NHS
Coventry and Warwickshire
Integrated Care Board

Policy for Patient Group Directions (PGDs)

Reference Number:	This will be applied to all new ICB-wide PPSs by the Governance and Corporate Affairs Team and will be retained throughout its life span.
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Name of author and title:	
Name of reviewer and title:	
Department:	Corporate Office

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.

Contents

1. Background

Patient Group Directions (PGDs) provide a legal framework that allows defined registered health professionals to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber (such as a doctor or nurse prescriber). 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. PGDs are not a form of prescribing.

This policy outlines the approach to be taken by NHS Coventry and Warwickshire Integrated Care Board ('the ICB') to the development, approval, and implementation of PGDs.

1.1 Where can PGDs be used?

This ICB policy aligns with national guidance. PGDs may be used in all areas in which NHS healthcare is directly provided, and where services in the private, voluntary or charitable sector are NHS funded. PGDs do not however, extend to independent and public sector care homes or independent sector schools that provide healthcare entirely outside the NHS.

1.2 Limitations on PGDs usage

A PGD is not required:

- If an exemption exists under the Medicines Act;
- If the medicine involved is on the General Sales List (classified as GSL);
- For medical gases: these are not usually classified as Prescription Only Medicines (POMs);
- For dressings, appliances, medical devices, or chemical agents: these are not legally classed as medicines;
- For medicines e.g. adrenaline for anaphylaxis where exemptions in legislation allow their supply and/or administration without the need for a PGD

1.3 When is use of a PGD inappropriate?

PGDs **will not** be used for the following:

- Unlicensed medicines, including:
    - The mixing of two licensed medicines to form a new (unlicensed) product, unless one is a vehicle for administration, such as water for injection;
    - Special manufactured medicines;
- Radiopharmaceuticals;
- Anabolic steroids, and any injectable preparation used for treating addiction;
- Abortifacients, such as mifepristone
- For management of long-term conditions, such as hypertension or diabetes;
- Where uncertainty remains about the differential diagnosis, particularly when further investigations or diagnostic tests are needed, for example erectile dysfunction;
- Where the medicine needs frequent dosage adjustments, or frequent or complex monitoring, for example anticoagulants or insulin.
- For unlicensed medicines

PGDs should not be used to circumvent the repeat prescribing systems used in general practice, therefore a PGD will not be permitted when a prescription (FP10), or a Patient Specific Direction (PSD) could be written in advance.

1.4 Drugs requiring special consideration

Certain medicines require special consideration before inclusion in a PGD and some are restricted by legislation.

1.4.1 Use outside the terms of Summary of Product Characteristics (SPC)

In exceptional circumstances, and justified by best practice, licensed medication can be used outside the terms of its product license (so-called 'off label' use) and as such may be included in a PGD (the status of the product must be clearly described).

In taking a decision whether or not to support inclusion in a PGD, the ICB's PGD Approval Group will consider whether there is acceptable evidence for the use of that product for the intended indication, e.g. follows nationally agreed guidelines, such as the Joint Committee on Vaccination and Immunisation (JVCI).

1.4.2 Drugs subject to special reporting arrangements (Black Triangle Drugs ▼)

Black triangle drugs (licensed in the previous 12 months) will only be considered in exceptional circumstances by the ICB's PGD Approval Group.

Treatment guidelines must be followed and the PGD must clearly state the status of the product.

1.4.3 Antimicrobial drugs

Since antimicrobial resistance is a major public health concern. Inclusion of antibiotics and antimicrobials in a PGD will only be considered where there is no reasonable alternative and where measures to combat resistance will not be compromised. Use will follow Coventry and Warwickshire antimicrobial guidelines or follow the specialist advice of a microbiologist, who must be involved in the drawing up of the PGD if the local guidelines do not cover the particular PGD indication. Antimicrobial PGDs will be reviewed annually.

