Bedfordshire, Luton and Milton Keynes
Integrated Care Board

Patient Group Directions Policy

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Implementation Plan

Development and Consultation:	The following individuals were consulted and involved in the development of this document: ▪ Associate Director and Head of Medicines Optimisation ▪ Medical Director ▪ Deputy Chief Nurse ▪ Area Prescribing Committee members
Dissemination:	Staff can access this document via the website and will be notified of new / revised versions via the staff briefing. This document will be included in the organisation's Publication Scheme in compliance with the Freedom of Information Act 2000.
Training:	The following training will be provided to make sure compliance with this document is understood: ▪ Not applicable for this policy
Monitoring:	Monitoring and compliance of this document will be carried out via: ▪ Area Prescribing Committee approval and working group
Review:	The Document Owner will ensure this document is reviewed in accordance with the review date on page 2.
Equality, Diversity and Privacy:	Appendix 1 - Equality Impact Assessment Appendix 2 - Data Protection Impact Assessment
Associated Documents:	The following documents must be read in conjunction with this document: ▪ Not applicable for this policy
References:	The following articles were accessed and used to inform the development of this document: ▪ The Human Medicines Regulations 2012 The Human Medicines Regulations 2012 (legislation.gov.uk) ▪ NICE Patient group directions Medicines practice guideline [MPG2] Published: 02 August 2013 Last updated: 27 March 2017 Overview | Patient group directions | Guidance | NICE ▪ Competency framework for people developing and/or reviewing and updating patient group directions https://www.nice.org.uk/guidance/mpg2/resources ▪ Competency framework for health professionals using patient group directions. https://www.nice.org.uk/guidance/mpg2/resources ▪ NICE PGD template Patient Group Directions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

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1.0 Introduction

1.1 NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (ICB) aims to ensure robust governance through its formal written procedural documents, such as this document, which communicate standard organisational ways of working. These documents help clarify operational requirements and consistency within day-to-day practice. They can improve the quality of work, increase the successful achievement of objectives and support patient safety, quality and experience. The ICB aims to ensure its procedural documents are user friendly, up-to-date and easily accessible.

1.2 The ICB must design and implement procedural documents that meet the diverse needs of our service and workforce, ensuring that none is placed at a disadvantage over others, in accordance with the Equality Act 2010. The Equality Impact Assessment initial screening, which was used to determine the potential impact this policy might have with respect to the individual protected characteristics is incorporated at Appendix 1.

1.3 A Data Protection Impact Assessment is a process which helps assess privacy risks to individuals in the collection, use and disclosure of personal information. The Data Protection Impact Assessment initial screening, which was used to determine the potential impact this policy might have with respect to an individual's privacy is incorporated at Appendix 2.

1.4 Patient Group Directions (PGDs) provide a legal framework that allows some registered health professionals to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber (such as a doctor or non-medical prescriber). As a commissioner, the Integrated Care Board (ICB) must confirm that the PGD development and organisational process is thorough and has the correct signatories before it can legally authorise the PGD for use. It is the responsibility of the organisation developing the PGD to assure governance around clinical content. Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care without compromising patient safety, and there are clear governance arrangements and accountability.

1.5 Legislation establishing PGDs was introduced in 2000 and the Health Service Circular (HSC 2000/026) provided additional guidance. The current legislation for PGDs is included in The Human Medicines Regulations 2012 and subsequent amendments.

2.0 Scope

2.1 This policy applies to all private providers (non-NHS) organisation where the ICB commissions services. This policy does not apply to providers or commissioners who are able to develop and authorise their own PGD under legislation. The ICB cannot authorise PGDs on behalf of Local Authorities under Section 75 agreements.

3.0 Definitions

3.1 Patient Group Direction (PGD) – a PGD is a written instruction for the supply or administration of a licensed medicine (or medicines) in an identified clinical situation, where the patient may not be individually identified before presenting for treatment. This should not be interpreted as indicating that the patient must not be identified; patients may or may not be identified, depending on the circumstances.

3.2 Patient Specific Direction (PSD) – a PSD is individually prescribed for a patient remains the preferred option for most of the care.

3.3 Off Licence Use - Medicines can be used outside the terms of their Summary of Products Characteristics (SPC) known as 'off licence' use (as opposed to unlicensed).

