Bedfordshire, Luton and Milton Keynes (BLMK)
Area Prescribing Committee (APC)

Patient Group Direction Subgroup
Terms of Reference (v1) Approved May 2023

Purpose	The BLMK APC is a strategic local decision- making group with responsibility to promote rational, evidence-based, high quality, cost-effective medicines optimisation across Bedfordshire, Luton and Milton Keynes in order to ensure equity of access to medicines for all residents. The Patient Group Direction Sub-group reports to the BLMK APC and recommends patient group directions that the group have agreed are clinically appropriate for use within the commissioned service and meet all the legal requirements. **Responsibilities** • To ensure that the ICB PGD policy 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
Membership	• 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) **QUORUM:**

The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Integrated Care Board; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust

	The group is a virtual group and agreement must be obtained from the following: • ICS Medical Director or designated deputy (chair) • Head of Medicines Optimisation or designated deputy (pharmacist) • Quality/patient safety lead-nurse or designated deputy (nurse) The chair of the review group has designated responsibility for signing PGDs on behalf of the authorising body.
Committee Secretariat and setting the agenda	The group will be supported by administrative staff from the Medicines Optimisation team as required
Frequency of Meetings	Virtual group – frequency will be dictated by requests from providers for approval of PGDs
Responsibilities	**CHAIR** 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 **MEMBERS** • The responsibilities of the members 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 • Legal requirements have been met Additional responsibilities • The ICB Head of Medicines Optimisation (or deputy) is responsible for submitting PGDs to the BLMK APC for ratification. • The Professional Secretary of the BLMK APC will keep a copy of all PGDs authorised by the ICB. • 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 • Providers have full responsibility and legal liability for management of practitioners working to PGDs within services they are delivering.
Relationship to other bodies	The BLMK Patient Group Direction Sub-group makes recommendations to the BLMK APC on approval of PGDs to be used within the BLMK integrated care system.

Output and Communication	Recommendations from the BLMK Patient Group Direction Sub-group are shared with the BLMK APC for approval.
Nature of decisions and reporting mechanisms	The BLMK Patient Group Direction Sub-group is an advisory body.
Equality and Diversity	The BLMK Patient Group Direction Sub-group commits to have due regard to Equality, Inclusion and Human Rights considerations in its decision-making process.
Appeals Process	The BLMK APC is the ultimate decision-making body.
Document history	Version 1, May 2023

Appendix 1

PGD legal requirements

- Name of the business who owns the Direction
- Start and end date of the PGD
- Description of the medicines
- Health Professional who will be supplying or administering the medicine
- Signature of a Doctor and a Pharmacist
- Signature of the Clinical Governance Lead for the Clinical Commissioning Group
- Specified condition/conditions that can be treated
- Description of patients excluded from treatment under the direction
- Description of when to request advice from a doctor and arrangements for referral
- Details of appropriate dosage, maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period to administer the medicine
- Relevant warnings, including potential adverse reactions
- Details of any necessary follow-up actions
- Statement of the records to be kept for audit purposes

In addition to the above, the Provider Organisation should demonstrate in their process document:

- Type of medicines eligible to be prescribed i.e., prescription only, pharmacy, general sale list
- Type of medicines that cannot be prescribed i.e., unlicensed medicine, dressings, appliances and devices, radiopharmaceuticals, abortifacients, such as mifepristone
- Up to date and signed authorisation
- Appropriate levels of skill and competence
- The requirements of any specific guidance i.e., local formularies
- Directly observed competencies
- Evidence of appropriate education, motivation, training and development with commitment to ongoing training, updates and PDP
- Evidence of a safe and secure environment
- Evidence of a safe and efficient service
- Highest standards of clinical governance
- Maintained expertise
- Evidence of appraisal
- Indemnity insurance
- NICE Guidance
- Indemnity Insurance
- Professional Registration
- Prescription charge process if applicable