1.4.4 Controlled drugs

Only certain controlled drugs can be given under a PGD, in accordance with the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations (2001):

- Schedule 2: Morphine and diamorphine may be used by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person. Not for treating addiction)
- Schedule 2: Ketamine
- Schedule 3: Midazolam

- Schedule 4: All drugs except anabolic steroids and injectable medications used for treating addiction.
- Schedule 5: All drugs

Not all professions listed in the PGD legislation can administer controlled drugs under a PGD. The following regulated professions groups **cannot** administer or supply any CDs in any of the five schedules under a PGD:

- Dieticians
- Speech and language therapists
- Dental therapists
- Dental hygienists

1.6 Who can use a PGD?

Under UK legislation only the following registered health professionals can give medication under a PGD:

Chiropodists and podiatrists
Dental hygienists
Dental therapists
Dietitians
Midwives
Nurses
Occupational therapists
Optometrists
Orthoptists
Orthotists and prosthetists
Paramedics
Pharmacists
Physiotherapists
Radiographers
Speech and language therapists

In each case individual health professionals will be named and specifically authorised to practice under a PGD.

2. Purpose and Scope

This policy applies to authorised healthcare professionals providing directly commissioned NHS services, which may include:

- Practice nurses and pharmacists working in Coventry & Warwickshire GP practices;
- Pharmacists working in community pharmacies that provide NHS services across Coventry & Warwickshire;
- Nurses and other authorised healthcare professionals working for providers that are directly commissioned by the ICB.

This Policy has been written to consider the National Institute of Health and Care Excellence (NICE) Guidelines (MPG2) on Patient Group Directions (published August 2013, updated 2017).

3. Process for Development of PGDs

3.1 Proposals for PGD Development

Prior to development of a PGD the need for the PGD must be assessed, with due consideration given to the other available options for the supply and administration of medicines

The ICB requires that use of PGDs is reserved for those situations where they would offer benefit to patient care without compromising safety. For a clinical condition to be catered for by a PGD, the presenting characteristics and treatment requirements must be sufficiently consistent. Examples of such groups are:

- Those requiring immunisation as part of a national programme;
- Those requiring sexual and reproductive health services;
- Those requiring treatment of a minor injury e.g. analgesia.

When commissioning a new service, the requirement for development and implementation of PGDs will be considered as early as possible in the commissioning process.

3.2 Working Group for PGD development

The NICE Patient Group Directions Medicines Practice Guideline (MPG2), recommends that a PGD working group should be established for each individual PGD, although the same group may be responsible for developing a number of PGDs.

Whilst the responsibility for the membership of the PGD Working Group will lie with the provider organisation, the ICB requires that:

- Membership reflects recommendations of MPG2, including appropriate input from relevant primary care practitioners.
- The name, role and responsibilities of the service lead be clearly identified
- The roles and responsibilities of each member of the PGD working group, how they work together to develop the PGD, and how the group operates, will be determined by the PGD Working Group and documented.
- Each PGD has a named lead author, agreed by the PGD working group, who will have overall responsibility for clinical content.
- Where appropriate, input is sought from Public Health England and NHS England & NHS Improvement.
- The PGD working group complies with the recommendations of the NICE competency framework for people developing, reviewing or updating PGDs
- Where requires, additional expertise will be utilised, a local specialist in microbiology for PGDs containing an antimicrobial agent/medication.

Key stakeholders for the development of the PGD will be identified by the PGD working group and consulted on the development of the PGD. Draft PGDs will be sent to representatives of the professional groups for comment and suggested amendments.

3.3 Competency assessment for operating under the PGD

For each PGD, the named PGD author will ensure that the training and competency requirements for staff wishing to operate under the PGD are clearly described, in line with the NICE competency framework for health professionals using PGDs, including

- Understanding of the requirements of individual PGDs;
- Knowledge of pharmacology of the drug to be included in the PGD;
- Knowledge of relevant legislation relating to use of the medicines and medical

4. Process for approval of PGDs

- **4.1 PGD Authorisation**

PGD authorisation will be recommended to the PGD Approvals Group, which will comprise:

- A senior Pharmacist
- A senior Doctor (or dentist)
- The Executive Nurse for the ICB
- A representative of the professional group who will work under the PGD.

The doctor (or dentist) and pharmacist signatories will establish that the clinical and pharmaceutical content are accurate and supported by the best available evidence.

Prior to signing a PGD as a commissioner, the Chief Nurse (as Clinical Governance Lead) will establish that:

- Processes and governance arrangements have been followed;
- All legal requirements have been met.

Note that electronic signatures are acceptable:
https://www.sps.nhs.uk/articles/can-electronic-signatures-be-used-to-sign-off-a-pgd/.
However, attaching a scanned picture of a signature is not acceptable.

