CONTROLLED DOCUMENT

University Hospitals Birmingham
NHS Foundation Trust

Procedure for implementing a new compassionate use Scheme or free of charge (FOC) medicine in the Trust

CATEGORY:	Procedural Document
CLASSIFICATION:	Clinical
PURPOSE	• To ensure that the Trust complies with legislation regarding the prescribing, procurement, supply, dispensing and administration of unlicensed medicines. • The procedure is intended to satisfy the standards in the associated documentation.
Controlled Document Number:	1080
Version Number:	2.1
Controlled Document Sponsor:	Chief Pharmacist
Controlled Document Lead:	Principal Pharmacist Governance
Approved By:	Medicines Management Advisory Group
On:	May 2019
Review Date:	May 2021
Distribution: • **Essential Reading for:** • **Information for:**	All staff and their line managers involved with the prescribing, supply, receipt or administration of medication. All Pharmacy staff Associate Divisional Directors Associate Directors of Nursing Ward/Department Managers

Contents

1. STATEMENT

1.1 This document describes the Trust procedure for the prescribing, supply, dispensing and the administration of new compassionate use scheme or free of charge (FOC) medicines in the Trust.

1.2 In this document the term FOC medicines will be interchangeable with the term compassionate use scheme medicines.

1.3 FOC medicines are mostly classed as unlicensed medicines as the use of these medicines is prior to granted MHRA approval. Unlicensed medicines are only used when no pharmaceutically equivalent licensed product or suitable alternative licensed product is available for use at the time the patient requires it. All medicines used by the Trust must be supplied via the Trust Pharmacy (UHB in patient dispensary, QEHB Pharmacy or QEHB Discharge Pharmacy) or in accordance with this procedure.

2. SCOPE

2.1 This document covers the introduction of medicines into the Trust that will be supplied through FOC agreement to individual patients.

2.2 It applies to all staff within the Trust including substantive staff, students, locum and agency staff and all staff employed on honorary contracts, who are involved in prescribing, supply, dispensing and administration of FOC medicines.

2.3 Prescribers must give sufficient information to patients, whenever possible, for them to be aware that they are being prescribed a medicinal treatment in a FOC manner and to make an informed choice to consent.

3. INTRODUCTION

3.1 Medicines can be provided FOC to the Trust via three main different schemes:

3.1.1 Early Access to Medicines Schemes (EAMS) which are NHS England endorsed schemes to give patients faster access to promising medication.

3.1.2 Compassionate use scheme, whereby manufacturers run individual schemes to supply their medicines FOC to a specific group of patients who meet specific criteria.

3.1.3 Consultants approach pharmaceutical companies and request for drugs FOC medicines for an individual patient with unmet needs. The company will consider each individual case.

4. PROCEDURE

4.1 Requests for the medicine

Prescribers of FOC medicines carry their own responsibility and are professionally accountable for their actions and in the case of adverse events they may be called upon to justify their actions.

4.1.1 The request to use a FOC medicine must initially come from the consultant who wishes to use the medication. The following points must be addressed when liaising with requesting consultant to obtain the FOC medicine;

- Ensure that there is clinical justification for the use of the FOC medicine.

- Ensure that patient and/or carer(s) are informed that they have been prescribed an FOC medicine and the implications of using the FOC medicine; and always obtain written consent for this, see Appendix A. It must be documented in the patient's records that consent has been obtained.

- For all unlicensed products new to the Trust (or where unlicensed medicines are to be used outside any restriction previously imposed) ensure that the Risk Assessment and Approval Form for Unlicensed Medicines (Appendix B) is completed by the requesting consultant. The completed form must be forwarded by the Lead Pharmacist to the relevant divisional Medicines Management Expert Panel (MMEP) to be reviewed, including both Advanced Clinical Pharmacist – Medicines Management and the requesting consultant.

- Ensure that incidents relating to the use of FOC medicines (actual events or near-misses) are reported through the Trust incident reporting scheme. Any adverse reactions must also be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card scheme.

4.1.2 The request must be made on a DRUG APPLICATION FORM (Free of Charge drug), see Appendix C and forward to the relevant Lead Pharmacist within the speciality. The Lead Pharmacist shall review the document and confirm all sections are completed correctly.

