NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Policy for the development, approval and implementation of Patient Group Directions (PGDs) for use across BNSSG

Shaping better health

Please Complete the table below: *To be added by corporate team once policy approved and before placing on website*	
Policy ref no:	ICB PGD Policy
Responsible Executive Director:	Joanne Medhurst (Medical Director, Clinical Effectiveness)
Author and Job Title:	Debbie Campbell (Chief Pharmacist), Michelle Jones (Principal Medicines Optimisation Pharmacist)
Date Approved:	20th October 2023
Approved by:	Joanne Medhurst (Chief Medical Officer)
Date of next review:	20h October 2026

Policy Review Checklist

	Yes/ No/NA	**Supporting information**
Has an Equality Impact Assessment Screening been completed?	Yes	Appendix 4
Has the review taken account of latest Guidance/Legislation?	Yes	The Human Medicines Regulations 2012. Amended April 2013 NICE PGD MPG2 updated March 2017
Has legal advice been sought?	n/a	
Has HR been consulted?	n/a	
Have training issues been addressed?	Yes	Competency and training addressed in section 4.4
Are there other HR related issues that need to be considered?	No	
Has the policy been reviewed by Staff Partnership Forum?	n/a	

	Yes/ No/NA	Supporting information
Are there financial issues and have they been addressed?	n/a	
What engagement has there been with patients/members of the public in preparing this policy?	n/a	
Are there linked policies and procedures?	No	
Has the lead Executive Director approved the policy?		To be reviewed by Jo Medhurst
Which Committees have assured the policy?		Will go to October APMOC
Has an implementation plan been provided?	Yes	Appendix 5
How will the policy be shared with: • Staff? • Patients? • Public?		The policy will be shared via email and will be available on the intranet
Will an audit trail demonstrating receipt of policy by staff be required; how will this be done?	Yes	This will be done by asking recipients to respond to the email to confirm that have read and understood
Has a DPIA been considered in regards to this policy?	n/a	
Have Data Protection implications have been considered?	Yes	Aligns with The Data Protection Act 1998

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Policy for the Development, approval and implementation of Patient Groups Directions (PGDs) for use across BNSSG.

1 Introduction

This policy outlines the approach to be taken by NHS Bristol, North Somerset and South Gloucestershire (BNSSG) ICB for the development, approval, and implementation of patient group directions (PGDs) for use by authorised healthcare professionals working in providers that are directly commissioned by the NHS and local authorities. This Policy has been written to take into account the National Institute of Health and Care Excellence (NICE) Good Practice Guidance (GPG2) on Patient Group Directions (published August 2013, updated March 2017). The scope of this policy is outlined in section 0.

1.1 Background

The preferred method for patients to receive medicines is for prescribers to provide care for individual patients on a one-to-one basis. However, in some cases, it may be necessary, or more convenient for a patient to receive a medicine directly from another healthcare professional. There are several legal options for prescribing, supplying and/or administering medicines:

- Independent prescribing: the prescriber (a doctor, dentist or non-medical independent prescriber) takes responsibility for the clinical assessment of the patient, establishing a diagnosis, the clinical management needed, and prescribing.
- Supplementary prescribing: a voluntary partnership between a doctor or dentist and a supplementary prescriber, to prescribe within an agreed patient-specific clinical management plan with the patient's agreement.
- Patient Specific Directions (PSDs): written instructions, signed by a doctor, dentist, or non-medical prescriber for a medicine to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. PSDs can be used for a group of patients, all of whom should be named on the direction. PSDs are direct instructions and do not require an assessment of the patient by the health care professional instructed to supply and/or administer. Writing a PSD is a form of prescribing. The professional administering medication under PSD should be aware that they must ensure that the medication is appropriate for the patient and in line with NICE and other local guidance.
- Patient Group Directions (PGDs): written instructions for the supply and/or administration of specified prescription-only (POM) or pharmacy (P) 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 (Health Service Circular HSC 2000/026). Using a PGD is not a form of prescribing.

