NHS
North East and North Cumbria

Corporate	Policy for the Development and Authorisation of Patient Group Directions

Version Number	Date Issued	Review Date
1	July 2022	July 2024

Prepared By:	Senior Manager of Clinical Services, NECS
Consultation Process:	ICS Integrated Governance workstream
Formally Approved:	July 2022
Approved By:	Executive Committee

EQUALITY IMPACT ASSESSMENT

Date	Issues
June 2022	None noted

POLICY VALIDITY STATEMENT

Policy users should ensure that they are consulting the currently valid version of the documentation. The policy will remain valid, including during its period of review. However, the policy must be reviewed at least once in every 3-year period.

ACCESSIBLE INFORMATION STANDARDS

If you require this document in an alternative format, such as easy read, large text, braille or an alternative language please contact necsu.comms@nhs.net

Version Control

Version	Release Date	Author	Update comments
1	July 2022	Senior Manager of Clinical Services, NECS	Not applicable. First Issue

Approval

Role	Name	Date
Approval	Executive Committee	July 2022

Contents

1. Introduction

The policy and supporting procedures and processes have been developed to meet the requirements for the Integrated Care Board (ICB) to consider and approve the use of Patient Group Directions (PGDs).

This policy applies to PGDs that have been authorised by the ICB for the treatment of NHS patients by authorised healthcare professionals working in the ICB provider organisations.

1.1 Status

This policy is a Corporate policy.

1.2 Purpose and scope

Patient group directions allow healthcare professionals to supply and administer specified medicines to pre-defined groups of patients, without a prescription. This guideline aims to ensure that patient group directions are used in line with legislation and appropriate governance.

The purpose of this Policy is to

- To set out the process for the identification, development, dissemination, implementation, monitoring, audit, and review of Patient Group Directions (PGDs).
- To provide the framework for service, clinical and professional leads to assist in the identification of and outline the process for the development of PGDs.
- To outline the role the ICB has in the authorisation of PGDs used to support NHS health care services commissioned by the ICB.
- To provide a robust approach across the whole organisation, and incorporates the recommendations made in the Patient Group Directions NICE Guideline (MGG2) NICE August 2013 (updated March 2017)

The supply and administration of medicines is controlled by The Medicines Act 1968 and controlled drugs (CDs) are regulated by The Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001.

The legislation enabling registered practitioners to operate under a PGD was outlined in the Health Service Circular (HSC 2000/26). This sets out the legal requirements to develop and operate under a PGD. Failure to comply with these criteria falls outside of the law and could result in criminal prosecution under the Medicines Act (Department of Health, 1968).

A PGD is not an authorisation to prescribe.

The preferred way for patients to receive medicines is for an appropriately qualified health care professional to prescribe for an individual patient-specific basis.

The use of PGDs should be limited to specific situations where they offer an advantage to patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.

A PGD should not be used when it is reasonable to expect that a prescription (FP10) or a PSD (patient specific direction) could be obtained.
PGDs should not be used to circumvent the repeat prescribing systems used in general practice.

ICB commissioned service providers are unable by law to authorise **and** implement PGDs. A PGD must be developed by the ***commissioned service provider*** and submitted to the ICB (see below) for review and approval if deemed to meet the necessary criteria.

The commissioned service provider is responsible for implementation of the PGD.

Private Practice - The development of PGDs for privately funded services will not be supported by the ICB e.g. some vaccines required for overseas travel. Under the Human Medicines Regulations 2012 (Part 3, Chapter 12, paragraph 230) NHS GP practices are not permitted to use NHS PGDs to administer treatment for non-NHS circumstances, e.g. Hepatitis B vaccine given on a private basis for travel purposes. NHS practices can however use a private PGD.

2. Definitions

Patient Group Direction:

> *" These are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment."* HSC2000/026 'Patient Group Directions [England Only]

3. Development and management of PGDs

Specialist Pharmacy Service (SPS) provide useful guidance for organisations and potential authors and signatories of PGDs as a prompt, to think about and follow necessary procedures before and during the stages of developing and authorising PGDs.

3.1 Identifying the need for a Patient Group Direction

The need for a PGD should be established

The SPS Guidance 'When to use a PGD' should be used to establish if a PGD is legal and/or appropriate.

3.2 Obtaining agreement to develop a patient group direction

Once the need for a PGD is established, an application for permission to develop a PGD should be completed in accordance with the relevant SOP. (See Appendix A)

Controlled drugs, black triangle medicines and off-label use of a licensed medicine should be included in a PGD only when clearly justified by best clinical practice and legally permitted.

A PGD should only be used for antibiotics if clinically essential and clearly justified by best practice guidance. a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented and the use of the PGD is monitored and reviewed regularly.

3.3 Who should be involved?

Legislation does not specify who must be involved in developing PGDs.

The Health Service Circular (HSC 2000/026) states that PGDs 'should be drawn up by a multidisciplinary group involving a doctor, a pharmacist and a representative of any other professional group expected to supply medicines under the PGD'. The NICE MPG2 calls this the 'PGD Working Group'.

Legislation does not specify who must be involved in developing PGDs. The Health Service Circular (HSC 2000/026) states that PGDs 'should be drawn up by a multidisciplinary group involving a doctor, a pharmacist and a representative of any other professional group expected to supply medicines under the PGD'. The NICE MGP2 calls this the 'PGD Working Group'.

The responsibility for the membership of the PGD Working Group will usually lie with the Provider Organisation. It is expected that the PGD Working Group is set up in line with NICE MPG2 Recommendations 2.3 'Developing Patient Group Directions'.

For commissioned services – The responsibility for the membership of the PGD Working Group will lie with the provider organisation, and it should be set up in line with NICE MPG2 recommendations.

Review and renewal of PGDs should be done by the PGD Working Group.

3.4 Medicines That May Be Included in A Patient Group Direction

Not all medicines are suitable to be included in a PGD

A PGD cannot be used for:

- unlicensed medicines
- dressings, appliances and devices
- radiopharmaceuticals
- abortifacients, such as mifepristone.

Controlled drugs, black triangle medicines and off-label use of a licensed medicine should be included in a PGD only when clearly justified by best clinical practice and legally permitted.

Only certain controlled drugs can be included in a PGD according to The Misuse of Drugs Regulations (2001). The SPS provides useful information on the Supply and/or administration of Controlled Drugs under a PGD

A PGD should only be used for antibiotics if

- clinically essential and clearly justified by best practice guidance.
- a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented
- the use of the PGD is monitored and reviewed regularly

In accordance with NICE guidance (MPG2), medicines needing frequent dosage adjustments or frequent or complex monitoring, should not be included in a PGD. Risk Minimisation Measures (RMM) are a regulatory requirement for some medicines and are a critical part of the product licence (marketing authorisation) to help maintain a favourable benefit-risk profile. Medicines with a requirement for RMM may not be suitable for inclusion in a Patient Group Direction (PGD)

If a decision is taken to include a medicine with RMM in a PGD, the requirements of the RMM must be included in the PGD

3.5 Who Is Permitted to Use Patient Group Directions

PGDs must only be used by those qualified registered health care professionals listed in the current legislation

Staff authorised can only use PGDs as named individuals.

3.6 Developing PGDs

The development of the PGD should follow the principles set out in the SPS Guidance "How to develop a Patient Group Direction".

If the request for PGD development is supported by ICB Medicines Committee and approved by the ICB Director of Medicines approval should be communicated in writing and should include:

- Confirmation of the doctor, pharmacist and other members of the working group proposed or, if not identified in the request, identification of the persons to develop the PGD.

- Where appropriate to do so, staff employed by external organisations such as a Commissioning Support Unit may be involved in the development of a PGD.

- Stipulation of any specific requirements or limitations to the PGD including:
  - Minimum qualification/training requirements for those using the PGD
  - Maximum doses or length of treatment
  - Criteria for patients to be excluded from the PGD
  - Criteria for exclusions or restrictions on the use of the PGD regarding service provision.

PGDs must comply with legal requirements so must include specific information (PGD Template: Appendix B). This template must not be amended.

Information about how the PGD will be audited should be included within the individual PGD.

The PGD author will ensure that the draft PGD is put into the current PGD template (See Appendix B). The current PGD template has been developed to comply with legal requirements set out in the HSC 2000/26 and should not be altered in any way.

A clinical protocol must be developed and implemented in conjunction with the PGD.

Specific training needs for individuals working under a PGD must be identified within the individual PGD.

The PGD will be informed by legislation, local and national frameworks, polices, guidelines, local formularies, and other bodies with medicines expertise.

References – all relevant guidelines and pertinent reference sources must be consulted as part of the development / review. All reference sources must be noted in the PGD documentation.

A PGD should include processes to ensure NHS prescription charges are collected where necessary.

3.7 Approving and Ratifying a PGD

For NHS commissioned services only Integrated Care Boards (ICBs – subject to legislation), local authorities, NHS Trusts, NHS Foundation Trusts, Special Health Authorities and NHS England can authorise PGDs.

National PGDs from the Specialist Pharmacy Service (SPS) will be adopted by the ICB if appropriate.

The PGD is to be presented to ICB Medicines committee, or delegated subgroup once it had been approved by a doctor, pharmacist and practitioner involved in the PGD development.

When the PGD authors have signed and submitted the proposed PGD, the MO administrative team will arrange for the PGD to be assessed by the ICB Medicines committee, or delegated subgroup, who can then recommend authorisation from the Medical Director for Medicines Optimisation.

A copy of each PGD with the recommended paperwork (including details of the any proposed training package and implementation plan) will be submitted to the MPC and then to the ICB Executive Committee to provide assurance to the Governing Body that the PGD has been developed with appropriate governance in place.

For each PGD, the provider organisation should:

a) Identify a senior, responsible medical representative from within the service to authorise named, registered health professionals to practice under the PGD
b) Ensure that authorised health professionals have signed the appropriate documentation.

Arrangement for sign off and ratification of the PGD by the Medical Director may diverge from the usual related processes during extraordinary circumstances (e.g. during a pandemic) to ensure that PGDs remain within legislation and that patient safety is protected.

3.8 Implementing a PGD

Once ratified the PGD will be shared with the proposers for implementation.

Providers will then disseminate to relevant staff. They will ensure that those who are going to be operating under the PGD have access to the document, have signed to operate under it and that any training needs have been identified and addressed.

Professionals using a PGD must hold a current registration as identified within the PGD and act within their appropriate codes of conduct.

Providers will retain a copy of the signed authorisation sheet at the back of each PGD and keep a record of staff who have signed up to the PGD. These records may be inspected by relevant bodies e.g., ICB, CQC or MO team.

In the clinical setting where the PGD is being used the following must be in place:

- Copy of supporting protocol, SOP, or guideline
- Copy of current PGD
- List of staff authorised to work under the PGD

3.9 PGD Review and Revalidation

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 should be considered and determined on a case-by-case basis with patient safety paramount. NICE recommend that this should be a maximum of 3 years from the date the PGD was authorised (or re-authorised following review).

The commissioned service provider is responsible for ensuring that PGDs are reviewed in good time to ensure continuity of care. It is also responsible for identifying / ensuring that appropriate persons form the PGD Working Group. PGDs should be reviewed and revised following the same processes as for new PGDs and involve consultation with all stakeholders.

The expiry date of a PGD can only be extended if there is a justifiable delay in renewing a PGD. For PGDs where a review is not completed within 1 year of the expiry date will be withdrawn from use.

PGDs updated before their review will need to be re-ratified.

Each new or revised PGD should be re-signed by all appropriate staff to ensure competence is up to date.

PGD staff authorisation records must be kept for 10 years for adults and 25 years if they relate to children.

The Clinical Lead or manager of the provider service should establish a robust and transparent process for the unscheduled review and updating of a PGD, when the need for this has been identified. This should include responding to:

- changes in legislation
- important new evidence or guidance that changes the PGD, such as new NICE guidance
- new information on drug safety
- changes in the summary of product characteristics
- changes to the local formulary

Any senior medical representative of a commissioned service or lead of a provider organisation can request an unscheduled review and updating of a PGD, when the need for this has been identified.

Any proposed changes, including minor amendments, will require the PGD to go through the review process and be re-authorised.

Each version of the PGD must be kept by the MO team for 10 years for adults and 25 years if they relate to children.

3.10 PGD Version Control

The ICB Director of Medicines (and their team) will ensure PGD version control

a) During the development process, strict version control must be followed, and draft versions must be watermarked on each page as “draft”.
b) A new PGD in development will begin as 0.1
c) Subsequent amended versions will become 0.2, 0.3, 0.4 etc.
d) The first ratified PGD will be version 1.0
e) When a PGD is under review the version changes to 1.1. As different groups are consulted and changes are made, the version changes 1.2, 1.3 etc.
f) The next final reviewed and ratified guideline becomes 2.0, and so on.

4. Duties and Responsibilities

Each PGD signatory has responsibilities appropriate to their role in PGD development, authorisation, and implementation.

The doctor (or dentist) and pharmacist signatories must establish that the clinical and pharmaceutical content are accurate and supported by the best available evidence. The doctor should have relevant expert clinical knowledge. The representative of the professional group expected to supply medicines under the PGD must ensure that they are satisfied that the PGD is fit for purpose for the health professional (e.g. nurses) delivering care to patients in that particular service and locality.

Organisations have a responsibility to ensure that a PGD is authorised within the legal framework and local governance arrangements (see section 3.4 of NICE MPG2 PGD guidance).

Those signatories who have designated responsibility for signing PGDs on behalf of the ICB for a ICB commissioned service must establish that:

- Processes and governance arrangements have been followed
- All legal requirements have been met
- There is effective implementation of the policy
- There has been full consideration of the service in which the PGD is to be used for governance purposes, the clinical governance signatory should not be involved in developing the PGD and will not practice under the PGD.

The clinical governance signatory on behalf of the authorising organisation should not be required to check clinical content of the PGD in detail but should be provided with sufficient evidence to be assured that the doctor (or dentist) and pharmacist signatories (and anyone else involved in the development of the PGD) have the competency, skills and experience to carry out their role and responsibilities.

Note: Electronic signatures may be used in line with MHRA guidance. However, attaching a scanned picture of a signature is not acceptable.

All staff, including temporary and agency staff, are responsible for:

- Compliance with relevant process documents. Failure to comply may result in disciplinary action being taken.
- Co-operating with the development and implementation of policies and procedures and as part of their normal duties and responsibilities.
- Identifying the need for a change in policy or procedure because of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly.
- Identifying training needs in respect of policies and procedures and bringing them to the attention of their line manager.
- Attending training / awareness sessions when provided.

5. Implementation

A PGD may need to be 'adopted' by the provider organisation(s) if they have not been involved in developing and authorising it. For example, when a PGD is developed and authorised by a ICB for use across multiple GP practices, a process would need to be in place for each GP practice to adopt the PGD for use in their practice.

Organisations must follow the ICB Process of Adopting a PGD SOP.

6. Training

PGD development:

- This policy will be available to all staff who use/develop Patient Group Directives within the ICB.
- All directors and managers are responsible for ensuring that relevant staff within their own directorates and departments have read and understood this document and are competent to carry out their duties in accordance with the procedures described.

PGD Use:

- Specific training needs for individuals working under a PGD must be identified within the individual PGD.
- The senior medical representatives within the commissioned service are responsible for ensuring that all staff using a PGD are competent to assess all relevant aspects of the patient's clinical condition, take responsibility for supply and/or administration of the medicine and make related decisions.
- All staff supplying and/or administering medicines under PGDs must have written evidence of competence, training, knowledge, experience, and continuing education relevant to the clinical condition/situation to which the PGDs apply.
- The practitioner operating under the PGD must take personal responsibility for ensuring they maintain their competence and knowledge and attend additional training when appropriate.
- In the service provider organisation (e.g. GP Practice) it is the responsibility of the senior partner or designated senior doctor/clinical lead to ensure the competency, and to counter sign the documents for any nurse, or other authorised healthcare professional working under PGDs within the service.
- The provider organisation will keep these signed authorisations as both evidence of individuals' competency and as a record of staff authorised to use the PGD.
- Adequate educational materials should be available to enable individual people and organisations to deliver safe and effective services in which PGDs are used.
- Training and re-training of health professionals using PGDs should incorporate a post-training assessment of competency.

7. Monitoring, Review and Archiving etc

7.1 Monitoring

The ICB Board will agree a method for monitoring the dissemination and implementation of this policy. Monitoring information will be recorded in the policy database No deviation from this policy will be allowed. Any PGD that has been developed independently of this policy will not be authorised for use by ICB.

7.2 Audit

As stated in HSC 2000/026, care provided under a patient group direction must be audited.

It is a legal requirement as per HSC 2000/026 to keep records of administration and/or supply under PGD for audit purposes.

It is the responsibility of the service lead and/or provider to monitor and audit the use of PGDs within their setting to ensure compliance with procedures

Information about how the PGD will be audited should be included within the individual PGD.

There must be a list of professionals who are able to work under the PGD available at any given time.

Monitoring and evaluation of PGDs within the ICB may be undertaken in conjunction with CQC or ICB Medicines Optimisation team. The results of the audit should be shared within the service and reported to the ICB Medicines Committee on request..

The records of administration or supply against each PGD must be audited as frequently as determined by the commissioner by each provider so that the appropriateness of the supply or administration (or of not supplying or administering a medicine) can be reviewed.

It is the responsibility of the signatory senior medical representative or delegated other member of the provider to ensure that the audits are completed and that practitioners are working in accordance with the PGD.

It is recommended that an audit of PGDs is undertaken annually. For new staff, practice should be audited six months after commencing the post.

The results should highlight areas of best practice as well as areas of concern and identify any areas of training and development need.

PGDs will not normally be accepted for revision unless an audit report has been provided.

7.3 Record Keeping

When a health care professional is working to a PGD the following information must be recorded:

- Patient's details: name, condition presented, medical history.
- Patient assessment and diagnosis.
- Contra-indications to any medicines.
- Medicines which have caused allergic reactions or side effects.
- Allergies to the drug and/or excipients.
- Current and recent prescription medicine, including over the counter (OTC) medicines and herbal preparations.
- Reasons for exclusion and referral.
- Medicine supplied and/or administered: name; form; strength; quantity; batch number; expiry date; information and advice given.
- Name and/or signature of the health care professional providing treatment and supplying the medicine.

All records must be signed, dated, and kept for 10 years after last attendance, or up to the patient's 25th birthday if longer than 10 years away. Records should be kept in the patient's notes and either sent to the patient's GP, or as detailed in the individual PGD.

Details of administration of vaccines to children must be sent to the appropriate Child Health Information System.

Where available, an entry on the computer record under the healthcare professional's individual identification and password is an acceptable alternative.

7.4 Organisational Governance

For each PGD, the commissioning and provider organisation(s) should collaborate to firmly establish local governance arrangements with clear lines of responsibility and accountability and arrangements are in place to ensure compliance with the Organisational Governance recommendations in the NICE MPG 2.

7.5 Incident reporting

Compliance with this policy will be monitored using an analysis of incidents and complaints where there has been a failure to follow procedure. It is the contractual responsibility of the service provider to notify the ICB of errors/incidents.

Quarterly medication medicines error/incident reports will be reviewed by the ICB Medicines Committee and as appropriate reported to the Quality and Safety Committee. Action plans to manage improvement in compliance will be developed where necessary.

7.6 Compliance

No deviation from this policy will be allowed. Any patient group direction that has been developed independently of this policy will not be authorised for use.
Key findings of both audit and monitoring of compliance will be reported to the Quality and Safety Committee.

7.7 Administration and Dissemination of new PGDs

Notification of newly published PGDs (new or updated) will be sent to designated individual(s) to co-ordinate distribution to appropriately trained staff.

It is the responsibility of the designated individual (usually the Service Lead / Manager) to ensure new staff are authorised to use relevant PGDs. This means that they are responsible for all paperwork being correct (i.e., current version on intranet) and all professionals using that PGD being signed up to it in advance.

Copies of this paperwork must be kept in a safe place e.g. in a folder specifically for that purpose and may be required for inspection.

7.8 Policy Review

The ICB Board will ensure that this policy document is reviewed in accordance with the timescale specified at the time of approval. No policy or procedure will remain operational for a period exceeding three years without a review taking place.

Staff who become aware of any change which may affect a policy should advise their line manager as soon as possible. The Executive Director or nominated deputy will then consider the need to review the policy or procedure outside of the agreed timescale for revision.

For ease of reference for reviewers or approval bodies, changes should be noted in the ‘document history’ table on the front page of this document.

NB: If the review consists of a change to an appendix or procedure document, approval may be given by the Executive Director in the ICB and a revised document may be issued. Review to the main body of the policy must always follow the original approval process.

7.9 Archiving

The ICB Board will ensure that archived copies of superseded policy documents are retained in accordance with Records Management: NHS Code of Practice 2021.

8. Indemnity insurance

Those signing PGDs must ensure that adequate indemnity arrangements are in place.

Individual health care professionals should have their own Professional Indemnity Insurance and ensure that the insurance provider is aware that they are operating under PGDs.

Those employed (as opposed to being self-employed), may be covered for these purposes but individuals should check with their employer. Most employers provide vicarious liability insurance to cover the acts or omissions of their employees, but health care professionals must check that they are covered.

The service lead/manager authorising staff to operate under PGDs within their service should also ensure that their professional indemnity insurance covers their authorising PGDs for use within their service.

Health care professionals, who are members of a professional organisation, or trades union, may also be covered additionally by this body.

9. Related Documents

9.1 Other related policy documents

- Appendix A - Request for the Development of a Patient Group Direction
- Appendix B - (Template) Patient Group Direction (PGD) for the Administration of XX
- Appendix C - Equality Impact Assessment
- Appendix D - Management & Monitoring of Patient Group Direction
- Appendix E - PGD Service Specification

9.2 Legislation and statutory requirements

- HSC 2000/026: Patient Group Directions (England only); Department of Health, Health Service Circular 9th August 2000

9.3 Best practice recommendations

- NICE. Patient Group Directions. Medicines Practice Guideline (MPG2). (August 2013, updated March 2017). Available at: https://www.nice.org.uk/guidance/mpg2
- MHRA Guidance. Patient Group Directions: who can use them. (December 2017). Accessed December 2021. Available at: https://www.gov.uk/government/publications/patient-group-directions-pgds/patient- group-directions-who-can-use-them
- NHS Patient Group Directions (PGD) website. Available at: https://www.sps.nhs.uk/home/guidance/patient-group-directions/ MHRA. Accessed December 2021

- Specialist Pharmacy Services (SPS). Retaining PGD documentation. (August 2018). Accessed December 2021. Available at: https://www.sps.nhs.uk/articles/retaining-pgd-documentation/

Appendix A

Request for the Development of a Patient Group Direction

Request for the Development of a Patient Group Direction - Template

The following document should be completed prior to the development of a full PGD.

Request to Develop a Patient Group Direction

Title of PGD (i.e. Drug and Clinical Indication)	
New PGD or Review of Existing PGD	
Ref No (revision only)	
Expiry date (revision only)	
Timescale for development/revision	
Proposer details:	
Name:	Job Title:
Organisation:	Email Address:
Telephone No.:	
Head of Service details:	
Name:	Email Address:
Telephone Number:	
Organisational details:	
Commissioning Organisation:	
Provider Organisation;	
Organisation delivering service where PGD used	
Setting(s) where the PGD will be used	
Health professional groups working under the PGD	
Persons who will be writing the PGD (PGD Signatories) where known:	
Lead Author:	Organisation:
Profession:	Email Address:
Doctor / Dentist (delete as appropriate)	
Organisation:	Email:
Pharmacist:	
Organisation	Email

Professional Group Representative (working to the PGD)	
Organisation:	

Email Address:	
Service Manager/Lead:	
Organisation:	Email:
Clinical Lead (This may be doctor or dentist):	
Organisation:	Email:
Email:	

PGD Purpose and Benefit to Patient Care:

Provide details to the criteria below and include supporting evidence:

Circumstances in which the PGD is to be used
Condition or health need to be met & benefit to patient care
Medicine(s) to be included in PGD (include dosage, quantity, formulation and strength, route and frequency of administration, duration of treatment, license status (licensed, unlicensed and or off-label use), class e.g. POM, CD, Black Triangle and whether it is included in the local formulary)
Please tick below to indicate how the medicine will be provided:

Supply		Administration		Both		

Professional group(s) to be included in PGD
Specific qualifications or training & competency requirements.
Benefits and advantages of using a PGD over other methods of supply or administration e.g. prescribing, patient specific direction.
Is the PGD required to support a new service development? Yes / No **If yes please provide details including indication as to whether service development has been approved and funded.**

Potential risks to patient safety
Resources needed to deliver the service (details of how medicine will be funded, purchased, stored, staff resources required, including development and implementation)
Current and/or future service provisions for supplying and/or administering the medicine(s), including its position within the care
Current and/or future service provisions for supplying and/or administering the medicine(s), including its position within the care
Other available options to provide the service – risks and benefits
Stakeholder View

Please send completed form to [nominated ICB Medicines Safety Group email address TBC**]**

Appendix A - continued

Part 2
The request to develop a Patient Group Direction for use within NHS NENC ICB has / has not been (delete as appropriate) approved for development.

	Signature	Date
ICB PGD Approval group (chair)		

Approval has been granted on the condition that the following requirements or restrictions are included in the Patient Group Direction.

Qualifications, training and competency
Other requirements / restrictions

Other comments/reasons for not granting:

Appendix B

(Template) Patient Group Direction (PGD)

ICB PGD Template.pdf

ICB PGD Template.doc

Appendix C

Equality Impact Assessment

Initial Screening Assessment (STEP 1)

As a public body organisation we need to ensure that all our current and proposed strategies, policies, services and functions, have given proper consideration to equality, diversity and inclusion, do not aid barriers to access or generate discrimination against any protected groups under the Equality Act 2010 (Age, Disability, Gender Reassignment, Pregnancy and Maternity, Race, Religion/Belief, Sex, Sexual Orientation, Marriage and Civil Partnership).

This screening determines relevance for all new and revised strategies, policies, projects, service reviews and functions.

Completed at the earliest opportunity it will help to determine:

- The relevance of proposals and decisions to equality, diversity, cohesion and integration.
- Whether or not equality and diversity is being/has already been considered for due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED).
- Whether or not it is necessary to carry out a full Equality Impact Assessment.

Name(s) and role(s) of person completing this assessment:

Name: Ian Morris
Job Title: Senior Manager of Clinical Services
Organisation: North of England Commissioning Support Unit (NECS)

Title of the service/project or policy: Policy for the Development and Authorisation of Patient Group Direction (PGD)

Is this a;

Strategy / Policy ☒ **Service Review** ☐ **Project** ☐
Other Click here to enter text.

What are the aim(s) and objectives of the service, project or policy:

Click here to enter text.

Who will the project/service /policy / decision impact?

(Consider the actual and potential impact)

- **Staff** ☒
- **Service User / Patients** ☒
- **Other Public Sector Organisations**☒
- **Voluntary / Community groups / Trade Unions** ☐
- **Others, please specify** Click here to enter text.

Questions	Yes	No
Could there be an existing or potential negative impact on any of the protected characteristic groups?	☐	☒
Has there been or likely to be any staff/patient/public concerns?	☐	☒
Could this piece of work affect how our services, commissioning or procurement activities are organised, provided, located and by whom?	☒	☐
Could this piece of work affect the workforce or employment practices?	☒	☐
Does the piece of work involve or have a negative impact on: • Eliminating unlawful discrimination, victimisation and harassment • Advancing quality of opportunity • Fostering good relations between protected and non-protected groups in either the workforce or community	☐	☒

If you have answered no to the above and conclude that there will not be a detrimental impact on any equality group caused by the proposed policy/project/service change, please state how you have reached that conclusion below:

This policy is for the development of Patient Group Directions in line with legal requirements. It therefore does not exclude any groups apart from defining the defined professionally registered groups who are legally able to develop, sign and use PGDs.

If you have answered yes to any of the above, please now complete the 'STEP 2 Equality Impact Assessment' document

Accessible Information Standard	Yes	No
Please acknowledge you have considered the requirements of the Accessible Information Standard when communicating with staff and patients. https://www.england.nhs.uk/wp-content/uploads/2017/10/accessible-info-standard-overview-2017-18.pdf	☒	☐
If any of the above have not been implemented, please state the reason: N/A		

Governance, ownership and approval

Please state here who has approved the actions and outcomes of the screening		
Name	**Job title**	**Date**
Dr Neil O'Brien	Medical Director	July 2022
Presented to (Appropriate Committee)		**Publication Date**
ICB Board		July 2022

Publishing

This screening document will act as evidence that due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED) has been given.

If you are not completing 'STEP 2 - Equality Impact Assessment' this screening document will need to be approved and published alongside your documentation.

Equality Impact Assessment: Policy – Strategy – Guidance (STEP 2)

This EIA should be undertaken at the start of development of a new project, proposed service review, policy or process guidance to assess likely impacts and provide further insight to reduce potential barriers/discrimination. The scope/document content should be adjusted as required due to findings of this assessment.

This assessment should then be updated throughout the course of development and continuously updated as the piece of work progresses.

Once the project, service review, or policy has been approved and implemented, it should be monitored regularly to ensure the intended outcomes are achieved.

This EIA will help you deliver excellent services that are accessible and meet the needs of staff, patients and service users.

This document is to be completed following the STEP 1 – Initial Screening Assessment

STEP 2 EVIDENCE GATHERING

Name(s) and role(s) of person completing this assessment:

Name: Ian Morris
Job Title: Senior Manager of Clinical
Organisation: NECS

Title of the service/project or policy: Policy for the Development and Authorisation of Patient Group Directions

Existing ☐ **New / Proposed** ☐ **Changed** ☒

What are the intended outcomes of this policy/ service / process? (Include outline of objectives and aims;
This is the adaption of an existing policy to make it applicable for the ICB

Who will the project/service /policy / decision impact?
(Consider the actual and potential impact)

- **Consultants** ☐
- **Nurses** ☐
- **Doctors** ☐
- **Staff** ☒
- **Service User / Patients** ☒
- **Others, please specify** All staff involved in the development, approval and use of Patient Group Directions

Current Evidence / Information held	Outline what current data / information is held about the users of the service / patients / staff / policy / guidance? Why are the changes being made?
(Census Data, Local Health Profile data, Demographic reports, workforce reports, staff metrics, patient/service users/data, national reports, guidance ,legislation changes, surveys, complaints, consultations/patient/staff feedback, other)	The development of Patient Group Directions in line with policy will ultimately require information to be held regarding those professionals who have signed up to the PGDs

STEP 3: FULL EQUALITY IMPACT ASSESSMENT

The Equality Act 2010 covers nine 'protected characteristics' on the grounds upon which discrimination and barriers to access is unlawful. Outline what impact (or potential impact) the new policy/strategy/guidance will have on the following protected groups:
Age *A person belonging to a particular age*
No Impact
Disability *A person who has a physical 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*
No Impact
Gender reassignment (including transgender) and Gender Identity *Medical term for what transgender people often call gender-confirmation surgery; surgery to bring the primary and secondary sex characteristics of a transgender person's body into alignment with his or her internal self perception.*
No Impact
Marriage and civil partnership *Marriage is defined as a union of a man and a woman or two people of the same sex as partners in a relationship. Civil partners must be treated the same as married couples on a wide range of legal matters*
No Impact
Pregnancy and maternity *Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the period after the birth, and is linked to maternity leave in the employment context.*
No Impact
Race *It refers to a group of people defined by their race, colour, and nationality, ethnic or national origins, including travelling communities.* •
No Impact

Religion or Belief *Religion is defined as a particular system of faith and worship but belief includes religious and philosophical beliefs including lack of belief (e.g. Atheism). Generally, a belief should affect your life choices or the way you live for it to be included in the definition.*
No Impact
Sex/Gender *A man or a woman.*
No Impact
Sexual orientation *Whether a person's sexual attraction is towards their own sex, the opposite sex or to both sexes*
No Impact
Carers *A family member or paid helper who regularly looks after a child or a sick, elderly, or disabled person*
No Impact
Other identified groups relating to Health Inequalities *such as deprived socio-economic groups, rural areas, armed forces, people with substance/alcohol abuse and sex workers.* *(Health inequalities have been defined as "Differences in health status or in the distribution of health determinants between different population groups."* *Health inequalities can therefore occur across a range of social and demographic indicators, including socio-economic status, occupation, geographical locations.)*
No Impact

STEP 4: ENGAGEMENT AND INVOLVEMENT

Have you engaged stakeholders in testing the policy/guidance or process proposals including the impact on protected characteristics? **Guidance Notes** • List the stakeholders engaged • What was their feedback? • List changes/improvements made as a result of their feedback • List the mitigations provided following engagement for potential or actual impacts identified in the impact assessment.
No

If no engagement has taken place, please state why:
This policy is adapted from one which was already in place for a CCG so stakeholders have not been involved with this redraft partly due to tight timescales for completion.

STEP 5: METHODS OF COMMUNICATION

What methods of communication do you plan to use to inform service users/staff about the policy/strategy/guidance?
☐ Verbal – meetings ☐ Verbal - Telephone ☐ Written – Letter ☐ Written – Leaflets/guidance booklets ☐ Written - Email ☐ Internet/website ☒ Intranet page ☐ Other If other please state: Click here to enter text.

Step 6 – Accessible Information Standard Check

From 1st August 2016 onwards, all organisations that provide NHS care and / or publicly-funded adult social care are legally required to follow the Accessible Information Standard. The Standard sets out a specific, consistent approach to identifying, recording, flagging, sharing and meeting the information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss.

https://www.england.nhs.uk/wp-content/uploads/2017/10/accessible-info-standard-overview-2017-18.pdf

Tick to confirm you have you considered an agreed process for:
☒ Asking people if they have any information or communication needs, and find out how to meet their needs. ☒ Have processes in place that ensure people receive information which they can access and understand, and receive communication support they need it.

STEP 7: POTENTIAL IMPACTS IDENTIFED; ACTION PLAN

Ref no.	Potential/actual Impact identified	Protected Group Impacted	Action(s) required	Expected Outcome	Action Owner	Timescale/ Completion date
N/A	N/A	N/A	N/A	N/A	N/A	N/A

GOVERNANCE, OWNERSHIP AND APPROVAL

Please state here who has approved the actions and outcomes of the screening		
Name	**Job title**	**Date**
Dr Neil O'Brien	Medical Director	July 2022

Presented to (Appropriate Committee)	**Publication Date**
ICB Board	July 2022

Appendix D
Management & Monitoring of Patient Group Direction

PGD Number *Name of Medication*

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD.

The following healthcare professionals are authorised to administer

Name of Medication under the Patient Group Direction (*PGD number*)

PGD Valid from date: PGD Expiry Date:

Healthcare Professional			Authorised by:		
Name	Signature	Date	Name	Signature	Date

PGD Valid from:	Review Date:	Expiry Date:

APPENDIX E

PGD - Title
Service Specification

Service Specification No.	
Service	
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1.	**Population Needs**
1.1	**National/local context and evidence base**
2.	**Outcomes**
2.1	**NHS Outcomes Framework Domains & Indicators**
3.	**Scope**
3.1	**Purpose**
3.2	**Aims and Intended Service Outcomes**
3.3	**This service should benefit patients when:**
3.4	**Scope of Service**
3.5	**Pharmacy & Pharmacist Accreditation**
3.6	**Population covered**
3.7	**Any acceptance and exclusion criteria and thresholds**
3.8	**Interdependence with other services/providers**
4.	**Applicable Service Standards**
4.1	**Applicable national standards (eg NICE)**
4.2	**Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)**
4.3	**Additional reading / further learning options**

4.4 Other Local Policies to Note
5. Applicable quality requirements
5.1 Applicable Quality Requirements **5.2 Clinical Incident Reporting** **5.3 Complaints Procedure**
6. Location of Provider Premises
The Provider's Premises are located at:

Quality Requirements

Quality Requirement	**Threshold**	**Method of Measurement**	**Consequence of Breach**	**Timing of application of consequence**