NHS Lanarkshire Patient Group Directions Processes

TARGET AUDIENCE	Registered health care professionals across NHS Lanarkshire who are likely to work under or manage the process of patient group directions.

WHAT IS A PATIENT GROUP DIRECTION?

A Patient Group Direction (PGD) is a legal, written instruction for the supply and/or administration of medicines to groups of patients who may not be individually identified before presenting for treatment. Only licensed medicines with UK marketing authorisation can be considered for a PGD.

A PGD allows a specified registered health care professional to supply and/or administer a prescription only medicine (POM) directly to a patient with an identified clinical condition without the need for a prescription or an instruction from a prescriber. PGDs can be used for the supply of a Pharmacy Only (P) medicine but not for their administration and PGDs cannot be used for supply or administration of a General Sales List (GSL) medicine.

The supply and/or administration of medicines under a PGD cannot be delegated – the whole episode of care must be undertaken by the registered health care practitioner operating under the PGD.

The preferred way for a patient to receive a medicine is for a prescriber to provide care for an individual patient on a one to one basis. A PGD should not be used unless there are clear benefits for patient care without compromising patient safety, and there are clear governance arrangements and accountability.

Further detail on all aspects of PGDs can be found at the following website - Patient Group Directions – SPS - Specialist Pharmacy Service.

Key links within the Specialist Pharmacy Service guidance on PGDs include:

- An introduction to PGDs: definitions and examples of use
- The 7 Steps for developing a PGD
- When to use a PGD?
- When not to use a PGD
- What are the roles and responsibilities of the PGD signatories

NHS Lanarkshire Patient Group Directions Processes

DEVELOPMENT OF A PGD

Before developing a PGD or reviewing an existing PGD, the need for a PGD should be assessed. Consider if there is already an opportunity in the care pathway for the medicine to be prescribing in a safe and timely manner.

A PGD should be developed by a multi-disciplinary group that includes a doctor, a pharmacist and a representative of the professional group expected to supply the medicine under the PGD. Knowledge about PGD legislation and governance as well as clinical expertise in the medicines and service where the PGD is being considered is essential. Health professionals involved in PGD development should refer to their own regulatory or professional standards.

It is important to ensure the lead author has the competencies and experience required to write a PGD. They should also ensure all contributing authors are involved at all stages of development, to check for clinical accuracy and validity according to the specialty.

CLINICAL AND ORGANISATIONAL SIGNATORIES

CLINICAL SIGNATORIES should be identified at an early stage and they should know why they are signing and understand their roles/responsibilities. Clinical Signatories must include:

1. A doctor (or dentist) involved in the development of the PGD
2. A pharmacist involved in the development of the PGD
3. A signatory who is a representative of the registered health professional group expected to supply and/or administer the medicine under the PGD

Where the representative of the registered health professional group is a pharmacist, it would be good practice to involve an additional pharmacist with expertise in the specific clinical area of practice who would use the PGD.

ORGANISATIONAL SIGNATORIES may vary depending on the type of PGD – further details can be found under the relevant PGD category later in this guidance. The clinical governance or patient safety lead involved in the organisational authorisation of the PGD should not be involved in developing the PGD and will not practice under the PGD. Organisational Signatories can include:

- Executive Medical Director
- Director of Pharmacy or Associate Director of Pharmacy
- Executive Nurse Director

