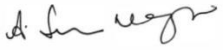
University Hospitals of Derby and Burton
NHS Foundation Trust

TRUST POLICY FOR MEDICINES FORMULARY, COMMISSIONING AND CONTRACT

Reference Number	**Version:** **5**		**Status:** **Final**	**Author:** Esther Kirk **Job Title:** Lead Pharmacist
Version / Amendment History	Version	Date	Author	Reason
	5	2023	E Kirk	Updated concession form. Updated CCG to ICB Updated new medicine form to include homecare. Amendments to reflect new commissioning arrangements. Updated NHSE IFR process
Intended Recipients: All wards and departments				
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 on Koha				
To be read in conjunction with: Trust Policy for Medicines Management, Trust Prescribing Policy, Trust Homecare Policy and Trust Unlicensed Medicines Policy.				
In consultation with and Date: Drugs and Therapeutics Committee / July 2023				
EIRA stage One Completed Yes *June 2008* stage Two Completed No				
Approving Body and Date Approved			Trust Delivery Group - 31 July 2023	
Date of Issue			July 2023	
Review Date and Frequency			July 2026 (every three years)	
Contact for Review			Chief Pharmacist or Lead Pharmacist – Commissioning	
Executive Lead Signature			 Dr Sreeman Andole, Interim Executive Medical Director	

Contents

1. Introduction

This Policy describes the broad strategy for the safe, clinical and cost-effective prescribing of medicines in the University Hospitals of Derby and Burton NHS Foundation Trust (the Trust), together with policies and procedures for formulary management.

The introduction and use of new medicines within the Trust must be undertaken in a proactive, planned way. All prescribers should familiarise themselves with this Policy to ensure clinical and financial governance and to safeguard the quality of patient care. Where these assurances cannot be given then the medicine must not be prescribed and the pharmacy department is not authorised to obtain the medicine.

Policies and procedures for the safe prescribing and administration of medicines are found in the Trust Policy for Medicines Management, which can be accessed via Trust Policies Procedures & Guidelines catalog (koha-ptfs.co.uk).

2. Purpose and Outcomes

a. Medicines Management Strategy

Clinical Governance requires the Trust to have robust systems for researching, assessing, implementing and monitoring the introduction of new medicines. The Drugs and Therapeutics Group (D&T) is required to demonstrate both clinical and financial assurances for these processes and reports to the Clinical Effectiveness Group and is accountable to the Trust Quality Governance Steering Group.

b. Purpose

The overall remit of D&T is to promote and ensure SAFE (minimising risk from adverse drug events, medication errors and drug omissions), EFFECTIVE (promoting best practice and evidence-based decision support) and APPROPRIATE (cost effective, rational and timely) medicines therapy in all five sites of the Trust.

3. Definitions Used

Most definitions are included within the body of text. Common terms used throughout the document include:

- Formulary – evidence based, agreed list of medicines available for prescribing, which represents a safe, clinical and cost-effective choice for patients
- Tariff – medicines included within the national reference costs under Payment by Results (PbR)
- Tariff-excluded medicines (generally high cost and low volume medicines) which are excluded from the national tariff and commissioned locally.

4. Key Responsibilities / Duties

a. Drugs and Therapeutics Committee (D&T)

D&T oversees the introduction, prescribing and therapeutic monitoring of new medicines and clinical guidelines involving medicines, in conjunction with other Trust groups and committees. D&T works closely with the Derbyshire Joint Area Prescribing Committee (JAPC) to maintain a joint formulary of appropriate, evidence-based medicines and shared-care guidelines. D&T publishes a regular newsletter and maintains the hospital formulary and Medicines Management pages on the on the Trust Intranet.

5. Prescribing Policy Details

a. Legislation and Local Standards

Prescribing of medicines is governed by the Medicines Act and for Controlled Drugs by the Misuse of Drugs Act and Misuse of Drugs Regulations. In addition, the Department of Health (DoH), Royal Colleges and Professional bodies and regulatory organisations provide leadership and good practice guidance on prescribing and the safe use of medicines.

The Trust publishes a prescribing formulary in conjunction with the Derbyshire JAPC, which lists the medicines that are available for prescribing. A traffic light system is used to assign classifications to medicines providing assistance to clinicians in making decisions about the medicines and some medical devices they should prescribe. The Derbyshire JAPC traffic light system is divided into five categories:

GREEN:	Medicines or medical devices regarded as suitable for primary care prescribing
AMBER:	Medicines or medical devices that are initiated in secondary care or other specialist settings but are suitable for GPs to continue on-going prescribing under a shared care protocol, once the patient has been stabilized or dose predictable
RED:	Medicines or medical devices considered suitable for a consultant or specialist, usually within a secondary or tertiary care service, to initiate and continue prescribing
GREY:	Medicines or medical devices not recommended for use except in exceptional circumstances

Do Not Prescribe (DNP):	Medicines or medical devices not recommended or commissioned *(clinicians should submit an individual funding request, and await a positive outcome, before initiation of treatment for a DNP medicine/treatment/medical device for NHS prescribing)*

b. Clinical and Cost-effective Prescribing

Only medicines that are considered to be clinically appropriate and cost- effective are included within the formulary. D&T reviews published evidence, along with guidance from national advisory groups such as the National Institute of Clinical Excellence (NICE) when horizon scanning new medicines and in response to requests from clinicians to introduce new medicines.

c. Prescribing Specification

The JAPC publish a prescribing specification which outlines the contractual standards that Trusts are expected to comply with for the safe, clinical- and cost-effective use of medicines. Good communication with patients, carers and GPs, underpins all prescribing decisions, and transfers of care, and this is emphasised throughout the prescribing specification and Trust Prescribing Policy.

d. Rational Decision Making

The NHS Constitution confirms that patients have the 'right to expect local decisions about the funding of medicines and treatments to be made rationally following a proper consideration of the evidence' [1]. This relies on effective collaborative working across primary and secondary care to ensure that decision making policy and procedures are consistent, robust and transparent and that decisions about funding medicines are not taken in isolation.

