PATIENT GROUP DIRECTIONS POLICY (M-007)

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Policies should be accessed via the Trust intranet to ensure the current version is used

Contents

1. INTRODUCTION

The use of group protocols that allowed “non-prescribers” to supply or administer medicines used to be commonplace in the NHS. The Department of Health in April 1998 commissioned a review on prescribing, supply and administration of medicines. The subsequent report proposed that the legal issues surrounding group protocols, needed to be nationally agreed, to ensure that they were being used in a consistent way and were within the law. As a result a legal framework was established, that as long as it was adhered to, allowed the supply and administration of medicines by a Patient Group Direction (PGD) (Health Service Circular 026 (2000). The Human Medicine Regulations (2012) is now the legal framework that allows the sale, supply and administration of medicines under a PGD. The Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance on the legal requirements for PGDs, who can supply or administer a PGD and medicines you can supply under a PGD https://www.gov.uk/government/publications/patient-group-directions-pgds. NICE have developed guidance and competency to support the PGD process https://www.nice.org.uk/guidance/mpg2/resources.

Definition
“PGDs provide a legal framework that allows the sale supply and/or administration of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber” (NICE 2013 accessed 6/11/2023).

Having a PGD policy for suitably competent practitioners, ensures that specific medicines are accessible to patients and should be supplied and administered in a timely and safe manner.

2. SCOPE

Only PGDs that have been authorised by Humber Teaching Foundation Trust’s signatories may be used by Trust practitioners. Practitioners should only supply and or administer medicines under PGDs if there is an advantage for the patient without compromising their safety.

Specific registered practitioners can sell/supply and/or administer a specific medicine to a patient with a defined condition under a PGD. These include registered nurses, physiotherapists, pharmacists, podiatrists, dieticians and paramedics. They must have:

- undertaken the appropriate training
- completed the appropriate competency
- Signed the back of the in date PGD to confirm they are registered to use a PGD. It also has to be signed by their clinical lead to authorise the practitioner’s competency and permission to use.

3. POLICY STATEMENT

Most medications continue to be prescribed by a specific prescriber to a specific individual patient and prescribing is undertaken using a Patient Specific Direction (e.g. a prescription).

PGD’s are used to manage a specific treatment episode (or episodes), for which the sale supply or administration of a medicine is necessary. A PGD allows specified registered professionals to supply and/or administer a medicine directly to a patient with an identified clinical condition, without the patient seeing a prescriber. PGD’s are not meant to be a long term means of managing a patient’s clinical condition (NICE 2013, accessed 6/11/2023).

PGDs for the sale supply and administration of medicines will only be considered, where it offers a benefit to patient care without compromising safety. If a new PGD is identified, it will be written within the legal framework. Humber Teaching Foundation NHS Trust has a catalogue of PGDs in

use, these will need to be reviewed and re-authorised at an appropriate interval specified on the PGD. In order to maintain standards and a clear audit trail of those professionals writing, reviewing, authorising and signing PGDs, the production of PGDs will be strictly controlled as defined in the policy.

This Policy has been reviewed and amended to ensure that the Trust develops and uses PGDs in line with the NICE Medicines Practice Guidelines issued on PGDs (MPG 2) (NICE 2013).

4. DUTIES AND RESPONSIBILITIES

Chief Executive
The Chief Executive, Directors and Trust Board are responsible for ensuring that the PGD policy is in place. All staff working in the Trust are aware of, comply with and operate within this policy.

Medical Director and Director of Nursing, Allied Health and Social Care Professionals
To authorise each new PGD that is developed and when the PGD is renewed. They are responsible for maintaining their competency in authorising PGDs as directed by NICE (2013) (Appendix 1).

Chief Pharmacist

- To authorise each PGD and its renewal
- To maintain competency in authorising PGDs as directed by NICE (2013) (Appendix 1)
- To ensure PGDs are appropriate and that the development and implementation of the PGD standards follows the legal framework. Responsible for maintaining competency in developing, reviewing and updating PGDs as directed by NICE (2013) (Appendix 2)
- To monitor the PGD implementation and make the appropriate changes if needed

PGD Pharmacist

- To support the Chief Pharmacist in developing, reviewing and updating PGDs and lead the Multidisciplinary Group
- To initiate all PGD reviews in a timely manner to ensure service continuity
- To maintain competency in developing, reviewing and updating PGDs as directed by NICE (2013) (Appendix 2)
- To ensure all completed PGDs authorised by the Trust signatories are uploaded to the Trust Intranet and available for staff use