4.0 Policy Statement

4.1 This policy is to set out the arrangements for development, review, and authorisation of PGDs by BLMK ICB.

5.0 Roles and Responsibilities

5.1 The following have specific responsibilities in relation to this policy.

BLMK ICB Area Prescribing Committee
Medical Director
Director of Nursing
Associate Director and Head of Medicines Optimisation

6.0 Processes and Procedures

6.1 General Principals

6.1.1 Providers must have in place their own PGD policy as part of a suite of Medicines Management policies to support safe handling of medication.

6.1.2 PGDs developed by providers who are not legally able to authorise them must be clinically signed off by the provider organisation before being submitted in the ICB for authorization.

6.1.3 The ICB expects that providers will use nationally developed template PGDs e.g., immunisations and vaccinations; if available, and only develop their own PGDs if suitable national/commissioner ones are not available. The NHS Specialist Pharmacy Service (SPS) have several templates PGDs on their website available for use within the NHS.

6.1.4 Providers requiring ICB commissioner authorisation must submit their PGDs to the ICB via the Medicines Optimisation team blmkicb.medsopt@nhs.net See Authorisation Process.

6.1.5 A PGD is drawn up locally by doctors, pharmacists and other health professionals and must meet certain legal criteria. Each PGD must be signed by a doctor or dentist, as appropriate, and a pharmacist, and approved by the organisation in which it is to be used. PGDs must also be authorised for use by the commissioner where the provider organisation is not legally able to authorise its own PGDs.

6.1.6 Each PGD has a list of individuals named as competent to supply/administer under the direction. The organisation using the PGD should ensure a senior person in each profession locally is designated with the responsibility to ensure that only fully competent, registered, and trained professionals operate within directions.

6.1.7 Off Licence Use; provided such use is supported by best clinical practice, and the PGD must state when the product is being used outside the terms of the SPC and why this is necessary. Medicines used outside the terms of the relevant SPC, e.g., as used in some areas of specialist paediatric care, may be included in PGDs provided such use is exceptional, justified by current best clinical practice (e.g., NICE guidance) and that a direction clearly describes the licensing status of the product. Each PGD should clearly state when the product is being used outside the terms of the SPC ('off-license') and the documentation should include the reasons why, exceptionally, such use is necessary.

6.1.8 Controlled drugs -Only certain controlled drugs are legally eligible to be included in a PGD in accordance with The Misuse of Drugs Regulations (2001); see table 1.

Table 1 Controlled drugs that may be considered for inclusion in a Patient Group Direction

Schedule	**Controlled drugs that may be considered for inclusion in a Patient Group Direction**	**Additional conditions/ comments**
Schedule 2	Morphine Diamorphine	Only when used by registered nurses and pharmacists, for the immediate necessary treatment of a sick or injured person. **Not for treating addiction**
	Ketamine	
Schedule 3	Midazolam	Specifically note that since their reclassification as Schedule 3 controlled drugs (CD No Register POM) tramadol, gabapentin and pregabalin **must not be supplied and administered under a PGD.**

Schedule 4	All drugs, including benzodiazepines	**Except -**Anabolic steroids and any injectable preparation used for treating addiction **must not be supplied and administered under a PGD.**
Schedule 5	All drugs, including codeine	

6.1.9 Permitted Professional Groups-Legislation requires that PGDs must only be used by registered healthcare professionals as named in legislation- see Patient Group Directions: who can use them.

6.1.10 Individual health professionals must be named and authorised to practice under a PGD. The registered healthcare professional cannot delegate the administration/ supply of a medicine via a PGD to another member of staff e.g., a nurse cannot delegate the administration of a vaccine to a healthcare assistant when the instruction to administer is via a PGD.

6.1.11 However, if the medicine supplied under the PGD is a take-away pack it is within the law for another person to administer this medicine in accordance with the directions on the labelled supply/information leaflet.

6.1.12 PGD must be developed in accordance with legislation and national guidance as listed below (this is not an exhaustive list)

- MHRA Patient group directions (PGDs) Guidance
- Human Medicines Regulations 2012
- NICE MPG2 Patient Group Directions
- Specialist Pharmacy Service Patient Group Directions resources
- British National Formulary (current online edition)
- Immunisation against Infectious Disease (The Green Book) (current online edition)
- The Misuse of Drugs Regulations 2001.

6.1.13 Within the NHS, PGDs fall into three categories.

- Supply or administration of medicines by NHS bodies
- To assist a doctor or dentist providing primary care national health services
- The supply and or administration of medicines by a person lawfully conducting a retail pharmacy business pursuant to an arrangement with an authorised body.