Decisions about the use of medicines are therefore subject to agreement with JAPC, where these impact on GP prescribers. Under Payment by Results (PbR) most medicines are included within national tariff, but some specialist and high-cost medicines are excluded from the national tariff and are funded directly by either Integrated Care System (ICS) or NHS England.

NHS Trusts are required to operate within existing budgets, and ensuring cost effective use of medicines is a high priority, particularly in the current economic climate when the NHS faces a significant quality and productivity challenge to ensure that patients receive 'best care at best value'.

Decisions to introduce new medicines and manage existing prescribing costs are therefore subject to challenge not only on grounds of clinical and cost- effectiveness but also affordability.

e. NICE Guidance

NICE was set up in 1999 to reduce variation in the availability and quality of NHS treatments and care. NICE publishes evidence-based clinical guidelines, Technology Appraisals (TAs) for medicines and interventional procedures, and quality standards for use by the NHS.

NHS providers have a statutory responsibility to ensure availability of treatment recommended by a NICE TA no later than 90 calendar days (30 calendar days for EAMS products or for products appraised via the Fast Track Appraisal process) after the guidance is published, unless otherwise specified in the guidance. The majority of TAs refer to high cost, tariff-excluded medicines.

Following publication of Innovation, Health and Wealth[2] in 2011, the DoH have confirmed that all NICE technology appraisal recommendations are incorporated automatically into relevant local NHS formularies in a planned way that supports safe and appropriate clinical practice'. JAPC and the D&T work collaboratively to ensure formularies reflect NICE TAs and clinicians should offer NICE approved therapies where patients meet the inclusion criteria in accordance with good practice guidance[2].

f. Commissioning

A number of high cost drugs, devices, procedures and products have been excluded from the scope of the national tariff of payment by results. Following the re-organisation of the NHS these drugs are commissioned by:

- NHS England
- Integrated Care Board (ICB)

A list of Derby & Derbyshire ICB commissioned medications can be found here. NHS England commissioned medications can be found here. NHS England is the responsible commissioner for the management of the Cancer Drugs Fund (CDF); for details of the CDF click here.

In March 2020 all NHS Trusts moved from pass-through payments to block contracts as part of the NHS response to COVID-19. This simplified basis of contracting for the duration of the crisis ensured NHS organisations had sufficient funds to respond to the crisis. NHS trusts continue to receive block contract payments from commissioners (ICB, NHS England) for 23/24 for high-cost drugs, devices, procedures and products. There are some exceptions for specific NHS England commissioned drugs which are funded on a cost and volume basis. It is anticipated that there will be further changes to the commissioning arrangements for high-cost drugs as the NHS continues to recover from the COVID-19 pandemic. The impact of any such future change will be discussed at the Trust's Drugs and Therapeutics Committee once arrangements are confirmed.

Clinicians are required to abide by the agreed commissioning policies set out by either set of commissioners. Inappropriate or unauthorised prescribing is a significant financial risk for the Trust; only medicines and regimens that have been explicitly approved by D&T may be prescribed.

g. Compliance Monitoring

Tariff-excluded medicines are subject to scrutiny to ensure that they are being prescribed only according to strict commissioning policies and NICE guidelines. For specific medicines the Trust is required to keep patient level records to audit compliance and guarantee payment for expensive therapies. To facilitate this, the D&T finance sub-group regularly report patient level data to Derby & Derbyshire ICB and NHS England to provide assurances on compliance with agreed commissioning pathways. Certain non-tariff medication requires prior approval (using the BlueTeq system) by the commissioners before usage. An approved BlueTeq code is required by pharmacy before supply can be made. D&T also require evidence of compliance to assure the Trust that medicines are used clinically and cost-effectively and that patients have access to 'best care at best value' within available resources.

Prescribing concerns are submitted to a secure platform via an e-form on the Trust internet. These prescribing concerns are reviewed on a quarterly basis at D&T and actioned accordingly.

h. Concession

Occasionally formulary medicines will be unsuitable for use due to patient-specific factors such as intolerance or adverse drug events. In these circumstances a non-formulary medicine may be requested to meet the clinical needs of a specific patient.

Requests to use non-formulary medicines that are funded in Tariff (Trust- funded) require a completed Trust concession form (see Appendix 2). Requests to use tariff- excluded medicines outside of commissioned indications are referred to the ICB or NHS England for consideration for an individually funded request (IFR). All requests for non-formulary medicines must be triaged by D&T irrespective of how they are funded.

Concession requests can ONLY be made for Tariff (Trust) funded non-formulary medicines and cannot be transferred to another clinician or GP. Medicines prescribed under concession are for a specific named patient and can ONLY be obtained through the Hospital Pharmacy, at Trust expense.

Concession requests will be reviewed by the Lead Commissioning Pharmacist for safety and efficacy and must be approved by the relevant division budget holders before they are dispensed by Pharmacy. After three concessional uses of a particular medication have been approved, D&T will request the relevant specialty submit an application for introduction to the hospital formulary. D&T will review published evidence to confirm clinical appropriateness and cost-effectiveness and will consider whether the treatment should be added to the Trust formulary.

