University Hospitals of Derby and Burton NHS Foundation Trust

TRUST POLICY FOR FREE OF CHARGE (FOC) MEDICINES SCHEMES

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Version / Amendment History	Version	Date	Author	Reason
	1	12/12/2018	D Moore	New Policy written in line with RMOC guidance
	3	15/03/24	E kirk	Updated based on NHS England Free of charge medicines schemes -national Policy recommendations for local systems
Intended Recipients: All wards and departments				
Training and Dissemination: Training and Dissemination: via memo to Clinical Directors and Associate Clinical Directors for cascade to prescribers within each Division. To include in D&T newsletter and Medicines Intranet				
To be read in conjunction with: Trust Policy and Procedures for Medicines, and Staff Handbook (Trust Standards for Safe Medicines Practice), both available on Intranet at: http://flo/depts/Division-of-integrated-care/pharmacy-therapies- business-unit/pharmacy-medicines/mmg-med-code				
In consultation with and Date: Drugs and Therapeutics Group - 19 March 2024				
EIRA Stage One Yes Stage Two No				
Approving Body and Date Approved			Trust Delivery Group 3 June 2024	
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Contact for Review			Lead Pharmacist	
Executive Lead Signature			Dr Gis Robinson Chief Medical Officer	

Contents

1 Introduction

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 (EMA).

Independent of this, there is an increasing number of schemes being made available by pharmaceutical companies that offer medicines 'free-of-charge' (FOC), to an identified cohort of patients, in advance of NICE approval.

These pre-NICE FOC schemes could potentially override existing local pathways that have been agreed that prioritise existing NICE approved treatments. Some FOC schemes presented by pharmaceutical companies aim to provide the treatment for a licensed indication that falls outside of NICE recommendations e.g. as a first line treatment when NICE only recommends after other treatment options have been tried.

Unlike medicines that are part of the EAMS scheme, medicines made available via pharmaceutical FOC schemes have not yet been identified by the MHRA as providing significant advantage over existing treatments of life threatening conditions.

The aim of this Policy is to address this issue and ensure there is a consistent and equitable approach through providing guidance when considering the use of FOC medicines schemes.

2 Purpose and Outcomes

- This Policy is intended to be used by anyone considering the implementation or approval of a FOC scheme
- This Policy does not preclude access to treatments which are approved by the commissioner's individual funding request process
- This Policy excludes schemes that allow access to treatments for rare conditions which would ordinarily be covered by a compassionate use scheme or clinical trial
- There are other mechanisms of free of charge medicines supply, which are outlined below, where there is a more defined framework. For the purpose of this work this Policy will only provide signposting to these schemes
- Compassionate use schemes as defined by the European Medicines Agency: www.ema.compassionate use schemes
- NICE approved Patient Access Schemes: www.nice.org.uk/atient-access- schemes-liaison-unit.

- MHRA Early Access to Medicines Schemes: www.gov.uk/guidance/Early Access to Medicines Scheme

3. Definitions Used

Compassionate use schemes

Refers to schemes involving unlicensed medicines.

European Medicines Agency (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. 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 compassionate access to medicines programme.

Patient Access Schemes Liaison Unit (PASLU)

The Patient Access Scheme Liaison Unit (PASLU) has been set up by NICE to work with manufacturers who are considering a patient access scheme for their drug or treatment. PASLU looks at the proposal made by the manufacturer to see if it is a scheme that would work in the NHS. PASLU 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 technology appraisal (TA).

A Clinical Trial

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

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 manufacturer or pharmaceutical 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 3 months (unless otherwise specified) of the date of publication of the TA.

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.

An off-label medicine

Is one that is being used in a way that is different to that described in the UK licence (e.g. crushing & dispersing a tablet to aid administration).

4. Roles and Responsibilities

Chief Medical Officer

- The Chief Medical Officer is the lead Executive responsible for the FOC medicines Policy and ensures organisational adherence on behalf of the Trust Board
- They are responsible for approving FOC schemes when a significant financial or clinical risk has been identified
- The Chief Medical Officer will delegate authority for assuring monitoring of adherence to this procedure to the relevant service medical/ clinical leads / Directors.

Chair of Drugs and Therapeutics Group (D&T)

- The Chair of the D&T 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 D&T is responsible for ensuring that the FOC medicine offers the patient additional benefit over and above existing treatment options
- D&T would be responsible for requesting Chief Medical Officer approval for all FOC schemes approved by the committee.