Designated Clinical Lead
Once it is agreed that the development of a PGD is appropriate, a senior practitioner with expertise in the PGDs clinical area, will be designated with the responsibility for leading the development of the PGD. The Designated Clinical Lead must take responsibility for identifying clinical staff to assist in developing the PGD, who should also have expertise in the clinical area and include a pharmacist from the Trust's Pharmacy Department. The format of a PGD is seen in Appendix 3. All new PGDs must be submitted to the Trust PGD Pharmacist who will arrange for a multidisciplinary review. The designated clinical lead is responsible for maintaining their competency in developing, reviewing and updating PGDs as directed by NICE (2013) (Appendix 2).

When the PGD needs reviewing it will be the responsibility of the designated lead to:

- Decide if a PGD is still required.
- Review the existing PGD and submit any suggested changes to the PGD Pharmacist at least three months before its expiry date.

Pharmacy Department
To maintain an updated list of PGDs for each service area on the intranet.

Non-Medical Prescribing Lead/Medicines Optimisation Lead Nurse

- To ensure training is available for practitioners using PGDs.
- To liaise with the clinical practice areas and pharmacy to aid and maintain implementation of the policy.

Clinical Team Leader

- Authorise by signing the back of the PGD, that the practitioner administering and supplying the PGD has completed the appropriate training, can evidence their competency in each PGD they are supplying and administering, and has signed the PGDs
- Maintain a team record of who is competent to use which PGD
- Ensure updated PGDs are reviewed and resigned
- To ensure new staff are appropriately trained, competent and authorised before supplying and administering their service areas PGD's
- To keep a copy of the signed PGD; in adults for 8 years and for children until the child is 25 years old or for 8 years after a child's death
- Ensure copies of the PGD are available for practitioners using PGDs

Practitioners Supplying and Administering a PGD

- To supply and administer a PGD, the practitioner must have attended the appropriate training and be able to evidence their competency as directed by NICE (2013) (see Appendix 4) in each PGD
- Has signed the current in date PGD they are going to use in the future to supply or administer medication

5. PROCEDURES

5.1. Development, Review and Updating a PGD

5.1.1. The Identification of Need for a Patient Group Direction

Requests for new PGDs will be made by contacting the Trust PGD Pharmacist either directly or through a third party
The need for the PGD should ideally have been discussed and agreed at Clinical Network Meetings or where appropriate.
The PGD pharmacist will be able to advise if a PGD is appropriate.

PGDs do not need to be developed for parenteral administration of Prescription Only Medicines that are exempt from legislative restrictions, when administered for the purpose of saving life in an emergency.

Special considerations are necessary in the following circumstances: -

Antimicrobials
Microbial resistance is a public health matter of major importance and it should be ensured that their inclusion in a PGD is necessary and will not jeopardise strategies to combat increasing resistance. A local microbiologist must be involved in drawing up the PGD. The PGD must be consistent with local policies and should be subject to regular internal and external audit.

Black Triangle Drugs and Medicines used Outside the Terms of the License
Black triangle drugs (i.e. those recently licensed and subject to special reporting arrangement for adverse reactions) and medicines used outside the terms of the Summary of Product Characteristics (SPC), (e.g. as used in some areas of paediatric care) may be included in PGDs. Such use will be exceptional, justified by current evidence (e.g. NICE guidance) and the PGD will clearly describe the status of the product. Black triangle vaccines used in immunisation programmes may be included in PGDs, provided they are used in accordance with the schedules recommended by the Joint Committee on Vaccination and Immunisation. Where the medicine is for

children, particular attention will be needed to specify any restrictions on the age, size and maturity of the child. Each PGD will clearly state when the product is being used outside the terms of the SPC and documentation will include the reasons why such use is necessary.

Controlled drugs

The Misuse of Drugs Regulations 2001 governs controlled drugs usage and, in October 2003 and April 2012, they were amended to allow some controlled drugs to be supplied and/or administered under a PGD. The following controlled drugs can be supplied or administered under a PGD:

- Diamorphine and Morphine (Schedule 2) registered nurses and registered pharmacists can supply or offer to supply these medicines, under a PGD, for the immediate and necessary treatment of a sick and injured person in any setting (excluding the treatment of addiction).
- Midazolam (Schedule 3).
- All drugs listed in Schedule 4 of the 2001 Regulations (mostly benzodiazepines), except anabolic steroids.
- All drugs listed in Schedule 5 of the 2001 Regulations (i.e. low strength opiates such as codeine).