6.1.14 Since 2003, many non-NHS organisations have been able to use PGDs:

- Independent hospital, medical agencies, and independent clinics
- Prison healthcare services
- Police services
- Defence medical services

6.1.15 Many private organisations - including social enterprises/community interest companies- must seek authorisation from the commissioning body for the commissioned service before PGDs can be legally operated.

6.1.16 Any patient group direction must follow the proforma as laid out in NICE guidance.

6.1.17 A PGD must relate to medicines which have a marketing authorisation.

6.1.18 Any PGD must:

- Recognise that administration and supply under PGD must only be undertaken by approved practitioners where there are clear benefits of improved patient care or organisational advantages without any reduction in patient care.
- Specify the additional training process and competency for approval a practitioner must undergo before authority is granted to that individual to supply and/or administer under a PGD, as an approved practitioner. This will be developed by the (provider) working group developing the PGD and approved as part of the PGD approval process.
- Specify the mechanism and time scale for regular updating of knowledge and review of relevant skill and knowledge of approved practitioners.
- Refer to an audit process by which administration and supply can be monitored.
- Contain a means of reporting and recording errors and incidents relating to administration and supply by an approved practitioner.
- Specify the review period for the PGD

6.1.19 All professions must act within their appropriate Code of Professional Conduct.

6.2 Developing Patient Group Directions

6.2.1 Organisations will have in place a process for agreeing the need and development of PGDs as laid out in the NICE guidance. Approval for the ICB to develop PGDs must be obtained by the ICB commissioner as part of the service business case approval process, which must include discussions with the Medicines Optimisation team.

6.2.2 Developing PGDs requires a detailed knowledge of the service being delivered, the staff training requirements and the cohort of patients presenting for treatment.

6.2.3 PGDs must be produced in the light of current best practice. Supporting references should be included in the PGD document with links to the full references available electronically.

6.2.4 The organisation developing the PGD ('owner') will ensure that a named lead author has responsibility for developing a PGD, supported by a locally determined multidisciplinary PGD working group. Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Define their roles and responsibilities, and consider their training and competency needs.

6.2.5 The organisation developing the PGD ('owner') is responsible for the clinical contents of PGDs it develops; the provider implementing the PGD is responsible for ensuring that staff are trained and competent to operate the PGDs and for ensuring that appropriate governance and audit of development and management of PGDs is in place. A competency framework is available.

6.2.6 PGDs must contain the names and signatures of the working group, including the Lead author/ Practitioners, Pharmacist(s) and Doctor(s) who developed the PGD- who are responsible for signing off the clinical content of the PGD.

6.2.7 For PGDs submitted to the commissioner for authorisation, the provider must follow their own internal process for sign off and internal approval before submitting to the commissioner for authorisation.

6.2.8 Where the PGD has been developed by the ICB, the professionals involved in working group will not be part of the ICB authorisation/review group.

6.3 Authorisation of Patient Group Directions

6.3.1 The ICB review group is a virtual group and is responsible for assuring and authorising, PGDs that are prepared by provider organisations or developed by the ICB for providers it commissions See flow chart (appendix 1). This will not apply to providers or commissioners who are able to develop and authorise their own PGD under legislation.

a ICB PGD review group members:

- ICS Medical Director or designated deputy (chair)
- Head of Medicines Optimisation or designated deputy (pharmacist)
- Quality/patient safety lead-nurse or designated deputy (nurse)

In addition, if appropriate

- Clinician with expertise in the clinical area (this may be a representative from the provider organisation who would therefore be excluded from the authorisation process)
- Lead author for PGDs (not involved in the authorisation process)
- Other ICB pharmacist co-opted by review group (expert in relevant field, optional)

b Organisational Authorisation for PGDs is dependent on review by the ICB group

Responsibilities of this group are:

- To ensure that this ICB PGD process is applied and that appropriate governance relating to PGD preparation is in place by the organisation preparing the PGD
- To review all PGD documentation submitted and inform the PGD authorisation decision by assuring the safety and quality of the PGD including the development process
- To feedback to the PGD working group and ensure that appropriate action is taken where issues relating to the PGD have been identified
- To ensure that the provider organisation has an appropriate audit process in place to assure safe and effective service provision using the PGD
- To ensure that the equality impact of the PGD has been considered and appropriately addressed

c The chair of the review group has designated responsibility for signing PGDs on behalf of the authorising body.