Clinical Directors (CD)

- The CD is responsible for having an overview of FOC medicines schemes within their Business Unit and ensuring the affected specialties comply with this Policy
- The CD or delegated Manager is responsible for planning any expenditure and resource issues that may be necessary if entering a FOC scheme. Particularly planning for if the scheme is ceased by the company, if the medicine becomes commissioned by the NHS and for the non-drug costs that may be incurred.

Consultant / General Manager

- The Consultant is responsible for ensuring that the D&T has considered and supported a medicine available through a FOC scheme prior to offering it as option to patients

- The Consultant must liaise with the lead / specialist pharmacist as soon as possible and the Trust's chief pharmacist should be informed of any proposed FOC scheme
- Consultants are responsible for providing information to the General Manager to allow them to plan for the on-going management of patients on a scheme and identify the potential financial risk the Division may be exposed to
- The General Manager must confirm that funding is available for any additional drug and non-drug costs incurred by the scheme (e.g. clinic activity, drug monitoring). Where there is a potential financial risk to the Trust this should be approved by the Divisional Finance Business Partner
- Consultants are responsible for taking patients 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 scheme cease and no on-going NHS funding is identified the treatment will cease, even if it is being effective. It is a requirement that a letter confirming this agreement is signed by the patient and a copy retained in the medical notes
- Consultants must ensure that the patient's General Practitioner is made aware of any 'free of charge' medicines prescribed
- Consultants must not agree supply of medicines and associated contracts with a company directly. All schemes should be referred to pharmacy for processing
- Consultants are responsible for monitoring outcomes of treatment.

Chief pharmacist (or delegated authority) and pharmacy team

- The chief pharmacist is responsible for ensuring that the FOC scheme does not contradict current NICE guidance or local commissioning arrangements.
- Appropriate specialist pharmacists are responsible for supporting consultants providing information to D&T to help make a decision whether to support a FOC scheme
- All contracts for FOC schemes should be scrutinised by the lead commissioning pharmacist and the agreement signed by them or their appointed deputy if supported by them and D&T
- The pharmacy team is responsible for the ordering of all FOC medicines.

5. Recommendations for all FOC Schemes

These recommendations have been made by NHSE. They apply to all FOC schemes regardless of whether a NICE TA or NICE highly specialised (HST) has been published or not:

Early discussion of potential FOC schemes (with an identified clinical need) should be undertaken with the relevant Integrated Care System (ICS) stakeholders to allow robust suitability assessment of potential impact on current commissioning pathways (locally or nationally commissioned through NHS England).

NHS England recommended 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 PASLU, 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 PASLU price for indications as defined within the NICE guidance, FAD (i.e. post NICE TA)
- If a PASLU 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 patients who are eligible for access as this leads to inequity.

6. Key considerations

The principles outlined in section 9 should be adhered to in order to minimise governance and resource risks.

Governance risks and arrangements

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

1. After NICE TA publication, the Trust 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 must have provision set up for patients who do not meet the NICE eligibility criteria to ensure the company continues to supply the medicine FOC until the clinician or patient decides to stop treatment.

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, the FOC scheme must have provision set up for patients to ensure

the company will continue to supply the medicine FOC until the clinician or patients decide to stop the treatment.

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.

- Trusts should not sign up to a FOC scheme for a medicine indication that the company has chosen not to submit to NICE. This is generally not supported because the clinical and cost effectiveness of the treatment is unknown
- Standard medicines governance processes must be followed in order to prevent the introduction of inequity with patients of equal clinical need being treated differently. There is also the risk of undermining the NICE process and local commissioning decision making processes including pathways and guideline development
- A memorandum of understanding (MOU) between the pharmaceutical company supplying the FOC medicine and the Trust must be signed.
- FOC schemes must be discussed and approved at the Trust's Drugs and Therapeutic Group.

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 individual funding request (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 supplied, free of charge medicines as part of a NICE patient access scheme or the MHRA early access to medicines scheme.

7. Risk of FOC schemes

Resource Risks

- 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.

