Joint Policy for Cumbria Partnership Foundation Trust & North Cumbria University Hospital NHS Trust

Policy Title: Medicines - Patient Group Directions

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Accountable Director	Medical Director
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Policy On A Page

SUMMARY & AIM

The objective of this policy is to outline the process for the application, development, review and use of Patient Group Directions (PGDs).

TARGET AUDIENCE:

- This policy applies to all eligible non-medical clinical staff who use/wish to use PGD's

TRAINING:

The line managers of staff who will use PGDs are responsible for keeping a record of all staff approved to use a PGD in their service and ensuring staff have undertaken the Trust approved PGD training which consists of:

- Patient Group Directions e-Learning module
- Local assessment of clinical competence for the administration and/or supply of the drug
- A signed copy of the relevant PGD acknowledging its content which is then held by the staff member

KEY REQUIREMENTS

1. The Policy defines the process by which PGDs are created and used within the Trust.

2. PGDs are used where there is an advantage for patient care without compromising patient safety

3. All staff using PGDs must complete the relevant PGD training

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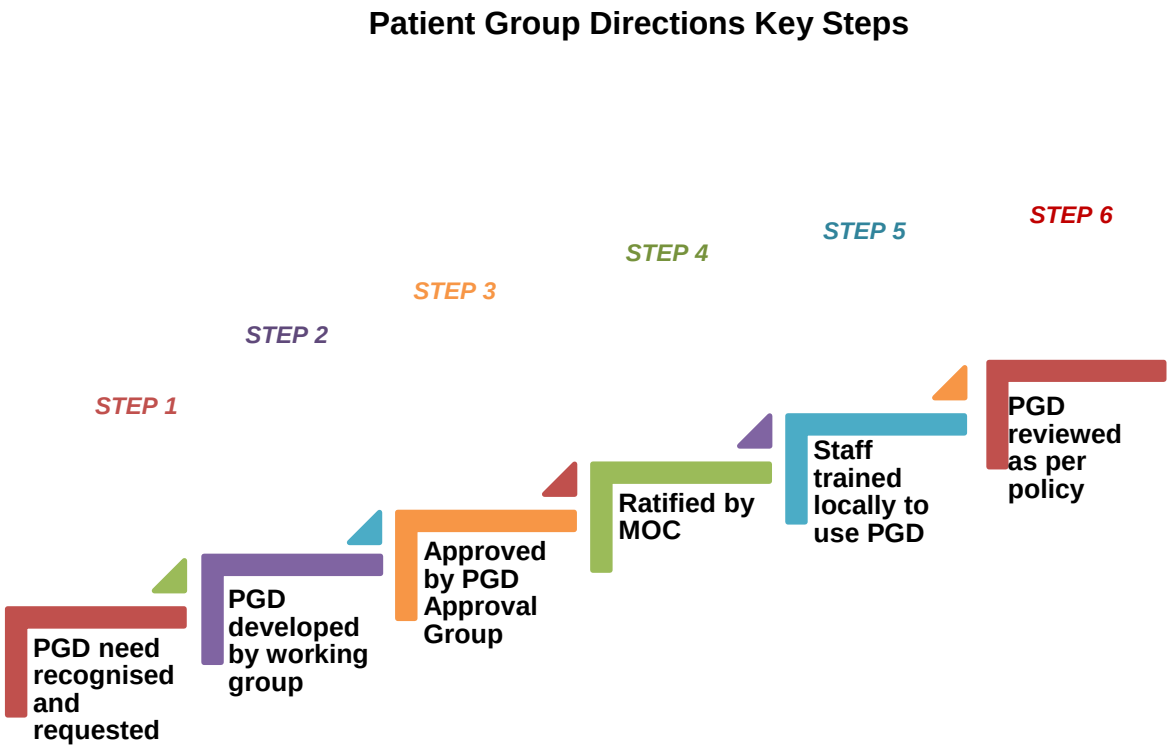
SUMMARY FLOWCHART:



1. INTRODUCTION

A Patient Group Direction (PGD) is a written direction, relating to the supply and/or administration of a prescription only medicine (POM) or pharmacy (P) medicine. It is a written document, which states the circumstances in which the medicine can be supplied. It lists those excluded from treatment, states when further advice should be sought from the doctor, and includes details of any follow-up action and records needed.