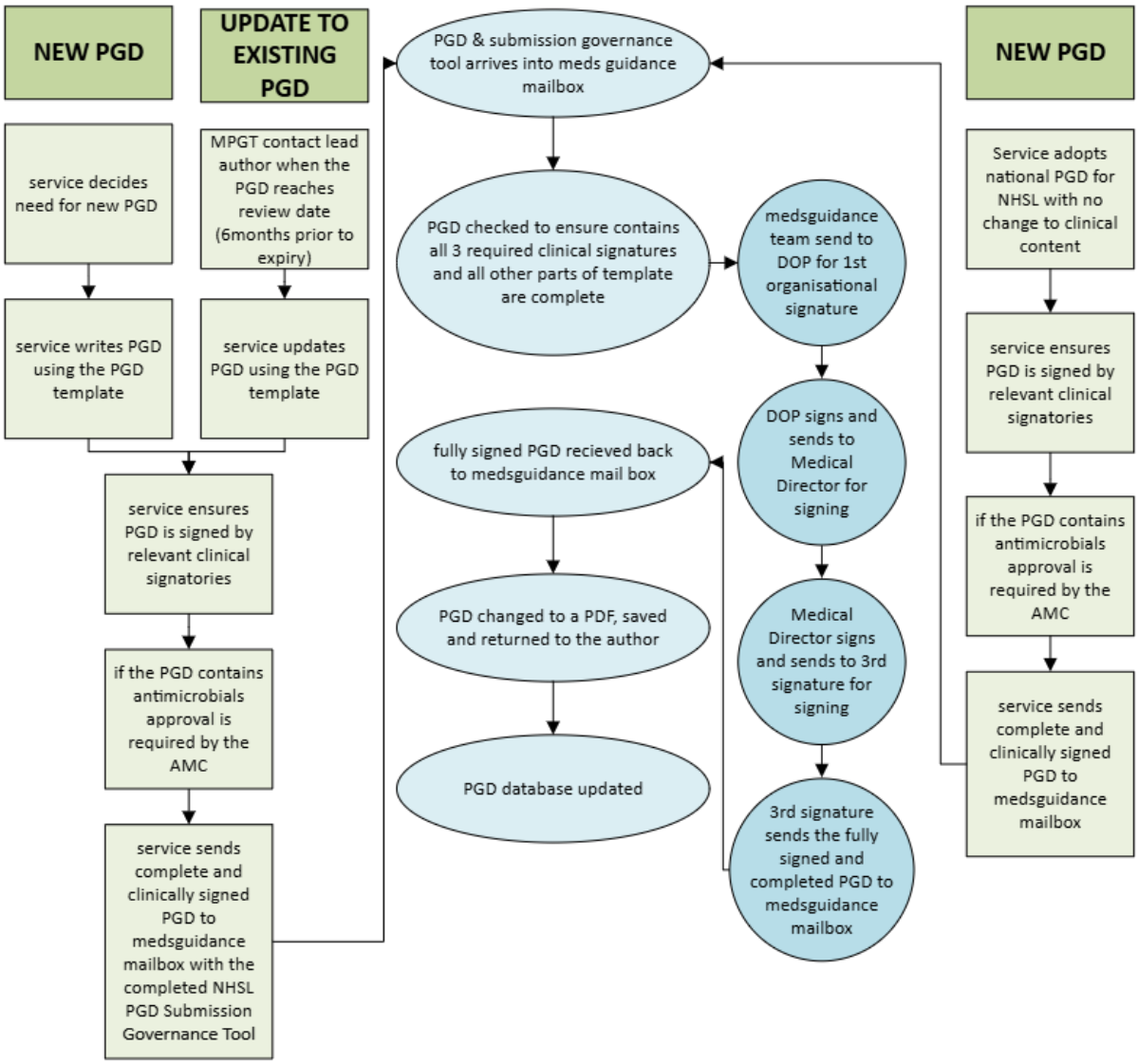
Additionally, for Immunisation PGDS

- Associate Primary Care Medical Director / Chair Vaccine Services Clinical Governance Committee
- Immunisation Coordinator

NHS Lanarkshire have a PGD template that all PGD's developed by NHS Lanarkshire teams are required to use which can be found at here. This should be emailed to the medicines Guidance team as a word document with electronic signatures. Please see the following link for more details. https://www.sps.nhs.uk/articles/questions-electronic-systems-and-pgds/

NHS Lanarkshire Patient Group Directions Processes

NHS LANARKSHIRE PGD DEVELOPMENT AND APPROVAL PROCESS



Any specifics relating to processes for the individual categories are detailed below.

The NHSL PGD Submission Governance Tool should be submitted to the Medicines Policy and Guidance Team (MPGT) along with the PGD which is requiring board sign off and can be found here.

NHS Lanarkshire Patient Group Directions Processes

ACUTE & PRIMARY/COMMUNITY CARE PGDS

NHS Lanarkshire template for use with all primary/community care and acute sector PGDs can be found here.