Financial Risks

- Provider tariff activity costs that have not been commissioned, e.g. admissions, outpatient appointments, follow up ratios, monitoring, treating adverse effects
- Staff costs, equipment costs, concomitant medicines provision
- Ongoing drug costs following the end of the FOC scheme
- Additional medicines costs if the FOC medicine is used in combination with another funded treatment

- 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. However review of the commissioning arrangement at the time of approval will be needed to ensure the financial risk can be identified and the impacted organisation is in agreement and is happy to approve this financial risk
- Potential for harm and medical negligence claim should an untoward event occur. This could also have an impact on the reputation of the Trust
- Any additional costs outside of the FOC scheme should be included in the FOC framework (appendix 1) and agreed at DTC before a decision to progress the scheme is made, particularly if new activity is involved.

Workforce Risks

- Staff time needed for assessment of the scheme, e.g. discussions with the pharmaceutical company, reviewing the written agreement, producing the MOU, following governance processes, obtaining legal advice where required
- Ongoing management of the scheme
- Establishment on e-prescribing systems
- Impact on clinic capacity (especially with parenteral therapies)
- Procurement – FOC schemes require individual patient ordering, anonymised stock etc.

Operational Risks

- Cumulative burden of managing multiple schemes
- Failure of supply route
- Waste management.

Inequity

- It cannot be presumed that NICE will make a positive recommendation. Patients started on a medicine via a FOC scheme prior to NICE approval are likely to continue to receive this drug. However, patients for whom the FOC scheme was not available at the same time will not have the same opportunity. As such these schemes have the potential to introduce inequity and, moreover, to undermine the evidence based recommendations made by NICE or local commissioning organisations
- FOC schemes that allow patients to access medicines that contradict NICE or locally agreed pathways should not be endorsed
- The FOC scheme may reduce the impact of local commissioning arrangements including approved pathways and guidelines.

Clinical Governance

- Details of transparent arrangements for criteria for use and monitoring of the medicine should be included in the MOU
- The FOC medicine should not replace an existing therapeutic option in an established pathway simply to reduce cost
- The appropriate route for the long-term supply of the medicine to the patient should be considered. When the pharmaceutical company chooses to provide

the medicine via homecare as one of the delivery routes, the national governance arrangements for pharmaceutical company commissioned homecare must be followed and standards adhered to.

Patient Consent

- Discussions with the patient (or their parent / carer) must take place prior to commencing the treatment
- The patient must be made aware and understand that, where there is already a NICE approved treatment available, treatment with the FOC medicine will be stopped if the medicine is no longer provided free of charge by the pharmaceutical company, even if they perceive they have had benefit from treatment
- Patients should also be informed this does not affect their right to access NICE approved treatments
- 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 patient identifiable information is not acceptable
- The patient must be provided with the following information as a minimum:
    - Uncertainties in the efficacy / safety data (if the medicine is still in development / unlicensed / off-label)
    - 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 patients health records
    - How to obtain supplies of the medicine
    - Details of what will happen if the treatment is stopped due to end of FOC scheme.

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.

8. Responsibilities and Accountabilities

Pharmaceutical companies

- 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 a scheme. The agreement should include a funding statement.

For further information on roles and responsibilities see section 3.6 of NHS England

Policy on FOC medicine scheme.

(https://elht.nhs.uk/application/files/7915/6456/8821/RMOC_Item_7.2_FOC-medicine-scheme-policy-v-1.0Final.pdf#:~:text=6.1.1%20Aim%20to%20understand,for%20use%20in%20the%20NHS)

9. Principles

The Royal Pharmaceutical Society (RPS) has published guidance and a framework for medicines optimisation. In this guidance there are 3 overarching global dimensions. The FOC scheme principles listed below have been mapped to the 4 RPS principles.

Free of charge scheme principle	Additional information
6.1.1 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 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 contract 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 involved 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 hadn't entered into 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.
6.1.2 Evidence based choice of medicines	
The submission to Drugs & Therapeutics Committee (D&T), or equivalent, should be supported by all the published evidence for the effectiveness of	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.
6.1.3 Ensure medicines use is as safe as possible	
The submission to the Trust's D&T 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.
6.1.4 Make medicines optimisation part of routine practice	
All proposals for a FOC medicine scheme must be reviewed and supported by the Trust's D&T. 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 in 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 Policy.
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 contract has been signed with the pharmaceutical company.	This provides assurance that the pharmaceutical company is able to 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 recommendation. These risks could outweigh the benefits. These include financial, resource and operational risks. See section 5 for further details.
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 MOU should express clearly where financial responsibility lies following the end of the FOC scheme. This could be a mutual responsibility. This should include drug 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 MOUs are adhered to.	There is a risk to an organisation if schemes are not administered according to the agreements with the pharmaceutical company.