A PGD provides a safe and legal framework, which enables medicines to be given in circumstances when a doctor or other prescriber is not available to prescribe that medicine for an individual.

The majority of clinical care should be provided on an individual, patient specific basis. The process where different professionals prescribe, dispense and administer medication is desired for the majority of clinical care. The training and appointment of independent prescribers has been identified as the preferred long term solution for the Trust. The supply and administration of medicines by PGDs must be reserved for those **limited situations** where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

All staff utilising or developing PGDs **must** have undergone PGD Patient Group Directions e-Learning module.

2. PURPOSE

The objective of this policy is to outline the process for the application, development, approval, implementation and review of PGDs.

3. POLICY DETAILS

PGDs require safeguards to be in place to ensure that only fully competent qualified and trained professionals operate within PGDs (Appendix 1)

3.1 PGD Requests and Development

This process is summarised in Appendix 2

3.1.1 PGD Request

If a team or an individual recognises a need for a PGD, they should contact the chair of the PGD Approval Group who will check the PGD database and advise on whether a potentially suitable PGD already exists. Note that there are national PGDs for immunisations, available from Public Health England (PHE) and regional approved PGDs in sexual health and other services but before any of these are used by Trust staff they must be ratified by the Medicines Optimisation Committee.

If a Trust approved PGD already exists, it may be used by the team/individual, provided they have line management approval, can demonstrate competence and have completed the PGD e-Learning and the local competency assessment.

If the requested PGD does not exist in a suitable format, an application form (Appendix 3) will need to be completed, to apply for permission to develop a new PGD.

This application must state:

- Details of the drug
- Indications
- Professional group requesting to use the PGD
- Reason for request
- Lead contact for the PGD

Funding for the drug supply via the PGD must also be agreed with the relevant budget holding manager before submitting the proposal for a PGD.

Completed application forms must be sent to the PGD Approval Group.

If the PGD application is not approved by the Group, the reasons for this will be discussed with the lead contact. This discussion will include advice on alternative methods of delivering the required service to patients.

3.1.2 PGD Development

If the PGD application is approved, the lead contact will be provided with a PGD document template, Appendix 5, along with advice on developing the PGD by the PGD Approval Group.
A multi-disciplinary PGD working group must draw up the PGD and must include a doctor (consultant level), pharmacist (minimum band 7) and a representative of the professional group (see Appendix 1) expected to supply medicines under that PGD. If the PGD is for an antibiotic, a microbiologist must be involved in the process.

The PGD must be completed within 3 months of receipt of the PGD template.

Once the multi-disciplinary group is satisfied with the clinical and managerial content of the PGD, it must be returned to the PGD Approval Group to undergo the assurance process.

If approval is not given, the chair of the PGD Approval Group will inform the lead contact of the reasons and provide assistance, as required.

If approval is given, the PGD Approval Group will send to Medicines Optimisation Committee (MOC) for final Trust ratification and will then update the PGD database, ensuring that the PGD is uploaded onto the Trust intranet. The PGD will be returned to the lead contact for local distribution within the service/department as appropriate.

A PGD cannot be used for the supply of medicines until it has been ratified by the Medicines Optimisation Committee.

3.2 Dissemination and Review

This process is summarised in Appendix 4.

The PGD Approval Group will coordinate the database of all Trust PGDs and ensure that staff have access to it on the Trust intranet. The database will be used to remind authors when PGDs are due for review.

Six months prior to the review date of an individual PGD the PGD Approval Group will inform the lead contact (or person in most similar role) that the PGD needs to be reviewed and updated.

A review team must review the PGD. As a minimum the group should consist of a doctor (consultant level), a pharmacist (minimum AFC band 7), and one health professional from each profession or group of staff who will be using the PGD.

Once the review team is satisfied with the clinical and managerial content of the PGD, it must be returned to the PGD Approval Group to undergo the assurance process.

