Wrightington, Wigan and Leigh Teaching Hospitals
NHS Foundation Trust

STANDARD OPERATING PROCEDURE	**Patient Group Directions: Production, Approval and Review**
SOP ID NUMBER	**TW15-010 SOP 1**
VERSION NUMBER	**4**
APPROVING COMMITTEE	**MMSG** (Medicines Management Strategy Group)
DATE THIS VERSION APPROVED	**July 2023**
RATIFYING COMMITTEE	**PARG** (Policy Approval and Ratification Group)
DATE THIS VERSION RATIFIED	**March 2024**
AUTHOR(S) (JOB TITLE)	**Associate Director of Pharmacy (Governance & Risk)**
DIVISION/DIRECTORATE	**TRUSTWIDE**
ASSOCIATED TO WHICH POLICY?	**TW15-010 Patient Group Direction Policy**
CONSULTED WITH	**MMSG Membership**

DATES PREVIOUS VERSION(S) RATIFIED	**Version 3 – September 2020**
DATE OF NEXT REVIEW	**July 2026**
MANAGER RESPONSIBLE FOR REVIEW (Job Title)	**DIRECTOR OF PHARMACY**

The WWL Way

Version Control

Version	Date	Amendment
4	July 2023	• 2.6 – Advised that the only physical signature required is the Medical Director provided that written (or email) approval has been given and retained for the previous steps in the approval process • 3 – Streamlined the Divisional approval process so that Divisions can determine which group approve PGDs for them prior to MD sign off • Divisionally approved PGDs to go back to the Associate Director of Pharmacy so the database can be updated prior to sending to MD for sign off and oversight maintained

Contents

1 INTRODUCTION

1.1 This Standard Operating Procedure (SOP) details the process to be followed in producing, approving and reviewing Patient Group Directions (PGD) is for use within the Trust.

1.2 This SOP should be used in conjunction with the Patient Group Direction Policy as this contains further information and background to the use of PGDs.

2 WRITING THE PGD

2.1 The first stage in the process at the trust is to form a local PGD working group that can consider whether the PGD is required and develop the specific details for the PGD.

2.2 This working group must include:-

2.2.1 The author – usually a senior member staff from the group of healthcare professionals to which it applies.
2.2.2 A doctor (or dentist) – usually a Consultant.
2.2.3 A pharmacist - usually a Divisional Principal Pharmacist but this can be delegated to a pharmacist of Band 7 or above with appropriate experience of PGDs.
2.2.4 Where the PGD involves antimicrobials then a Consultant Microbiologist must be involved.

2.3 The PGD working group may include other members of staff such as nursing or other professional representatives and/or managers.

2.4 The standard PGD template (Appendix 1) should be completed so that all legally required information is included and the information is presented in a consistent format across the organisation.

2.5 The medicine should generally be used in accordance with the Summary of Product characteristics (SmPc) available at www.medicines.org.uk as well as any national guidance or restrictions in place via MHRA in the form of “Risk Minimisation Measures” or “Black Triangle Status”. All guidance should be referenced in the PGD.

2.6 The author, authorising doctor (or dentist) and pharmacist are not required to physically sign the PGD document providing that there is an evidence chain in writing or email that they have reviewed and are happy to approve the PGD to go for consultation and divisional approval.

3. APPROPRIATE CONSULTATION AND DIVISIONAL APPROVAL

3.1 The PGD working group must ensure appropriate and adequate consultation before the PGD is passed on for further approval.

3.2 Appropriate and adequate consultation involves distribution to the appropriate professional group and staff that will be operating under the PGD.

3.3 The PGD should then be amended by the PGD working group if needed (based on this consultation) before being submitted for Divisional Approval

3.4 The respective Divisions can determine what groups they will allow to approve PGDs and will communicate this to the staff involved in production and review of PGDs in use within their Division.

3.5 The Divisional Group members will be asked to approve the PGD and can request further information or amendments as appropriate if they are not happy with the PGD at this stage.

3.6 The name of the group and the date of divisional approval will be added to the front cover of the PGD and sent back to the Associate Director of Pharmacy by the secretary of the divisional approval group.

4 MEDICAL DIRECTOR SIGN OFF

4.1 The Trust Medical Director will receive all PGDs for sign-off as delegated authority for the Trust.

4.2 The Associate Director of Pharmacy will send the Medical Director the PGD after Divisional sign off.

4.3 After the Trust Medical Director has signed the PGD, it is fully approved and may be used within the Trust by members of staff that are authorised to operate under it, are trained and competent and are signed up to the PGD.

5 POST-APPROVAL REGISTRATION OF THE PGD

Further actions take place once the PGD is fully approved:

5.1 The Medical Director sends the signed copy to the Associate Director of Pharmacy (Governance & Risk) for storage in the pharmacy department.

5.2 The Associate Director of Pharmacy (Governance & Risk) scans the documents and sends an electronic copy to the intranet webmaster for the trust to be uploaded onto the intranet. A second copy is retained on the Pharmacy Project Register.

5.3 The Associate Director of Pharmacy (Governance & Risk) adds the PGD to list provided to the Medicines Management Group for information.

5.4 The Associate Director of Pharmacy (Governance & Risk) informs the Divisional Governance Facilitator that the PGD is fully approved so that it can be registered onto the clinical audit programme for the wards and departments where it is to be used.