The PGD must be signed by a doctor (or dentist) and a pharmacist who have been involved in the development of the PGD. It is also good practice for PGDs to be signed by representative(s) of the registered health professional group intended to supply and/or administer the medicine under the PGD. Where the representative of the registered health professional group is a pharmacist, it would be good practice to involve an additional pharmacist with expertise in the specific clinical area of practice who would use the PGD.

In primary care where there is no clearly relevant specialist pharmacist e.g. physiotherapy please contact the MPGT for further advice.

CLINICAL SIGNATORIES include:

- Lead Author
- Doctor/Dentist
- Pharmacist
- Relevant healthcare professional

Please note; the lead Author may be the same individual as one of the other 3 named producers of the PGD.

If the PGD contains antimicrobials it must be approved by the NHS Lanarkshire Antimicrobial Committee prior to health board sign off.

The finished PGD is then sent to the Medicines Policy and Guidance Team ***medsguidance@lanarkshire.scot.nhs.uk*** to obtain the following:

ORGANISATIONAL SIGNATORIES:

- Medical Director or Associate Medical Director
- Director of Pharmacy or Associate Director of Pharmacy
- Executive Nurse Director

NHS Lanarkshire Patient Group Directions Processes

COMMUNITY PHARMACY PGDS

The current list of approved PGDs for community pharmacy within NHS Lanarkshire can be found here https://www.communitypharmacy.scot.nhs.uk/nhs-lanarkshire/pages/pgds/ and includes PGDs for the treatment of a range of conditions including herpes zoster, bacterial skin infections, impetigo, urinary tract infection and seasonal allergic rhinitis.

Most of community pharmacy PGD's are developed from national templates with final approval locally in each health board. The process within NHS Lanarkshire for approval is coordinated by the Lead Pharmacist for Community Pharmacy Services.

Community Pharmacy (Pharmacy First) PGDs are not required to be approved by any additional committees in NHS Lanarkshire because they are developed from national templates. The exception is any PGDs that include antibiotics will be approved by the NHS Lanarkshire Antimicrobial Committee.

The national PGD is then sent to the Medicines Policy and Guidance Team ***medsguidance@lanarkshire.scot.nhs.uk*** to obtain the following:

ORGANISATIONAL SIGNATORIES:

- Medical Director
- Director of Pharmacy
- Associate Director of Pharmacy or Lead Pharmacist for Pharmacotherapy and Community Pharmacy Services

Once signed the final copy of the PGD is saved in the NHS Lanarkshire PGD database and sent to the Lead Pharmacist for Community Pharmacy Services who is then responsible for dissemination to community pharmacies and also for uploading them to the above community pharmacy Scotland website.

Any PGDs used in community pharmacy which are NHS Lanarkshire board authored, e.g. Levonorgestrel for emergency hormonal contraception, should go through the same development steps detailed for PGDs used within primary care.

NHS Lanarkshire Patient Group Directions Processes

IMMUNISATION PGDS

Public Health Scotland develops specimen national PGD templates for specific vaccines in order to assist NHS Boards. Further information can be found here – Public Health Scotland – PGDs.

It is not expected that the contents of the national templates will be altered, however if changes are required they must be approved by the Area Oversight Vaccination and Immunisation Group prior to organisational approval.

These national immunisation PGDs require to be approved and signed by the following CLINICAL SIGNATORIES:

- Lead Medical Clinician for Vaccine Services
- Lead Pharmacist for Vaccine Services or Senior Medicines Guidance Pharmacist
- Lead Nurse for Vaccine Services

The national PGD is then sent to the Medicines Policy and Guidance Team ***medsguidance@lanarkshire.scot.nhs.uk*** to obtain the following:

ORGANISATIONAL SIGNATORIES:

- Medical Director or Associate Primary Care Medical Director and Chair Area Oversight Vaccination and Immunisation Group
- Director of Pharmacy or Associate Director of Pharmacy
- Immunisation Coordinator

Once signed the final copy of the PGD is saved in the NHS Lanarkshire PGD database and sent to the immunisation coordinator for dissemination.

