Wrightington, Wigan and Leigh Teaching Hospitals
NHS Foundation Trust

POLICY NAME:	**PATIENT GROUP DIRECTIONS POLICY**
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VERSION NUMBER:	**4**
APPROVING COMMITTEE:	**MMSG (Medicines Management Strategy Group)**
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AUTHOR (S) (JOB TITLE)	**Associate Director of Pharmacy (Governance & Risk)**
DIVISION/DIRECTORATE:	**TRUSTWIDE**
LINKS TO ANY OTHER POLICIES/PROCEDURES:	**TW15-010 SOP 1 PATIENT GROUP DIRECTIONS** **TW10-037 – Medicines Management Policy**
CONSULTED WITH:	**Pharmacy Quality & Safety Group (PQSG)** **MMSG Membership**

DATES PREVIOUS VERSION(s) APPROVED	Version: 3	Date: October 2020
NEXT REVIEW DATE:	**July 2026**	
MANAGER RESPONSIBLE FOR REVIEW	**DIRECTOR OF PHARMACY**	

The WWL Way

Version Control

Version	Date	Amendment
4	July 2023	• Advised that the only physical signature required is the Medical Director (MD) provided that written (or email) approval has been given and retained for the previous steps in the approval process • 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 A Patient Group Direction (PGD) is defined in Health Service Circular (HSC 2000/026) as: 'Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.' (*This doesn't mean that the patient shouldn't be identified, just that they don't need to have an individual treatment plan in place for a PGD to be allowable).*

1.2 PGDs provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients (through the use of inclusion and exclusion criteria) needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber. Using a PGD is not a form of prescribing.

2 POLICY STATEMENT

2.1 The purpose of this guidance is to provide information about best practice when developing, authorising, using and updating Patient Group Directions (PGDs) at Wrightington, Wigan & Leigh Teaching Hospitals NHS Foundation Trust (hereafter referred to as "the Trust").

2.2 This guidance explains the mechanism by which PGDs must be developed and the various approval steps that are required before they can be used by healthcare professionals working for the Trust.

2.3 This policy describes governance arrangements that are required to ensure that patients receive safe, legal and timely treatment and that records which staff are operating under the PGD, assures that they are trained and retrained at regular intervals and that regular audit is carried out to ensure that the PGD is still required and is the most appropriate method of providing the medication in question for the group(s) of patients being treated – it also describes records needed for patients treated under the PGD.

2.4 This policy is based on MHRA guidance (2014, updated Dec-17) and NICE Guideline MPG2 (2013, updated Mar-17) to provide a local adaptation of the national regulations that the Trust must adhere to.

2.5 The policy applies to the following groups of staff:-

2.5.1 All medical staff.
2.5.2 All registered nursing staff and midwifery staff.
2.5.3 All other Health Care Professionals (that are able to use PGDs – detailed later in this policy).

3 RESPONSIBILITIES

3.1 **Trust Board**

The Trust Board will receive reports from the Medicines Management Board on an annual basis to enable the monitoring of compliance with this policy.

3.2 **Chief Executive**

The Chief Executive has the overall statutory responsibility for the safe and secure handling of medicines. Within the trust the responsibility for signing off PGDs on behalf of the organisation has been delegated to the Medical Director.

3.3 **Medical Director**
The Medical Director will sign off all PGDs before they are accepted for use within the trust thus assuring that the statutory requirement for organisational approval is upheld.

3.4 **Medicines Management Board**
The Medicines Management Board will receive notification of all new or amended PGDs from the Associate Director of Pharmacy (Governance & Risk)

3.5 **Associate Director of Pharmacy (Governance & Risk)**
Will be responsible for maintaining an up-to-date list of all PGDs and advising authors when they require review so they can be submitted to the Divisional approval group.

3.6 **Divisional Approval Groups**
Appropriate Divisional Groups will approve all PGDs submitted to them. 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.

3.7 **Ward/Department Managers**
- 3.7.1 Maintain a list of all PGDs in operation within their area of responsibility.
- 3.7.2 Maintain a list of all staff operating under each of those PGDs.
- 3.7.3 Ensure that all staff using PGDs are competent, have been trained and are suitably qualified, including an annual review of their knowledge of the PGDs.
- 3.7.4 Maintain a method of identifying patients treated with PGDs in their area for audit and quality assurance purposes.
- 3.7.5 Notify any changes to PGDs or staff operating under them to the Deputy Chief Pharmacist (Governance) so that up-to-date electronic records can be maintained.
- 3.7.6 Investigate occurrences of staff not following written instructions within the PGD as per the Trust Medication Error Procedure (TW10-037 SOP 19).