- There are some exemptions from medicines legislation, for example:
  - A range of exemptions enable certain groups of health professionals, such as chiropodists and podiatrists, midwives, paramedics, optometrists, to sell, supply and/or administer particular medicines directly to patients,
  - Occupational health schemes
  - Treatment of pandemic disease
  - In life threatening situations certain medicines are exempt from medicines legislation, e.g. adrenaline (epinephrine)

1.2 Where can PGDs be used

PGDs can be used in all areas in which NHS healthcare is directly provided, and where services in the private, voluntary or charitable sector are NHS or Public Health funded.

PGDs do not extend to independent and public sector care homes or independent sector schools that provide healthcare entirely outside the NHS.

The majority of clinical care involving supplying and/or administrating medicines should be provided on an individual, patient-specific basis. Therefore, having medicines prescribed on a prescription is considered the best route.

1.3 When are PGDs not required?

A PGD is unnecessary:

- If an exemption exists under the Human Medicines Regulations 2012, such as:
  - Schedule 17 exemptions for paramedics, orthoptists, midwives and chiropodists. These exemptions allow these registered health professionals to administer or supply certain specified medicines within their scope of practice and competency without the directions of a doctor.
  - Schedule 19 exemptions allows administration of certain parenteral medicine without a prescription in an emergency.
- Under Schedule 17 Occupational Health Schemes are exempt from the restrictions that apply to prescription only medicines, where medicinal products are supplied or administered in the course of the OHS by a doctor, or by a registered nurse acting in accordance with the written (and signed) directions of a doctor.
- If the medicine involved is on the General Sales List (classified as GSL)

- If the medicines to be administered are P medicines (a PGD is needed for supply of Ps). However some individual provider's medicines policies may require PGDs for both supply and administration of Ps and GSLs as PGDs are considered to be a method to assure patient safety that is more rigorous than procedures and protocols. However, this is a local decision and may not always apply or be appropriate.
- For medical gases: these are not usually classified as POMs
  For dressings, appliances, medical devices, or chemical agents: these are not legally classed as medicines.

1.4 When is use of a PGD inappropriate?

The following **must not** be included in a PGD:

- Unlicensed medicines, including:
  - The mixing of two licensed medicines to form a new (unlicensed) product, unless one is a vehicle for administration, such as water for injection.
  - Special manufactured medicines.
- Radiopharmaceuticals.
- Anabolic steroids, and any injectable preparation used for treating addiction.
- Abortifacients, such as mifepristone.

A PGD should not be used when it is reasonable to expect that a prescription (FP10), or a PSD could be written in advance. PGDs should not be used to circumvent the repeat prescribing systems used in general practice. In addition, PGDs should not be used for minor self-limiting conditions where the patient can reasonably self-care and purchase the medicine over-the-counter.
The NICE Good Practice Guidance recommends that there are some clinical situations in which alternatives to PGDs should be used, for example:

- 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.

The NHS Specialist Pharmacy Service resources may be used to aid decision making and help to consider whether a Patient Group Direction (PGD) is appropriate for an area of practice that involves the supply or administration of medicines.

1.5 Drugs requiring special consideration

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

1.5.1 Use Outside the terms of Summary of Product Characteristics

Medication, which is licensed, but used outside the terms of its product licence ('off label'), can be included in a PGD. However, such use must be clearly justified by best practice, and the status of the product must clearly be described and communicated to the patient.

Information should be provided to the PGD Approval Group to demonstrate that there is acceptable evidence for the use of that product for the intended indication, e.g. follows nationally agreed guidelines, such as the Joint Committee on Vaccination and Immunisation (JVCI).

1.5.2 Newly Licensed drugs subject to special reporting arrangements (Black Triangle Drugs ▼)

Newly licensed drugs should only be considered in exceptional circumstances, when clearly justified by best clinical practice. Treatment guidelines must be followed and the PGD must clearly state the status of the product.

1.5.3 Antimicrobial drugs

Antimicrobial resistance is a major public health concern. The use of antibiotics and other antimicrobials in PGDs must, therefore, be given careful consideration. Inclusion in a PGD should only be considered where absolutely necessary and where measures to combat resistance will not be compromised. Use should be in line with BNSSG antimicrobial guidelines and the PGD should be regularly reviewed.