The Vaccine Service also uses National Protocols for Influenza and COVID vaccinations. These cannot be modified at Health Board level so there is no local sign off but the process for dissemination and publication is the same as for PGDs.

NHS Lanarkshire Patient Group Directions Processes

ACCESS AND STORAGE OF PGDS

Currently PGDs are being catalogued in a database and final copies of PGDs are stored by the Medicines Policy and Guidance Team.

A central database is under development by the Medicines Policy and Guidance Team to allow oversight and to send reminders and alerts when PGDs are nearing expiry. PGDs generally have a 3-year expiry with a review date set for 6months before expiry date.

The responsibility of the content of the PGD will rest with the signatories and not the Medicines Policy and Guidance Team.

MONITORING, REVIEWING & EVALUATING PGD USE IN PRACTICE

When a PGD is due for review, the ongoing need for the PGD should be assessed as the preferred way for individuals to receive medicines is for a prescriber to provide care for an individual on a one-to-one basis.

Each PGD has an expiry date and 6 months prior to the expiry date, the lead author will be alerted and the requirement of review of the PGD from the team overseeing the PGD database. Even if only minor amendment is required following review, the PGD must go through the same authorising process as outlined above. The full process must be complete before the final expiry date of the existing PGD lapses.

AUDIT

There are 4 stages to the ongoing audit of PGDs within NHS Lanarkshire. Further information can be found in Appendix 3.

A. Governance – Process Oversight
B. Governance – PGD Content
C. Clinical Patient Factors/clinician decision factors
D. Operational – Staff Factors/Service Level Factors

FREQUENTLY ASKED QUESTIONS

1. ***Are there standard templates that a service can use when developing a PGD?***
   Yes – there is a specific template which can be found here. As long as the PGD fulfils the legal needs and is clearly presented, there can be minor amendments to some standard sections if required.
2. ***Where can I get further information on the detail of PGDs and what I might need to consider in developing or signing off a PGD?***
   There is very helpful guidance in the SPS website - Patient Group Directions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice.
3. ***Who do I contact if I want to know the availability or status of a PGD in NHS Lanarkshire?***
   Please contact ***medsguidance@lanarkshire.scot.nhs.uk*** for more information
4. ***What specific expertise should be involved in signing off a PGD?***
   Please refer to the following guidance for further information - What are the roles and responsibilities of the PGD signatories
5. ***What happens if one of the signatories leaves NHS Lanarkshire?***
   When a signatory signs a PGD they are acting within their role as agreed by their organisation/ detailed in role specification - as such there is no requirement for a PGD to be resigned if a signatory leaves an organisation.

NHS Lanarkshire Patient Group Directions Processes

APPENDICES

1. GOVERNANCE INFORMATION FOR GUIDANCE DOCUMENT

Lead Author(s):	Medicines Policy and Guidance Team
Endorsing Body:	ADTC
Version Number:	2
Approval date	22/01/2025
Review Date:	22/01/2028
Responsible Person (if different from lead author)	

CONSULTATION AND DISTRIBUTION RECORD	
Contributing Author (s)	
Consultation Process / Stakeholders:	• Heads of Pharmacy at Hairmyers, Monklands and Wishaw • Primary care central prescribing team • Margot Russell - Director NMAHP Practice Development, Practice Development Centre • Dr Henry A. Prempeh - Immunisation Coordinator • Dr Chris Deighan - Executive Medical Director • Graeme Bryson – Director of Pharmacy
Distribution	ADTC

CHANGE RECORD			
Date	**Lead Author**	**Change**	**Version**
27/12/2024	Medicines Policy and Guidance Team	Review, revise and update of policy in line with contemporary professional structures and practice Clarity around submission and update process Inclusion of governance process	2

NHS Lanarkshire Patient Group Directions Processes

2. PGD RECORD MANAGEMENT

The National Institute for Health Care Excellence (NICE) sets out what is required for the maintenance and storage of PGD records. Full information can be found here: https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations#organisational-governance

RESPONSIBILITY OF SERVICE USING PGD

- Signatures of people signing a PGD
- A list of named, registered health professionals authorised to practise under each PGD used within the service
- Training records
- Reporting of patient safety incidents, such as medication errors, near misses and suspected adverse events for board scrutiny