The PGD Approvals Group will assess implementation requirements and either develop a communications plan or confirm that one is in place to support the dissemination of PGDs. This will include designation of an identified person to be responsible for ensuring that the communications plan is effectively implemented.
Protected copies of PGDs (as PDFs) developed and authorised will be posted onto the relevant ICB website.

4.2 Decision

Decisions to accept or reject the proposal, including the rationale for the decision will be recorded by the PGD Approvals Group and communicated to the person who submitted the proposal

4.3 PGD document database

A database of all approved PGD documents will be maintained by the ICB. The ICB will give each PGD a unique PGD identifier and include this on the summary front page of the relevant PGD. The expiry date for each PGD will also be recorded on the database. Each of the provider organisations, including GP practices, will hold copies of those PGDs in use within their organisation.

Copies of expired PGD master (original signed) documents will be kept as for all other patient records. For adults all PGD documents will be kept for a minimum of 10 years, and those that apply to children will be kept for 25 years.

4.4 Production and distribution of PGDs

To ensure version control, when any new or amended PGD is posted onto the ICB website, the ICB will arrange for the relevant providers to be notified by email. It is the responsibility of each provider organisation to ensure that the name of the service lead is current and the responsibility of the service lead to act on the notification, update their records and ensure that this information is cascaded to all relevant staff.

4.5 PGD Review Process

PGDs must have an expiry date, and must not be used beyond their expiry date, because any supply and/or administration of a medicine(s) would be without legal authorisation. The expiry date for a PGD will be considered and determined on a case-by-case basis, with patient safety paramount, but with a maximum of 3 years from the date the PGD was authorised (or re-authorised following review), as per NICE guidance.

All proposed changes, including minor amendments and review due to expiry, will require the PGD to go through a review process and be re-authorised by the PGD Approvals Group. It is the responsibility of the lead author to initiate the review process in sufficient time to ensure continuity of care. A senior doctor and pharmacist must be involved in the review and review must involve consultation with key stakeholders.

5. Roles/ Responsibilities of authorised practitioners

5.1 **Doctor (or dentist) signatory** is responsible for the provision of medical advice and support including advice on the feasibility of the PGD with reference to the most appropriate options for clinical care and associated clinical guidelines within that service and area of practice. The Doctor/Dentist is responsible for ongoing provision of medical advice and support when the PGD is in practice and during/following audit and or during review of the PGD.

5.2 **Pharmacist signatory** is responsible for provision of pharmaceutical advice and support prior to and during PGD development, including advice on the feasibility of the PGD with reference to licensed status of the medicine, local formulary and other guidelines relating to the medicine. The Pharmacist is responsible for ongoing provision of pharmaceutical advice and support when the PGD is in practice and during/following audit and review.

5.3 Representative **of the professional group signatory** expected to administer/ supply medicines under the PGD is responsible for the provision of specialist professional advice and support including provision of information on service delivery within their clinical area. They are responsible for on-going professional advice and support for practitioners when the PGD is in practice. They may also be a management lead with additional management responsibilities. A number of professional leads maybe consulted within the development of a PGD.

5.4 **Authorised signatory**
Involved in the authorisation of the PGD; authorises that a PGD is fit for purpose i.e. it has been developed according to the correct organisational procedures and that those involved in the development of the direction are competent to do so. They will receive guidance and advice on this from the Medicines Optimisation Team.

5.5. **Managers of clinical areas/Service Lead e.g. Lead GP** where PGDs are being developed, implemented and used. Managerial responsibilities apply. This is a senior, responsible person from within the service who will authorise named, registered health professionals to practice under the PGD; and ensure appropriate indemnity insurance is in place; and ensure that authorised health professionals have signed the appropriate documentation; and ensure that appropriate training and competency for all staff involved in using the PGDs. This lead will be required to maintain an up to date register of healthcare professionals authorised use the PGDs

5.6. **Practitioners/professionals working under PGDs** - professionals using a PGD must be registered (or equivalent) members of their profession. All professions must act within their appropriate Code of Professional Conduct. All authorised practitioners supplying and/or administering medicines under PGDs must be named and provide written evidence of competence, training, knowledge, experience and continuing education relevant to the clinical condition/situation to which the PGDs apply. Each practitioner is expected to take personal responsibility for ensuring they maintain their competence and knowledge and attend additional training when appropriate. In addition, the HCP must follow professional and CQC guidance in relation to record keeping, labelling and provision of patient information leaflets.