Consideration should be given to aligning with the NHS England and Improvement Framework for risk assessment of infection management patient pathways encompassing supply of antimicrobials under a patient group direction (PGD) guidance. This includes advice that a specialist in antimicrobial therapy should be involved in the development of a PGD for an antibiotic medicine (Appendix 1).

1.5.4 Controlled Drugs (CDs)

Only certain controlled drugs are legally eligible to be included in a PGD and not all professions listed in the PGD legislation can administer controlled drugs under a PGD, in accordance with The Misuse of Drugs Regulations (2001):

- The following regulated profession groups cannot administer or supply any controlled drugs, in any of the five schedules, under a PGD:
    - Dietitians

    - Speech and language therapists
    - Dental therapists
    - Dental hygienists
- The following details which controlled drugs can be supplied/administered under PGDs.
    - Morphine and diamorphine may be use by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person not for treating addiction)
    - Ketamine
    - Midazolam
    - Drugs in Schedule 4 except anabolic steroids and injectables for treating addiction.
    - Any drug in Schedule 5, including codeine.

1.6 Who can use a PGD?

PGDs must be used only by named and authorised registered health professionals who can legally supply and/or administer medicines using a PGD in line with the Human Medicines Regulations 2012. This currently includes the following registered health professions and may be subject to change:

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

Individual health professionals must be named and authorised to practice under a PGD.

2 Purpose and scope

This policy sets out the processes to be followed within Bristol, North Somerset, and South Gloucestershire (BNSSG) for the development and approval of PGDs for treatment of NHS patients by authorised healthcare professionals working for provider organisations directly commissioned by BNSSG Integrated Care Board (ICB), Bristol City Council (BCC), North Somerset Council (NSC) and South Gloucestershire Council (SGC), BNSSG commissioners will only authorise PGDs for use within the BNSSG Region.

This policy applies to the following practitioners and organisations (this list is not exhaustive):

- Registered Health Care professionals named within the legislation as able to work under a PGD, working in GP practices in Bristol, South Gloucestershire and North Somerset.
- Pharmacists working in community pharmacies that provide NHS or Public Health services in Bristol, South Gloucestershire and North Somerset.
- Registered Health Care professionals named within the legislation as able to work under a PGD, working for providers that are directly commissioned by BNSSG ICB, NSC, SGC and BCC.

This policy applies to independent contractors and providers commissioned by BNSSG ICB, NSC, BCC, SGC who wish to develop and/or work under a PGD when treating NHS patients under the terms of a contract.

Acute trusts currently fall outside the scope of this policy, as they have their own internal authorisation processes and do not require the ICB to sign as they are legally authorised to approve PGDs.

However, there is a process in place to standardise PGDs across the system to reduce duplication and improve efficiency and productivity. The process for the development of BNSSG wide PGDs can be found on the BNSSG formulary website.

Note: Where the PGD is developed and supplied to the provider e.g. immunisation PGDs given to community providers or GP practices, these organisations must sign the PGD to adopt it for use. The commissioning organisation may sign on behalf of a group of providers e.g. immunisation PGDs are signed by the commissioner for GP practices and community providers within their area. This is required by the legislation governing PGDs. This also applies for community pharmacies that use PGDs that have been authorised by the commissioner.

3 Approval group

PGDs must be authorised only by an appropriate authorising body in line with legislation. Commissioning and provider organisations may be authorising bodies. In the NHS in England, the organisations that are legally authorised to approve PGDs are:

- Integrated Care Board (ICBs)
- Local authorities
- NHS trusts or NHS foundation trusts
- Special health authorities
- NHS England
- UK Health Security Agency (UKHSA)

4 Process for development of PGDs

4.1 Requests for PGD development

In the majority of cases, the most appropriate clinical care should be provided on an individual basis by a prescriber to a specific named patient. The use of PGDs should be reserved for those situations where they would offer benefit to patient care without compromising safety. Careful consideration should be given to opportunities within the care pathway to use a prescription or a written Patient Specific Direction and also consider the use of exemptions.