3.8 **Staff Working Under PGDs**
- 3.8.1 Will only operate under a PGD once they have read it, have been trained in its use and have the qualifications stated therein.
- 3.8.2 Will record all patients treated under the PGD in the manner determined locally by the ward/department where it is being used.
- 3.8.3 Will report any incidents or concerns arising from the use of the PGD to their line manager.
- 3.8.4 Will maintain competence by at least annual review of the PGD with their ward/department manager.
- 3.8.5 Will be signposted to the free CPPE package Patient Group Directions available via the E-Learning for Healthcare (e-LfH) website.

4. KEY PRINCIPLES

4.1 When considering whether a PGD is the best way to provide the particular treatment to a patient, it is important to be aware of the ways that medicines can be supplied in England. It may be that it is more appropriate to supply the medicine in one of the other ways and this should be ruled out before a PGD is developed.

4.2 The historical model is that a doctor (or dentist) writes a prescription for a patient and the medicine is dispensed against this prescription by a pharmacist or dispensing doctor and supply the medication to the patient. Historically, a doctor (or dentist) would identify that a medicine(s) was needed as part of the care pathway and prescribe a medicine for the patient. A pharmacist (or dispensing doctor) would then dispense the medicine(s) against the prescription and supply the medicine(s) to the patient.

4.3 Changes in legislation now mean that there are other ways to legally prescribe, supply and administer medicines. These options provide organisations with a range of alternatives to consider when making decisions about the safest and most appropriate way for patients to get the medicines they need:-

- 4.3.1 **Independent prescribing** – the prescriber (a doctor, dentist or non-medical independent prescriber) takes responsibility for the clinical assessment of the patient, establishing a diagnosis, the clinical management needed and prescribing.
- 4.3.2 **Supplementary prescribing** – a voluntary partnership between a doctor or dentist and a supplementary prescriber, to prescribe within an agreed patient-specific clinical management plan with the patient's agreement.
- 4.3.3 **Patient Specific Directions** (**PSDs**) – written instructions, signed by a doctor, dentist, or non-medical prescriber for a medicine to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. Writing a PSD is a form of prescribing.
- 4.3.4 **Patient Group Directions (PGDs)** as described in this policy.
- 4.3.5 **Exemptions** from medicines legislation, for example:
  - 4.3.5.1 A range of exemptions enable certain groups of health professionals, such as chiropodists and podiatrists, midwives, paramedics and optometrists, to sell, supply and administer particular medicines directly to patients (Pharmacy can provide further information on this if required).
  - 4.3.5.2 Occupational health schemes exist that are exempt.
  - 4.3.5.3 Pandemic disease allows for provision of vital medications outside of the usual medicines legislation.
- 4.3.6 **Parenteral medicines** that can be administered in an emergency without the directions of a prescriber.
- 4.3.7 **Emergency supplies** – in an emergency and under certain conditions, a pharmacist working in a registered pharmacy can supply a previously prescribed Prescription-Only Medicine (POM) to a patient without a prescription, if requested by a prescriber or the patient.

5. PURPOSE OF PATIENT GROUP DIRECTIONS

5.1 The Health Service Circular (HSC 2000/026) states that 'the majority of clinical care should be provided on an individual, patient-specific basis. NICE guidance agrees that prescribing or a PSD remains the preferred option for the majority of care. Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care without compromising patient safety, and there are clear governance arrangements and accountability.

5.2 The NICE guideline states that the purpose of a PGD has 6 elements:-

5.2.1 Deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety.
5.2.2 Offer a significant advantage to patient care by improving access to appropriate medicines.
5.2.3 Provide equity in the availability and quality of services when other options for supplying and/or administering medicines are not available.
5.2.4 Provide a safe legal framework to protect patients.
5.2.5 Reduce delays in treatment.
5.2.6 Maximise the use of the skills of a range of health professionals.