RESPONSIBILITY OF THE MEDICINES POLICY AND GUIDANCE TEAM

- A list of all PGDs in use within the organisation, including their review date and expiry date
- Master authorised copies of PGDs. Final authorised copies of PGDs are to be kept for a specific number of years after expiry depending on the patient group and the content of the PGD:
    - If relates to adults only: 8 years after expiry
    - If relates to adults only AND it relates to an implant: 10 years after expiry
    - If it relates to children: 25 years after expiry
    - Further information can be found here: Retaining legal mechanism documentation - Specialist Pharmacy Service
- Terms of reference and minutes or notes of the Medicines Clinical Oversight Board pertaining to PGDs
- Expired versions of PGDs
- Results of monitoring and evaluation

NHS Lanarkshire Patient Group Directions Processes

3. PGD AUDIT

PGD AUDIT – PART A – GOVERNANCE: PROCESS OVERSIGHT

RESPONSIBILITY OF THE MEDICINES POLICY AND GUIDANCE TEAM

This will be completed annually by the Medicines Policy and Guidance team and reported to the Medicines Clinical Oversight Board

	Questions		Yes/No
A1	Does NHS Lanarkshire have a PGD oversight group or similar?		
A2	Are there records of terms of reference and minutes or notes by the group?		
A3	Does the PGD oversight group or similar report into the organisation's clinical governance framework?		
A4	Is there current PGD guidance?		
A5	Does the current PGD guidance include:		
	A5.1	Considering the need for a PGD and obtaining agreement to develop a PGD	
	A5.2	Developing and submitting a PGD including review of need for a PGD/alternative mechanisms for administration/supply	
	A5.3	Authorising a PGD	
	A5.4	Authorising named, registered health professionals to use a PGD	
	A5.5	Training and competency	
	A5.6	Audit, review and updating a PGD (including review of continued need for PGD)	
A6	Is there a current and up-to-date list of all the PGDs in use within the organisation, including their review/expiry dates?		
A7	Are all master authorised copies of all current PGDs held by NHS Lanarkshire?		
A8	Are master copies of all expired versions of the PGDs held by the NHS Lanarkshire?		
A9	Is there an audit timetable for PGD audits within each service?		
A10	Are there any PGD related risks on the risk register?		

NHS Lanarkshire Patient Group Directions Processes

PGD AUDIT – PART B – GOVERNANCE: PGD CONTENT

RESPONSIBILITY OF THE MEDICINES POLICY AND GUIDANCE TEAM

This is an overarching review of all PGDs in use within an organisation. This will be completed by the Medicines Policy and Guidance team annually and reported to the Medicines Clinical Oversight Board.

The information will be complied using the NHS Lanarkshire PGD Submission Governance Tool which is completed by the PGD author and is submitted with the PGD at the point of organisational signatories. The NHS Lanarkshire PGD Submission Governance Tool can be found in appendix 4.

	Questions		Yes/No
B1	Number of PGDs currently in use within the primary care in NHS Lanarkshire		
B2	Do all medicines administered/supplied under a PGD have a UK Marketing Authorisation?		
B3	Have all medicines which have a current "black triangle" status been clearly indicated on the relevant PGD?		
B4	Is any off-label use clearly indicated on the relevant PGD?		
B5	Is there evidence that all antimicrobial PGDs have had an input from the local microbiology specialist?		
B6	Are there any PGDs that have been developed and used for the management of long-term conditions?		
B7	Are any of the medications included in PGDs for **administration** of a GSL, P or medicines exempt under schedule 17 or 19 of the Human Medicines Regulations (HMR) 2012?		
B8	Are any of the medications included in PGDs for **supply** of a GSL, P or medicines exempt under schedule 17 of the HMR 2012?		

NHS Lanarkshire Patient Group Directions Processes

PGD AUDIT – PART C – CLINICAL PATIENT FACTORS / CLINICAL DECISION FACTORS

TO COMPLETE AT INDIVIDUAL PGD LEVEL EITHER IN A SINGLE SERVICE OR CLINICAL AREA

This is to be completed by retrospective review of clinical records every 3 years on a rolling basis or sooner if indicated. The information collated can then be used to assess the ongoing need for the PGD at the point of review. This information will be submitted to the Medicines Policy and Guidance team and presented to the Medicines Clinical Oversight Board.