Rarely, non-formulary or unlicensed medicines, which are tariff-excluded, and do not meet the requirements of commissioned policy or an IFR application is rejected, are required to meet the urgent clinical needs of a patient. In this situation the Trust may agree to support treatment at hospital expense, on a case by case basis, as long as this has received funding approval by the division, and has been authorised by the Chair of D&T or Medical Director.

i. Individual Funding Requests

Individual Funding Requests (IFR) are required where the lCB or NHS England has no commissioned policy for the condition or the request for treatment falls outside the treatment parameters or commissioned service levels.

The Policy is NOT a means of introducing new medicines, which must be weighed up against other developments as part of the local operational plan within the annual operating framework. All IFR requests must be submitted to D&T for review, before being submitted to the relevant commissioner IFR panel. The Medical Director has delegated responsibility for approval of IFR applications to the Chair of D&T.

Clinicians who are considering treatment of a patient outside commissioned policy are advised to discuss this at the earliest opportunity with their Divisional Lead Pharmacist or a member of D&T. Guidance for clinicians wishing to submit an IFR application to the ICB or NHS England is available:

- Derby & Derbyshire ICB – Guidance notes for clinicians
- NHS England – Commissioning Policy: Individual Funding Requests

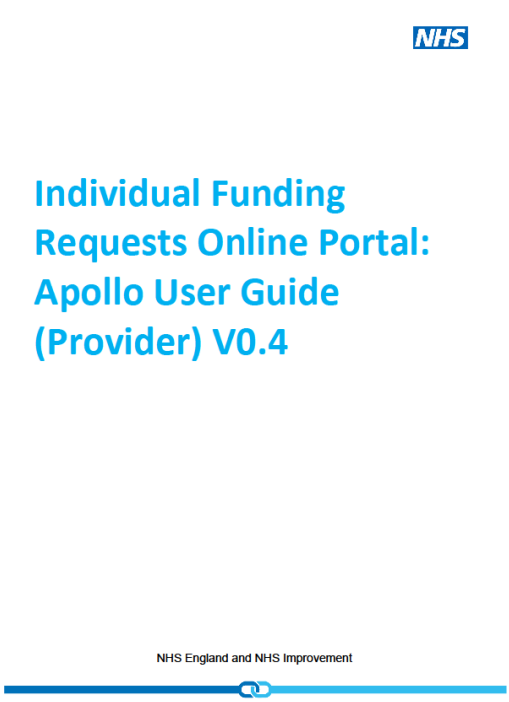
Where there is no commissioned policy, IFR must demonstrate either that the condition being treated is very rare with no more than 1-2 new patients per million per year likely to benefit and the total number of patients receiving the intervention for the condition (at the same stage of progression) is less than 10 per million at any one time (40 people across the East Midlands).

Where there is a commissioned policy, the IFR must demonstrate that the patient is exceptional, whilst taking into account national standards and patient choice. This requires that there are clinical features of the patient's case which makes them significantly different to the general population of patients with the condition in question AND that the patient is likely to gain significantly more clinical benefit from the requested intervention than might be normally expected for the general population of patients with the same condition and stage of progression.

The fact that a patient has failed to respond to, or is unable to be provided with, all treatment options available for a particular condition (either because of a co-morbidity or because the patient cannot tolerate the side effects of the usual treatment) is unlikely, on its own, to be sufficient to demonstrate exceptional clinical circumstances. There are common co-morbidities for many conditions.

Many conditions are progressive and thus inevitably there will be a more severe form of the condition – severity of a patient's condition does not in itself usually indicate exceptionality. Many treatments have side effects or contraindications, and thus intolerance or contraindication of a treatment does not in itself, usually indicate exceptionality.

A new electronic portal called Apollo is now used to submit IFR's to NHS England. Below are links to the Apollo user guide and FAQ documents which will help guide clinicians through the process of completing an IFR application. Once completed this will then need to be discussed and approved at D & T and signed by the Chair of D &T before it is submitted for review by NHS England.



NHS

Individual Funding Requests Online Portal: Apollo User Guide (Provider) V0.4

NHS England and NHS Improvement

Q1: What can I use the online portal for?
Clinicians at your Trust will be able to:

- register with the onlWho ine portal and create IFR applications. This will replace the Word document and email process;
- start, pause and stop the form at any point during completion;
- upload supporting documents to the online portal, there will be no need to email them separately;
- view the completed application at any time through the online portal.

Authorisers at your Trust will be able to:

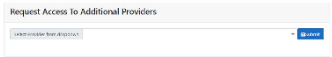
- register with the online portal and review applications before authorising;
- return the application to the clinician for review/further information before submitting to the NHS England IFR team;
- submit the application through the online portal, there will be no need to email the NHS England IFR team separately.

Q2a: Who needs to register to use the portal?
Clinicians at your Trust who will be submitting, or contributing to, IFR applications. Staff at your Trust who will be Authorisers. Anyone within your Trust who contributes to an IFR application will need to be registered with the portal.

Q2b: What do I need to register and how long does it take?
You only need your secure email, name, a password, your Trust and whether you require 'authoriser' access (see Q3a). Approval of registrations is carried out by the IFR team and takes place Monday to Friday, 9am to 5pm. If you register outside these days/times the approval will take place the next working day.

Q2c: I work across different Trusts, can I be registered at each Trust and how do I swich between them? *NEW*
Yes, this function is now available in Apollo. When you login to Apollo the Trust that you are currently registered for will show in the blue bar at the top of the screen:

If you click on the Trust name (displayed in the red box above) this will take you to a new screen where you can request to add a Trust:



Once you have selected the Trust click the 'submit' button. The IFR Team will be checking this section on a daily basis and once it has been approved you will receive an automated email which also explains how to switch between Trusts.