This must be two months prior to the expiry date to allow time for final approval and ratification with MOC.

If approval is not given, the Group will inform the lead contact of the reasons and provide assistance as required.

If approval is given, the PGD Approval Group will send to MOC for final Trust ratification and amend the PGD database, ensuring that the PGD is uploaded onto the Trust intranet. The PGD will be returned to the lead contact for local distribution within the service/department as appropriate.

3.3 Accountability

Responsibility and accountability for the supply and/or administration of a medicine under a PGD lies with the individual practitioner using the PGD.

A practitioner is not permitted to supply/administer a medicine in any way other than that stated in the PGD.

The PGD lead author or local service lead must keep an up-to-date list of authorised practitioners who are competent to use the PGD.

3.4 Record Keeping and Retention

Accurate records must be made of the patient consultation that results in the use of the PGD, as outlined in the PGD template (Appendix 5). This includes decisions not

to supply a medicine under a PGD and information gathered during the consultation with the patient when using a PGD such as allergy status etc.

All PGD documentation must be retained as per Trust policy on Health Retention of Records. The same rules that apply to the retention of patient records apply to PGDs.

In addition to following Trust standards for record keeping and retention, the PGD lead author is responsible for keeping a record of authorised practitioners assessed as competent to use the PGD within their clinical area.

4. TRAINING, COMPETENCY AND SUPPORT

Baseline training consists of undertaking the e-Learning module Patient Group Directions. Also, any individual administering or supplying a medicine by a PGD must be authorised by name and assessed as clinically competent. Clinical competency, including any procedures/tests required for the use of each PGD, should be assessed and documented locally, by a suitable clinical lead (not necessarily the PGD lead contact/author) or a nominated deputy. This local authorisation is valid for the life of the PGD. It can be undertaken more frequently in line with service requirements/changes in best clinical practice.

Line managers of staff who will use PGDs are responsible for ensuring staff members have undertaken the above training. Line managers should retain a list of those staff who are authorised to use the PGD in order to inform the PGD Group of who is authorised to supply/administer a particular drug under a PGD at any time.

Retention of a signed copy of the particular PGD, acknowledging its content, is held by the staff member.

5. PROCESS FOR MONITORING COMPLIANCE

The process for monitoring compliance with the effectiveness of this policy is as follows:

Aspect being monitored	Monitoring Methodology	Reporting		
		Presented by	Committee	Frequency
Audit of incidents involving medicines	Ulysses incident reports	PGD Approval Group	Medicines Optimisation Committee	Quarterly
PGD audit against policy	Random selection of 10 PGDs	PGD Approval Group	Medicines Optimisation Committee	Annually

Wherever the above monitoring has identified deficiencies, the following must be in place:

- Action plan

- Progress of action plan monitored by the Clinical Director of Pharmacy and Medicines Optimisation
- Risks will be considered for inclusion in the appropriate risk registers

6. REFERENCES:

NICE Guidance MPG2 - Patient Group Directions March 2017 - https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations

7. ASSOCIATED DOCUMENTATION:

Medicines Policy
Trusts Records Retention Schedule and the Records Management: NHS Code of Practice

8. DUTIES (ROLES & RESPONSIBILITIES):

8.1 Chief Executive Officer / Trust Board Responsibilities:

The Chief Executive and Trust Board jointly have overall responsibility for the strategic and operational management of the Trust, including ensuring that Trust policies comply with all legal, statutory and good practice requirements.

8.2 Executive Director Responsibilities: Medical Director

The Medical Director has the executive responsibility for Medicines Optimisation.

8.3 Managers Responsibilities:

Managers are responsible for ensuring adequate dissemination and implementation of policies relevant to the staff in their areas. Managers are also responsible for making sure staff understand how to access policies on the Intranet.

Immediate line managers of staff using PGDs are responsible for authorising those members of staff to work under the PGD and to assess their competency against the relevant criteria in the PGD.

8.4 PGD Approval Group Responsibilities:

The Group will agree the approval of the final draft of this policy. The Chair of the approving committee will ensure the policy approval is documented in the final section of the Checklist for Policy Changes.