	Questions	Yes/No
C1	Is the clinical indication (which is listed in the PGD's inclusion criteria) stated in the patient's record?	
C2	Is there a record of all of the following: patient's full name, date of birth, registered GP (where applicable)	
C3	Is there a statement in the patient's record that supply and/or administration of the medicine was made using a PGD?	
C4	Is there a record of written or verbal information/advice that was given to the patient when supplying/administering any medicine under the PGD?	
C5	Is there a record of the patient's consent?	
C6	If the patient was excluded, is the reason recorded?	
C7	If the patient was excluded, is there a record of action taken?	
C8	If the patient refused treatment, is there a record of advice provided on alternatives/risk of no treatment?	
C9	Is there a register or other record of stock received and issued to patients under this PGD?	
C10	Does the Patient Record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)?	
C11	For vaccines, (or other medicines in line with local procedure) is both the batch number and expiry date recorded?	
C12	For injectable or topical medicines and implants is the site of administration recorded?	
C13	Is the date of supply or administration recorded?	
C14	Are all medicine packs supplied in their original pack (or a licensed pre pack) when supplied under a PGD? (i.e. packs not split)	
C15	Do all medicines supplied under any PGD have appropriate instruction labels on the pack including the health boards name, address and contact details?	
Name of PGD review:		
number of records reviewed and rationale for sample size:		

NHS Lanarkshire Patient Group Directions Processes

PGD AUDIT – PART D – OPERATIONAL – STAFF FACTORS/SERVICE LEVEL FACTORS

TO BE COMPLETED AT INDIVIDUAL SERVICE LEVEL

This should be completed annually and is the full responsibility of each individual service who utilises PGDs.

	Questions	Yes/No
D1	Do staff always have access to a copy of the latest version of the PGD they are working under available for reference at the time of the consultation?	
D2	Have all staff working under the PGD signed the latest version of that PGD?	
D3	Are all staff working under the PGD competent to work under that PGD?	
D4	Are all staff authorised to work under the PGD employed as one of the registered health professions listed in the PGD?	
D5	Is there an up-to-date list held within the service, of all staff authorised to work under each PGD in use?	
D6	Have all staff completed the necessary training and continuing professional development specified in the PGD/s they are authorised to work under?	
D7	Is there an up-to-date record within the service of all staff who have attended any required specific PGD training?	

Comments	
Completed by	
designation	
date	

4. NHSL PGD SUBMISSION GOVERNANCE TOOL

PGD Title	

	Questions	Yes/No/NA
1	Do all medicines administered/supplied under this PGD have a UK Marketing Authorisation?	
2a	Does this PGD contain any medicines which have current "black triangle" status? (denoted with an inverted black triangle next to its name in the BNF and indicates it is a new medicine and therefore is being more are intensively monitored)?	
2b	If answered yes above: have all medicines which have a current "black triangle" status been clearly indicated within the PGD?	
3a	Does this PGD contain any off label use of medications (being used for an indication out with the product license)?	
3b	If answered yes above have all medicines which are being used off label been clearly indicated within the PGD?	
4a	Does this PGD contain any antimicrobials?	
4b	If answered yes above has this PGD been approved by the Anti-Microbial Committee (AMC)?	
5	Is this PGD to be used for the management of a long term condition?	
6a	Are any of the medications included in this PGD for **administration** of a General Sales List (GSL) product, Pharmacy Only (P) medicine or medicine exempt under schedule 17 or schedule 19 of the Human Medicines Regulations (HMR) 2012?	
6b	Are any of the medications included in this PGD for **supply** of a General Sales List (GSL) product, Pharmacy Only (P) medicine or medicine exempt under schedule 17 of the HMR 2012?	
Comments		

Completed by (lead author of PGD)	
Designation	
Date	

FOR MPGT USE ONLY

Date of PGD approval	
Date added to PGD database	
PGD expiry date	