To switch between Trusts you click on the Trust name (displayed in the red box above) which will take you to this screen:

5.1 Private Prescribing

A private prescribing Policy is currently under development at the Trust. If any private prescribing queries arise before this Policy is available, please direct to the Trust's Drugs and Therapeutic Committee for discussion.

6. Introducing new medicines to the Formulary

New medicines will only be introduced to the formulary where they offer evidence-based clinical benefits over existing therapies and meet other clinical and financial governance for cost-effective and rational prescribing. Only medicines that have been approved for use by D&T or JAPC may be prescribed in the Trust.

a. New Medicine Request Form (Appendix 1)

All requests for new medicines should be made via a Division Lead Pharmacist or the secretary of D&T. All requests will require completion and submission of the D&T New Medicine Request Form together with supportive evidence. Requests will receive independent review prior to review by D&T.

b. Evidence Based Review

An evidence-based review of the new medicine will be provided by a member of the pharmacy department. This will include the following:

Introduction	provides background t o the request; information on mechanism of action; doses etc
Clinical evidence	summarises the major trial evidence, including where relevant methodology, participants (e.g. numbers completing, lost to follow up etc), comparison groups, outcomes and any relevant comments
Adverse effects	cautions / contra-indications / interactions as appropriate
Place in therapy	recommendations should be based on the evidence
Other issues	for discussion / attention of the committee
Cost	comparison / implications: using hospital discounted costs as well as BNF / Drug Tariff prices
References	list supporting references

c. Documentation

Evaluations will generally be around two pages in length and will follow a standard template. All evaluations should be dated. Where appropriate evaluations published from other evidence-based sources e.g. NICE, SPS, SMC, DTB, MTRAC etc. will be used.

d. Criteria for inclusion of studies in evaluations

The best available published evidence should be used. Randomised controlled trials (RCT) and systematic reviews are generally considered to be gold standard evidence. Abstracts and conference reports are not usually of sufficient quality to be included as they are not peer-reviewed.

e. Assessment of the methodological quality of trials

Evidence is classified according to the following levels:

Ia Evidence obtained from a meta-analysis of RCTs/a single good quality RCT
Ib Evidence obtained from at least one RCT (usually small RCTs)
IIa Evidence obtained from at least one well-designed controlled study without randomisation
IIb Evidence obtained from at least one other type of well-designed quasi- experimental study (e.g. historical controls)
III Evidence obtained from well-designed non-experimental descriptive studies e.g. trials without controls, case series, cross-sectional studies
IV Evidence obtained from expert committee reports or opinions and / or clinical experience of respected authorities

Grade of recommendation:

A requires at least one RCT as part of literature of overall good quality and consistency (Evidence levels Ia, Ib)

B requires the availability of well-conducted clinical studies but no RCTs (Evidence levels IIa, IIb, III)

C requires evidence obtained from expert committee reports or opinions and / or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (Evidence level IV)

7. Prescribing for Hospital In-Patients

Only medicines that have been approved for use and are listed in the Trust Hospital Formulary may be routinely prescribed, using approved prescription charts or electronic prescribing systems. Formulary medicines should be prescribed in accordance with approved Trust-wide or local clinical guidelines available on the Trust Intranet.

Where a Consultant wishes to prescribe a medicine that is not included in the Trust Formulary, the following criteria must be met:

1. No alternative formulary medicine is available
2. The request is for a tariff (Trust-funded) medicine
3. The benefits of therapy outweigh any risks to the patient and Trust
4. A D&T Concession Form is completed and approved
5. Where required a funding strategy has been approved by the Division
6. Where appropriate an implementation plan is agreed for safe use

a. D&T Concession Form (Appendix 2)

The Concession Form is to request use of a non-formulary Tariff (Trust- funded) medicine for the treatment of a specific named patient. The form must be completed and signed by the Commissioning Pharmacist (and, where appropriate, Division Accountant) prior to the medicine being procured or used in the Trust.

b. Use of Unlicensed Medicines

Please see Trust Unlicensed Medicines Policy available on the Trust intranet.

c. Funding of Medicines Requests

Where the introduction of a medicine is cost-neutral or has minimal financial implications then it can usually be procured in-year. Medicines that have significant financial implications require approval by the Division before procurement and may have to await the outcome of annual contractual negotiations with ICB in the Local Operating Plan.

8. Prescribing for Hospital Out-Patients

In order to rationalise prescribing across the health community, only medicines that are approved by the JAPC may be prescribed for hospital out-patients. The Trust's formulary can be accessed here and the Derbyshire JAPC traffic light classification can be accessed from the Derbyshire Medicines Management website.

Hospital prescribers must not prescribe or recommend non-formulary medicines as detailed in previous sections. Hospital prescribers are required to ensure compliance with JAPC Traffic Light Classification for prescribing.

Prescriptions should be prescribed in the Trust EPMA system, or written on the standard Trust Out-Patient Prescription Form, which has a 'tear-off' section to advise the patient and their GP regards continuation of supplies. In order to rationalise prescribing and reduce waiting times, Out-Patient prescriptions should only be written for:

- New clinically urgent medicines. These are defined as medicines that must be started within 5 working days of the outpatient consultation. These will be supplied by the Trust outpatient pharmacies or via a hospital FP10 prescription

- Medicines that are only available in hospital or which cannot be dispensed from a community pharmacy or dispensing practice (e.g. some specialised paediatric formulations)

- Where a prescription involves the use of an unlicensed medicine then the patient must be advised of this. The GP should be advised by means of a formal letter following the outpatient consultation

- Where a hospital clinician recommends that an out-patient goes to their GP for commencement of new treatment, 5 working days from receipt of the letter will be given for the GP to action the request and issue a prescription

- Repeat prescriptions / further supplies should always be obtained via the GP and must not be prescribed from outpatient clinics

The hospital pharmacy will routinely dispense 28 days' supply of medicines (unless the intended treatment course is shorter). In accordance with legislation an NHS dispensing fee will be charged unless patients are exempt.

The Trust has access to hospital FP10 prescriptions to facilitate the supply of outpatient medication at all sites for clinics. All FP10s must be stored safely & securely within the relevant departments. Medication prescribed on a hospital FP10 prescription should be in line with the Trust & ICB formulary. The use of FP10 prescriptions are routinely monitored by the pharmacy team and reported in the D&T. A Trust-wide Policy covering all aspects of FP10 usage within the Trust is in development.

9. Shared Care Agreements

Following discharge or an out-patient consultation, the hospital prescriber will routinely write to the GP regarding the outcome and transfer prescribing responsibility for ongoing formulary medicines to the GP.

Where the ongoing treatment is complex or requires specialised clinical monitoring then a shared care arrangement must be agreed between the hospital prescriber and patient's GP in accordance with published shared care guidance developed with JAPC (medicines subject to shared-care arrangements are classified amber within the traffic light classification).

Occasionally individual GP prescribers lack clinical experience or access to specialist support, and may not be able to take on the responsibility for ongoing prescribing. In these circumstances, further supplies of medicines will continue to be dispensed from the Hospital Pharmacy or the Trust outpatient pharmacy. It is however, expected that ICB's will support GPs to take up shared care arrangements wherever possible.

Individual GP prescribers taking on shared care are accountable for routine safety monitoring as part of the prescribing process. Specialist clinicians may continue to review patients to monitor efficacy or make alterations to treatment.

Prior to transfer of prescribing and monitoring arrangements, from a hospital specialist to a GP, the patient must be stabilised on the prescribed treatment and have all appropriate monitoring undertaken. During this period, appropriate supplies of medicines will be made by the Trust.

Details of approved shared care agreements can be found on the Derbyshire Medicines Management website at:
www.derbyshiremedicinesmanagement.nhs.uk/guidelines/shared_care_guidelines

National guidance on the shared care of medicines can be found here:
https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/

Requests for new shared care guidelines should be made via the Lead Commissioning Pharmacist and will be reviewed by D&T prior to being submitted to the JAPC for approval. Wherever possible, Derbyshire-wide shared care arrangements will be adopted.

10. Homecare

Please refer to the Homecare Policy available on the Trust Intranet page.

11. Monitoring Compliance and Effectiveness

Monitoring requirement :	Prescribing compliance with formulary
Monitoring method:	Monitoring concession process (and in future non-formulary prescribing in ePMA)
Report prepared by:	Concessions are collated by the Medicines Information Department
Monitoring report presented to:	Drugs & Therapeutics Group
Frequency of report	Monthly

12. References

1. Supporting rational local decision-making about medicines (and treatments). National Prescribing Centre http://www.npci.org.uk/ldm/public/home_page.php

2. Innovation, Health and Wealth: accelerating adoption and diffusion in the NHS. Gateway 16978. DH London Dec 2011

Appendix 1 – Request for the Introduction of a New Medicine

Please complete this form with aid of the Commissioning Pharmacist. The medicine will not be available until approved by D&T (and JAPC where GP prescribed) and funding agreed.

Please ensure all sections are complete. Incomplete requests will be returned.

Clinical Review

Requesting Consultant / Lead Prescriber					
Approved Name of Medicine					
Trade Name					
Form and Strength					
Which sites will this product be used at	**RDH**	**QHB**	**Lichfield**	**Tamworth**	**LRCH**
Medicine been reviewed by NICE	**Yes**	**No**	**Pending**	**Date due:**	
Indication for use:					
Intended Dosage Regimen:					
Is this product licensed for this indication	**Yes**	**No**	**No UK license**	**Unlicensed**	
If no, ***please give reason for not using current Formulary product***					
Therapeutic Benefits / Advantages over currently available therapy					
Safety of product *Common ADRs and Serious ADRs (frequency, reversibility, detectability)* *Clinically important interactions* *Monitoring requirements – tests, frequency, responsibility (Primary Care / Secondary Care)* *Special precautions (e.g. any particular groups of patients in which drug is contra-indicated or where it should be used with caution)*					
Discussed with Consultant Colleagues\Lead Prescribers (list)					
Will this product replace the use of any other drugs?	Yes	No	Not sure		
If yes please provide details:					
What impact will this product have on hospital activity (*Points to consider Outpatient appointments:, Follow up requirements e.g. monitoring:, Continued prescribing, Day case attendances (e.g. to administer the medicine),Inpatient stay)*					
Will GPs be expected to continue to prescribe this agent?	Yes	No	Not sure		
If yes, after what time period should care be transferred to GPs?					
Expected number of patients to be treated	***per year***				
Will other hospital prescribers wish to prescribe this medicine?	Yes	No	Not sure		

Expected number of patients other prescribers will treat	***per year***		
Will patients be supplied this medicine via homecare	Yes	No	Not sure
IfExpected number of patients	**Per year**		
Declaration of conflict of interest			
Applicants are required to declare any potential conflicts of interest, in accordance with the NHS standards of professional conduct			
List literature evidence in support of request **(please provide links or copy with request)**			

Training Required	**Yes**	**No**	**Clinical guideline required**	**Yes**	**No**
If yes, detail of training / when guideline will be completed					

Financial Analysis (pharmacy to complete prior to submission)		
Is the medicine excluded from the national tariff (PbR excluded)?	**Yes**	**No**
If yes: who is the responsible commissioner for the medicine	**CCG**	**NHS England**

	Hospital	**Community**
Costs of requested medicine per pack	= £	= £
Annual cost per patient (full year effect)	=£	=£
Annual cost for expected number of patients	= £	= £

Purchasing for Safety (pharmacy to complete prior to submission)	**Yes**	**No**
Purchasing for safety Risk assessment completed (refer to page 3 for full details)		
Risk assessment approved by Divisional Pharmacist		
Actions to complete before new product is introduced to clinical areas (Yes – refer to executive summary page 3)		

Division Approval	**Print Name**	**Signature**
Consultant / Lead Prescriber		
Commissioning Pharmacist		
Division Director		

Division Finance		

D&T Decision (completed post meeting)

D&T review Date:		**Approved**		**Restricted use** Specialty:	
Referred JAPC	**Date due:**			**Outcome:**	
Classification	**Hospital formulary**	**Shared Care**		**Joint formulary**	**Declined**
Date available for use in	**UHDB**		**Primary Care**		
Date letter sent to Consultant / Lead Prescriber					

Purchasing for safety Risk Assessment Form (to be completed by Pharmacy prior to submission)

Executive Summary action plan to be completed before new product is introduced into clinical areas.

No	Risk identified	Action proposed to reduce the risk	Person responsible	Timescale	Complete
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
Once decision from DTC confirmed:		DTC decision communicated to Pharmacy Logistics			
		If approved new product request form completed			
		If approved & purchased new product risk assessment on receipt to be completed if appropriate	Logistics	On first receipt	

Completed Action Plan Signed Off:	Name & Signature of Divisional Pharmacist:	Date:	Product to be purchased and introduced into Clinical / Pharmacy Areas	Yes / No

Proposed actions could be:

➢ Training	➢ Segregation of stock	➢ Updates to electronic systems	➢ Special records in Pharmacy
➢ Guideline	➢ Pre-printed prescription	➢ Additional labelling	➢ Worksheet in production/Cytolab
➢ Poster	➢ Special restriction on stock holding	➢ Restricted prescribing: Consultant only	➢ Tall Man labelling e.g. DiPYRidamole, DiSOPyramid

Section One – Logistics Technician to complete

Logistics Technician nominated to complete details		Date Logistics Technician to complete by	
		Date Logistics Technician completed	

Manufacturer(s)				
Supplier (importer / wholesaler / direct from manufacturer)				
Product License / Market Authorisation / European License number	**Number**		**Not available**	
Is an image / SPC of the product available?	**YES / NO**			
If Yes copy of Image / SPC saved in:	**Electronic location:**			

Section Two – Pharmacist to complete

Pharmacist nominated to complete details		**Date Pharmacist to complete by**	
		Date Pharmacist completed	
Is this an unlicensed / Special product?		**YES / NO**	
If Yes: Are there alternative licensed products?			
Give reason for not using the licensed products and requesting the special			
Has an unlicensed risk assessment been completed?			
Is there a local or national guideline related to this medicine in use at DHFT?			
Which patient group will use this product	**ADULTS / PAEDIATRICS / NEONATES**		
Name of Areas / Wards where stock will be required			
Are there any legal requirements for this product e.g. CD			
Are there any associated governance implications with this product e.g. NPSA alert, common error on Datix, Never Event			

Section Three – Risk Assessment (sections to be completed by **T** = Logistics technician or QA B5+ or **P** = Pharmacist)

A. Risk of Confusion with another Medicine			**Comments**	**Action required to reduce the risk**
A.1	**T**	List other medicines that have a similar name a) similar spelling b) similar sound List those that are listed on the DHFT pharmacy computer system		

A.2	**T**	Are any of the similar named medicines stocked at DHFT used in the area that is making this request? If yes, list them.		
Visual Checks – Is there an image / SPC available for this product? YES / NO **Yes – go to section A.3 No – go to section B.1 (if approved for purchase an 'on receipt risk assessment' will be completed)**				
A.3	**T**	Is the generic name, form and strength of the medicine, as stated in the SPC, clearly printed in English on 3 non-opposing sides of the packaging?		
A.4	**T**	Are the strengths clearly expressed on the packaging? • Appropriate abbreviations of units • No trailing zeros • Total quantity per total volume		
A.5	**T**	Is there good differentiation between different medicines within the corporate livery of the company inc different strengths / forms / routes?		
A.6	**T**	Does DHFT pharmacy stock other products manufactured by this company? If so, what is the risk within pharmacy of confusing stock?		
A.7	**T**	Where applicable, is the generic name, form and strength clearly stated in English on ampoules / vials?		
A.8	**T**	Where applicable, are tablets / capsules / blisters marked for easy identification?		
A.9	**T**	Do liquids contain alcohol, sugar, gelatine, gluten?		
A.10	**T**	What are the storage requirements? e.g. temperature, light		
A.11	**T**	Are cytotoxics clearly identifiable as cytotoxics?		
A.12	**T**	Is this product robot friendly? a) Barcode b) size / weight / shape		
A.13	**T**	Are all the licensed indications clearly stated on the SPC, PIL or packaging?		
A.14	**T**	Are the licensed routes of administration clear and obvious?		

