Document Type:	Policy	
Reference Number : **2637**	Version Number: **1**	Next Review Date: **6 November 2023**
Title:	**Free of Charge Medicines Schemes**	
Document Author:	Specialist Pharmacist - High Cost Drugs	
Applicability:	As Defined In Document	

1. Introduction

1.1 A free of charge (FOC) medicines scheme is defined as an arrangement where a medicine is provided free of charge by the pharmaceutical company to an individual patient or an identified cohort of patients.

1.2 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

1.3 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.

1.4 These schemes have the potential to undermine the evidence based recommendations made by NICE or local commissioning organisations because they may alter existing treatment pathways.

1.5 The aim of this policy is to ensure the Trust has a consistent and equitable approach when considering FOC schemes

Scope

This policy excludes clinical trials, EAMS and compassionate use schemes.

2. Key considerations

2.1 Assessment process

The consultant should complete the request form below, which will be assessed by the Trust medicines approval committee (MAC)

2.2 Place in therapy

Treatments under the FOC scheme will only be agreed where there is a clear unmet clinical

need, i.e. the individual patient has failed all other existing NICE-approved options, or these other treatment options are inappropriate

2.3 NICE approval

2.3.1 FOC schemes will only be considered if the company has submitted the medicine and indication to NICE for review

2.3.2 The FOC scheme will not be considered if the current NICE appraisal consultation document (ACD) or final appraisal document (FAD) is negative

2.3.3 The FOC scheme will not be considered if it aims to provide treatment for a licensed indication that falls outside of existing NICE guidance, e.g. as a 1st line treatment when NICE only recommends it after other options have been tried

2.4 Financial Risks

2.4.1 The FOC scheme will only be agreed if the treatment remains free of charge until:

a) If NICE is positive: 90 days after NICE approval, or 30 days after NICE approval if drug was part of an EAMS scheme.

b) If NICE is negative, or the patients who started treatment under the FOC scheme don't meet the criteria under NICE: indefinitely, until the patient and clinician decide to stop treatment.

2.4.2 There may be additional costs associated with FOC drugs, eg

- Provider tariff activity costs, eg. admissions, extra outpatient appointments, follow up ratios, monitoring, treating adverse effects, day case appointments for administering an IV infusion.
- Staff costs.
- Equipment costs.
- Additional medicine costs if FOC medicine is used in combination with another (funded) treatment.

If the service is NHSE-commissioned, be aware that if NHSE do not approve the use of the FOC scheme, then all activity and costs associated with the scheme would be at trust risk if it was taken up.

The consultant will need to confirm that any additional costs have been agreed with the relevant service manager. Any expected increase in tariff activity should be agreed with the trust income team based in finance.

2.5 Patient consent

2.5.1 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.

2.5.2 The consultant will need to confirm that the patient understands that if the scheme ceases and no ongoing NHS funding is identified, their medicine will be stopped even if the patient perceives they have had benefit from treatment.

The consultant should consider asking the patient to sign a consent form to confirm they understand their treatment will be stopped if the scheme is no longer available.

2.6 Administrative burden

The scheme will only be agreed if any additional workload resulting from the administration of the scheme by the pharmacy/ clinical dept is minimal. This includes staff time needed for assessment of the scheme, ongoing management of the FOC scheme, and procurement of the drug which may require individual patient ordering, or rebate claim forms.

2.7 Equity

2.7.1 FOC schemes have the potential to introduce inequity of access to the medicine:

a) Inequity between patients started on a drug under the FOC scheme, and patients unable to access the same drug if the scheme is no longer available (eg in the event that NICE does not recommend the treatment).

b) Inequity if the FOC scheme is only offered to some NHS trusts in England.

c) Inequity if some Trusts sign up to a scheme but others decide not to.

2.7.2 Assurances should be obtained from the company that the same FOC scheme is being offered to all Trusts in England.

2.7.3 The relevant commissioner will be informed of all applications considered.

2.7.4 Where possible there should be a consistent position across all Trusts in Devon, in order to avoid the potential for postcode prescribing.

Ref:

Free of charge (FOC) medicines schemes: Advice ratified by the Regional Medicines Optimisation Committee for adoption as local policy version 3, Jan 2020
https://www.sps.nhs.uk/wp-content/uploads/2018/07/FOC-medicine-scheme-policy-v-3.0-Final.pdf

Free of charge scheme request form

Please submit form to the Medicines Approval Committee with a copy of the FOC scheme agreement

Section 1- To be completed by consultant:

Name of Requester	
Email address of requester	
Date request submitted	
Name of treatment	
Route of administration (eg oral/ IV etc)	
Indication	
Eligibility criteria for FOC scheme:	
Number of patients likely to be started on FOC medicine per year:	
Expected date of publication of NICE approval	
Existing alternative treatment options:	1.
	2.
	3.
	4.
	5.
Reason for requesting drug under FOC scheme: There is a clear unmet clinical need (e.g. the patient(s) have failed all other existing NICE-approved options, or these other treatment options are inappropriate)	Yes/ No
Please give any further details, e.g. proposed place in therapy/ characteristics of patients who may be suitable for treatment:	