For a clinical condition to be catered for by a PGD, the presenting characteristics and treatment requirements must be sufficiently consistent. Examples of such groups are:

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

Service Leads considering the development of a PGD for use should consider whether a PGD is needed using the NHS Specialist Pharmacy Service PGD resources. Requests for PGDs can be put forward using the documentation in Appendix 2. Requests for new PGDs should be sent to the commissioner/ provider service leads.

The commissioner/provider service lead should review the request to ensure it is appropriate and then consider:

- If a national PGD template is available, this should be adopted first line.
- If a BNSSG template PGD is available this should be adopted second line.

- If there is no national or local PGD template available, the request should be reviewed and approved by the commissioner/provider lead. Consideration should be given to developing a BNSSG PGD template if appropriate. If not appropriate, and if the request is approved, the service lead will be required to develop and write the PGD for the service.

The request should include consideration of the other available options for the supply and administration of medicines (e.g. non- medical prescribing). It should also consider the PGDs potential impact on inequalities. It is recommended that the request be considered and prioritised depending on:

- The appropriateness
- Benefit to patients
- Risk to patients
- Financial implications
- Staff resources (both for development and implementation).

The availability of resources required for development and implementation of PGDs should be considered early in the commissioning process of a service. If the commissioned organisation does not have this resource the funding for provision will have to be resolved between the provider and the commissioner.

Once the request has been approved a PGD working group should be established (see section 4.2) to develop and write the PGD.

4.2 Working group for PGD development

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 Good Practice Guideline (GPG) expands on this and states that a PGD working group should be established for each individual PGD, although the same group may be responsible for developing a number of PGDs.

The responsibility for the membership of the PGD Working Group will lie with the BNSSG PGD development group for BNSSG PGD templates or the provider organisation for PGDs for specific service, and it is expected that:

- The PGD Working Group is set up in line with GPG2 recommendations.
- Membership reflects recommendations of GPG2, including appropriate input from relevant primary care practitioners.
- 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.

- Individual PGDs will be developed by a named lead author, agreed by the PGD Working Group, who will have overall responsibility for clinical content.
- Where appropriate it seeks input from UK Health Security Agency (UKHSA)and NHS England
- It takes into consideration the recommendations of the NICE competency framework for people developing, reviewing or updating PGDs.

Additional expertise may be needed, for example:

- A specialist with appropriate expertise, such as a local specialist in microbiology for PGDs containing an antimicrobial.

All stakeholders in the development of the PGD should be identified by the PGD Working Group and consulted on the development of the PGD. Draft PGDs will be sent to representatives of the professional groups who will be operating under the PGD for comment and for identification of potential issues that may arise when PGDs are implemented.

4.3 Template for development of PGDs

PGDs should be developed using the SPS PGD exemplar templates It is the responsibility of the lead author to manage all drafts of the PGD(s) from initial development to approval. Version control must be maintained, including dates of each draft, and version numbers, so that changes made can be tracked.

4.4 Competency assessment for operating under the PGD

The PGD Working Group alongside the Service Lead should consider and agree training and competency requirements for staff wishing to operate under the PGD, in line with the NICE competency framework for health professionals using PGDs, including:

- Understanding of the requirements of individual PGDs.
- Knowledge of pharmacology of the drug to be included in the PGD.
- Knowledge of relevant legislation relating to use of the medicines and medical conditions and the content will be agreed by the PGD working group.

5 Process for approval of PGDs

5.1 PGD authorisation

Approved PGDs require the signature of the authorising body and should also be signed by a senior pharmacist and a senior doctor (or dentist). It is also good practice for the lead health professional working under the PGD to also sign. The signatories make up the Approval Group.

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

When signing a PGD as a commissioner, the commissioner lead must establish that:

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

Note that electronic signatures are acceptable: https://www.sps.nhs.uk/articles/questions-electronic-systems-and-pgds/, however, attaching a scanned picture of a signature is not acceptable.

The Approval Group will assess implementation requirements and support development of a communications plan to support the dissemination of PGDs (see section Production and distribution of PGDs5.4 below). The group with identify an appropriate person who is responsible for ensuring that this occurs.

Protected copies of PGDs (as PDFs) developed and authorised will be emailed directly to the provider who should post on the relevant websites.

For each PGD, the provider organisation should:

- Identify a senior, responsible person from within the service to authorise named, registered health professionals to practise under the PGD.
- Ensure that authorised health professionals have signed the appropriate documentation.

5.2 PGD document database

A database of all approved PGD documents will be maintained by the provider organisation. This includes GP practices. The database will be maintained on the appropriate secure drive. Each PGD will be given a unique PGD identifier and will be included on the summary front page of the relevant PGD. The expiry date for each PGD will also be recorded on the database.

Copies of expired PGD master (original signed) documents will be kept as for all other patient records. For adults all PGD documents must be kept for 8 years after the expiry date of the document if it relates to adults (10 years if it relates to an implant) and for 25 years after the expiry date if it relates to children.

5.3 Database of authorised practitioners

The names of the healthcare professionals who have been authorised to operate under PGDs must be kept by the service lead within the provider organisation. The

ICB Medicines Optimisation Team, provider organisation or Local Authority may request details of authorised practitioners.

It is the responsibility of the service lead for the provider organisation that is using the PGD to ensure that the list is updated to reflect both new staff authorised to operate under the PGD, and staff no longer authorised to operate under the PGD.

Examples of service leads include:

- Lead GP within a GP practice, who would authorise individual practice nurses.
- Superintendent pharmacist of a small, local chain of pharmacies, who would authorise individual pharmacists (managers and locums).
- Clinical and Operational Lead for a particular service e.g. MIU
- Responsible Clinician e.g. No Worries

Staff authorisation records should be kept for 8 years after the expiry date of the if it relates to adults only (10 years if relates to an implant) and for 25 years after the expiry date of the if it relates to children.

5.4 Production and distribution of PGDs

To ensure version control the provider will only distribute PGDs through signposting to the relevant website. Provider organisations will **NOT** email copies to any service.

When any new or amended PGD is posted onto the website, the organisation responsible for the development of the PGD will arrange for the relevant providers to be notified by email. Where these are primary medical care providers then this will be done through the authorising body. It is the responsibility of each provider to ensure that this information is cascaded to all relevant staff.

A copy, including the signatory page should be printed off by the service lead/manager, and this will be used to prepare individual copies for staff to refer to. The service lead/manager is responsible for ensuring the completeness and quality of the final copy for use by staff.

Each individual member of staff working to a PGD must be authorised by name to work to that PGD and sign and date the document to agree to work under that PGD at that time. A senior practitioner in the service or service manager must ensure that only staff who are competent to work under the PGD are signed up to it. There is no requirement for the individual authorisation to be kept as a hard copy; where systems exist for the declaration of competence and maintenance of records, this is acceptable, for example PharmOutcomes.

The original signed copy with signatures of the authorised healthcare professionals should be kept for a minimum of 10 years, if treatment relates to adults, and those that apply to children must be kept for 25 years.

The main content of a PGD (i.e. an unauthorised final copy), which contains no patient identifiable information or staff authorisation records, may be retained by an organisation for up to 20 years for purposes of business planning/continuity if there is reason to do so (i.e. reference for future PGDs).

In the GP practice setting, it is the responsibility of the Senior Partner (or designated 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 practice. The GP practice will keep these signed authorisations as both evidence of individuals' competency and as a record of staff authorised to use the PGD.

5.5 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 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 (including any extensions) from the date the PGD was authorised (or reauthorised following review).

In exceptional circumstances e.g. organisation or service transition, an extension to the expiry date may be applied for, to allow the PGD to be used without review and re-authorisation. Extension of expiry dates without review of a PGD is not without risk (e.g. licence of medicine may have changed/national guidance may have changed) but the organisation may deem this necessary where it is in the interests of patient safety; for example there may be a risk where withdrawing the PGD could result in significant service disruption and potential patient safety issues due to lack of access to medicines.

Where an extension is required the lead pharmacist should clinically check the PGD to ensure it would remain safe to use and contact the organisational signatory via email explaining the reasons why an extension to expiry date is required and the consequences of not having the extension. Where an extension is agreed this should be for an agreed period for no longer than one year. The total valid period of a PGD including the extension should not exceed three years.

The PGD extension letter (

Appendix 3) should be agreed and signed and provided to the service lead. It is important that the letter is brought to the attention of all the individual healthcare professionals who currently operate under the PGDs.

Any proposed changes, including minor amendments, will require the PGD to go through the review process and be re-authorised. It is the responsibility of the lead author to initiate the review process in good time to ensure continuity of care. A senior doctor and pharmacist must be involved in the review. The review process should involve consultation with all stakeholders.

6 Responsibility of authorised practitioners

All staff in professional groups able to work under PGDs are expected to do so, where this is a requirement of the service and/or it is included in their job description. Each individual will have to sign an agreement to work to a PGD.

Authorised practitioners must only undertake the extended role under a PGD in circumstances where they 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. If the authorised practitioner is in any doubt about their competency they should not administer and/or supply in accordance with the PGD and should seek advice from their relevant professional body, their line manager or the clinical lead for the service.

A practitioner authorised to work under a PGD cannot delegate the responsibility to another person.

All authorised practitioners supplying and/or administering medicines under PGDs must be named and have written evidence of competence, training, knowledge, experience and continuing education relevant to the clinical condition/situation to which the PGDs apply. The practitioner must take personal responsibility for ensuring they maintain their competence and knowledge and attend additional training when appropriate.

Practitioners should have a signed copy of the **current** PGD available for reference when supplying and/or administering a medicine.

Practitioners should keep a record of the supply and/or administration made under a PGD. This should be made available for audit purposes when necessary. The supply or administration must be attributable to an individual practitioner.

6.1 Criteria for the administration and/or supply of medicines

Supply and administration of the medicine must be strictly in accordance with the PGD and appropriate for the clinical condition. Evidence-based treatment guidelines should be used by the healthcare professional to inform clinical

decision-making. The individual must meet the eligibility criteria. Any variance from these criteria means that the individual must be excluded**,** alternative arrangements made and this documented.

6.2 Patient Counselling

The following should be discussed with the patient as a minimum standard:

- Reason for the treatment
- Why the medicines are supplied and/or administered
- Counselling on correct use of the medicine according to PGD and label
- The manufacturer's patient information leaflet (PIL) must be provided when medicines are supplied to patients. It is good practice to provide the PIL when administering a medicine. Discuss any queries that the patient/carer may have
- Possible side effects, their management and when to seek medical help
- Caution with interacting medicines
- Advice on follow-up treatment and referrals.
- Safety netting advice

6.3 Record Keeping

The following information must be recorded and ideally this would be electronically:

- Patient's details: name, date of birth, allergies, previous adverse events and the patient met the criteria of the PGD
- Patient assessment and diagnosis
- Contra-indications to any medicines
- Current and recent prescription medication, including over the counter (OTC) medicines and herbal preparations
- Reasons for exclusion and referral
- Details of medicine such as name, form, strength, quantity, route and site (if by injection) of administration (record batch number and expiry date for vaccines, blood-derived products and other medicines recommended by relevant national guidance)
- Relevant information and advice given to patient or their carer
- Name and/or signature (may be electronic) of the Health Care Professional providing treatment and supplying the medicine
- Whether patient consent was obtained

For adults all records must be signed, dated and kept for 8 years after last entry. For children all individual's clinical record must be kept until the child's 25th birthday (or 26th birthday if the child was 17 when treatment ended) or for 8 years

after a child's death. Where the PGD is for an implant in an adult then all documentation in an individual's clinical record must be kept for 10 years. For example, this would apply to contraceptive and sexual health PGDs for contraceptive implants or drug eluting coils. Records should be kept in the patient's notes and 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.

6.4 Security and storage of medicines

Medicines must be stored in safe, secure, locked cupboards, or pharmaceutical refrigerators, in a secure lockable room away from public access following best practice principles (refer to any local policies regarding storage of medicines):

- Storage conditions must be in line with the manufacturer's instructions.
- Internal and external medicines must be stored separately.
- Flammables must be stored appropriately in a flammables cupboard.

