GUIDELINE FOR MANAGEMENT OF FREE OF CHARGE MEDICINES SCHEMES FOR NHSE COMMISSIONED MEDICINES

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

The purpose of this guideline is to inform the implementation locally of NHS England » Free of charge (FOC) medicines schemes – national policy recommendations for local systems August 23 (as updated November 2023)

This guideline is for use by the following staff groups:

All consultants wishing to use NHSE commissioned free of charge medicines within the trust.

Lead Clinician(s)

Tania Carruthers Stephanie Cook	Director of Pharmacy Countywide lead pharmacist cancer and aseptic services.
Approved by Chemotherapy Action Group, Haematology Governance and Oncology Governance on:	March 2024
Approved by Medicines Safety Committee on:	8th May 2024
This guideline should not be used after end of This is the most current document and should be used until a revised version is in place:	8th May 2027

Key amendments to this guideline

Date	Amendment	Approved by:
Jan 24	Review based on national guidance issued August 23 • Update content • Simplify request form	

Abbreviations:

MOU Memorandum of Understanding

FOC Free of Charge

MPC Medicines and Prescribing Committee

EMA European Medicines Agency

MHRA Medicines and Healthcare Products Regulatory Agency

NICE National Institute for Health and Care Excellence

GUIDELINE FOR MANAGEMENT OF FREE OF CHARGE MEDICINES SCHEMES

1. Introduction

A free of charge (FOC) medicines 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. Medicines in FOC schemes are generally, high cost, tariff excluded medicines commissioned by NHS Integrated Care Boards (ICBs) or NHS England Specialised Commissioning.

When considering a FOC scheme, it must have a patient- centred approach, be safe, evidence-based and improve patient outcomes and should not be considered solely on the condition of a lower cost. Any application will therefore be reviewed against these key principles.

It is recommended that Commissioners and providers must only undertake a free of charge scheme if they follow the principles outlines in this document in order to:

1.1. Prevent the introduction of inequity with patients of equal clinical need being treated differently and to undermine the evidence based recommendations made by NICE.

1.2. Reduce the resource risk due to the need to support and monitor patients enrolled into these schemes and ongoing medicine costs following completion of the scheme.

2. Background

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

2.2. Any uptake of free of charge medicines must be for direct patient benefit in order to address an unmet clinical need.

2.3. It is recognised that there are various types of free of charge (FOC) schemes:

2.3.1.1. Access to medicines in advance of a commissioning agreement, for example prior to publication of a NICE Technology Appraisal Guidance. Within this document this definition will also include very deeply discounted products that are offered at a price so low that they are almost free of charge.

2.3.1.2. Access to an individual medicine for an individual patient in circumstances where no other suitable commissioned alternative medicines are available for the specific indication. This includes compassionate use of medicines in accordance with the European Medicines Agency (EMA) definition.

2.4. Trusts or commissioners should not sign up to a free of charge (FOC) scheme which is solely offering a licensed medicine free of charge in advance of NICE approval.

2.5. 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.

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

2.7. These pre-NICE FOC schemes could potentially override existing local pathways that have been agreed that prioritise existing NICE approved treatments.

2.8. 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 1st line treatment when NICE only recommends after other treatment options have been tried.

2.9. 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.

2.10. Currently, 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.

2.11. For most FOC pre-NICE schemes offered, there is already an established therapeutic treatment available.

2.12. Any scheme that puts a cap on the number of patients in a scheme should not proceed.

3. Risks with Free of Charge Schemes

3.1. supporting costs for staff, equipment, concomitant medicines.

3.2. ongoing ordering, supply, and monitoring of the medicine.

3.3. ongoing management of the scheme.

3.4. data anonymisation and transfer risks and the associated administrative workload.

3.5. waste management.

3.6. cost of medicines after the end of the FOC scheme.

3.7. provider tariff activity costs that have not been commissioned for example admissions, outpatient appointments, follow up ratios, monitoring, treating adverse effects.

3.8. potential for harm and medical negligence claim should an adverse incident occur, plus the resulting reputational risk.

3.9. There is a risk of undermining the NICE guidance as the funding mandate still applies to medicines approved by NICE, therefore any FOC scheme should not preclude patients from accessing a NICE approved treatment.

3.10. Where FOC medicine could be given in combination with currently funded medicine(s), there is a risk that this could lead to increases in the costs of the currently funded medicine(s) due to an increase in duration of treatment; this is more common in chemotherapy regimens

4. Patient Information

4.1. As with all treatments, discussions with the patient (or their parent and or carer) must take place prior to commencing the treatment. The patient must be made aware and understand that treatment with the FOC medicine will be stopped if the medicine is no longer provided free of charge by the pharmaceutical company, even if the patient perceives they have had benefit from treatment.

4.2. 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, including details of what will happen if the treatment is stopped due to the end of FOC scheme.

4.3. Patients should also be informed this does not affect their right to access NICE approved treatments.

4.4. 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.**

4.5. Each patient should give written consent that they have received the information listed above and that they understand that treatment might be stopped. This consent should be recorded in the patients' notes.