B. Risk of incorrect strength / form supplied / administered			Comments	Action required to reduce the risk
B.1	**T**	List the different strengths and forms available for this medicine		
B.2	**T**	Where applicable, are the concentrations the same across the product range? If no, state the different concentrations		
B.3	**P**	If applicable, are base and salt strengths clearly defined?		
B.4	**P**	If the product is listed in the BNF does the description of the constituents on the product match the conventional BNF description?		
C. Risk of use outside licensed indications			**Comments**	**Action required to reduce the risk**
C.1	**P**	Do other brands of this medicine have different licensed routes of administration?		
C.2	**P**	Is off-label or unlicensed use anticipated for this medicine? If so, what are the risks.		
D. Risk of incorrect dose administered ***For all intravenous preparations, complete the NPSA Risk Assessment Tool (Section Four)***				
Preparation of Product			**Comments**	**Action required to reduce the risk**
D.1	**P**	Will the product require preparation by an aseptic pharmacy service?		
If yes will the product be required as named patient CIVA / batch production (internal) / batch production (outsourced supplier)				
D.2	**P**	Are there differences between the reconstitution advice (displacement values, choice of diluent) between this product and the previous product used?		
D.3	**P**	Are there any specific administration issues?		
D.4	**P**	Interchangeability between generic / brands with respect to pharmacokinetics and stability		
D.5	**P**	Is there product specific shelf life data available?		
D.6	**P**	How much notice is expected for each treatment (time between prescription being written and administration)		

D.7	**P**	Does the product replace an existing aseptic product (please detail):		
If this product is to be used in the Pharmacy CIVA or aseptic manufacturing process the Production Manager and the Quality Assurance Manager must be informed and they should complete section D.5 – D.9				Date Informed:
If the product is to be used in the Extemporaneous manufacturing process the Dispensary Manager and the Quality Assurance Manager must be informed and they should complete section D.5 – D.9				Date Informed:
D.8	Are there differences between the reconstitution advice (displacement values, choice of diluent) between this product and the previous product used?		D1. – D.7 Completed by:	
D.9	Are there any specific administration issues?			
D.10	Interchangeability between generic / brands with respect to pharmacokinetics and stability			
D.11	Is there product specific shelf life data available?			
D.12	Will aseptic / extemporaneous worksheets paper / electronic need to be updated or created?			

Section Four : NPSA Risk Assessment of individual injectable medicine products prepared in clinical areas (Pharmacist to complete)

Clinical Area:		**Division:**			**Date:**
Name and strength of prepared injectable product			**Diluent**	**Final volume**	**Bag or syringe**
	Risk factors	**Description**			**P**
1	**Therapeutic risk**	Where there is a significant risk of patient harm if the injectable medicine is not used as intended (see Appendix A)			
2	**Use of a concentrate**				
3	**Complex calculation**	Any calculation with more than one step required for preparation and/or administration, e.g. microgram/km/hour, dose unit conversion such as mg to mmol or % to mg.			
4	**Complex method**	More than five on-touch manipulations involved or others including syringe-to-syringe transfer, preparation of a burette, use of a filter.			
5	**Reconstitution of powder n a vial**	Where a dry powder has to be reconstituted with a liquid.			
6	**Use of a part vial or ampoule, or use of more than one vial or ampoule**	Examples: 5ml required from a 10ml vial or four x 5ml ampoules required for a single dose.			
7	**Use of a pump or syringe driver**	All pumps and syringe drivers require some element of calculation and therefore have potential for error and should be included in the risk factors. However, it is important to note that this potential risk is considered less significant than the risks associated with not using a pump when indicated.			
8	**Use of non-standard giving set/device required**	Examples: light protected, low adsorption, in-line filter or air inlet.			
	Total number of product risk factors	Six or more risk factors = high-risk (Red). Risk reduction strategies are required to minimise these risks. Three to five risk factors = moderate-risk product (Amber). Risk reduction strategies are recommended. One or two risk factors = lower-risk product (Green). Risk reduction strategies should be considered.			
Risk Assessment undertaken by:		**Name of Pharmacist:**		**Name of Clinical Practitioner:**	

Risk factors															
Prepared injectable medicine	**Strength**	**Diluent**	**Final volume**	**Bag/syringe**	Therapeutic risk	Use of concentrate	Complex calculation	Complex	Reconstitute vial	Part/multiple container	Infusions pump or driver	Non-standard infusion set	**Risk assessment score**	**Risk reduction method(s)**	**Revised score**
					ü	**ü**	**ü**	**ü**	**ü**	**ü**	**ü**	**ü**			
Risk Assessment undertaken by:		**Name of pharmacist:**								**Name of clinical practitioner:**					

NPSA Risk Assessment Summary for High and Moderate-risk injectable medicines products

<u>NPSA suggested risk reduction methods that can be used to minimise risks with injectable medicines</u>

1. Simplify and rationalise the range of products and presentations of injectable medicines. Where possible, reduce the range of strengths of high-risk products and provide the most appropriate vial/ampoule sizes

2. Provide ready-to-administer or ready-to-use injectable products – this will minimise preparations risks and simplify administration
3. Provide dose calculating tools – for example, dosage charts for a range of body weights that eliminate the need for dose calculations
4. Provide additional guidance on how to prescribe, prepare and administer high-risk injectable medicines
5. Consider the provision of pre-printed prescriptions or stickers – this will help to ensure that information on the prescription about preparation and administration of high-risk products is clearer
6. Provide locally approved protocols that clarify approved unlicensed and 'off-label' use of injectable medicines
7. use double-checking systems – an independent second check from another practitioner and/or the use of dose-checking software in 'Smart' infusion pumps and syringe drivers
8. Use an infusion monitoring form or checklist – this will help to ensure that infusions are monitored throughout administration