There must be a secure system for the recording and monitoring of medicines used from which it should be possible to reconcile incoming stock and outgoing stock on a patient- by-patient named basis.

When supplying a medicine, the medicine must be supplied in an original pack obtained from an approved supplier. Health professionals (other than pharmacists or dispensing doctors) should not split packs. The contents of pre-packs should not be altered to suit individual patients. They should be advised to take the recommend course and return excess doses to their community pharmacy for destruction.

Each medicine should be supplied in an appropriately labelled pack. In most cases, the pack to be issued under a PGD will need to be labelled to reflect the dose exactly as authorised in the PGD, as if it were being dispensed against a prescription. Separate requirements exist for prescription-only medicines (POMs) and for pharmacy (P) and general sales list (GSL) medicines. In practice, medicines supplied for use under a PGD are often in packs that are pre-labelled by a licensed manufacturing unit. These labels include all the standard labelling requirements, leaving a space on the pack for the patient's name, date of dispensing and address of the supplying service to be added at the time of supply. This is sometimes known as over-labelling.

Each pre-pack must be labelled with the following:

- Name of the medicine, form, strength and quantity.
- Directions for use, dose and frequency.
- Cautions and advisory labels.
- Additional warning 'to keep out of reach of children'.
- Special handling or storage instructions.
- Batch number and expiry date.
- Name and address of the service provider.

At the point of supply the Healthcare professional must add both the name of the patient, and the date of issue.

In addition, the manufacturer's patient information leaflet (PIL) must be provided each time a medicine is supplied to comply with European Council Directive 2004/27/EC.

Arrangements for the collection of prescription charges, or identifying individuals who are exempt from such charges, need to be in place to comply with NHS Standing Financial Orders.

6.5 Premises

The service should be provided from premises with adequate facilities, which provide the necessary confidentiality and conform to any requirements stipulated in the PGD.

6.6 Indemnity insurance

Those employed, (as opposed to being self-employed), whether within or outside the NHS, will almost certainly be covered for these purposes. Individual practitioners should have their own Professional Indemnity Insurance and ensure that the insurance provider is aware that they are operating under PGDs. Practitioners who are members of a professional organisation, or trades union, may also be covered additionally by this body. Most employers provide vicarious liability insurance to cover the acts or omissions of their employees, but practitioners 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.

7 Monitoring compliance and effectiveness

7.1 Policy

This policy will be reviewed every 3 years but can be reviewed at any time if the commissioner/provider deems it necessary to do so or a review is requested by management or staff.

Enquiries relating to this policy should be directed to: bnssg.medicines-optimisation@nhs.net

7.2 PGDs

It is a legal requirement to keep records of administration and/or supply under PGD for audit purposes. Care provided under a PGD must be audited. It is recommended that an audit of PGDs is undertaken annually. For new staff, it is recommended that practice should be audited six months after commencing the post.

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

The audit must include:

- 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.

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

The NHS Specialist Pharmacies Service provide example audit tools which may be adapted to conduct an annual audit of PGDs.

All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the equality Act 2010. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Document Lead (author) who will then actively respond to the enquiry.

8 Equality Impact Assessment

All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the equality Act 2010. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Document Lead (author) who will then actively respond to the enquiry.

An initial Equality and Health Impact Screening Assessment has been undertaken on the revised policy which identified that a full assessment is not required at this stage.

9 References

1. The Human Medicines Regulations 2012. Amended April 2013. [Accessed online at http://www.legislation.gov.uk/uksi/2012/1916/contents/made]
2. NICE Medicines practice guideline. 2013 updated March 2017. Patient Group Directions. [accessed online at https://www.nice.org.uk/Guidance/MPG2]
3. Specialist Pharmacy Service. The first stop for professional medicines advice. PGDs [accessed online at Patient Group Directions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice]

10 Acknowledgements

This policy is based on the Policy for the Development, Approval and Implementation of Patient Group Directions (PGDs) for use in North Somerset

11 Appendices

Appendix 1: Framework for risk assessment of infection management patient pathways encompassing supply of antimicrobials under a patient group direction (PGD)

Framework for Risk Assessment of PGD

Appendix 2: Proposal for Development of a Patient Group Direction (PGD)

This form must be completed before the development of any patient group direction to ensure all aspects of the PGD are considered prior to full development.