5.7 **PGD Development Group**- should comprise of a named lead author, supported by multidisciplinary group including a doctor (or dentist), pharmacist and representative of any other professional group (s) using the PGD. Their roles and responsibilities should be defined. The PGD working group is responsible for developing the PGD and its subsequent review and updating.

5.8 **PGD Approval Group-** a locally defined mix of members, reviews proposals to develop PGDs. There should be clear lines of accountability with appropriate governance arrangements. Minutes and notes of the meetings should be retained.

6. Monitoring and Audit

Records of administration and/or supply under PGD will be kept for audit purposes and care provided under a PGD will be audited at least annually. For staff operating for the first time under a specific PGD their practice will be audited six months after commencing practice under a PGD.

Audits on the use of PGDs will be initiated and carried out by Service Leads at least annually to ensure compliance with procedures. The results of the audit will be shared within the service and reported to the PGD Approval Group upon request.

The audit must check compliance against the following:

- Reason for administering or supplying under PGD;
- Record of assessment criteria (e.g. appropriate history taking required for decision making);
- Reason for not making supply/administering and action taken;
- History of allergy recorded in notes;
- Advice given verbal and written;
- Appropriate storage of medicines.

7. Handling Adverse Drug Reactions and Clinical Incidents

All adverse drug reactions (ADR) should be reported in accordance with Medicines Healthcare Regulatory Agency (MHRA) Yellow Card system https://yellowcard.mhra.gov.uk
Each ADR and/or incident will also be recorded in the patient's clinical records. Serious incidents should be managed in line with the NHSE Serious Incident Framework. Further information is available in the ICB Serious Incident Policy

8. Key references and Resources

- Patient Group Directions. https://www.england.nhs.uk/south-east/our-work/info-professionals/pgd/ accessed 29.12.2020
- National Institute of Health and Care Excellence (2017) Patient Group Directions Medicines Practice Guideline (MPG2) https://www.nice.org.uk/guidance/mpg2. Accessed 29.12.2020
- Misuse of Drugs Regulations 2001. https://www.legislation.gov.uk/uksi/2001/3998/contents/made (accessed 29.12.2020
- National Institute of Health and Care Excellence (2017): Competency framework for people developing and/or reviewing and updating Patient Group Directions. https://www.nice.org.uk/guidance/mpg2/resources (accessed 29.12.2020)
- National Institute of Health and Care Excellence (2017): Competency framework for people authorising Patient Group Directions. https://www.nice.org.uk/guidance/mpg2/resources (accessed 29.12.2020)

- NHSE Serious Incident Framework- supporting learning to prevent recurrence 2015. https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf (accessed 22.01.2021)

- British Medical Association (2016) Patient Group Directions and Patient Specific Directions in general practice. https://www.bma.org.uk/media/1592/bma-patient-group-and-patient-specific-directions-jan-2016.pdf (accessed 30.12.2020)

- Specialist Pharmacy Service. When Patient Group Directions (PGDs) are not required: Guidance on when PGDs should not be used and advice on alternative mechanisms for supply and administration of medicines.

- Specialist Pharmacy Service: Patient Group Directions. https://www.sps.nhs.uk/home/guidance/patient-group-directions/ (accessed 30.12.2020)
- Care Quality Commission. Nigel's surgery19: Patient Group Directions (PGDs)/Patient Specific Directions (PSDs). https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-19-patient-group-directions-pgdspatient-specific-directions (accessed 30.12.2020)

9. Equality Impact Assessment (EIA)

Policy/Service	Policy for Patient Group Directions	**Person completing EIA**	Natasha Jacques
Date of EIA	January 2020	**Accountable ICB Lead**	Alison Walshe Andrew Harkness

Aim of Work	The Public Sector Equality Duty (PSED) requires us to eliminate discrimination, advance equality of opportunity, and foster good relations with protected groups. This EIA assesses the impact of the policy on protected groups.

Protected Group	Likely to be a differential impact?	Protected Group	Likely to be a differential impact?
Age	No	**Race**	No
Disability	No	**Religion or belief**	No
Gender reassignment	No	**Sex**	No
Marriage and civil partnership	No	**Sexual orientation**	No