Bedfordshire, Luton and Milton Keynes (BLMK)
Area Prescribing Committee (APC)
Terms of Reference (v5) 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 APC will make decisions in ways that are clear, consistent and defensible and take account of regional and national recommendations using an explicit ethical framework and decision-making criteria that clinicians are aware of when submitting applications for clinical support and for funding. There will be a systematic approach to whole therapeutic areas, not looking solely at single drugs in isolation from the care pathway; there will be consideration of other health-system costs to support and facilitate service redesign. The APC will include Medicines Safety and Antimicrobial Stewardship as standing agenda items. **Key Functions** • Advise BLMK Integrated Care Board (ICB) and NHS Trusts on the commissioning and provision of new medicines and new indications for medicines, including the financial implications. • Provide prescribing advice to BLMK clinicians across primary and secondary care • Inform the development of and ratify local medicine-related clinical guidelines or pathways and shared care guidelines, co-ordinating care across primary and secondary care. • Approve changes (additions/deletions) to the Bedfordshire and Luton Joint Formulary and the Milton Keynes Joint Formulary for medicines (including medical devices listed in the drug tariff) that are prescribed only in primary care or both primary and secondary care as well as those high cost drugs which are prescribed solely in secondary care but commissioned by the

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

	ICB or NHS England in accordance with NICE Technology Appraisals. (Those medicines which are used solely within secondary care and which are not designated as high cost drugs within the national contract and commissioned by the ICB or NHS England, are agreed by the Hospital DTC or Prescribing and Medicines Governance Committee.) • Maintain the traffic light classification for prescribing responsibility. • Review and ratify Patient Group Directions. • Work with local Provider Committees across BLMK and receive their meeting minutes for information. • Work with providers to develop prescribing policies/agreed care pathways linked to formulary changes that take account of the secondary/primary care interface and the overall cost implications of both primary and secondary care prescribing. • Prevent and assist in the resolution of problems relating to medicine provision at the interfaces of care. • Approve and adopt NICE Technology Appraisal (TA) Guidance that concern prescribing and medicines usage and where appropriate advise on their implementation. (**NB** NICE TAs may be added to the Joint Formulary prior to ratification by the APC as ICB/NHSE funding of these TAs is mandatory within specified timescales). • Note and advise (where appropriate) on the implementation of medicine-related NICE Clinical Guidelines. • Note the publications of the implementation of NICE Highly Specialised Technologies Guidance. • Approve and adopt medicine-related national Clinical Commissioning Policies, including interim policies (**NB** the policy may be adopted, and any necessary medicines added to the Joint Formulary prior to ratification by the APC as dictated by the timescale for implementation of the national policy). • Review and critically appraise the evidence and place in therapy for the commissioning of new medicines which are not being considered by NICE. • Support the East of England Priorities Advisory Committee (EoEPAC) and work with other neighbouring NHS organisations contributing to development, ratification and implementation of policies as appropriate. **NB** The APC would normally expect to adopt the EoEPAC recommendations with local amendment when required. • Support the Regional Medicines Optimisation Committee (East of England) by contributing to development and ratification of their policies and advise on the outputs from the national Regional Medicines Optimisation Committee for local consideration and adoption. • Respond to and prioritise NHS policy developments impacting on prescribing and medicines use, including medicines safety issues.

	• Define and ensure the completion, analysis and reporting of audits of use across the health system of formulary additions, against anticipated place in therapy. • Promote information sharing and good practice to ensure that medicines are being used safely. • Discuss and ratify recommendations of relevant sub committees to include Formulary changes. • Communicate recommendations and outputs effectively to all relevant member and stakeholder organisations and encourage implementation.
Membership	• Chair – Consultant in Public Health, Non-Executive Member, Lay member or BLMK ICS Clinician. • Chief Pharmacist or nominated deputy from acute trusts, mental health and community services - Bedfordshire Hospitals, Milton Keynes Hospital, East London Foundation Trust (NB ELFT will send one representative to represent Community and Mental Health), Cambridgeshire Community Services, Central and North West London Trust • Medical Director or nominated deputy - Bedfordshire Hospital, Milton Keynes Hospital and BLMK ICB • Associate Director and Head of Medicines Optimisation BLMK ICB • Place based lead Pharmacist – one per place • Place based GP – one per place • Nurse representative (Independent Prescriber) • Consultant in Public Health (if not the Chair) • Patient representative / lay member(s) • Commissioning lead pharmacists (Professional secretary) • Chair of subgroups (if not a member in another capacity) • ICS Chief Pharmacist **In addition to regular committee members, other clinicians are invited to attend to provide expertise, necessary to the deliberations of the Committee.** Other Heath Care Professionals may attend the meetings at the discretion of the Chair but do not have voting rights. **Chair** In the absence of the nominated Chair, the Professional Secretary will identify another voting member of the Committee to deputise.
Quoracy	The **Committee** will be **quorate** to make decisions if the following Committee members are present: • Three medically qualified doctors, of whom at least two should be practicing general practitioners. • Two clinicians from Secondary Care (of whom at least one should be a pharmacist) • Associate Director and Head of Medicines Optimisation • Professional Secretary to the Committee