4.1.3 The completed form must be forwarded by the Lead Pharmacist to the relevant divisional MMEP to be reviewed as per Trust 'Procedure for the introduction of New Drugs or Formulary changes', including both Advanced Clinical Pharmacist – Medicines Management and the requesting consultant in to all correspondence.

4.1.4 The request will be discussed at the divisional MMEP meeting prior to the drug being used. If the clinician requests to use the drug before the next meeting date, they must complete a Chairman's Action (CMA) form and obtain approval for use by the Chair of Medicines Management Advisory Group (MMAG), Divisional Finance Lead, and Divisional Director. The Advanced Clinical Pharmacist – Medicines Management and requesting consultant should also be copied into all correspondence.

4.1.5 The Lead Pharmacist must have both clinical information on the FOC agreement and information on how to order both the initial supply of drug and ongoing treatment. This information must be requested from the supplying pharmaceutical company. All relevant documents must be saved in the pharmacy common folder.

4.1.6 It is imperative that there is written confirmation from the drug company that the drug will be provided FOC for as long as the patient requires therapy, irrespective of the funding arrangements once the scheme closes. This agreement should be saved in the pharmacy common folder.

4.1.7 Once the drug has been approved for use, email a request for pharmacy files to be set up on SAGE, ASCRIBE and Analyst by the pharmacy buying office, using the form in Appendix D. The form must clearly state that the medicine is supplied under is a 'FOC Scheme' in Analysis A. Copy the relevant dispensary manager(s) into any correspondence regarding orders where the drug will be dispensed.

4.2 Ordering the medicine

4.1.8 The Lead Pharmacist(s) are responsible for ordering all FOC medicines through pharmacy. Clinicians are not permitted to order the drug from the company directly. The relevant dispensary manager(s) must be copied into all correspondence regarding FOC medicine orders.

4.1.9 The ordering process for all FOC medicines are different however there is usually a form to register the patient, which

requires delivery details. All deliveries must be made to Pharmacy Stores at Melchett Road, unless stated differently by the Lead Pharmacist.

4.1.10 Lead Pharmacist(s) are responsible for ordering FOC medicines from the pharmaceutical company, via the Buying Office, as patients details are often required. Buying Office purchase order number (PON) must be obtained before orders are placed with the pharmaceutical company and the PON must be included on the delivery note from the company.

4.1.11 The Lead Pharmacists are responsible for the management of ongoing orders for individual patients, including submission of individual order forms, to ensure that orders are completed in a timely manner for continuation of treatment.

4.1.12 Copy the relevant dispensary manager(s) into any correspondence about orders where the drug will be dispensed.

5. RESPONSIBILITIES OF CLINICAL PHARMACISTS OR SPECIALITY LEAD PHARMACISTS

5.1 When an FOC medicine is to be ordered for the first time or is to be used outside terms previously authorised under this procedure, there is a need for critical, evidence based evaluation for its use by the Lead Pharmacist within the clinical area.

5.2 Ensure that requests for new FOC medicines are presented to the Divisional Medicines Management Expert Panel (MMEP) for approval as per Trust **'**Procedure for the Introduction of New Drugs or Formulary Changes'.

5.3 Ensure that prescribers are aware of the licensing status of the product for both unlicensed and licensed medicines. Where possible a licensed alternative product should be recommended where appropriate.

5.4 Ensure that the use of an FOC medicine is clinically justified and the dose, frequency and route of administration are correct.

6. ADVERSE DRUG REACTIONS AND DEFECTIVE MEDICINES;

6.1 Adverse drug reactions and defective products must be handled and reported in the same way as commercial medicines. Healthcare professionals must report serious adverse drug reactions to the MHRA using the Yellow Card scheme

6.2 Suspected defects in FOC medicines must be reported to the Pharmacy Department or the on-call pharmacist (out of hours) who will

report them to the Principal Pharmacist for Governance. The Principal Pharmacist for Governance will inform the Pharmacy Quality Assurance Manager who will subsequently report the defect using the Regional Drug Defect Reporting Procedure. The Buying Office will report to the pharmaceutical company.

7. RECORDS

7.1 All FOC medicines orders must be recorded in the relevant pharmacy common folder by the Lead pharmacists. It is the Lead Pharmacists responsibility to ensure records are maintained.