10 Application Process

- When approached by a pharmaceutical 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 Trust's chief pharmacist (or pharmacist with delegated authority) is informed of a proposed FOC scheme
- The principles of this Policy should be applied to the application process
- 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
- The medicine, for the specified indication, must be approved by D&T before (or at the same time as) the FOC application is made.
- An MOU between the pharmaceutical company supplying the medicine free of charge and the Trust must be obtained
- An application form can be found in Appendix one. This should be submitted to D&T with a summary of the available evidence. The application must include confirmation by the General Manager that funding is available for any additional drug and non-drug costs incurred by the scheme (including clinic activity). Where there is a potential financial risk to the Trust this should be approved by the Divisional Director of finance
- Any potential financial risk to the commissioner must be agreed with the commissioner prior to the FOC scheme being started.

- The MOU should be approved by:
    a. Lead Clinician
    b. Trust Chief Pharmacist (or person with delegated authority)
    c. Trust Chief Medical Officer
    d. Homecare Manager (where applicable
    e. Lead Commissioner when financial risk to commissioner
    f. Trust Legal Team (where applicable)
    g. Caldicott Guardian (when data sharing considered).

- The MOU must be signed by:

    a. A representative of the pharmaceutical company
    b. The Trust D&T chair
    c. The Trust lead clinician
    d. The Trust chief pharmacist or deputy
    e. Lead commissioner representative.

- Under no circumstances should FOC medicines be supplied directly to wards,

clinics or medical staff.

11 Monitoring Compliance and Effectiveness

The key requirements will be monitored in a composite report presented on the Trusts Monitoring Report Template:

Monitoring Requirement :	Prescribing compliance with Policy
Monitoring Method:	Monitoring via finance data and D&T finance subgroup.
Report Prepared by:	Lead Commissioning Pharmacist
Monitoring Report presented to:	Drugs and Therapeutics Group
Frequency of Report	Yearly

12. References

1. RPS Medicines Optimisation Principles (2013)

2. Regional Medicines Optimisation Committee- Free of Charge (FOC) Medicines Schemes: RMOC Advice for adoption as local Policy. Accessed. 4th April 2022 Available from https://www.sps.nhs.uk/articles/free-of-charge-foc-medicines-schemes-rmoc-advice-for-adoption-as-local-Policy/

3. Free of charge (FOC) medicines schemes-national Policy recommendations for local systems Last updated November 2023 NHS England » Free of charge (FOC) medicines schemes – national Policy recommendations for local systems

13. Appendix one

Framework of questions and notes for consideration of free schemes and or added value from the pharmaceutical companies

Requesting Clinician		
Drug		
Preparation (strength and formulation)		
Pharmaceutical company		
Uk License status		
Clinical indication		
Line in therapy and what this replaces		
Regimen (dose , route frequency)		
Questions	**Notes or considerations**	**Answer**
Contractual Considerations		
1. Is the medicine available via EAMS	If yes see trust Free of Charge Medicines Policy	
2. Has the scheme been offered to both commissioners and provider organisations?	Commissioners must be aware of all FOC schemes approved in the local health economy in 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.	

3. Is the NICE publication a Final Appraisal Determination (FAD) or Assistant Clinical Director (ACD)?	Caution is advised if an ACD is published. The preliminary recommendations are substantially more restrictive than the terms of the marketing authorisation or do not recommend use of the technology. 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 licensing of SPCs	
4. If the medicine has a positive NICE FAD does the indication, dose frequency described in the FOC scheme fall outside of NICE criteria?		
5. Does the medicine have a PAS in place	If yes see trust Free of Charge Medicine Policy	
6. Is the offer legally binding?	The FOC scheme must only be undertaken after a written contract has been signed with the pharmaceutical company. This provides assurance that the pharmaceutical company is able to meet their contractual obligations as the medicine provider. The MOU should express clearly where financial responsibility lies following the end of the FOC scheme. This could be a mutual responsibility. This should include drug costs and associated on-going care of the patient.	
7. Offer of a FOC scheme from the date of a ACD to FAD	Schemes offered before an ACD has been published are likely to be rejected.	
8. 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 sign information.	
9. What happens in the event of a negative NICE TA?	Ensure that contracts / MOUs are clear that pharma will continue to fund for patients already on treatment. Providers take out costings and report to ICBs as separate lines. 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 the MOU / contracts.	
10. What happens in the event of pharma withdrawing from the scheme prematurely?	Contracts should include that Pharma will continue to fund for patients already on treatment who are continue to gain benefit.	
11. What happens in the event of a terminated NICE TA?	Ensure that contracts / MOUs are clear that pharma will continue to fund patients already on treatment who are continue to gain benefit.	
12. In the event of a NICE TA with different eligibility criteria	Ensure that contracts / MOUs are clear that pharma will continue to fund patients already on treatment who are continue to gain benefit. Providers take out costings and report to ICBs as separate lines. Note- NICE have a generic statement in their publications "People whose treatment with xxx is not recommended in this NICE guidance but was started within the NHS before this guidance was published, should be able to continue treatment '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 the MOU / contracts.	