5.1.2. Development of a Patient Group Direction

If it is agreed that the development of a PGD is appropriate, the PGD pharmacist will liaise with the team requesting the PGD and prepare a draft PGD for review. They must take responsibility for identifying persons to assist in developing it, who should have expertise in the clinical area. The format of a PGD is seen in Appendix 3. The review may take the form of an MDT as per 5.1.3 or may take place using “mark-up” and comments on the document, as appropriate.

5.1.3. Multidisciplinary Review Team (MDT)

A Trust virtual multidisciplinary team of registered health professionals will be utilised as appropriate, to obtain a multidisciplinary review of new or existing PGDs. At a minimum this team will include a pharmacist and expert clinicians from the professional groups going to supply and/or administer the medication under the PGD.

Each existing PGD will be reviewed by this group before its expiry date and as a minimum every three years. Their remit of the team is:

- Consider any feedback from the designated clinical lead
- Consider the validity and appropriateness of proposed new patient group directions.
- To review and amend existing patient group directions prior to their expiry date or in light of new national guidance
- To make recommendations to the Trust’s signatories about the validity and appropriateness of patient group directions.

5.1.4. Authorisation

The Patient Group Direction must be authorised on behalf of the Trust by the signatories who include:

- Chief Pharmacist
- Medical Director
- Executive Director of Nursing, Allied Health and Social Care Professionals

In addition, relevant approved delegates may act as signatories (refer to Appendix 7)

The signatories will take into account the views of the multidisciplinary team and the designated clinical lead before deciding if a PGD should be authorised. PGD signatories may not necessarily work in the same location. As the PGD is now developed as a word processed file and saved as a PDF file then it is possible to use an electronic signature for authorisation. The MHRA have confirmed that electronic systems can be used to authorise a PGD. An electronic signature must be linked uniquely to an individual and under their sole control. The final document must be

securely protected and the signature cannot be lifted out e.g. must be in a protected pdf format rather than a word processed document. PGDs may now also be approved remotely, by email authorisation. Following a formally agreed local process, a signatory can authorise a PGD by signing into their organisational email address and sending an email to a nominated individual.

For details and standards please refer to Appendix 7– Electronic signatures on PGDs, authorisation of a PGD by email and process for approval of a relevant delegate to act as a signatory for PGD authorisation

5.1.5. Administration and Dissemination

Original signed copies of all PGDs will be kept by the pharmacy department.

An electronic copy of all authorised and signed PGDs in pdf format, will be posted on the Trust intranet.

Updated PGDs will be advertised in the weekly global.

5.1.6. Regular PGD Review

All PGDs are to be reviewed and re-approved for use before they expire. They will normally be valid for one to three years. After the expiry date, if the PGD is not re-authorised it is not valid. Medicines **must not** be sold supplied or administered, by health professionals, on the direction of an expired PGD.

The Trust will take into account the views of the virtual multidisciplinary team and designated lead before deciding if a PGD should be re-authorised. The PGD will then, if considered appropriate be re-authorised on behalf of the Trust by the:

- Chief Pharmacist
- Medical Director
- Executive Director of Nursing, Allied Health and Social Care Professionals

In addition, relevant approved delegates may act as signatories (refer to Appendix 7)

A copy of the re-authorised and signed PGD will be posted on the Trust Intranet before its expiry date. The information pharmacist will inform the team manager and co-ordinate the distribution of the PGD to the practitioners registered to administer and supply the PGD.

5.1.7. Urgent PGD Review

Should there be a significant change in practice/guidelines and/or a change in the Summary of Product Characteristics (SPC) for a product during the life of an approved PGD, the designated lead must make arrangements for the PGD to be reviewed and amended. This should be done in consultation with the Trust PGD Pharmacist.

Trust signatories will take into account the views of the Trust PGD Pharmacist and designated lead before deciding if a PGD should be amended and re-authorised urgently. The PGD will then be re-authorised on behalf of the Trust by the signatories:

- Chief Pharmacist
- Medical Director
- Executive Director of Nursing, Allied Health and Social Care Professionals

A copy of the re-authorised and signed PGD will be posted on the Trust Intranet. The information pharmacist will inform the team manager and co-ordinate the distribution of the updated PGD to the appropriate practitioners.

In addition relevant approved delegates may act as signatories (refer to Appendix 7)

5.1.8. Choice of PGD templates

A local PGD template is available, (Appendix 3). Additionally for some specific medications and vaccines then there are national PGD templates prepared for local population and other resources available from websites such as UKHSA, GOV.UK and Specialist Pharmacist Service.

Immunisation PGD templates supported by UKHSA are available for selected vaccines from www.gov.uk/government/collections/immunisation-patient-group-direction-pgd.

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5.2. Practitioners Supplying and Administering a PGD

Practitioners can only supply and administer PGDs within their competency and those PGDs assigned to the service area they work in Each practitioner will have evidence that they have completed the basic PGD Core training and completed the PGD competency (NICE 2014 Appendix 4). They should be able to demonstrate their competency (see Appendix 4) in each PGD they use to supply and administer medicines. The supervision process can be used to demonstrate and record this. The practitioner will demonstrate they have reviewed their competency at the renewal of each PGD. The practitioner will sign the PGD and the clinical lead will sign and retain a copy (see Appendix 3). It will be identified which PGDs the practitioner is competent to supply and administer and agreed with their team leader in their Performance and Development Review (PADR) and/or on renewal. All practitioners will record when a medicine has been supplied under a PGD in the patient's clinical notes and/or Medicines Administration Record (MAR). The record should include all information identified as stated in the PGD. **Records of medicines administration or supply under a PGD may be made using an electronic template and electronic signature**.

Adverse Drug Reactions (ADRs) should be reported to a prescriber immediately or as appropriate action is taken to ensure patient safety. A separate report for all serious adverse reactions for established medicines and for all adverse reactions for black triangle medicines should be made to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme. The Trust policy for adverse incidents will also be adhered to.

5.3. Assurance of Practitioners Competence

The team leader is to ensure the practitioner administering and supplying the PGD has completed the appropriate training and can evidence their competence (see Appendix 4) in each PGD. The team leader will sign the PGD when the practitioners training and competence is achieved. The practitioner and the team leader (see Appendix 3) will retain a copy of the signed PGD. The team leader will maintain a data base of who is competent to use which PGD. The practitioner's competencies (see Appendix 4) will be reviewed each time the PGD is renewed. It is the team leader's responsibility to ensure the PGDs used are in date.

6. EQUALITY & DIVERSITY

An Equality and Diversity Impact Assessment has been carried out on this document using the Trust-approved EIA.

7. MENTAL CAPACITY

The implications of the Mental Capacity Act apply to this policy with particular focus on key principles of the Act:

- Presumption of capacity.
- Support to make own decisions.
- Right to make seemingly eccentric or unwise decisions.
- Best interests.
- Least restrictive intervention.

8. IMPLEMENTATION

This policy will be disseminated by the method described in the Policy and Procedural Documents Development and Management Policy.

Practitioners who are going to supply or administer medicines under a PGD will undertake PGD training. Practitioners will maintain evidence of their competency through the process of supervision. The team leader will ensure they maintain a register of the practitioners name and the medicine(s) they will supply and administer under a PGD.

Practitioners are advised to contact the Pharmacy department if they have any queries regarding medication.

The implementation of this policy will require additional resources. This is for the training and development of the staff in the initial phase.

9. MONITORING AND AUDIT

The Chief Pharmacist will ensure the appropriateness of a PGD. All incidents and patient complaints regarding the PGD must be reported according to the Trust's Incident Reporting policy and will be monitored by the Chief Pharmacist.

A regular report on PGD development and review is discussed at the Trust's Drug and Therapeutics Group.

The PGD pharmacist will review all established Trust PGDs every one to three years as stated in each individual PGD.

A signed copy of the PGD will be kept by the practitioner and their team leader. MyAssure will be used to monitor this.

Using the competency framework (Appendix 4) all practitioners using PGDs should be able to evidence their competencies. Competency should be agreed initially with the practitioner's supervisor prior to supplying or administering PGDs and reviewed when the specific PGD is updated.

Health professionals authorised to use PGDs, must allow appropriate access to the records of patients who have received medication under a PGD for audit purposes, so that the appropriateness of the supply or administration is reviewed. This is undertaken by Trust pharmacy technicians, or pharmacist, or within the practitioner's supervision to demonstrate competency.

Adverse Drug Reactions (ADRs) should be reported to a prescriber immediately and appropriate action is taken to ensure patient safety. A separate report for all serious adverse reactions for established medicines and for all adverse reactions for black triangle medicines should be made to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme. The Trust policy for adverse incidents will also be adhered to.

10. REFERENCES/EVIDENCE/GLOSSARY/DEFINITIONS

References

Department of health (1998) A review of prescribing, supply and administration of medicines. A report on the supply and administration of medicines under group protocols. London

Health Service Circular 026 (2000): Patient Group Directions (England)

Department Of Health (2006) A guide to mechanisms for the prescribing, supply and administration of medicines". London. Crown Copyright

NPC (2009) Patient Group Directions; A practical guide and framework of competencies for all professionals using patient group directions.

NICE (2013) Medicines Practice Guidance and Guidelines; last updated:27 March 2017 Available from-https://www.nice.org.uk/guidance/mpg2/resources

The Human Medicines Regulations (2012) The Human Medicines Regulations 2012 (legislation.gov.uk) Accessed on 18/10/2023

The Medicines and Health Care products Regulatory Authority (MHRA) Patient group directions: who can use them. Updated 4 December 2017.
Available from https://www.gov.uk/government/publications/patient-group-directions-pgds.Accessed 18/10/23

When to use a PGD. Available from : When to use a PGD – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice. Last updated 13/7/2022

Legal mechanisms to supply and administer medicines to individuals. Available at Legal mechanisms to supply and administer medicines to individuals – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice. Last updated 15/8/2023

Records Management Code of Practice. Last updated 19/9/2023 Available at Records Management Code of Practice - NHS Transformation Directorate (england.nhs.uk)

11. RELEVANT POLICIES/PROCEDURES/PROTOCOLS/GUIDELINES

Access to Health Records Policy N-011

Caldicott and Data Protection Policy

Consent Policy N-052

Information Governance Policy N-008

Information Sharing with Carers SOP16-007

Medicines Reconciliation Guideline G358

Risk Management Strategy (2021-2024)

Safe Haven Procedure Proc452

Safe and Secure Handling of Medicines Procedures Proc431

Waste Management Policy F-020

Appendix 1 – MPG2 Patient group directions: competency framework for people authorising Patient Group Directions

This competency framework has been developed as a tool to support individual people and organisations with responsibility for authorising PGDs. For the purpose of this competency framework, these are:

- doctors (or dentists) signing PGDs
- pharmacists signing PGDs
- other professionals signing PGDs as a representative of the professional group using the PGD, such as nurses
- People signing PGDs on behalf of the authorising body, such as clinical governance leads or patient safety leads.

It can be found at: www.nice.org.uk/guidance/mpg2/resources.

Appendix 2 – MPG2 Patient group directions: competency framework for people developing and/or reviewing and updating Patient Group Directions

This competency framework has been developed as a tool to support individual people who are developing PGDs (see section 3.3 of the guidance) and/or reviewing and updating PGDs (section 3.6 of the guidance).

It can be found at: www.nice.org.uk/Guidance/MPG2/Resources.

Appendix 3 – PGD Template

Humber NHS Foundation Trust

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

For the supply/administration of

xxxxxx

By Appropriately Registered Health Professionals for xxxxxxxxx in Humber NHS Foundation Trust

Version number: 2

Change history

Version number	Change details	Date
2		10/01/14

PGD Development

Name	Job title and organisation	Signature	Date

PGD Authorisation

Name	Job title and organisation	Signature	Date
	Medical Director or relevant approved delegate		
	Chief Pharmacist or relevant approved delegate		
	Director of Nursing, Allied Health and Social Care Professionals or relevant approved delegate		

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Health professional authorised to use PGDs in legislation and appropriately registered with their relevant professional body
Initial training	Prior to using PGDs staff will undergo basic training on PGDs and their use. Practitioners using this PGD must have undertaken appropriate training for working under PGDs for supply/administration of medicines (see NICE Competency framework for health professionals using PGDs)
Competency assessment	Competency assessments will be undertaken through the clinical supervision process following the standards of NICE competencies.
Ongoing training and competency	The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice. They must be able to demonstrate how they have maintained their competency to use the medicine listed. Additionally registered Health Professionals: • must have access to the PGD and associated online resources • must have undertaken appropriate training for working under written instructions, protocols and PGDs for supply/administration of medicines (see NICE Competency framework for health professionals using PGDs) • should fulfil any additional requirements defined by local policy The registered health professional must have signed the current in date PGD, and have been authorised and recorded by the team's clinical lead, before working according to the PGD.

Clinical condition

Clinical condition or situation to which this PGD applies	
Inclusion criteria	
Exclusion criteria	
Cautions (including any relevant action to be taken)	If a patient is taking any other medication, for the most up-to-date advice on interactions, consult the online BNF available at: https://bnf.nice.org.uk
Arrangements for referral for medical advice	Refer to GP or out of hours medical practitioner if necessary following local protocols.
Action to be taken if patient excluded	• Inform patient of reason for exclusion • Document in patient's clinical notes • Refer for medical advice if appropriate •
Action to be taken if patient declines treatment	• Advise patient of possible consequences to care • Document in patient's clinical notes • Refer for medical advice if appropriate • Document, in accordance with local policy, advice given and the decision reached.

Details of the medicine

Name, form and strength of medicine	
Legal category	
Indicate any off-label use (if relevant)	
Route/method of administration	
Dose and frequency	
Quantity to be administered and/or supplied	
Maximum or minimum treatment period	
Adverse effects	Refer to online BNF available at: https://bnf.nice.org.uk Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any adverse reaction to a medicine should be documented in the individual's record and the individual's GP should be informed.
Drug interactions	A detailed list of drug interactions is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk **If a patient is taking any other medication, for the most up-to-date advice on interactions, consult the online BNF available at: https://bnf.nice.org.uk.**
Records to be kept	**The following should be recorded in the patient's clinical notes.** • Patient's name, address, date of birth • Whether consent was given, (refer to Department of Health Reference guide to consent for examination or treatment • Known allergies or previous adverse events • Contact details of GP (if registered)Diagnosis • Date and time given • Name of drug given • Dose given • Route given • Any advice or warnings given to the patient • Any adverse drug reactions occurring after administration • Referral arrangements made (including self-care) • Name and signature of health professional administering drug **Records of medicines administration or supply under a PGD may be made using an electronic template and electronic signature.**

Patient information

Written information to be given to patient or carer	Patient information leaflet for xxxx available from https://www ……...
Advice to patient/carer	Explain treatment and possible side-effects and action to take if they occur.
Follow-up advice to be given to patient or carer	Contact this service or your own GP if you have any problems or concerns.

Appendices

Appendix A – Key references

HSC 2000/026 Patient Group Directions
British National Formulary (BNF Online) available at: https://bnf.nice.org.uk
Summary Product Characteristics for xxxxx. : Available from yyyyyy at: https://www.zzzzzzzz
NMC: The Code: Professional standards of practice and behaviour for nurses and midwives (2015). Updated 10/10/2028 Available at Read The Code online - The Nursing and Midwifery Council (nmc.org.uk)

NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2

NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017 https://www.nice.org.uk/guidance/mpg2/resources
Department of Health. Reference guide to consent for examination or treatment, published 4 August 2009. dh_103653__1_.pdf (publishing.service.gov.uk)

Appendix B – Health professionals' agreement to practise

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.
It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD.

Name of health professional	Signature	Senior representative authorising health professional	Date

Appendix 4 – MPG2 Patient group directions: competency framework for health professionals using patient group directions

This patient group direction (PGD) competency framework has been developed as a tool to support individual people and organisations that are using PGDs. Only registered health professionals who are listed in the legislation are eligible to use PGDs.

It can be found at: www.nice.org.uk/Guidance/MPG2/Resources.

Appendix 5 – Electronic signatures on PGDs, authorisation of a PGD by email and process for approval of a relevant delegate to act as a signatory for PGD authorisation

Electronic signatures

There is nothing in PGD legislation or guidelines which states that hard copies of documents must be signed by hand, or that individuals must sign a hard copy of the PGD as part of the individual authorisation process. The MHRA has confirmed that electronic systems can be used to authorise a PGD. The following guidance has been agreed with the MHRA and Department of Health and Social Care (DHSC).