5. Principles of use of FOC Medicine

5.1. FOC stock must not be used in the Trust without prior approval.

5.2. 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 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.

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

5.4. The approval committee will refuse any application for using FOC Stock if the scheme is solely offering a licensed medicine free of charge in advance of NICE approval.

5.5. The approval committee will assess an application and only accept applications for schemes 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.

5.6. Sharing of patient identifiable information as part of a FOC stock scheme is not acceptable.

6. Making an application to use FOC stock

6.1. The requesting consultant (aided by a specialist pharmacist) must obtain a signed MOU (Memorandum of Understanding) from the pharmaceutical company outlining the details of the scheme.

6.2. The requesting consultant should complete a FOC stock application form with the support of a designated pharmacist. (see appendix 1).

6.3. For NHSE commissioned medicines, the pharmacist will inform the NHSE regional lead for approval and then submit the application to the Director of Pharmacy. The requesting clinician will submit the application to a Lead Consultant for the relevant speciality.

6.4. If the medicine is a SACT medicine and will be used in combination, the requesting consultant will complete appendix 2 “Standard template for commissioner approval of free of charge medicines schemes”. This should be submitted to - england.wmscpharmacy@nhs.net .

6.5. For NHSE commissioned medicines such as cancer treatments, approval must be given by a Lead Consultant with expertise in the area that the medicine is being used and is not the requesting physician and by the Director of Pharmacy or nominated deputy.

6.6. For ICB commissioned medicines, application to the H&W Medicines and Prescribing (sub)Committee following their standard operating procedures is required.

6.7. The directorate manager should be consulted before submission if there are any cost implications to implementation of the scheme.

Note
This policy applies to medicines use not covered by the Compassionate Use Schemes as defined by the European Medicines Agency; NICE approved Patient Access Schemes; MHRA Early Access to Medicines Schemes; Clinical Trials or individual funding requests as detailed below.

Compassionate use | European Medicines Agency (europa.eu)

NICE | The National Institute for Health and Care Excellence

Apply for the early access to medicines scheme (EAMS) - GOV.UK (www.gov.uk)

7. Role of approver

7.1. The Director of Pharmacy and Lead Consultant will review the paperwork contained in the application on behalf of the Trust.

7.2. They will make a decision based on urgency of clinical need, consideration of equitable treatment pathways, safety and efficacy of the medicine concerned and the likely financial, clinical governance or information governance risks to the Trust.

7.3. For an application to be successful approvers will sign the request and a copy will be kept in pharmacy for reference.

8. Ordering FOC Stock

8.1. All orders for FOC stock will be processed through the pharmacy procurement team following standard operating procedures.

9.0. Roles and Responsibilities

9.1. The CMO is the lead director responsible for the free of charge medicines policy and ensures organisational adherence on behalf of the Trust Board. This is delegated to the Director of Pharmacy.

Monitoring Tool

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	All Free of charge schemes approved following completed application and risk assessment.	Report and investigation of any scheme in place that has not been through the approval process following introduction of this policy.	Ongoing	Pharmacy staff supplying patient's medicines for FOC schemes	Medicines Safety Committee.	Ongoing
	All Free of charge medicines managed by pharmacy following approval according to policy.	Report and investigation of any medicines that have not been managed by pharmacy following introduction of this policy.	Ongoing	Pharmacy staff supplying patient's medicines for FOC schemes	Medicines Safety Committee.	Ongoing

References

NHS England » Free of charge (FOC) medicines schemes – national policy recommendations for local systems November 2023

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Tania Carruthers (Director of Pharmacy)
Heather Perry (Lead pharmacist WRH)
Gurminder Bhogal (Lead pharmacist AH)
Karen McCredie (Directorate Manager Haem/ Onc)
Dr Shafeek (Consultant Haematologist)
Dr Mills (Consultant Haematologist)
Dr Pemberton (Consultant Haematologist)
Dr Murukesh (Consultant Oncologist)
Dr Kurec (Consultant Oncologist)
Samantha Toland (Lead chemotherapy nurse)
Gaynor Jenkins (Deputy Directorate Manager)

This key document has been circulated to the chair(s) of the following committees / groups for comments;

Committee
Chemotherapy Action Group Haematology Governance and Oncology Governance
Medicines Safety Committee

Supporting Document 1 - Equality Impact Assessment Tool

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	x	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	**Stephanie Cook**

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Stephanie Cook	**Lead Pharmacist**	**Stephanie.cook5@nhs.net**
Date assessment completed	**4th June 2024**		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title: GUIDELINE FOR MANAGEMENT OF FREE OF CHARGE MEDICINES SCHEMES FOR NHSE COMMISSIONED MEDICINES**			
What is the aim, purpose and/or intended outcomes of this Activity?	To have a risk managed patient- centred, evidence-based approach to the management of free of charge schemes to improve patient outcomes.			
Who will be affected by the development & implementation of this activity?	❑ X❑ ❑ ❑	Service User Patient Carers Visitors	❑ ❑ ❑ ❑	Staff Communities Other _____

Is this:	X❑ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	National guidance from NHSE
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Cancer Services team including clinicians, nurses and directorate managers.
Summary of relevant findings	Local policy needed to support update of national policy.

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		x		Schemes are available to all who have a specific malignancy.
Disability		x		Schemes are available to all who have a specific malignancy.
Gender Reassignment		x		Schemes are available to all who have a specific malignancy.
Marriage & Civil Partnerships		x		Schemes are available to all who have a specific malignancy.
Pregnancy & Maternity		x		Schemes are available to all who have a specific malignancy although the pregnant patients due to risk benefit may not be eligible to schemes.
Race including Traveling Communities		x		Schemes are available to all who have a specific malignancy.
Religion & Belief		x		Schemes are available to all who have a specific malignancy.
Sex		x		Schemes are available to all who have a specific malignancy.
Sexual Orientation		x		Schemes are available to all who have a specific malignancy.
Other Vulnerable and Disadvantaged		x		Schemes are available to all who have a specific malignancy.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)				
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)				Schemes are available to all who have a specific malignancy.

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	N/A	.		
How will you monitor these actions?	N/A			
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	N/A			

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Stephanie Cook
Date signed	04/06/2024
Comments:	
Signature of person the Leader Person for this activity	Stephanie Cook
Date signed	04/06/2024
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

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

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.

Appendix 1 Assessment and application for Free of Charge Stock Scheme

This risk assessment form is to be used in conjunction with the Trust Guideline on Free of Charge (FOC) Medicines Schemes. To be completed by the Requesting Clinician in conjunction with Specialist Clinical Pharmacist and submitted for approval with an MOU.

Medicine Name (including brand and generic name)	
Preparation details e.g. tablet/infusion	
Pharmaceutical company	
UK licensed status	
Clinical Indication	
Line of therapy and where would this medicine fit within the current treatment pathway?	
Regimen (i.e. dose, route, duration and frequency, number of cycles. Include all anticancer medicines and supportive care medication used in combination with FOC medicine)	
Summarise the efficacy and safety of this medicine (include references)	
Is the medicine available via official MHRA EAMS? (Yes or No)	
Does the medicine have a positive NICE FAD? (Yes or No) If yes, see national policy recommendations.	
If the medicine has a positive NICE FAD, does the indication, dose, frequency described in the FOC scheme fall outside of NICE criteria? (Yes or No)	

Does the medicine have a PAS in place? (Yes or No) If yes, see national policy recommendations.	
Estimated number of anticipated patients per financial year	
Funding arrangements agreed with pharmaceutical company for existing patients if medicine gains NICE approval	
Funding arrangements agreed with pharmaceutical company for existing patients if medicine gains NICE approval but the patient does not fit the funding criteria	
Funding arrangements agreed with pharmaceutical company for existing patients if the medicine does not gain marketing authorisation / NICE approval	
What monitoring is required for patients on this medication?	
Trust activity – please detail number of attendances (outpatient, inpatient, follow-ups) required for the use of the medicine	
Any other information or supporting evidence (level of evidence, phase of trial, protocol etc.) Embed scheme details	
Minimum dataset required by the company to administer the FOC scheme	
Please give your reasons why you think this should be approved?	

Applicant Details and Declaration

Name		
Job Title		
Signature of Applicant	Signature……	Date……
Name and signature of directorate lead (if required)	Name:…… Signature:……	Date……
Name and signature of clinical pharmacist	Name:…… Signature:……	Date……
Approval of Lead Consultant (must not be requesting consultant)	Name:…… Signature:……	Date……
Approval of Director of Pharmacy	Name:…… Signature:……	Date……

Appendix 2 Free of Charge (FOC) Supply – Request for approval sent to NHS England

Send completed form to england.WMSCPharmacy@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.
Completion of this form **does not** ensure future commissioning arrangements.

Trust Name	
Medicine Name – Approved (and generic / biosimilar – if known)	
Preparation (strength and formulation)	
Pharmaceutical 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 medicines and supportive care medication used in combination with FOC medicine	
Estimated number of anticipated patients per financial year	
Funding arrangements agreed with pharmaceutical company for existing patients if medicine gains NICE approval	
Funding arrangements agreed with pharmaceutical company for existing patients if medicine gains NICE approval but the	

patient does not fit the funding criteria			
Funding arrangements agreed with pharmaceutical company for existing patients if the medicine does not gain marketing authorisation / NICE approval			
Trust activity – please detail number of attendances (outpatient, inpatient, follow-ups) required for the use of the medicine			
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-1.0Final.docx

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 medicine 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 medicine is not likely.**
   f. **Patient numbers will not have an impact on activity and service capacity.**

There is a clear plan for continuation of treatment of patients on the FOC scheme when NICE guidance / marketing authorisation is issued.