6 RECORD KEEPING

6.1 Each ward or department where PGDs are used must have a named person responsible for ensuring that all staff operating under each PGD are fully competent, suitably trained and qualified to do so*. This will usually be the ward/department manager but may be delegated.

* This competence will include a review of the PGD with the ward/department manager or suitable deputy

6.2 This named person is responsible for maintaining a register of such suitable staff able to operate under each PGD and a separate register detailing all PGDs that the staff member is able to operate under (See Appendices 2 & 3).

6.3 This named person is responsible for ensuring that the competency of such suitable staff is reviewed every 12 months and recorded on the register. (Appendices 2 & 3).

6.4 A copy of the registers must be kept on the ward/department and be available for inspection by management teams as well as CQC or other inspection bodies

6.5 The Ward/Department manager is required to keep a list of all patients treated under the PGD. The format of this may be locally determined as the service dictates but as a minimum must record the PGD in question and the patient's PAS number. The record may be paper-based or electronic.

7 MONITORING AND REVIEW

7.1 The PGD review process should start 6 months prior to the expiry date to ensure continued use. They have an expiry date on that can't be breached under the legislation authorising their use so it is vital that this review is commenced in good time.

7.2 The PGD must be reviewed by a PGD working group (as described in Section 2)

7.3 The reviewed and consulted PGD must be submitted to the relevant Divisional Group at least 3 months prior to the expiry date to allow the governance processes and signing to be completed in time.

7.3 PGDs may be reviewed sooner if needed due to (amongst other things):-

7.3.1 Changes in legislation.
7.3.2 New evidence of guidance such as new NICE guidance.
7.3.3 New information on drug safety.
7.3.4 Changes in the summary of product characteristics.
7.3.5 Changes to the local or regional (GMMMG) formulary.

7.4 The planned review of all PGDs within a ward/department must be part of that areas audit calendar and duly registered with the audit department.

7.5 Failure to follow written instructions in a Patient Group Direction will be investigated under the Trust Medication Error Procedure (TW10-037 SOP 19).

8 HUMAN RIGHTS ACT

Implications of the Human Rights Act have been taken into account in the formulation of this document and they have, where appropriate, been fully reflected in its wording.

9 ACCESSIBILITY STATEMENT

This document can be made available in a range of alternative formats e.g. large print, Braille and audio cd.

For more details, please contact the HR Department on 01942 77 3766 or email equalityanddiversity@wwl.nhs.uk

Title:	Patient Group Direction (PGD) for the use of **Drug Name** by *group of staff*
Date PGD comes into effect:	
Date PGD is to be reviewed:	(review date to be 6 months prior to expiry date)
Date PGD expires: (No more than 3 years after approval date)	
Medicine Name:	
Concentration:	
Form:	
Legal Classification:	
Healthcare Professionals allowed to administer the medicine under the terms of this PGD:	
Specialist training required by the Healthcare Professionals and requirements for maintaining competence that must be met before they can administer the medicine under this PGD:	

SIGNATURES and APPROVAL

Author:	
Authorising Clinician: (A doctor or dentist working in the area that the PGD is to be used)	
Authorising Pharmacist: (PDCA Pharmacist or Deputy Band 7 & above)	
Name and Date of Divisional Approval Group:	**Name of Group and Date Approved**
On behalf of WWL (Medical Director)	**Name & Date of Signature – Medical Director**

PATIENT GROUP DIRECTION DETAIL:

Clinical Condition:	
Inclusion Criteria:	
Exclusion Criteria:	
When to seek further advice:	
Description of Treatment	
Name of Medicine:	
Legal Status:	
Form:	
Dosage:	
Maximum Total Daily Dose:	
Maximum Duration of Treatment:	
Maximum Total Treatment Quantity:	
Follow Up:	
Adverse Reactions:	
Written and Verbal Advice to be given to the patient/carer. Note: All medicines to be taken away must have an approved Patient Information Leaflet supplied	
References: (Link to Summary of Product Characteristics and any NICE or other national/regional/local guidance)	

RECORD KEEPING AND AUDIT

Method of recording which patients have been treated under this PGD	
Method of recording which staff are currently authorised to use this PGD (CQC or other bodies can request this at any time)	

REVIEW

- The PGD must be reviewed every 3 years by the author, pharmacist and clinician
- Number of patients treated under the PGD must be recorded at ward/department level
- Number of staff currently authorised to use the PGD at time of review must be recorded at ward/department level
- PGDs can be reviewed sooner in the event of any significant changes

Appendix 2: PGD Individual Staff Signature Sheet

Department/Ward:

Staff Member Name:

The signatures below indicate that the staff member named has been trained in the specified PGDs by the named trainer. The staff member has read and understands the PGDs listed and agrees to abide by the protocols as set out. The training must be reaffirmed every 12 months.

Staff requiring general training in PGDs are encouraged to complete the CPPE package “Patient Group Directions” available to registered staff via the e-LfH Hub as this provides a good grounding in the subject area.

Patient Group Direction (PGD)	Date	Staff Signature	Trained By Signature	Trained By Printed	Date Reviewed	Reviewed By	Date Reviewed	Reviewed By

Appendix 3

PGD Ward/Department Signature List

Department/Ward:

PGD Title:

The staff detailed below are currently authorised to operate under this PGD in the ward/department specified. Staff are suitably trained and competent to do so, as detailed on their individual Signature Sheets. Staff must be re-trained and re-sign every 12 months.

Staff Member (Printed Name)	Staff Member (Signature)	Date of Signing: