NHS
Coventry and Warwickshire
Integrated Care Board

Policy for Patient Group Directions (PGDs)

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Name of reviewer and title:	Sheena Vithlani (Medicines Optimisation Pharmacist)
Department:	Medical Directorate

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.
1st Oct 2024	2.0	• Background and scope updated. • New/updated links embedded. • Terminology updated. • Formatting/ structure changes • List of healthcare professions who can use PGD updated - pharmacy technicians added. • Governance and decision making	Policy Development Group- recommended for adoption 15/10/2024 Quality Team Review- no significant concerns 24/10/2024 Policy Advisory Group approved 22/11/2024

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 needing to see a 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 should only be developed after careful consideration of the legal classification of the medicines and all the potential methods of supply and/or administration. This includes prescribing and consideration of the legal exemptions that may be applicable.

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.

This ICB policy aligns with national guidance NICE Medicines Practice Guideline Patient Group Directions MPG2 (2017) which makes recommendations on when PGDs should and shouldn't be used. It also aims to ensure that patient group directions are used in line with legislation, so that patients have safe and speedy access to the medicines they need.

NHS England's Specialist Pharmacy Service (SPS) have developed a national system for the standardisation of PGDs. This is where details about the relevant legislation and changes can be found (SPS Patient Group Directions).

2. Purpose and Scope

The purpose of this Policy is to set out the process for the identification, development, authorisation, dissemination, implementation, monitoring, audit, and review of PGDs, including an outline of roles and responsibilities of staff and the relevant legal requirements.

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

- Registered health care professionals working in Coventry & Warwickshire GP practices
- Registered Pharmacists and Pharmacy Technicians 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). It also uses the NHS England's Specialist Pharmacy Service (SPS) PGD resources for any changes after 2017, developed to offer national standarised medicines policies .

2.1 When can PGDs be used?

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. PGDs must only be used where

there is no other suitable mechanism for the administration or supply of the medicine within the legislation.

Examples of when a PGD can be used include:

- Vaccinations
- Minor injury units and other, non-prescriber led, first contact services
- Services where assessment and treatment follows a clearly predictable pattern (NHS immunisation clinics and contraception and sexual health services, for example)

2.2 When NOT to use a PGD

PGD's MUST not be used for the following medicines or groups of medicine:

- Unlicensed medicines, including:
  - The mixing of two or more licensed medicines to form a new (unlicensed) product, unless one is a vehicle for administration, such as water for injection
  - Special manufactured medicines
- Radiopharmaceuticals
- Certain controlled drugs (see later for more information)
- Abortifacients

PGD's MUST not be used in the following settings or scenarios:

- For training or as part of training
- Where there is delegation of responsibility
- To make dose adjustments of a medicine already in an individual's possession
- Care homes and independent schools providing healthcare entirely outside the NHS
- For dressings or medical devices (as these are not medicines)
- By Health professionals not authorised to use PGDs

Note that the MHRA provide further advice on PGDs in the private, prison and police sectors.

2.3 PGDs are not always appropriate:

In the following scenarios, a PGD is not required, and a protocol or standard operating procedure should be used instead:

- The *supply* of a General Sales List (GSL) medicine
- The *administration* of a GSL or Pharmacy (P) medicine
- Medical gases which are not Prescription Only Medicines (POMs).
- Where there is an exemption under the Human Medicines Regulation 2012 and so a PGD is not necessary.

A PGD is not suitable in the following scenarios:

- 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.

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.

A PGD is not necessary and should not be used when there is an opportunity in the care pathway for the medicine to be safely prescribed on an individual basis by a qualified prescriber.

2.4 Medicines requiring special consideration

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

2.4.1 Off Label use of medicines

In exceptional circumstances, and justified by best practice, licensed medication can be used outside the terms of its product license ('off label' or off-license use) and as such may be included in a PGD (the status of the product must be clearly described as being outside the terms of its Market Authorisation (MA) as detailed in the Summary of Product Characteristics (SPC).

In taking a decision whether 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).

2.4.2 Medicines licensed in the previous 12 months (Black Triangle Medicines ▼)

Black triangle medicines (licensed in the previous 12 months) will only be considered in exceptional circumstances when clearly justified by best clinical practice by the ICB's PGD Approvals Group.

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

2.4.3 Antimicrobial medicines

Since antimicrobial resistance is a major public health concern. Inclusion of antibiotics and antimicrobials in a PGD will only be considered where measures to combat resistance will not be compromised and it is clinically essential and clearly justified by best practice guidance. Use will follow Coventry and Warwickshire antimicrobial guidelines and/or national guidelines and 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.

2.4.4 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. These should not be used for management of addiction.
- Schedule 2: Ketamine
- Schedule 3: Midazolam
- Schedule 4: All listed medicines except anabolic steroids and injectable medications used for treating addiction
- Schedule 5: All listed medicines

Not all professions listed in the PGD legislation can administer controlled drugs under a PGD. Currently, the following regulated professions or 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
- Pharmacy Technicians

However, in case of changes, it is important to check the most recent legislation.

2.4.5 End of life care

PGDs for the supply and/or administration of medicines in end-of-life care is often not appropriate.

2.4.6 Medicines with a requirement for Risk Minimisation Measures (RMM)

These may not be suitable for inclusion in a PGD.

2.5 Who can use a PGD?

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

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

However, in case of changes, it is important to check the most recent legislation. In each case individual health professionals will be named and specifically authorised to practice under a PGD.

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. SPS provide guidance on planning for a PGD.

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. Where clarity is required the feasibility of a PGD should be discussed with an expert in medicines governance.

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. SPS provide guidance on PGDs in Complex Commissioning Scenarios.

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 several PGDs. SPS provide guidance on writing a PGD.

Whilst the responsibility for the membership of the PGD Working Group will lie with the commissioned 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.
- Each PGD will require an Equality and Quality impact assessment
- Where appropriate, input is sought from UK Health Security Agency (UKHSA) and NHS England and the Specialist Pharmacy Service .
- 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. Impact on services should be considered.

Draft PGDs will be sent to representatives of the professional groups for comment and suggested amendments.

3.3 Using standardised templates

SPS have developed national PGD templates with experts for clinical specialties as part of a Do-Once Programme to reduce duplication and variation and improve consistency of care across England. They provide a consistent presentation which has been reviewed by specialists within the given area, and they ensure that the legislative and clinical parameters have been fully considered. These should be used and adapted where possible.

Standardised National Templates of Common PGDs are available on the SPS Templates Web page

3.4 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 medicine 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 considered by the ICB PGD Approvals group, which will comprise:

- A pharmacist
- A senior Pharmacist
- A Doctor (or dentist)
- A primary care nurse
- A representative of the professional group who will work under the PGD

The ICB PGD Approvals group will establish that the clinical and pharmaceutical content are accurate and supported by the best available evidence. The ICB PGD Approvals group will provide a recommendation to the ICB's Chief Medical Officer, Deputy Director of Medicines Optimisation and Chief Nurse who are responsible for providing the signatories on the PGD.

The ICB 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.

Prior to signing a PGD as a commissioner, the Deputy Director of Medicines Optimisation will establish that:

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

Note that electronic signatures are acceptable. However, attaching a scanned picture of a signature is not acceptable.

The final stage for the PGD authorisation will be by the Quality Safety Experience Committee.

The authorised PGD will be hosted on the ICB website.

4.2 Decision

Decisions to accept or reject the proposal, including the rationale for the decision will be recorded by the ICB PGD Approval Group and communicated to the person who submitted the proposal. This may include stipulation of any specific requirements or limitations to the PGD.

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 reauthorised following review), as per NICE guidance.

All proposed changes (e.g. due to new safety information or change in formulary status of a medicine), including minor amendments and review due to expiry, will require the PGD to go through a review process and be re-authorised by the approvals process described in section 4.1. 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 may be consulted within the development of a PGD.

5.4 **Authorised signatories.** 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 ICB PGD Approvals Group.

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 ICB PGD Approvals 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.

5.9 Quality Safety Experience Committee- will provide final ICB authorisation of a PGD.

6. Monitoring and Audit

Records of administration and/or supply under each 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 should 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 ICB PGD Approvals 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

This PGD Audit tool may be useful

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 Medicines Practice Guideline (MPG2). National Institute of Health and Care Excellence (2017). Accessed 03.09.2024
- PGD use within the NHS, Medicines and Healthcare product Regulatory Agency (MHRA). Accessed 03.09.2024
- Patient Group Directions, Specialist Pharmacy Service (SPS), Accessed 12.09.2024
- When PGDs can be used, SPS, Accessed 03.09.2024
- The Human Medicines Regulations 2012, Legislation.gov.uk, Accessed 09.09.2024
- Misuse of Drugs Regulations 2001, Legislation.gov.uk, Accessed 03.09.2024
- Patient Group Directions and Abortifacients SPS, Accessed 09.09.2024
- Competency framework for people developing and/or reviewing and updating Patient Group Directions. National Institute of Health and Care Excellence (NICE) 2017, Accessed 09.09.2024
- Understanding roles and responsibilities of PGD signatories, SPS, Accessed 09.09.2024
- Writing a PGD, SPS, Accessed 09.09.2024
- National PGD Templates, SPS, Accessed 26.09.2024
- Serious Incident Framework- supporting learning to prevent recurrence 2015, NHS England, Accessed 09.09.2024
- Patient Group Directions and Patient Specific Directions in General Practice, 2016, British Medical Association, Accessed 09.09.2024
- When not to use a PGD, Specialist Pharmacy Service, Accessed 09.09.2024
- Patient Group Directions, Specialist Pharmacy Service, Accessed 09.09.2024
- Nigel's surgery19: Patient Group Directions (PGDs)/Patient Specific Directions (PSDs), Care Quality Commission. Accessed 09.09.2024

9. Equality and Quality Impact Assessment Tool

The following assessment screening tool will require judgement against all listed areas of risk in relation to quality. Each proposal will need to be assessed whether it will impact adversely on patients / staff / organisations.

Insert your assessment as positive (P), negative (N) or neutral (N/A) for each area.
Record your reasons for arriving at that conclusion in the comments column. If the assessment is negative, you must also calculate the score for the impact and likelihood and multiply the two to provide the overall risk score. Insert the total in the appropriate box.

Quality Impact Assessment

Quality and Equality Impact Assessment

Scheme Title:	Policy for Patient Group Directions		
Project Lead:	Natasha Jacques	***Senior Responsible Officer:***	Altaz Dhanani
		Quality Sign Off:	Anna Crane, Lee Hill, Annette Walker, Dawn Baker, Mary Mansfield, Sharon Stuart
Intended impact of scheme:	To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility. This policy has been updated to the new ICB format.		
How will it be achieved:	This will set out a clear policy for the approval process for Patient Group Directions		

Name of person completing assessment:	**Sheila Sarup**
Position:	**Medicines Optimisation Pharmacist**

Date of Assessment:	**13/09/2024**

Quality Review by:	**Quality Team as above**
Position:	**Team Members**
Date of Review:	**24 10 24**

High level Quality and Equality Questions

The risk rating is only to be done for the potential negative outcomes. We are looking to assess the likelihood of the negative outcome occurring and the level of negative impact. We are also seeking detail of mitigation actions that may help reduce this likelihood and potential impact.

AREA OF ASSESSMENT		OUTCOME ASSESSMENT (Please tick one)			Evidence/Comments for answers	Risk rating (For negative outcomes)			Mitigating actions
		Positive	Negative	Neutral		Risk impact (I)	Risk likelihood (L)	Risk Score (IxL)	
Duty of Quality Could the scheme impact positively or negatively on any of the following:	Effectiveness – clinical outcome	✓			Policy to implement an integrated local approach in delivery of national evidenced based guidance, that will produce the best outcomes for those eligible patients. Clinical outcome will be accounted for in each PGD				
	Patient experience	✓			Patients will obtain the service delivered by the PGD in a timely and reproducible manner , delivered by trained registered healthcare				

					professionals with more localised access.				
	Patient safety	✓			Policy to implement national evidenced based guidance widens access for patients to receive clinically appropriate treatment. Patient safety will be included in the PGD development process. The provider will follow the Patient Safety Incident Response Framework (PSIRF) national guidance on reporting incidents via the Learning from Patient Safety Events (LFPSE) system as per individual policy/procedures to protect patients and maintain safety.				
	Parity of esteem	✓			Policy to implement national evidenced based guidance widens access for patients to receive clinically appropriate treatment which includes access to mental health and physical health support within the Tier1-4 services				
	Safeguarding children or adults			✓	Maintenance of current safeguarding				

					arrangements as per ICB Local Authority and/or Provider safeguarding policies and procedures. A systemwide approach to care with a collaborative, integrated approach, will enable learning from incidents to be shared across the system.				
NHS Outcomes Framework Could the scheme impact positively or negatively on the delivery of the five domains:	Enhancing quality of life	✓			Policy to implement national evidenced based guidance widens access for patients to receive clinically appropriate treatment which will reduce the risk of diseases and/or improve outcomes. Large cohorts of patients can benefit from the use of PGDs				
	Ensuring people have a positive experience of care	✓			Policy to implement national evidenced based guidance will ensure equity of an integrated service for patients to receive clinically appropriate treatment				
	Preventing people from dying prematurely	✓			Policy to implement national evidenced based guidance widens local access for patients to receive clinically appropriate treatment which will reduce the risk				

					of diseases and disease progression and should reduce incidence of mortality as a result . For example the timely and at scale delivery of vaccinations				
	Helping people recover from episodes of ill health or following injury	✓			Policy to implement national evidence based guidance widens access for patients to receive clinically appropriate treatments.				
	Treating and caring for people in a safe environment and protecting them from avoidable harm	✓			Policy to implement national evidenced based guidance widens local access for patients to receive clinically appropriate treatment in an environment that has measures to protect from avoidable harm and be undertaken in a safe environment.				
Patient services Could the proposal impact positively or negatively on any of the following:	A modern model of integrated care, with key focus on multiple long-term conditions and clinical risk factors	✓			Policy to implement national evidenced based guidance has an integrated care approach to ensure patients receive clinically appropriate treatments				
	Access to the highest quality urgent and emergency care	✓			Policy to implement national evidenced based guidance has an integrated care approach to ensure patients have				

					access to urgent and emergency care services which can direct patients, including those most complex and unwell patients, and their carers appropriately. PDGs can allow for the delivery of a treatment to occur in many settings.				
	Convenient access for everyone	✓			Policy to implement national evidenced based guidance has an integrated care approach to ensure patients are treated in various settings				
	Ensuring that citizens are fully included in all aspects of service design and change			✓	Policy to implement national evidenced based guidance where engagement has already been completed at a national level. Patients invited to participate in current providers National/Local staff satisfaction surveys				
	Patient Choice	✓			The offer of PGDs will widen patient choice as it will expand availability of the drugs covered within the PGD to more locations.				
	Patients are fully empowered in their own care	✓			Patients will need to consent to the PGD. Informed consent and Shared decision making				

					will be part of the delivery				
	Wider primary care, provided at scale	✓			PGDs are used for these situations such as vaccinations and using community pharmacies so will expand the availability of drugs covered within the PGD to more locations.				
Access Could the proposal impact positively or negatively on any of the following:	Patient choice	✓			PGDs will allow greater choice for patients in regard to the supply and administration of medicines				
	Access	✓			PGDs will allow patients to visit settings other than GP surgeries allowing greater access to communities				
	Integration	✓			Improved collaboration with the ICB with registered healthcare professionals in various settings.				
Compliance with NHS Constitution	Quality of care and environment	✓			Release of GP time, better utilisation of registered health care professionals as a resource. Improved access to treatment in a timely manner.				
	Nationally approved treatment/drugs	✓			Adopting NHSE guidance. Integrated approach to delivery of national evidenced based				

					guidance of treatment and care				
	Respect, consent and confidentiality	✓			All usual ICB and/or Provider respect, consent and confidentiality policies and mechanisms will apply				
	Informed choice and involvement	✓			Patients will be fully involved in their care planning through shared decision-making, personalised care, and support planning. Individual PGDs will allow for shared decision making and discussion with the patient.				
	Complain and redress	✓			All usual ICB and/or Provider respect, consent and confidentiality policies and mechanisms will apply.				

*Risk score definitions are provided in the next section.

Equality Impact Assessment

Project / Policy Details

What is the aim of the project / policy?
To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility. To define the procedure for the development of and approval of Patient Group Directions (PGDs) by NHS Coventry and Warwickshire ICB. This policy will be published on the ICB Healthy Living Website. Communication will also be sent to Practices and Community Pharmacies within CWICB to highlight this updated policy.

Who will be affected by this work? e.g staff, patients, service users, partner organisations etc.
Patients Prescribers Health Care Professionals

Is a full Equality Analysis Required for this project?			
Yes	Proceed to complete this form.		Explain why further equality analysis is not required.
If no, explain below why further equality analysis is not required. For example, the decision concerned may not have been made by the ICB or it is very clear that it will not have any impact on patients or staff.			

Equality Analysis Form

1. Evidence used
What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.
• National Institute of Health and Care Excellence (2017) Patient Group Directions Medicines Practice Guideline (MPG2) https://www.nice.org.uk/guidance/mpg2. Accessed 03.09.2024 • SPS Patient Group Directions Accessed 12.09.2024

2. Impact and Evidence:
In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.
Age: A person belonging to a particular age (e.g. 32 year olds) or a range of ages (e.g. 18-30 year olds)
This policy does not contain any statements that would impact this protected characteristic.