The PGD Approval Group is responsible for offering advice and guidance to staff in developing and reviewing PGDs, and for ensuring that the clinical and managerial content of the PGD are complete. It is also responsible for keeping the PGD database up-to-date and for ensuring that it is uploaded on to the Trust intranet. The Group is also responsible for ensuring all clinical data and criteria for use is

appropriate and that the PGD has received appropriate consultation. The Group will approve the PGD in line with this policy. The chair of the PGD Approval Group will take the approved PGD to the Medicines Optimisation Committee for final ratification.
It will review incidents associated with PGD medicines reported through the Trust's incident reporting system, Ulysses.

8.5 Responsibilities of consultant and pharmacist members of the PGD working group:

The consultant and pharmacist involved in the development of a PGD are responsible and accountable for ensuring the clinical, pharmaceutical and managerial details and criteria for use are accurate.

8.6 PGD Signatory Responsibilities:

The Clinical Director of Pharmacy and Medicines Optimisation, Chair of Medicines Optimisation Committee and Head of Patient Safety and/or Clinical Governance sign the PGD and are responsible for ensuring the PGD has been through the correct process i.e. approved by the PGD Approval Group and ratified by the Medicines Optimisation Committee.

8.7 Staff Responsibilities:

All staff are responsible for co-operating with the development and implementation of Trust policies as part of their normal duties and responsibilities. They are responsible for ensuring that they maintain up-to-date awareness of corporate and local policies, with regard to their own roles and responsibilities.

8.8 Medicines Optimisation Committee (MOC) Responsibilities:

- Final ratification of all PGDs
- Make recommendations for changes in policy or practice as a consequence of incident reviews and audit of compliance to policy

9. ABBREVIATIONS / DEFINITION OF TERMS USED

ABBREVIATION	DEFINITION
AfC	Agenda For Change
MOC	Medicines Optimisation Committee
PGD	A written direction relating to the supply and administration, or administration only, of a prescription-only medicine to persons generally (subject to specified inclusions and exclusions) and which is signed by a pharmacist and a doctor or a dentist.
PHE	Public Health England
POM	A medicine subject to the Prescription Only Medicines (Human Use) Order 1997
TERM USED	**DEFINITION**
Prescriber	Doctor or dentist.

	Suitably qualified non-medical health professional working as an independent non-medical prescriber.

DOCUMENT CONTROL

Equality Impact Assessment Date	
Sub-Committee & Approval Date	Medicines Optimisation Committee 17/05/2019

History of previous published versions of this document:

Version	Ratified Date	Review Date	Date Published	Disposal Date
NCUH MM07	10/12/2018	Dec 2021	18/12/2018	
No CPFT				

Statement of changes made from previous versions

Version	Date	Section & Description and Description of Change
6.0	10th Dec 2018	• Previous NCUHT PGD Policy amended to include introduction of PGD Approval Group (new process) and NICE Guidelines March 2017, creating new Joint Policy, version 1.0
		• No previous CPFT PGD Policy