6. LEGAL FRAMEWORK GOVERNING THE USE OF PATIENT GROUP DIRECTIONS

6.1 Legislation establishing PGDs was introduced in 2000 and the Health Service Circular (HSC 2000/026) provided additional guidance. The current legislation for PGDs is included in The Human Medicines Regulations 2012, which came into force in August 2012. This legislation was amended in April 2013 to reflect changes to NHS organisational structures in England, as a result of the Health and Social Care Act 2012.

6.2 Legislation requires that a PGD must be signed by a doctor (or dentist) and a pharmacist. In the trust, this will usually be the lead clinician and Principal Pharmacist* in the area in which the healthcare professional is operating. (* This can be delegated by the Principal Pharmacist to a doctor and pharmacist Band 7 and above with experience in authorising PGDs).

6.3 The PGDs must also be signed on behalf of the trust - this duty is assigned to the Medical Director.

7. HEALTH PROFESSIONALS ELIGIBLE TO USE PATIENT GROUP DIRECTIONS

7.1 PGDs can only be used by specified healthcare professionals under the legislation:-

7.1.1 Chiropodists and podiatrists
7.1.2 Dental therapists & hygienists
7.1.3 Dieticians
7.1.4 Midwives
7.1.5 Nurses
7.1.6 Occupational therapists
7.1.7 Optometrists
7.1.8 Orthoptists and Prosthetists
7.1.9 Paramedics
7.1.10 Pharmacists
7.1.11 Physiotherapists
7.1.12 Radiographers
7.1.13 Speech and Language therapists

7.2 Being a member of these groups does not automatically allow you to operate under a PGD - Individual health professionals must be named, trained and authorised to practice under a PGD as detailed in paragraph 3.9

7.3 The manager of the area in which the PGD operates (ward, clinic, theatre etc) must maintain a register of all healthcare professionals working under specific PGDs that are in

operation there. This register must be kept on the ward/department where the PGD is in operation.

7.4 A central electronic register of PGDs will also be made available on the trust intranet – it is the manager's responsibility to advise changes to the Associate Director of Pharmacy (Governance and Risk) so that an up-to-date list may be maintained.

8. MEDICINES AND HEALTHCARE PRODUCTS EXCLUDED FROM PGDS

8.1 Unlicensed medicines (a licensed medicine may be used "off-label" in exceptional circumstances but which must be included in the PGD – e.g. no other product available).
8.2 Special manufactured medicines.
8.3 Dressings, appliances and devices.
8.4 Radiopharmaceuticals.
8.5 Abortifacients, such as mifepristone.
8.6 Controlled drugs unless they appear in the table below:

Schedule	Controlled drugs that may be considered for inclusion in a PGD	Additional comments
Schedule 2	Morphine Diamorphine Ketamine (from 30/11/15)	Use by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person (except for treating addiction)
Schedule 3	Midazolam	Tramadol is Schedule 3 since 10/06/14 and so may not be supplied and administered under a PGD
Schedule 4	All drugs except those mentioned in the associated comments	Anabolic steroids and any injectable preparation used for treating addiction must not be included in a PGD
Schedule 5	All drugs, including codeine	

8.7 Medicines with "Risk Minimisation Measures (RMM)" such as MHRA mandated requirements for additional warning cards, checklists or controlled access schemes may not be suitable for inclusion in a PGD. Where they are included, the requirements of the RMM must be included in the PGD and complied with in full.

8.8 Black Triangle medicines are those that are new to market that are intensively monitored and subject to special reporting arrangements for adverse events. They should only be included in a PGD when clearly justified by best clinical practice. The black triangle status must be clearly stated within the PGD.

9 INFORMATION TO BE INCLUDED IN A PATIENT GROUP DIRECTION

9.1 Full instruction on required information and the process to be followed to produce a PGD is found in the associated SOP "Patient Group Directions: Production, Approval and Review".

9.2 The following information is required in the PGD:-

9.2.1 The date when the PGD is operational - start and stop date.
9.2.2 The medicine to which the PGD relates as well as details of the form, class, route, frequency.
9.2.3 The condition(s) that may be treated with the medicine under the PGD.

9.2.4 Any restrictions on individual dose or total quantity to be sold, supplied or administered and any conditions relating to this including maximum length of treatment.
9.2.5 Inclusion and exclusion criteria – Who can and can't be treated under the PGD.
9.2.6 The circumstances when further advice should be sought from a doctor or dentist or immediate referral for medical help and what form that emergency help will take.
9.2.7 Whether there are any relevant warnings to note and, if so, what warnings.
9.2.8 Whether there is any follow up action to be taken in any circumstances and, if so, what action and in what circumstances.
9.2.9 Details of the records to be kept of the supply, or the administration, of products under the direction. This includes: patients treated and staff members using the PGD.