An electronic signature must be linked uniquely to an individual and under their sole control. The standards laid down for electronic prescribing should be observed:

- Uniquely linked to the signatory.
- Capable of identifying the signatory.
- Created using means that the signatory can maintain under his sole control.
- Linked to the data to which it relates in such a manner that any subsequent change of data is detectable.
- The final document must be securely protected and the signature cannot be lifted out e.g. must be in a protected pdf format rather than a word processed document.

The use of a JPEG or similar picture of a signature inserted into a file is unacceptable unless the document is securely protected to prevent the signature being removed or changed as described previously.

The authorising organisation takes responsibility for the system in place and to ensure that lines of accountability and governance within the organisation or any partner organisation are documented. The authorising organisation will need to risk assess the process of how signatures are collected. If local circumstances dictate that these standards cannot be achieved then steps should be taken to ensure that the process is as secure as possible and adheres to organisational policy.

Authorisation of a PGD by email

The following practice is permitted providing that the organisation(s) involved in any part of the process of authorisation (clinical or organisational) concerned are compliant with points above.

Following a formally agreed local process, a signatory can authorise a PGD by signing into their organisational email address and sending an email to a nominated individual. It would not be considered good practice to use a personal email address.

There are a number of electronic systems which enable individuals to log in, submit, review and approve documents. In such cases, the documents themselves do not need a visible, handwritten signature where there is a secure, electronic audit trail of approval. For example, a JPEG picture of the signature does not have to appear in the PGD although some organisations do insert these securely as part of their locally agreed procedure.

It is suffice to state in documents developed using electronic systems which adhere to the guidance above that ‘signatories have approved this PGD using approved electronic authorisation systems’ or similar alongside the names and job titles of all involved and the date of authorisation under this statement.

The email authorisation or the information on the electronic system must be filed and saved according to Information Governance Alliance Records Management Code of Practice. Available at Records Management Code of Practice - NHS Transformation Directorate (england.nhs.uk) Last updated 19/9/2023

Organisations are advised to seek confirmation from their local Information Governance (IG) Lead to ensure that any systems and processes that are developed are robust and are in line with IG and organisational policy requirements.

Process for approval of a relevant delegate to act as signatory for PGD authorisation
Delegates may be approved to act as signatories for authorisation of either individual PGDs or groups or types of PGDs. This may be done remotely by email; the email authorisation of the relevant delegate(s) must be filed and saved as above. The relevant approved delegate signatories will take into account the views of the multidisciplinary team and the designated clinical lead before deciding if a PGD should be authorised.

In Primary Care and Community Services Division, PGDs authorised by NHS England, NHS Improvement or Public Health England for registered practitioners employed by organisations/providers commissioned by NHS England and NHS Improvement within Yorkshire and the Humber can be approved by the Clinical Lead, Lead GP and the Principal Pharmacist in the Primary Care & Community Services Division.

Appendix 6 – Document Control Sheet

This document control sheet, when presented to an approving committee must be completed in full to provide assurance to the approving committee.

Document Type	Patient Group Directions Policy (M-007)		
Document Purpose	This policy, for suitably competent practitioners, ensures that specific medicines are accessible to patients and should be supplied and administered in a timely and safe manner		
Consultation/ Peer Review:	Date:	Group / Individual	
list in right hand columns consultation groups and dates ->	30 November 2023	Drugs and Therapeutic Group	
Approving Committee:	QPaS	Date of Approval:	22 February 2024
Ratified at:	N/A minor amends	Date of Ratification:	N/A
Training Needs Analysis: *(please indicate training required and the timescale for providing assurance to the approving committee that this has been delivered)*		Financial Resource Impact	
Equality Impact Assessment undertaken?	Yes [✓]	No [ ]	N/A [ ] Rationale:
Publication and Dissemination	Intranet [✓]	Internet [ ]	Staff Email [ ]
Master version held by:	Author [ ]	HealthAssure [✓]	
Implementation:	*Describe implementation plans below - to be delivered by the Author:*		
	• Will be placed on the intranet and update information in Midweek Global		
Monitoring and Compliance:	• The Chief Pharmacist will ensure the appropriateness of a PGD. All incidents and patient complaints regarding the PGD must be reported according to the Trust's Incident Reporting policy and will be monitored by the Chief Pharmacist. • A regular report on PGD development and review is discussed at the Trust's Drug and Therapeutics Committee. • The PGD pharmacist will review all established Trust PGDs every one to three years as stated in each individual PGD. • A signed copy of the PGD will be kept by the practitioner and their team leader. Perfect Ward will be used to monitor this.		

Document Change History:			
Version Number / Name of procedural document this supersedes	*Type of Change i.e. Review / Legislation*	*Date*	*Details of Change and approving group or Executive Lead (if done outside of the formal revision process)*
1.0	*New policy*	*04/02/13*	*New policy.*
2.0	*Policy review*	*21/08/14*	*Updated in line with NICE Medicines Practice Guidelines (MPG 2) August 2013.*
2.1	*Minor amends following review*	*11/08/17*	*Reviewed and updated the pharmacy register is not being used therefore changed to the clinical team leader will now maintain a register of which practitioners are using which PGD. This will be audited by Perfect Ward.*
2.2	*Full review*	*December 2020*	*Full review including an additional paragraph to be added on page 28:* *In Primary Care and Community Services Division, PGDs authorised by NHS England, NHS Improvement or Public Health England for*

			registered practitioners employed by organisations/providers commissioned by NHS England and NHS Improvement within Yorkshire and the Humber can be approved by the Clinical Lead, Lead GP and the Principal Pharmacist in the Primary Care & Community Services Division.
2.3	*Full review – minor amends*	*February 2024*	*References updated* *5.1 process updated* *Appendices 5 and 6 removed as not applicable.* *Approved at DTG (30 Nov 2023) and then at QPaS (22 February 2024).*

Appendix 7 – Equality Impact Assessment (EIA) Toolkit

For strategies, policies, procedures, processes, guidelines, protocols, tenders, services

1. Document or Process or Service Name: Patient Group Direction Policy
2. EIA Reviewer: Simon Price, Trust PGD Pharmacist
3. Is it a Policy, Strategy, Procedure, Process, Tender, Service or Other? Policy

The purpose of this document is to enable the safe and effective use of Patient group directions.
Please indicate in the table that follows whether the document or process has the potential to impact adversely, intentionally or unwittingly on the equality target groups contained in the pro forma

Equality Target Group	Is the document or process likely to have a potential or actual differential impact with regards to the equality target groups listed?	How have you arrived at the equality impact score?
1. Age 2. Disability 3. Sex 4. Marriage/Civil Partnership 5. Pregnancy/Maternity 6. Race 7. Religion/Belief 8. Sexual Orientation 9. Gender re-assignment	Equality Impact Score Low = Little or No evidence or concern (Green) Medium = some evidence or concern(Amber) High = significant evidence or concern (Red)	a) who have you consulted with b) what have they said c) what information or data have you used d) where are the gaps in your analysis e) how will your document/process or service promote equality and diversity good practice

Equality Target Group	Definitions	Equality Impact Score	Evidence to support Equality Impact Score
Age	Including specific ages and age groups: Older people Young people Children Early years	Low	For patients in Trust inpatient wards, crisis teams, minor injury units, neighbourhood care services, school nurses, occupational health and GP practices. As directed on the PGD
Disability	Where the impairment has a substantial and long term adverse effect on the ability of the person to carry out their day to day activities: Sensory Physical Learning Mental Health (and including cancer, HIV, multiple sclerosis)	Low	All patients with any disability included
Sex	Men/Male Women/Female	Low	Any gender included
Marriage/Civil Partnership		Low	All patients included
Pregnancy/ Maternity		Low	Only as directed on the PGD
Race	Colour Nationality Ethnic/national origins	Low	All patients included
Religion or Belief	All religions Including lack of religion or belief and where belief includes any religious or philosophical belief	Low	All patients included
Sexual Orientation	Lesbian Gay Men Bisexual	Low	All patients included

Equality Target Group	Definitions	Equality Impact Score	Evidence to support Equality Impact Score
Gender Reassignment	Where people are proposing to undergo, or have undergone a process (or part of a process) for the purpose of reassigning the person's sex by changing physiological or other attribute of sex	Low	All patients included

Summary

Please describe the main points/actions arising from your assessment that supports your decision above: All patients included, however, see individual PGDs for - Patients who are pregnant/breastfeeding and young children who would be given medication as directed on the PGD.	
EIA Reviewer: Simon Price, Trust PGD Pharmacist	
Date completed: 6/11/23	Signature Simon G Price