List of Stakeholders who have reviewed the document

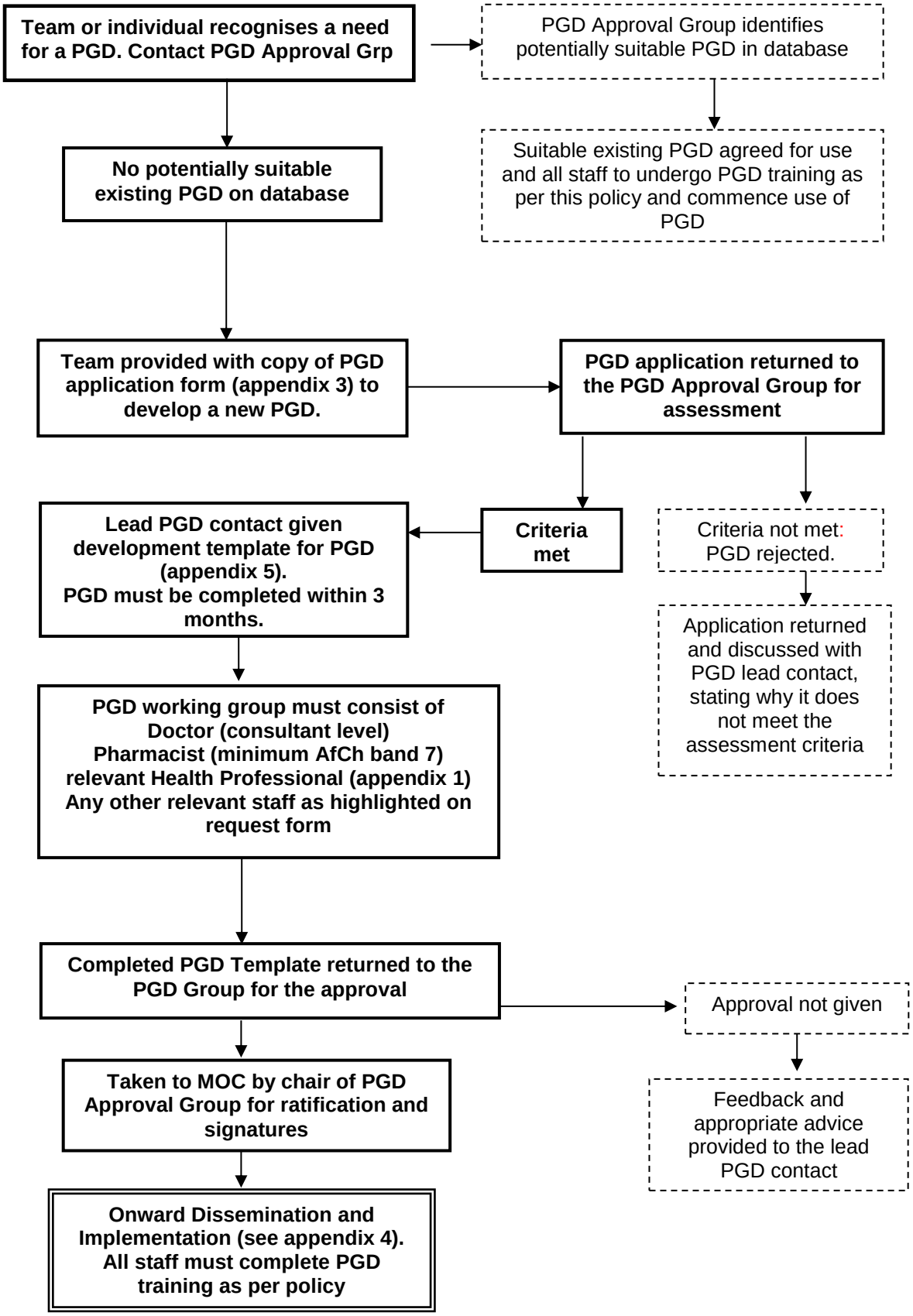
Name	Job Title	Date
PGD Approval Group		17th May 2019
Medicines Optimisation Committee		17th May 2019
Vincent Connolly	Medical Director	17th June 2019
Kathy Barnes	Head of Clinical Standards	17th June 2019
Maureen Gordon	Head of Patient Safety	17th June 2019

APPENDIX 1 - CLASS OF HEALTHCARE PROFESSIONAL WHO CAN USE PGDS

Qualified:

- Nurses
- Midwives
- Pharmacists
- Health Visitors
- Optometrists
- Chiropodists
- Dieticians
- Radiographers
- Physiotherapists
- Ambulance paramedics
- Occupational therapists
- Speech and language therapists
- Prosthetists
- Orthoptists
- Dental Hygienists
- Dental Therapists
- Podiatrists

APPENDIX 2 - REQUEST FOR AND DEVELOPMENT OF A PGD



APPENDIX 3 - APPLICATION FOR A NEW PATIENT GROUP DIRECTION

Details of PGD requested:

Drug:_____

Condition:_____

Class of health professional who may supply or administer the medicine:

_____

Does this proposed PGD meet the criteria in the PGD flowchart?