RISK FACTOR 1. Therapeutic Risk

This is described as where there is significant risk of patient harm if the injectable medicine is not used as intended. The risk depends upon the inherent properties of the medicine. Therefore it remains regardless of the dose, indication or route of injectable administration.
A useful list*, based on those medicines reported to the NPSA to have caused severe harm or death (Safety in doses: medication safety incidents in the NHS. PSO/4, 2007) and the Institute of Safe Medication Practice's list of High-Alert Medications (2007) is given below:

- Chemotherapeutic agents,
- Biological agents e.g. gene therapy
- Medicines affecting the immune response (excluding corticosteroids)
- Medicines used by spinal, epidural and intrathecal route
- Parenteral nutrition
- Agents affecting the coagulation cascade: glycoprotein IIb/IIIa inhibitors, thrombolytics, anticoagulants (excluding heparinised saline), activated protein C, antiplatelet agents, aprotonin, dextrans, thrombin inhibitors (excludes coagulation factors and inhibitors)
- Cardiovascular active agents: sympathomimetics, beta- blockers, vasoactives, antiarrythmics, dinoprostone
- Cardioplegia concentrate and solutions
- Insulin
- Liposomal medicines,
- Neuromuscular blockers
- Sedative and anaesthetic agents
- Opiates
- Anticonvulsants with narrow therapeutic range e.g. phenytoin
- Hypertonic or hypotonic injections and infusions (dextrose only above 10%) including electrolyte concentrates
- Agents affecting acid-base balance e.g. acetazolamide
- Amphotericin, aciclovir and voriconazole
- Clinical trial agents

- Aminoglycoside and glycopeptide antibiotics, sodium stibogluconate
- Venoms, toxins and live vaccines
- Oxytocin
- Desmopressin
- Aminophylline, caffeine
- Apomorphine
- Dimercaprol, dicobalt edentate

13.

Appendix 2 – Concession Form Concession Form

Please complete this form and send through to the Commissioning Pharmacist (esther.hillman@nhs.net) or nominated deputy. Please note:

- The medicine will not be available until approved
- A concession form must be completed for each patient treatment
- If requesting this drug for likely > 3 patients, please complete a full new product request (new product request form)
- Form must be completed by a senior member of the medical team (Registrar/Consultant).

<table>
<tr><th colspan="3">PATIENT DETAILS</th></tr>
<tr><td>1.</td><td>Patient Name:</td><td></td></tr>
<tr><td>2.</td><td>Hospital number:</td><td></td></tr>
<tr><td>3.</td><td>Date of Birth:</td><td></td></tr>
<tr><td>4.</td><td>Is the patient an inpatient or outpatient?</td><td>☐ Inpatient on ward ……
☐ Outpatient</td></tr>
<tr><td>5.</td><td>What is the clinical urgency of the request – when is the drug needed by?
Please note that it will take at least one working day to obtain the medicine if it is not routinely stocked</td><td></td></tr>
<tr><td>6.</td><td colspan="2">Previous Therapies Tried
<table><tr><th>Medicine</th><th>Dose</th><th>Duration</th></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr></table></td></tr>
<tr><th colspan="4">DRUG AND INDICATION DETAILS</th></tr>
<tr><td>7.</td><td>Drug Name, Strength and Formulation</td><td colspan="2"></td></tr>
<tr><td>8.</td><td>Indication for Drug Use</td><td colspan="2"></td></tr>
<tr><td>9.</td><td>Intended dose, route and treatment schedule</td><td colspan="2"></td></tr>
<tr><td>10.</td><td>Likely treatment duration</td><td colspan="2"></td></tr>
<tr><td>11.</td><td>Is the GP expected to continue prescribing?</td><td>YES</td><td>NO</td></tr>
<tr><td>12.</td><td>Rationale for request (claimed advantage over formulary drug(s). Include any relevant references)</td><td colspan="2"></td></tr>
<tr><td>13.</td><td>Was the patient admitted on this therapy?</td><td>YES</td><td>NO</td></tr>
</table>

14.	Is there any clinical training or clinical guideline required to use this medication	**YES**	**NO**
15.	How will you monitor effectiveness of treatment?		
16.	What is the stopping criteria for this treatment?		
LICENSING INFORMATION			
17.	Is the product a licensed medicine in the UK?	**YES**	**NO**
18.	Is the product being used for a licensed indication?	**YES**	**NO**
19.	Is the route of administration licensed for this product?	**YES**	**NO**
If NO to any of the above, please complete:			
20.	*I understand that the above product is an unlicensed medicine or is being used for an unlicensed indication/route as stated above. I also understand that I am professionally accountable when prescribing this medicine.*	**c** *(please tick)*	
21.	*I have consented the patient/carer that the above medication is unlicensed and discussed all potential benefits and risks as per UHDB unlicensed medicines policy. Pease note this is not required for paediatric medication unless high risk as per Unlicensed Medicines Policy.*	**c** *(please tick)*	

FIANACIAL IMPLICATIONS (to be completed by pharmacy)				
Costs of requested medicine		*= £*	**12 months = £**	
Mitigating costs (include reduction in hospital stay, transport, therapy)		*= £*	**Total Cost = £**	
Application for	Hospital funded	Patient funded	Tariff excluded – funded by commissioner	No funding stream

Completed by (requesting Consultant):			
Name	Designation	Signature*	Date
Please note: Pharmacy will obtain non-medicines only where the request has been approved for use within the Trust. *Electronic signatures may be pasted into this section			

Approval		
	Signature	Date
Divisional Lead/Commissioning Pharmacist:		
Division Director:		
Division Finance:		

Review by Drugs and Therapeutics Group				
Date Reviewed:	Declined	Approved for single use	Approved for private top up therapy	Refer for IFR
Date letter sent to Consultant / Lead Prescriber:				