Please confirm you will obtain patient consent to treatment under a FOC scheme	Yes/ No
Please confirm that you will ensure the patient understands that if the scheme ceases and no ongoing NHS funding is identified the treatment will cease, even if it is effective	Yes/ No
Please specify any additional drug/ non-drug costs incurred by this scheme (See section 2.4.2 of the policy)	
Please confirm that you have discussed the scheme with the relevant service manager, and Finance (income.sdhcft@nhs.net), and they have agreed that funding is available for any additional drug/ non-drug costs incurred by the scheme	Yes/No
	Please give further details:

Section 2- To be completed by pharmacy:

Name of treatment:	
FOC scheme available until (date):	
Date NICE guidance due:	
Has ACD or FAD been published?	Yes/ No
	Please provide further details:
If NICE is positive, confirm that the FOC drug will be available until 90 days after NICE approval (or 30 days after NICE approval if drug was part of an EAMs scheme)	Yes/ No
	Please provide further details:
If NICE is negative, or patients who started treatment under the FOC scheme don't meet the criteria under NICE, confirm that the drug will continue to be available FOC indefinitely	Yes/ No
	Please provide further details:
Does the scheme offer treatment for an indication that falls outside of existing NICE recommendations? eg as a 1st line treatment when NICE only recommends it 2nd line?	Yes/ No
	Please provide further details:
Who would be the commissioner for this drug?	NHSE/ CCG
Has the relevant commissioner been made aware of this scheme? Do they support its use?	Yes/No
	Please provide further details:
Supply Route	Homecare/ Outpatient pharmacy/ Inpatient pharmacy
Is there potential for additional drug costs if used in combination with another (funded) drug?	Yes/No
	If Yes, please provide further details:
Is there additional workload for pharmacy staff, eg. ordering stock for individual patients, claim forms etc? Please give details:	
Current position of other Trusts in Devon re. this FOC scheme:	

Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

Ref No:	2637		
Document title:	Free Of Charge Medicines Scheme		
Purpose of document:			
Date of issue:	6 November 2020	**Next review date:**	6 November 2023
Version:	1	**Last review date:**	
Author:	Specialist Pharmacist - High Cost Drugs		
Directorate:	Pharmacy		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Clinical Director of Pharmacy		
Date approved:	30 October 2020		
Links or overlaps with other policies:			

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes ☐	
	Please select *Yes*	*No*
Does this document have implications regarding the Care Act? *If yes please state:*	☐	☐
Does this document have training implications? *If yes please state:*	☐	☐
Does this document have financial implications? *If yes please state:*	☐	☐

Is this document a direct replacement for another? *If yes please state which documents are being replaced:*	☐	☐

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
6 November 2020	1	New	Clincal Director of Pharmacy

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on ICON.

https://icon.torbayandsouthdevon.nhs.uk/areas/mental-capacity-act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

NHS
Devon
Clinical Commissioning Group

NHS
Torbay and South Devon
NHS Foundation Trust

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)		**Version and Date**	
Policy Author			
An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.			
Who may be affected by this document?			
Patients/ Service Users ☐	Staff ☐	Other, please state…	☐
Could the policy treat people from protected groups less favourably than the general population? ***PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below***			
Age	Yes ☐ No☐	Gender Reassignment	Yes ☐ No☐
Race	Yes ☐ No☐	Disability	Yes ☐ No☐
Gender	Yes ☐ No☐	Pregnancy/Maternity	Yes ☐ No☐
Sexual Orientation	Yes ☐ No☐		
Religion/Belief (non)	Yes ☐ No☐		
Marriage/ Civil Partnership	Yes ☐ No☐		
Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population? (substance misuse; teenage mums; carers[1]; travellers[2]; homeless[3]; convictions; social isolation[4]; refugees)	Yes ☐ No☐		
Please provide details for each protected group where you have indicated 'Yes'.			
VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion			
Is inclusive language[5] used throughout?	Yes ☐ No☐ NA ☐		
Are the services outlined in the policy fully accessible[6]?	Yes ☐ No☐ NA ☐		
Does the policy encourage individualised and person-centred care?	Yes ☐ No☐ NA ☐		
Could there be an adverse impact on an individual's independence or autonomy[7]?	Yes ☐ No☐ NA ☐		
EXTERNAL FACTORS			
Is the policy a result of national legislation which cannot be modified in any way?	Yes ☐ No☐		
What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)			
Who was consulted when drafting this policy?			
Patients/ Service Users ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups)	☐
Staff ☐	General Public ☐	Other, please state…	☐
What were the recommendations/suggestions?			
Does this document require a service redesign or substantial amendments to an existing process? ***PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below***	Yes ☐ No☐		
ACTION PLAN: Please list all actions identified to address any impacts			
Action	**Person responsible**	**Completion date**	
AUTHORISATION: **By signing below, I confirm that the named person responsible above is aware of the actions assigned to them**			

Name of person completing the form		**Signature**	
Validated by (line manager)		**Signature**	

Please contact the Equalities team for guidance:
For Devon CCG, please email d-ccg.equalityanddiversity@nhs.net & d-ccg.QEIA@nhs.net
For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pfd.sdhct@nhs.net
This form should be published with the policy and a signed copy sent to your relevant organisation

Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user
[2] Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them
[3] Consider any provisions for those with no fixed abode, particularly relating to impact on discharge
[4] Consider how someone will be aware of (or access) a service if socially or geographically isolated
[5] Language must be relevant and appropriate, for example referring to partners, not husbands or wives
[6] Consider both physical access to services and how information/ communication in available in an accessible format
[7] Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy

Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes ☐ No ☐

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our GDPR page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our Data Protection site on the public internet.