Yes / no / not sure

(If “no” or “not sure” please contact the chair of the PGD Approval Group for further advice before proceeding)

Rationale for employing the Patient Group Direction

Identify the patient/staff benefits, which stem from the Patient Group Direction

_____

_____

_____

_____

Existing PGDs

Is there an existing PGD in the Trust or national PGD for this drug and condition, which could be used or adapted?

Yes / No / Not sure

Is there an existing PGD in another NHS area which you have found which could be adapted for use in the Trust? If so, please attach it.

Development of PGD

You need a minimum of a doctor (consultant level), a pharmacist (minimum AfC band 7), and a member of the class of health professionals who will be using the PGD, to meet together and develop the PGD. If the PGD is for an antibiotic you must include a microbiologist in the development process.

Please name below the people who will be directly involved in developing the PGD.

Doctor_____

Pharmacist_____

Other health professional_____

Are there any committees or working groups, which currently meet who would be interested in the detail of this PGD? If so, please list them below.

_____

_____

Is there any further information you feel is relevant?

_____

_____

Please sign below. The lead contact will, as the name suggests, act as the main point of contact for the PGD working group for the development of this PGD. Please ensure you have the approval of your line or department manager.

Lead contact (Usually doctor)

Name _____ Job title _____

Email _____ Phone number _____

Signature _____

Pharmacist

Name _____ Job title _____

Email _____ Phone number _____

Signature _____

Business/Department/Service Manager/senior representative of named professional group working under the PGD