10 ASSOCIATED REGULATIONS

10.1 Prescription Only Medicines (POMs) supplied under a PGD must be labelled in accordance with legislation even if supplied under a PGD. As such all such medicines should be provided by the pharmacy department as appropriate.

10.2 A manufacturer's patient information leaflet (PIL) must be provided to patients who have a medicine supplied under a PGD. This is not required by legislation when a medicine is administered. Original packs will contain a PIL – details of how to obtain further copies can be obtained from the pharmacy department.

10.3 If the patient receives a supply of medication that would usually attract a prescription charge then this must still be collected under a PGD. Prescription charges do not apply when medicines are administered under a PGD.

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

11 RECORD KEEPING

Full details of the records that are required to be kept are found in the associated SOP – Patient Group Directions: Production, Approval and Review.

12 MONITORING AND REVIEW

Full details of the monitoring and review arrangements that are required are found in the associated SOP – Patient Group Directions: Production, Approval and Review.

13 HUMAN RIGHTS ACT

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

14 INCLUSION AND DIVERSITY

The Policy has been assessed against the Equality Impact Assessment Form from the Trust's Equality Impact Assessment Guidance and, as far as we are aware, there is no impact on any protected characteristics.

15 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

APPENDIX 1

REFERENCES AND FURTHER INFORMATION:

1)	NICE Guideline [MPG2]: Patient Group Directions	May 2017
2)	MHRA Guidance: Patient Group Directions (PGDs)	Dec 2017
3)	SI: The Human Medicines Regulations 2012	Aug 2012
4)	To PGD or not to PGD? V9.4 – SPS.NHS.UK	Jan 2018

For instructions on how to produce a PGD and take it through the steps required receiving full Trust Approval please refer to the associated SOP – “Patient Group Directions: Production, Approval and Review”

Appendix 2

Equality Impact Assessment Form

STAGE 1 - INITIAL ASSESSMENT

For each of the protected characteristics listed answer the questions below using **Y** to indicate Yes and **N** to indicate No	Protected Characteristics														Reasons for negative / positive impact
	Male / Female	Age	Ethnicity	Learning Disability	Hearing Impairment	Visual Impairment	Physical Disability	Mental Health	Gay / Lesbian / Bisexual	Transgender	Religion / Belief	Marriage / Civil Partnership	Pregnancy & Maternity	Carers	
Does the policy have the potential to affect individuals or communities differently in a negative way?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
Is there potential for the policy to promote equality of opportunity for all / promote good relations with different groups – Have a positive impact on individuals and communities.	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
In relation to each protected characteristic, are there any areas where you are unsure about the impact and more information is needed?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	If Yes, please state how you are going to gather this information.

Job Title	**Associate Director of Pharmacy, Governance and Risk**	**Date**	8th September 2020

IF 'YES an NEGATIVE IMPACT' IS IDENTIFIED - A Full Equality Impact Assessment STAGE 2 Form must be completed. This can be accessed via
http://intranet/Departments/Equality_Diversity/Equality_Impact_Assessment_Guidance.asp

Please note: As a member of Trust staff carrying out a review of an existing or proposal for a new service, policy or function you are required to complete an EIA. By stating that you have NOT identified a negative impact, you are agreeing that the organisation has NOT discriminated against any of the protected characteristics. Please ensure that you have the evidence to support this decision as the Trust will be liable for any breaches in Equality Legislation.

POLICY MONITORING AND REVIEW ARRANGEMENTS

Para	Audit / Monitoring requirement	Method of Audit / Monitoring	Responsible person	Frequency of Audit	Monitoring committee	Type of Evidence	Location where evidence is held
	Review of this policy	Direct Review and distribution for comments to stakeholders	Director of Pharmacy	Every 3 years	Medicines Management Standards Group	Minutes of meeting	Project Register in Pharmacy

Please note that the review of the individual elements of the PGD process: Staff training, patients being treated (number and detail of the treatment received), number of staff operating under the PGD and review of the PGD as a whole every 3 years are detailed in the associated SOP – Patient Group Directions: Production, Approval and Review