confirm 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 made clear and approval compliant with the Trust's Standing Financial Instructions.
- Consultants are responsible for taking patients and/or their representatives through treatment options available to them and for providing high quality written information on treatment and ensuring they have enough information to consent to entering a FOC scheme. 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.
- Consultants must ensure that the patient's General Practitioner is made aware of any FOC medicines prescribed.
- Consultants must not agree supply of medicines and associated contracts with a company directly. All FOC schemes must be referred to pharmacy.
- Consultants are responsible for monitoring outcomes of treatment.

Clinical Director of Pharmacy and pharmacy team

- The Clinical Director of Pharmacy is responsible for ensuring that the FOC scheme does not contradict NICE recommendations, guidance, or local commissioning arrangements.
- Specialist pharmacists are responsible for supporting consultants providing information to MMG.
- All written agreements for FOC schemes should be scrutinised and signed by the Clinical Director of Pharmacy (or pharmacy persons authorised by them to sign FOC schemes).
- The pharmacy team is responsible for the ordering and supply of all FOC medicines.

4.0 Policy Detail

4.1 FOC medicines schemes

There are established frameworks in place in England to enable access to medicines without charge. These are the Medicines and Healthcare products Regulatory Agency (MHRA) Early Access to Medicines Scheme (EAMS) and, for compassionate use in certain scenarios, access as defined by the European Medicines Agency (EMA). These frameworks are not the primary focus of this policy, however some guidance about these schemes is given in 4.2 below.

Independent of the established frameworks, schemes are made available by companies that offer medicines FOC, to an identified cohort of patients, often in advance of potential commissioning approval. These schemes have the potential to override existing local treatment pathways and existing NICE recommended treatment pathways.

There is no standardisation in the types of FOC schemes being offered. The terms can vary as can the complexity and workload involved in assessing, managing and administering schemes.

The motivation of companies offering FOC schemes could be perceived as a marketing approach to build early clinician experience of a medicine, in effect to increase product sales over the longer term. This is not an evidence-based approach, although it is often argued that it provides earlier patient access and improves outcomes. To avoid FOC schemes being perceived as a marketing tactic 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.

FOC schemes can circumnavigate head to head trial processes in an attempt to gather ‘real life data’. These schemes can require submission of data back to the company and can therefore be an administrative burden.

FOC medicines may be offered in circumstances where the company has chosen not to make a submission on a topic that NICE has identified as requiring guidance. In such circumstances, commissioners will not support funding, so any future financial risk remains with the Trust.

Within this policy FOC schemes also includes very deeply discounted products that are offered at a price so low that they are almost free of charge.

4.2 Established frameworks to access medicines without charge

These frameworks are not the focus of this policy and information is given for guidance only.

Compassionate use schemes as defined by the EMA

- These medicines are offered by pharmaceutical companies where there is no alternative treatment for patients.
- The medicines are usually under development and are only made available under strict conditions.
- Any compassionate use programme must be able to demonstrate potential benefit to patients with a serious condition for which there is no alternative treatment, and who are not eligible for entry into a relevant clinical trial.
- The consultant must present all details of the compassionate use programme to the MMG for approval. Details must include information of treatment failure, any trial evidence available and the expected outcomes.
- The company must confirm, in writing, the proposed arrangements to maintain the free of charge supply to every patient enrolled in the scheme.
- No compassionate use programme will be entered into that does not have a satisfactory exit strategy.
- Ordering and supply must be by pharmacy.
- Further information can be found at www.ema.compassionate use schemes.

MHRA Early Access to Medicines Scheme (EAMS)

- This scheme allows access to medicines prior to marketing authorisation being granted.
- These medicines are granted only where there is an unmet clinical need and the medicinal product is beneficial compared to existing treatment options.
- EAMS must be approved by MMG.
- Once approved by MMG clinicians may register on the associated online portal and confirm patient eligibility for such schemes.
- Completion of Blueteq may apply.
- Ordering and supply must be by pharmacy.
- Further guidance can be found at www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams

NICE approved Patient Access Schemes

- These are medicines supplied via a pricing agreement as part of the NICE appraisal process.
- Ordering and supply must be by pharmacy.
- Further information can be found at www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit.

Access to medicines at the end of a clinical trial

Patients may have been established on a medicine as part of a clinical trial. An issue may arise at the end of the trial if no provision has been made for the funding to support continuation of treatment, therefore no trial must be approved without a clear exit strategy.

Samples

- These are sometimes offered by pharmaceutical companies in order for prescribers to

become familiar with a medicinal product and acquire experience in dealing with it. They tend to be of low value, usually in small size packs and are not delivered through the usual supply chains.