The responsibilities of the chair of the review group are to be assured that:

- The PGD has been agreed as the most appropriate mechanism for supply and administration of the medicine
- There is no opportunity in the pathway for the medicine to be prescribed in a timely manner
- Local processes and governance arrangements have been followed
- The views of all stakeholders have been considered
- Legal requirements have been met

d The decision to authorise the PGD by the chair of the review group will be approved by the Bedfordshire, Luton and Milton Keynes area prescribing committee (BLMK APC)

1. The ICB Head of Medicines Optimisation (or deputy) is responsible for submitting PGDs to the BLMK APC for ratification.
2. The Professional Secretary of the BLMK APC will keep a copy of all PGDs authorised by the ICB.
3. Until authorised by the ICB PGD review group, a PGD or amendments to an existing PGD are invalid. The ICB accepts no responsibility for an approved practitioner who acts in accordance with a PGD not authorised as above or acts in accordance with an expired/superseded PGD
4. Providers have full responsibility and legal liability for management of practitioners working to PGDs within services they are delivering.

6.4 Implementation

6.4.1 The Provider will make available any necessary additional training to meet the required competencies before individuals shall be authorised to work under a PGD and have the responsibility for identifying appropriately qualified and trained healthcare professionals to operate within the PGD.

6.4.2 The Provider will ensure that each identified healthcare professional is competent to operate the PGD and has received any additional training deemed necessary, and has been formally authorised to operate the PGD, including completion of all necessary documentation.

6.4.3 The Provider will ensure that a copy of each authorised PGD is available within the service area where it is in use for immediate reference of staff.

6.5 Governance Arrangements

6.5.1 PGDs will be authorised and ratified as laid out in section 7 (Authorisation of PGDs).

6.5.2 PGDs are valid for up to three years after authorisation. A robust process must be in place to assure PGD review. All PGDs should have a governance box on them which states when it was written, who by, when it was authorised and when it expires. An unscheduled review of a PGD may arise such as due to a change in the licence of the product, new national guidelines, following a patient safety incident or other important new evidence which requires changes in clinical practice under the PGD.

6.5.3 The final authorised PGDs must be kept for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children.

6.5.4 It is the responsibility of the service lead to monitor and audit the use of PGDs within their service setting.

6.5.5 The ICB Head of Medicines Optimisation (or deputy) is responsible for maintaining a log of all PGDs authorised by the ICB PGD review group and their review dates. A copy of the original signed PGD once approved by the APC will be kept by the APC professional secretary.

Appendix 1 - Equality Impact Assessment Initial Screening

Please answer the questions against each of the protected characteristic and inclusion health groups. If there are significant impacts and issues identified a full Equality / Quality Impact Assessment (EQIA) must be undertaken. It is against the law to discriminate against someone because of these protected characteristics. For support and advice on undertaking EQIAs please contact: agcsu.equalities@nhs.net

Name of Policy:	Patient Group Directions Policy
Date of assessment:	12-04-2023
Screening undertaken by:	Associate Director and Head of Medicines Optimisation

Protected characteristic and inclusion health groups. Find out more about the Equality Act 2010, which provides the legal framework to tackle disadvantage and discrimination: https://www.equalityhumanrights.com/en/equality-act/protected-characteristics	Could the policy create a disadvantage for some groups in application or access? (Give brief summary)	If Yes - are there any mechanisms already in place to mitigate the potential adverse impacts identified? If not, please detail additional actions that could help. If this is not possible, please explain why
Age A person belonging to a particular age (for example 32 year olds) or range of ages (for example 18 to 30 year olds).	No	
Disability A person has a disability if she or he 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	
Gender reassignment The process of transitioning from one gender to another.	No	
Marriage and civil partnership Marriage is a union between a man and a woman or between a same-sex couple. Same-sex couples can also have their relationships legally recognised as 'civil partnerships'.	No	
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	No	

employment context. In the non-work context, protection against maternity discrimination is for 26 weeks after giving birth, and this includes treating a woman unfavourably because she is breastfeeding.		
Race Refers to the protected characteristic of race. It refers to a group of people defined by their race, colour and nationality (including citizenship) ethnic or national origins.	No	
Religion or belief Religion refers to any religion, including a lack of religion. Belief refers to any religious or philosophical belief and includes a lack of belief. Generally, a belief should affect your life choices or the way you live for it to be included in the definition.	No	
Sex A man or a woman.	No	
Sexual orientation Whether a person's sexual attraction is towards their own sex, the opposite sex, to both sexes or none.	No	
Carers Individuals within the ICB which may have carer responsibilities.	No	
Please summarise the improvements which this policy offers compared to the previous version or position.		
N/A – new policy		
Has potential disadvantage for some groups been identified which require mitigation?		
No		