Age may be one of the exemptions listed under an individual PGD due to the restrictions in licenses use in children.
Disability: A person has a disability if he/she has a physical, hearing, visual or mental impairment, which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities
Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments: This policy does not contain any statements that would impact this protected characteristic
Gender reassignment (including transgender): Where a person has proposed, started or completed a process to change his or her sex.
Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment. This policy does not contain any statements that would impact this protected characteristic
Marriage and civil partnership: A person who is married or in a civil partnership.
Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities: This policy does not contain any statements that would impact this protected characteristic
Pregnancy and maternity: A woman is protected against discrimination on the grounds of pregnancy and maternity. With regard to employment, the woman is protected during the period of her pregnancy and any statutory maternity leave to which she is entitled. Also, it is unlawful to discriminate against women breastfeeding in a public place.
Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities: This policy does not contain any statements that would impact this protected characteristic Pregnancy/breastfeeding may be one of the exemptions listed under an individual PGD due the restrictions in licenses of medicine use in pregnancy/breastfeeding.
Race: A group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.
Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers: This policy does not contain any statements that would impact this protected characteristic
Religion or belief: A group of people defined by their religious and philosophical beliefs including lack of belief (e.g. atheism). Generally a belief should affect an individual's life choices or the way in which they live.

Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

This policy does not contain any statements that would impact this protected characteristic

Sex: A man or a woman

Describe any impact and evidence on men and women. This could include access to services and employment:

This policy does not contain any statements that would impact this protected characteristic

Sexual orientation: Whether a person feels generally attracted to people of the same gender, people of a different gender, or to more than one gender (whether someone is heterosexual, lesbian, gay or bisexual).

Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

This policy does not contain any statements that would impact this protected characteristic

Carers: A person who cares, unpaid, for a friend or family member who due to illness, disability, a mental health problem or an addiction cannot cope without their support

Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

This policy does not contain any statements that would impact this protected characteristic

Other disadvantaged groups:

Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

This policy does not contain any statements that would impact this group of the population

3. Human Rights

FREDA Principles / Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	This Policy aims to provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning

		responsibility.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	The population of Coventry and Warwickshire will be treated with respect by the CWICB. The Data control parameters and GDPR laws for NHS patients will be in place when this policy is used to create PGDs.
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	This Policy aims to provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB) or for the population of Coventry and Warwickshire .
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	All communication, written or verbal, will be provided in a confidential, clear, understandable, format. Individuals will have the opportunity to discuss their healthcare with the requesting clinician. If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	Individuals will have the opportunity to discuss their healthcare with the requesting clinician. If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.
Right to **Life**	Will or could it affect someone's right to life? How?	No
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No

4. Engagement, Involvement and Consultation
If relevant, please state what engagement activity has been undertaken and the date and with which

protected groups:		
Engagement Activity	**Protected Characteristic/ Group/ Community**	**Date**
N/A	N/A	N/A
For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):		
N/A		

5. Mitigations and Changes
Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.
N/A

6. How will you measure how the proposal impacts health inequalities?
e.g Patients with a learning disability were accessing cancer screening in substantially lower numbers than other patients. By revising the pathway the ICB is able to show increased take up from this group, this is a positive impact on health inequalities. You can also detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract.
The policy supports consideration of health inequalities at all stages of the PGD process including the development, approval and monitoring. It is required within the policy that 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 ICB PGD Approvals Group upon request.

7. Is further work required to complete this assessment?			
Please state what work is required and to what section. e.g additional consultation or engagement is required to fully understand the impact on a particular protected group (e.g disability).			
Work needed	**Section**	**When**	**Date completed**
None			

8. Sign off		
The Equality Analysis will need to go through a process of **quality assurance** by a Senior Manager within the department responsible for the service concerned before being submitted to the Policy, Procedure and Strategy Assurance Group for approval. Committee approval of the policy / project can only be sought once approval has been received from the Policy, Procedure and Strategy Assurance Group.		
Requirement	**Name**	**Date**
Senior Manager Signoff	Altaz Dhanani	18/10/2024
Which committee will be considering the findings and signing off the EA?	Finance & Performance	05/02/2025
Approved by the Policy Procedure and Strategy Assurance Group.		22/11/2024

Once complete, please send to the ICB's Governance Team