Title of patient group direction	
Medicines to be supplied or administered under this PGD (including dosage, quantity, formulation, strength, route and duration of treatment)	
What is the clinical situation that this PGD would be used in? to be treated	
Which patients will be included in treatment? (Specify age)	
In what setting would the PGD be used?	
Legal status of medicines (POM, P, GSL)	
BNSSG formulary status of medicines www.bnssgformulary.nhs.uk	Green / Blue / Amber / Red / Non-formulary
Staff groups to be operating under this PGD (e.g. nurses, physiotherapists etc)	
How is the medicine currently supplied?	
Why is a PGD needed for supply or administration of this medicine(s)?	

What other methods of supply have been considered? **Why is a PGD the most suitable method of supply?**	
What are the benefits of supplying this medicine using a PGD?	
What are the implications or consequences of not developing this PGD?	
What evidence is there to support the use of this medicine? E.g. NICE guidelines etc.	
Is this a service that is currently commissioned?	
Who commissions the service? E.g. ICB, Local Authority, NHS England	
What are the financial implications of implementing this PGD? (including drug costs, training etc?)	
Has Equalities and Health Inequalities been considered. What will be the impact of the	

PGD be? Consider EHIA assessment	
What training will be needed to supply/administer medicines using this PGD? How will these training needs be met?	
How will ongoing training and competence be undertaken and assessed?	
Who will be responsible for writing and updating the PGD?	
Form completed by **Base** **Contact details**	
Service Lead / Manager signature **Date**	

The above PGD has been approved for development by - _____	**YES / NO**
Comments	

Date	

Appendix 3: PGD extension letter

Dear,

Extension of validity of Patient Group Directions (PGDs) for [*insert service*] provided in [*insert area*]

We are aware that the PGD(s) currently in use at [*insert service*] have an expiry date of [*insert date*] and that full review and authorisation will not be completed by this date.

The legislation currently allows for PGDs validity to be extended for a limited period if necessary. We therefore think that this is a sensible step given the issues that would be caused if [*insert service*] were unable to use these PGDs for a period of time.

This letter gives notice that the PGD(s) listed below will have their period of validity extended to the [*insert date*], by which time the updated versions will be available.

INDICATION	DRUG	CURRENT EXPIRY

The PGD(s) listed above have been reviewed by the pharmacist lead and it has been assessed that the PGDs remain safe to use and will not put service users at increased risk of harm.

A copy of this letter should be kept with the PGD records in all areas where healthcare professionals are working to these PGDs. It should also be brought to the attention of the individual healthcare professionals who operate under the PGDs currently.

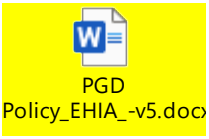
If you have any queries, please contact [*insert contact name and email address*].

Yours sincerely,

On behalf of [*insert authorising body*]

Doctor **(Name and role)**	**Pharmacist** **(Name and role)**	**Organisation** **(Name and role)**

Appendix 4: Equality Impact Assessment Screening



Appendix 5: Implementation Plan

Target Group	Implementation or Training objective	Method	Lead	Target start date	Target End date	Resources Required
APMOC	Ensure APMOC review the policy and have an awareness of ICB's responsibilities in relation to the development, approval and implementation of PGDs that are authorised by the ICB. Ensure that APMOC are assured that appropriate processes have been established.	Policy to be reviewed by APMOC	Michelle Jones, Principal Medicines Optimisation Pharmacist		5th October 2023	Staff time, APMOC members time
Community Provider PGD Leads Council PGD leads And relevant Medicines Optimisation Staff	Ensure awareness of ICB processes and procedures as well as being aware of relevant legislation.	Share at BNSSG ICB PGD work Policy to be placed on formulary website Circulate to relevant Medicines Optimisation staff, Medical Director (Clinical Effectiveness), Council PGD leads and Community Provider PGD leads.	Michelle Jones, Principal Medicines Optimisation Pharmacist	6th October 2023	30th October 2023	Staff time