- Samples will not be accepted for use within the Trust.
- Samples of medicines must not be left on wards, departments or offices for the treatment of patients.
- Samples of products requested for the private use of doctors must be sent to their private address and not to Trust premises.

4.3 Principles of FOC medicines schemes

The following principles must be met for all FOC medicines schemes:

- The medicine must address an unmet clinical need.
- There is equal access for all patients with the same indication.
- When the FOC scheme involves patient data collection, the scheme must have a non-disclosure agreement or the consent from patients to share relevant, non-identifiable information.
- Sharing of patient identifiable information as part of a FOC scheme is not permittable.
- Patients must be fully informed on the medicine and the associated scheme.
- Patient consent must be documented, including any restrictions on duration of treatment.
- Submission to MMG should be supported by all of the published evidence for the effectiveness of the medicine. Where an established treatment pathway exists, the evidence for the proposed place in treatment should also be submitted to the MMG.
- There should be clear expected outcomes from the use of the treatment.
- The submission to the MMG should be supported by information that identifies any clinical risks with the product.
- Patients who are entered into the scheme must be monitored appropriately.
- Packaging and labelling of products must meet regulatory and quality standards.
- All proposals for a FOC medicine scheme must be reviewed and supported by the relevant Clinical Director and Group Manager, and the MMG.
- Details of FOC schemes must be shared with local commissioners where there are financial implications and there must be consideration of local health economy impact from adoption of the FOC scheme.
- Consideration should be made to any potential burden for pharmacy that might be related to ordering, storage, supply, recording keeping and reporting.

- All FOC medicines must be ordered and supplied by pharmacy.
- 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.
- There should be a clear description of any additional costs such as extra tests, extra support and appointments.
- Consideration must be given as to whether use of the product is in line with the Conflict-of-Interest Policy i.e. Trust staff must declare any connections with the company supplying the product.

4.4 Application process for FOC medicine schemes

- All proposed FOC schemes must be notified to pharmacy at the earliest opportunity.
- The Consultant (with the support of the directorate pharmacist) must obtain a signed agreement from the pharmaceutical company outlining the details of the scheme.
- The company must confirm in writing the proposed arrangements to maintain the free of charge supply to every patient enrolled in the scheme, especially if the expert guidance is negative. In such circumstances, the pharmaceutical company must continue to the supply the free of charge medicine until the clinician and the patient decide the treatment should be stopped.
- The Consultant must present all details of the scheme at their directorate governance meeting and gain agreement from their Directorate or Group Manager, Clinical Director and Directorate Pharmacist. Due regard must be given to application of the principles described in this policy. It will be the responsibility of the Directorate Management Team to ensure any information required for rebate purposes are maintained and made readily available where necessary. Where there is potential financial risk to the Trust, this should be approved as per the Trust's Standing Financial Instructions.
- The Consultant must complete the 'Free of Charge Supply- Request Form' (appendix 1) and forward the completed form to rwh-tr.mmg@nhs.net for addition to the next MMG meeting.
- The Consultant will be required to present all the details of the scheme to the MMG at the next scheduled meeting, or if urgent approval is required this will be via the MMG urgent approval process. This should include evidence for the use of the medicine, how it will address an unmet clinical need, the proposed treatment pathway, identified clinical risks with the product and strategies for reducing such risk, and any required monitoring.
- Associated non-disclosure agreements should not prohibit sharing the details of such schemes with Trust groups such MMG.
- MMG will make a decision applying the principles within this policy and taking into consideration the RMOC advice.[1] Note that:

- MMG will refuse any application for using FOC medicines if the scheme is **solely** offering a licensed medicine FOC or at a nominal charge in advance of a commissioning agreement e.g. NICE approval.

- MMG will refuse any application for using FOC medicines in circumstances where the company has chosen not to make a submission on a topic that NICE has identified as requiring guidance.

- No FOC scheme will be entered into that does not have a satisfactory exit strategy or that has negative implications for revenue such as additional supportive drugs, additional appointments, testing requirements etc.

- MMG will minute the approval or rejection of the FOC scheme.

- If approved by MMG the written agreement will be signed by the Consultant and the Clinical Director of Pharmacy (or pharmacy persons authorised by them to sign FOC scheme agreements). Where there is financial or clinical risk the agreement must also be signed by the CMO, and the Trust legal team if required.

- Prior to the FOC scheme being started the Clinical Director of Pharmacy on behalf of the MMG, will forward the request form for the free of charge scheme and a copy of the signed agreement to the local commissioning representative (NHSE or CCG). If the commissioner does not agree to the scheme (including additional spend on funded medicines) then the financial risk lies with the Trust.

4.5 Ordering and supply of FOC medicines

- All agreements/contracts must be managed by pharmacy and archived appropriately.
- All orders for FOC medicines will be managed by pharmacy procurement.
- All FOC medicines will be supplied to patients by pharmacy, the out-patient pharmacy provider or a nominated homecare company.
- Under no circumstances will free of charge medicines be supplied directly to wards, clinics or medical staff.

4.6 Patient discussion and consent

The prescriber must have a discussion with the patient (or their parent/carer) before treatment is initiated. The patient must be made aware and understand that, where NICE recommended treatment is already available and the medicine is no longer available FOC by the company, treatment with the medicine will be stopped.

Patients must be provided with the following information as a minimum:

- Risks in regard to efficacy/safety data associated with medicine.
- Dosing instruction- how to use or take the medicine.
- How to manage side effects to the medicine.
- Written record of the details of their treatment (including start date, dose, frequency and monitoring requirements) so it can be shared with other healthcare staff.
- How to obtain their medicine.
- Details of what will happen if the treatment is stopped where the FOC scheme is no longer available.

Each patient receiving a FOC medicines should give written consent demonstrating they have received and understand the information above, and that they understand that treatment might be stopped.

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the implementation revenue resources of this policy require additional	No
3	Doe the implementation of this policy require additional manpower	No
4	Does the implementation of this policy release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments	

6.0 Equality Impact Assessment

An initial equality analysis has been carried out and it indicates that there is no likely adverse impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.

7.0 Maintenance

The Clinical Director of Pharmacy is responsible for keeping the policy up to date. Any revisions to the policy will be reviewed by the Trust's Medicines Management Group before being submitted through the Trust's policy approval procedure. Any revisions to the policy will be approved through the Trust's Medicines Management Group and ratified by the Policy Review Committee.

8.0 Communication and Training

Consultants are responsible for ensuring that all medical officers in their team are trained to be competent in all aspects of the prescribing of medicines, as specified in this policy. Nursing and departmental managers are responsible for ensuring that any non-medical prescribers working for them are similarly competent.

Divisional and Directorate Management Teams have a responsibility to ensure that staff area aware of and have access to the Medicines Policies applicable to their Ward/ Department / Clinical Area.

9.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Committee
FOC Schemes are compliant with this policy	Clinical Director of Pharmacy	Audit of a sample of FOC schemes against the principles within this policy	Each time the policy is reviewed / every 3 years	MMG

10.0 References - Legal, professional or national guidelines

1. Free of Charge (FOC) Medicines Schemes: Updated RMOC Advice for adoption as local policy – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
2. RPS Medicines Optimisation Principles (2013) **untitled (rpharms.com)**

Part A - Document Control

<table>
<tr><td>Policy number and Policy version:

MP-08
v.2.0</td><td>Policy Title

Policy for Free of Charge Medicines Schemes</td><td colspan="2">Status:

Final</td><td>Author: Clinical Director of Pharmacy

Chief Officer Sponsor: Chief Medical Officer</td></tr>
<tr><td rowspan="4">Version / Amendment History</td><td>Version</td><td>Date</td><td>Author</td><td>Reason</td></tr>
<tr><td>1</td><td>Feb 2018</td><td>Clinical Director of Pharmacy</td><td>Original Policy</td></tr>
<tr><td>1.1</td><td>Feb 2021</td><td>Clinical Director of Pharmacy</td><td>Reviewed by Director Sponsor – extended to September 2021 pending full review</td></tr>
<tr><td>2.0</td><td>March 2022</td><td>Clinical Director of Pharmacy</td><td>Reviewed by author and updated to reflect RMOC guidance</td></tr>
<tr><td colspan="5">Intended Recipients: All Trust employees with responsibility for prescribing, storage, ordering and administration of medicines. Group and Directorate Managers.</td></tr>
<tr><td colspan="5">Consultation Group / Role Titles and Date:
Pharmacy Clinical Governance February 2022
Medicines Management Group March 2022
Trust Policy Group May 2022</td></tr>
<tr><td colspan="2">Name and date of Trust level group where reviewed</td><td colspan="3">Trust Policy Group May 2022</td></tr>
<tr><td colspan="2">Name and date of final approval committee</td><td colspan="3">Trust Management Committee May 2022</td></tr>
<tr><td colspan="2">Date of Policy issue</td><td colspan="3">June 2022</td></tr>
<tr><td colspan="2">Review Date and Frequency
(standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)</td><td colspan="3">May 2025, every 3 years</td></tr>
<tr><td colspan="5">Training and Dissemination: Via Trust internet bulletin and Divisional Management forums</td></tr>
<tr><td colspan="5">Publishing Requirements: Can this document be published on the Trust's public page:

Yes</td></tr>
<tr><td colspan="5">To be read in conjunction with:
MP-01 Prescribing, Storage and Administration of Drugs</td></tr>
</table>

Initial Equality Impact Assessment (all policies): Completed Yes Full Equality Impact assessment (as required): Completed NA If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904	
Monitoring arrangements and Committee	Via Medicines Management Group
Document summary/key issues covered. This policy sets out the Trusts standards and procedure for free of charge medicines schemes. It is aligned with the Regional Medicines Optimisation Committee (RMOC) advice on Free of Charge (FOC) Medicines Schemes published January 2020.	
Key words for intranet searching purposes	Medicine Drug Free of charge Pharmacy FOC
High Risk Policy? **Definition:** • Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. If a policy is considered to be high risk it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee.	**No**

Part B **Ratification Assurance Statement**

Name of document: MP- 08 Policy for Free of Charge Medicines Schemes

Name of author: Angela Davis Job Title: Clinical Director of Pharmacy

I, Angela Davis, the above named author confirm that:

- The Policy presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.

- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.

- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).

- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.

- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.

- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.

- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:

Date:

Name of Person Ratifying this document (Chief Officer or Nominee):
Job Title:
Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version MP-08	**Policy Title Policy for Free of Charge Medicines Schemes**	
Reviewing Group		**Date reviewed:**
Implementation lead: Angela Davis angela.davis15@nhs.net		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	N/A	
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	N/A	
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	N/A	
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	N/A	
Financial cost implementation Consider Business case development	N/A	
Other specific Policy issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation	N/A	

Appendix 1 - Free of Charge (FOC) Supply Request- Form for Approval

Free of Charge (FOC) Supply- Request Form for Approval	
All sections of this form must be completed as thoroughly as possible and sent to rwh-tr.mmg@nhs.net to be reviewed by the MMG and relevant commissioner. The form should be completed in line with: Trust Policy MP- 08 Policy for Free of Charge Medicines Schemes RMOC Free of Charge Medicines Schemes advice www.sps.nhs.uk/wp-content/uploads/2018/07/FOC-medicine-scheme-policy-v-3.0-Final.pdf Completion of this form does not automatically mean the scheme has been approved by the MMG or ensure future commissioning arrangements. If the relevant commissioner has not agreed to the FOC scheme (including additional spend on funded medicines) then the entire financial risk lies with the Trust. Where there is potential financial risk to the Trust, schemes must be approved as per the Trust's Standing Financial Instructions.	
Trust Name	
Requesting Consultant	
Completed by	
Contact details for request	
Date approved at Directorate Governance Meeting	
Name and signature of approving Clinical Director	
Name and signature of approving Directorate Manager / Group Manager	
Medicine Information	
Medicine name- Approved name (and generic/biosimilar- if known)	
Current NICE status- is guidance due, has a ACD or FAD been published? For further information refer to: www.nice.org.uk/process/pmg19/chapter/the-appraisal-process	
Preparation- Strength and Formulation	
Company offering the scheme	
UK License Status	
Clinical Indication	

Line in therapy and what this replaces (if any)	
Regimen- including dose, route, duration and frequency, number of cycles. Include all anticancer drugs and supportive care medication used in combination with FOC drug.	
Financial Considerations- Funding Arrangements and Trust Activity	
Details of the scheme being offered- this should include the associated drug costs, monitoring requirements etc.	
Estimated number of anticipated patients per financial year	
Funding arrangements agreed with pharmaceutical company for existing patients if the drug gains NICE approval	
Funding arrangements agreed with pharmaceutical company 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 the NICE HTA is terminated	
What is the length of the FOC scheme	
Trust activity- please detail the number of attendances (outpatient, inpatient, follow-ups) required for the use of the drug	
Clinical and Administrative Considerations	
Is there an unmet clinical need?	
Is this an additional treatment option? (i.e. another option with similar indications, efficacy, cost and safety to its competitors)	
What administrative requirements are needed to obtain the medicine and who will oversee this?	
What administrative requirements are needed to obtain the cost of the drug detailed in the scheme and who will oversee this?	

What administrative requirements are needed to record the cost-savings associated with the Trust participating in the agreement and who will oversee this?	
What are the arrangements for patient consent? Where will this consent be documented?	
Contractual Considerations	
Is there an obligation for the Trust to purchase the FOC medicine i.e. is the scheme considered a purchase order?	
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, the agreement should express clearly where financial responsibility lies)	
Additional Information	
Any other information/supportive evidence (level of evidence, phase of trial, protocol etc)	
Other participating networks e.g. consensus from Integrated Care Systems.	