13. Any changes in trust activity?	please detail number of attendances (outpatient, inpatient, follow ups) required for the use of the drug	
14. How long does the FOC apply?	An FOC scheme applies up until the publication of a positive NICE TA and JAPC approval. Pharma schemes should continue to fund until the date the responsible commissioner agrees to fund following a positive NICE TA.	
15. What is the relationship with Pharma and information governance?	Only minimal pseudo anonymised patient level data should be shared with pharma to confirm use and for payment.	
16. How is the supply of medication obtained?	What is the proposed ordering mechanism for the FOC scheme. 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.	
17. Any additional costs outside the FOC scheme?	Any additional costs outside of the FOC need to be discussed and agreed before FOC scheme can be agreed.	

Clinical and Practical Considerations		
18. 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.	
19. Anticipated patient numbers	Please state the anticipated patient number for this scheme per financial year	
20. Detail the minimum dataset required by the company to administer the FOC scheme		

21. The submission to Drugs & Therapeutics Committee (D&T), 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. Commissioning for outcomes should be included in any agreement to ensure that the appropriate patient cohort is targeted.	
22. Is this a 'me too' type treatment?	✓ In the case of 'me too' type products, i.e. another option with similar indications, efficacy, cost and safety to its competitors. The review pharmacists must be confident that the drug is clinically effective and safe to the patient and the offer is in line with proposed NICE criteria. ✓ The true cost to the NHS must be considered and not the drug in isolation: The cost of treatment must take into consideration of PBR associated costs for example: • Initial monitoring • Ongoing monitoring • Follow ups • Day case consideration too of real costs of competitor treatments (patient access schemes or those in local gain sharing agreements) In the event of a negative NICE TA for a 'me too' product, ICS / Providers need to agree who pays for activity costs.	
23. Offer of a <u>stepwise change</u> 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. In the event of a negative NICE TA ICS will not pay providers for <u>any associated activity unless explicitly agreed at the time of assesment</u>. Provider Trusts must provide ICS assurance of splitting commissioned activity from pharma.	
24. Is the offer in line with NICE criteria?	The review pharmacists should ensure the offer is in line with NICE criteria and its licensed indication	
25. Does the offer restrict clinician choice?	No schemes that include restrictions on a clinician's choice will be accepted. Where there is more than one option with no obvious advantage a preference may be stated but the final decision rests with the treating clinician.	

26. 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.	
27. Is there a significant administrative burden to manage the scheme	It will remain the responsibility of the provider Trust to give ICS assurance that drug costs are reimbursed by pharma. ICS expect that any administrative burden to administer the schemes is absorbed by the Trust. Has the General Manager approved all associated drug & non drug costs. Is there a large administrative burden on the Trust to manage this scheme.	
Recommendation of the review pharmacists (if accepted this may include recommendations of whole acceptance or adopting a concessionary prior approval process)		

Review pharmacists=Pharmacist from both commissioner and provider with expertise in dealing with high-cost drugs excluded from tariff.

Review by UHDB Drug & Therapeutics Group

Based on the information provided, UHDB D&T has approved / rejected (delete as appropriate) this FOC scheme

Signed

a. Chair of D&T…….

b. Trust chief pharmacist (or person with delegated authority)……..

c. Lead commissioner when financial risk to commissioner…….

d. Trust legal team (where applicable)……..

e. Caldicott Guardian (when data sharing considered)……..

f. General Manager……