Appendix 2 - Data Protection Impact Assessment Initial Screening

Data protection is the fair and proper use of information about people. Before completing this form, please refer to the Data Protection Impact Assessment (DPIA) Guidance in the Information Governance (IG) section on the staff Intranet or contact the Data Protection Officer for support via blmkccg.ig@nhs.net

A DPIA is a process to help you identify and minimise the data protection risks. You must do a DPIA for processing that is likely to result in a high risk to individuals. You can use our screening checklist below to help you decide when to do one. If you have answered 'Yes' to any of the 10 screening questions, you must then carry out a full DPIA using the Stage 2 form, which is also available on the Intranet in the IG section.

Name of Policy:	Patient Group Directions Policy
Date of assessment:	12-04-2023
Screening undertaken by:	Associate Director and Head of Medicines Optimisation

Stage 1 – DPIA form **please answer 'Yes' or 'No'**

1.	**Will the policy result in the processing of personal identifiable information / data?** This includes information about living or deceased individuals, including their name, address postcode, email address, telephone number, payroll number etc.	No
2.	**Will the policy result in the processing of sensitive information / data?** This includes for living or deceased individuals, including their physical health, mental health, sexuality, sexual orientation, religious belief, National Insurance No., political interest etc.	No
3.	**Will the policy involve the sharing of identifiers which are unique to an individual or household?** e.g., Hospital Number, NHS Number, National Insurance Number, Payroll Number etc.	No
4.	**Will the policy result in the processing of pseudonymised information by organisations who have the key / ability to reidentify the information?** **Pseudonymised data -** where all identifiers have been removed and replaced with alternative identifiers that do not identify any individual. Re-identification can only be achieved with knowledge of the re-identification key. **Anonymised data -** data where all identifiers have been removed and data left does not identify any patients. Re-identification is remotely possible, but very unlikely.	No
5.	**Will the policy result in organisations or people having access to information they do not currently have access to?**	No
6.	**Will the policy result in an organisation using information it already holds or has access to, but for a different purpose?**	No
7.	**Does the policy result in the use of technology which might be perceived as being privacy intruding?** e.g., biometrics, facial recognition, CCTV, audio recording etc.	No
8.	**Will the policy result in decisions being made or action being taken against individuals in ways which could have a significant impact on them?** Including profiling and automated decision making. (This is automated processing of personal data to evaluate certain things about an individual i.e., diagnosis and then making a decision solely by automated means - without any human involvement)	No
9.	**Will the policy result in the collection of additional information about individuals in addition to what is already collected / held?**	No
10.	**Will the policy require individuals to be contacted in ways which they may not be aware of and may find intrusive?** e.g., personal email, text message etc.	No

Appendix 3 - Organisational Authorisation of PGDs

The organisation developing the PGD ('owner') must ensure that the PGD has been prepared with reference to NICE guidance:

a) confirm PGD is appropriate in this circumstance
b) developed by multi-disciplinary group (including service lead, doctor/dentist, pharmacist, and representative from professional group(s) using the PGD)
c) other appropriate specialists have been included in group e.g., microbiology
d) any use of a licensed medication outside licence should be referenced
e) signed by a senior pharmacist and a doctor (or dentist) confirming that the clinical and pharmaceutical content are accurate and supported by the best available evidence.
f) PGD has provider organisational authorisation (n/a where ICB is the 'owner')

PGDs should be sent to blmkicb.medsopt@nhs.net

PGD presented to ICB PGD review group
Responsibilities of this group are:

a) Review group is responsible for ensuring that this ICB PGD process is followed, and that appropriate governance has been applied by the provider organisation preparing the PGD
b) Review group members are responsible for reading all PGD documentation submitted and informing PGD authorisation decision by assuring the safety and quality of PGD

The chair of the review group has designated responsibility for signing PGDs on behalf of the authorising body
The chair must be assured:

a) PGD has been agreed as most appropriate mechanism for supply and administration of the medicine
b) There is no opportunity in the pathway for the medicine to be prescribed in a timely manner
c) Local processes and governance arrangements have been followed
d) The views of relevant stakeholders have been considered
e) All legal requirements have been met
f) The PGD is safe and presents routine practice
g) The PGD is authorised on behalf of the organisation by the chair of the review group

The decision to authorise the PGD by the chair of the review group is ratified by the BLMK Area Prescribing Committee