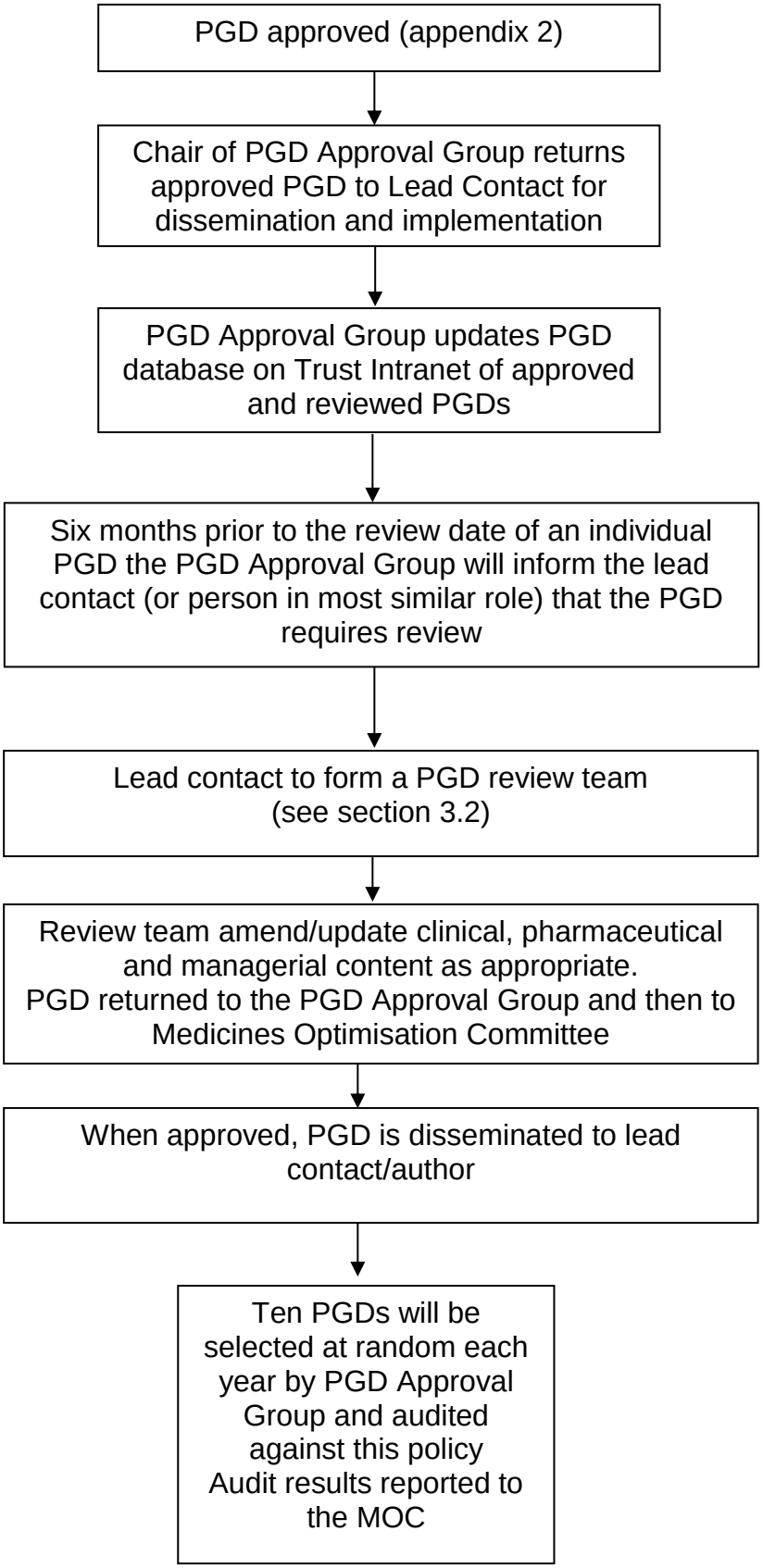
Name _____ Job title _____

Email _____ Phone number _____

Signature _____

Cost centre code _____

APPENDIX 4 - PGD ONWARD DISSEMINATION, IMPLEMENTATION AND REVIEW



APPENDIX 5 – PGD TEMPLATE

New Trust Logo

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR the administration and/or supply of ……..

Version:

Patient Group Direction Details: this includes details of the service(s) and location(s) in which the PGD will be used	
Date comes into effect	(insert date)
Date of expiry + review	(date 3 yrs. hence) or sooner in the light of significant changes in best practice Review date: 6 months prior to expiry date
Staff characteristics	Class of health professional, qualifications and professional registration Specific baseline training, to include e-learning module Patient Group Directions Local training in competency requirements, including clinical assessments needed to confirm indication Up to date with current evidence-based best practice, evidence of continued professional development, regular attendance at clinical supervision **YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT**

Clinical Details	
Indication	A clear and unambiguous definition of the clinical condition(s)/situation(s) to which the PGD applies
Inclusion criteria	Describe who is eligible to receive the drug e.g. Age (if applicable) Clinical criteria Relevant local/national policies/guidelines
Exclusion criteria	A description of patients excluded from treatment under the PGD e.g. • Age • Concurrent conditions • Concurrent treatment • Previous adverse reactions/hypersensitivity • Other exclusions in the SPC
Management of excluded patients	e.g. • Referral • Postponement • Further advice • Records to be kept
Action for patients not wishing to receive care under this PGD	e.g. • Referral • Postponement • Further advice • Records to be kept

Description of Treatment/Medicine	
Name of medicine	Generic name [with brand name(s) optional)]Indicate if 'black triangle' medicine
Formulation and route	State clearly in full
Strength	State clearly
Dosage	State clearly in full Dosage range permitted but state how to calculate/determine dose for an individual Maximum total dosage
Repeated dose instructions/ Frequency	(Where applicable) e.g. Two tablets up to four times a day e.g. A second dose may be given after x hours
Duration of treatment	State minimum or maximum period for administration or supply
Quantity to supply	e.g. Single dose, given immediately Number of tablets/capsules (issued as pre-pack)
Legal status	POM / P / GSL Black triangle status (where applicable)
Indicate any off-label use, if relevant	If relevant include statement supporting use if outside terms of licence
Special Precautions	e.g. Facilities for treatment of anaphylaxis (for vaccination) Special warnings, contra-indications and warnings from SPC Relevant action to be taken
Adverse effects	The most common adverse effects and serious effects that patients need to be alerted about Include statements:- This list is not exhaustive. Refer to BNF and SPC for complete list. If serious adverse effects are noted, complete & submit a Yellow Card (For ▼ drugs – report all suspected adverse drug reactions) For up-to-date SPCs and PILs www.medicines.org.uk.
Patient/Carer Advice	Patient information leaflet and/or other appropriate written information Counselling points/instructions Side effects and management Where to seek further advice if needed Further treatment (if applicable)