7.2 Records should facilitate tracking all FOC schemes.

7.3 As a minimum the following should be recorded;

Drug	
Indication	
Presentation	
Type of scheme e.g. compassionate use, EAMs	
Consultant	
FOC form completed	
Tabled/discussed at MMEP or CMA completed	
Approved for use?	
New Drug Files Requested	
PIP	
Ordering information	
Comments and any other info	

7.4 Individual patients' entries must be completed with dates of when a drug is required to be ordered next.

Appendix A

Enter Drug Name Patient Access Scheme Consent Form

I understand that I will be offered drug name on an individual named patient basis in accordance to the terms agreed by drug company name and University Hospitals Birmingham NHS Foundation Trust.

I understand that this medication will be made available free of cost for an as yet undisclosed period of time, and that there is no guarantee that I will continue to receive this medication when the period of free provision ends. The period of time will be as per the terms agreed with the company.

I understand that this medicine has not yet been approved by the National Institute for Health and Care Excellence (NICE) and accept that it may not be approved for use in the NHS in the future and as a result may potentially become unavailable for my use.

I understand that I need to comply with all assessment and monitoring prior to starting the drug and subsequent follow-up monitoring. I understand that the monitoring for this medication will take place at University Hospitals Birmingham.

Patient Name: …… Patient HN: ……
Patient Signature: …….. Date: …….
Patient Carer (if Under 18): ……..

PRESCRIBING CONSULTANT:……
SIGNATURE …….. Date …….

Appendix B

Risk Assessment and Approval Form for Unlicensed Medicines

This form should be completed by the prescriber in conjunction with a Clinical Pharmacist. This form must be completed and authorised by MMEP and MMAG prior to approval for purchase of a new unlicensed medicine or an unlicensed medicine to be used outside restrictions currently imposed on its use by the Trust.

Obtain copy of New Drug Request Form in the case of medication new to the Trust and complete with this form

Unlicensed Medicine Details

Product Name (International Non Proprietary Name)	
Proprietary name (if known)	
Pharmaceutical form	
Strength	
Manufacturer (if known)	

Why is an unlicensed medicine being considered?

1.	Pharmaceutically equivalent licensed product temporarily unavailable (Manufacturer Can't Supply (MCS))*
2.	Equivalent UK licensed product unavailable / unsuitable because*
3.	Other* Give details * delete as appropriate

Clinical Information

Is the product to be used for a single patient only? **Yes / No** If yes, provide patient's name and registration no.	Patient's name: Patient's reg. number:
Is the product for corporate use? **Yes / No** If no, provide details of which Division/s may prescribe.	Division/s:
Is the product to be restricted to prescription in a particular speciality/ies? **Yes / No**	Speciality/ies:
Further Restrictions (if applicable):	
Indication	Dose
Frequency	Route

Duration of Treatment	How will patient obtain future supplies?
Who will prescribe the medication? (designation not name)	

Purchasing

For Logistics Medicines Buying Office Use Only: Where is the medicine to be obtained from? What is the cost of the product?	
Is there a specification available already?	Yes / No
Is a Certificate of Analysis / Conformance available? state which	Yes / No
Is the supplier an approved supplier of unlicensed medicines for the Trust? See Approved Unlicensed Medicine Supplier list	Yes / No
Is the manufacturer in the UK?	Yes / No
If no, complete the following questions prior to purchase: Which country will the product be obtained from? What is the quoted importation time?	
Completed by: ……	

Outcome of Risk Assessment and Approval to Purchase

New Product Requests (not required for MCS):

Clinical Pharmacist's name ……..…
Consultant's name: …… **Speciality**: ……
I have read UHB Procedures for Unlicensed Medicines and I understand that the product is unlicensed. I understand that the responsibility for the use of this product in the treatment of the named patient/ group of patients* lies with myself. (*delete as applicable)

Signed: …… (Consultant) Date: ……..……

Medicines Management Expert Panel approval for use? Yes / No
If no, give
reasons……..……..…
Name (Divisional MMEP Chair):……
Signed:……..) Date: ……

For All Unlicensed Product Requests:
Form submitted to MMAG by:……
(Pharmacy Governance Lead/Advanced Clinical Pharmacist for Medicines Management)
Outcome of Risk Assessment:

Medicines Management Advisory Group (MMAG) approval for use? Yes / No
If no, give
reasons…….
Are there any restrictions on prescribing and use? Yes/No
If yes, please state:…..……..……..……
Review Date: …… (please complete or product will be ordered indefinitely)
Name(Chairman of MMAG):……

Signed:…… Date: ……

Appendix C

DRUG APPLICATION FORM (Free of Charge (FOC) drug)

All essential information, such as medicines information documents, in support of this application must be attached to this application form with full references provided electronically where needed.