Records and Follow Up	
Referral arrangements	To whom referral should be made if needed while using the PGD Arrangements for referral for medical advice Route of referral
Records to be kept	State records to be kept for audit purposes e.g. The patient record should include: • details of patient consent, in line with Department Of Health's advice on consent (2009)

	• date and time of treatment or supply • diagnosis • name, form, and strength of medication • dose, dosing instructions, including route, & quantity of medication • batch number and expiry date • identification of healthcare professional supplying/administering the medication, with signature Details of any reactions should be noted. State that supply is made under a PGD.
Written information to be given to patient or carer	List what written and verbal information will be given
Follow up	Any requirements for follow up e.g. for monitoring and/or further treatment e.g. action to take if certain side-effects are experienced

Patient group direction organisational authorisation signatures and individual working group signatures can be found on the managerial content sheet, along with other non-clinical details relating to this patient group direction.

Change history

Version number	Change details	Date

Key references

Examples

- NICE guideline
- SPC, including date of revision of text
- BNF, including no. and year
- Associated SLA, if relevant
- Local/national guidelines
- Journal/other references (using Vancouver style)
- Local/national guidelines
- Journal/other references (using Vancouver style)
- Professional regulator or profession-specific guidance

New Trust Logo

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR the administration and/or supply of ……..

Patient Group Direction Owner/Lead Author	
Details of patient group direction owner	Name: Position and Organisation: Contact Address: Contact Telephone: Contact Email:

Patient Group Direction Details	
Date comes into effect	(Insert date)
Date of expiry + review	Date 3 years hence, or sooner in the light of significant changes in best practice Review date: 6 months pre-expiry
Staff characteristics	Class of health professional, qualifications and professional registration Specific baseline training, to include e-learning module Patient Group Directions Local training in competency requirements, including clinical assessments needed to confirm indication Up to date with current evidence-based best practice, evidence of continued professional development, regular attendance at clinical supervision **YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT**

Members of Patient Group Direction working group/peer review group			
Name	**Position**	**Signature**	**Date**
Lead author/PGD owner			
Lead doctor (or dentist)			
Lead Nurse (or AHP using PGD)			
Lead pharmacist			
Other members of the PGD working group			

Patient Group Direction Organisational Authorisation	
PGD Approval Group	Date:
Medicines Optimisation Committee	Date:
Chairperson of Medicine Optimisation Committee	Name: Signature: Date:
Clinical Director of Pharmacy and Medicines Optimisation	Name: Signature: Date:
Trust Governance or Patient Safety Lead	Name: Signature: Date:

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MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR the administration and/or supply of ……

Individual Authorisation

THIS PGD MUST ONLY BE USED BY REGISTERED HEALTH PROFESSIONALS WHO HAVE BEEN NAMED AND AUTHORISED BY THEIR ORGANISATION TO PRACTICE UNDER IT. BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU HAVE READ AND UNDERSTOOD THE PGD AND THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT. PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY. IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTICE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE AND JOB DESCRIPTION.

THE MOST RECENT AND IN DATE FINAL SIGNED VERSION OF THE PGD SHOULD BE USED. IF THIS IS AN UPDATED OR REPLACEMENT PGD, ENSURE THAT ALL OLDER VERSIONS ARE WITHDRAWN FROM USE WITH IMMEDIATE EFFECT. IT IS YOUR REPONSIBILITY TO MAKE SURE YOU ARE USING THE CURRENT VERSION.
NOTE TO AUTHORISING MANAGERS: AUTHORISED STAFF SHOULD BE PROVIDED WITH AN INDIVIDUAL COPY OF THE CLINICAL CONTENT OF THE PGD AND A PHOTOCOPY OF THE AUTHORISATION SHEET SHOWING THEIR AUTHORISATION
Line managers and team leaders must maintain up to date lists of these health professionals. This PGD must be easily accessible in the clinical setting.

Name of Professional	Signature	Authorising Manager	Date