To be submitted to MMAG.
E-mail completed forms to MMAG@uhb.nhs.uk and divisional pharmacy representative prior to applying via the Chairman's Action process.

Section 1: Information on the Medicinal Product	
a) Brand/generic name	
b) Pharmaceutical form	
c) Strength	
d) Administration route	
e) Dosage/ frequency	
f) Course length, if applicable	
g) Manufacturer, if applicable	
h) BNF section number, if applicable	
i) Licensed indication for use , in the UK	
j) Proposed indication for use and dose (if different from license)	
K) Is this Free Of Charge or Commercial stock to be supplied to the Trust?	
L) What is the duration of supply agreed by the pharmaceutical company?	

Section 2: Evidence of Comparative Safety & Use	
a) How does the safety of this proposed drug compare to treatment options currently in use?	
b) What concerns are there over the safety of this product? List the principal/ significant concerns for each part below:	
i) Adverse effects	
ii) Cautions	
iii) Contra-indications	
iv) Drug interactions	
v) Toxicity e.g. narrow therapeutic index	
vi) Potential for misuse	
c) Please detail any specific pre-treatment requirements (e.g. baseline LFT)	
i) What are the monitoring requirements?	
d) How and when would you propose to audit/monitor use of the new therapy?	

e) Who will be responsible for monitoring?	
f) Would you recommend any prescribing restrictions	
g) Has a risk assessment been completed if this agent is a new Monoclonal Antibody?	
h) Will the drug complement existing treatments? If yes, give details	
i) Please detail any relevant safety concerns in relation to storage/prescribing/preparation/ use/administration/disposal	

Section 3: Additional Information	
a) Any additional information relating to the application- for example additional costs involved in providing this treatment from monitoring, extra clinic time or Pharmacy Lab constitution?	
b) Estimated number of patients to be treated when this drug becomes licensed and commissioned?	

Section 4: Application Sponsor
By signing this application you are confirming that:
a) You have agreement from Consultants within your directorate (and if appropriate other directorates who may have an interest in using this product) regarding the proposed place in the treatment pathway of this product as well any proposal you may have made to replace any existing product. b) Your Clinical Director, and/ Directorate Pharmacist support the proposed clinical benefit of this preparation. c) The information supplied is correct to the best of your knowledge at the time of submission.

Section 5: Application details and declaration	
To avoid any concern that commercial interests might have influenced your request to the Committee, you must indicate if you have an interest that may influence, or be perceived to influence, your request.	
c) Do you have any conflict of interest to declare? *Examples include:* *- Consultancy with the drug company;* *- Department receives research funds from the drug company;*	No Yes - Please give details:

- Staff within the department are funded by the drug company; *- You or your staff receive funding for attendance at scientific meetings from this company.*	

Applicants Details / Counter-signatory Details	
Name of requesting Clinician:	
Job title:	
Department / Specialty:	
Work base:	
Signature:	
Date:	

Appendix D

UHB LOGISTICS

NEW MEDICINE REQUEST FORM

REQUESTER OF NEW MEDICINE TO COMPLETE PART 1 AND RETURN TO MEDICINES BUYING OFFICE.

New medicines for use in UHB NHS Foundation Trust must have been authorised by a clinical Pharmacist-medicines management prior to purchase

PART 1	
Requester Name:	
Job Title:	
Organisation:	
Department:	
Contact Tel. Number:	
Full Product Description:	
Brand (if appropriate)	
Pip Code:	
Pack Size:	
Dose:	
Strength:	
Quantity Required (in packs)	
Site required: When required	
Any further information:	

PART 2	
For Medicines Buying Office	
Ordered from (Supplier)	
Order Number:	
Expected Delivery Date/Time	
Any further information:	
Completed by:	
Date:	