	N.B. All of the above representatives must have a nominated deputy. In the light of non-attendance by members / organisations resulting in the meeting not being quorate, the Chair may determine that there are appropriate people present to make decisions and allow the meeting to proceed. Some agenda items may be rescheduled if necessary. All decisions made when the meeting is not quorate must be circulated by email and approved by enough members to achieve quoracy. Some papers may receive virtual consideration by the Committee. Recommendations agreed by this process will need to be ratified at a full Committee meeting before they are issued. The same minimum quoracy is required to make virtual decisions. 'Chair's action' may be used to review and approve any urgent business, or where minor changes to previously agreed papers are required, between meetings. This will be in collaboration with the Chair of the Formulary sub-group when formulary amendments are required. Any such business agreed by Chair's actions will be documented and either circulated for virtual approval or shared at the following meeting for ratification by the committee.
Committee Secretariat and setting the agenda	The Committee will be supported by a Professional Secretary and administrative staff employed by BLMK ICB. All of the organisations represented on the Committee will be able to request agenda items for discussion at the meeting.
Frequency of Meetings	5 meetings (approximately bimonthly) per year on Wednesdays
Duties and Responsibilities	**CHAIR** • The Chair should consider any known interests of members in advance and begin each meeting by asking for declaration of relevant interests. The Chair should take appropriate action in relation to declarations of interest. • Ensure the smooth and timely running of meetings. • Ensure that the case supporting recommendations is consistent with the critical appraisal of the evidence and that the rationale for the recommendations are clearly captured for the record of the meeting. • Clarify and ensure that the rationale for each APC recommendation is documented and followed up. **MEMBERS** • Commit to regular attendance of BLMK APC meetings and their attendance to be regularly informed by the considered views of their service area / organisation and their peers. • Gather their service area / organisation's view on the evidence for clinical and cost effectiveness in the papers circulated to the group in advance of the meeting.

	• Critically appraise the evidence and test the rationale in the case for change, using their clinical and/or management knowledge to consider the impact on patient care. • Promote two-way communication between BLMK APC meetings and relevant service area / organisation and communicate/champion decisions from BLMK APC to these organisations for implementation. • Read relevant papers / discussion documents as supplied for the meeting prior to attendance at the BLMK APC meeting so that discussions can be informed and as concise as possible, and agreement can be reached • Undertake work as necessary between meetings. • Have the authority to make clinical and commissioning (where appropriate) decisions on behalf of their constituent organisations or professional groups • Complete an annual declaration of interests. The Chair will request any additional declarations at the beginning of each meeting which might have a bearing on their actions, views and involvement in discussions within BLMK APC
Relationship to other bodies	The BLMK APC makes recommendations to the whole Health Economy (ICBs and Trusts) about the effectiveness, cost-effectiveness and relative priority for funding of medicines.
Output and Communication	Recommendations from the BLMK APC are presented in a variety of formats including bulletins, additions/deletions to the two Joint Formularies, Pathways and Shared Care Guidelines. APC recommendations are summarised and issued to all GPs, Community Pharmacists, Committee Members and any other healthcare professionals who have asked to receive a copy of the recommendations. APC documents (including ratified notes of meetings) may be accessed via a Public Facing website. It is the responsibility of all Committee members to ensure that they communicate the APC recommendations in an appropriate manner to the organisation that they represent.
Nature of decisions and reporting mechanisms	The BLMK APC is a decision-making body with delegated funding authority in line with Standing Financial Instructions. Decisions which sit within the delegated funding limit will be reported to the BLMK ICB Quality and Performance Committeefor assurance purposes. If the proposed funding level exceeds the delegated funding limit, funding will need to be agreed (after APC consideration) by the Chief Finance Officer, Accountable Officer or Governing Body of BLMK ICB / BLMK Integrated Care System (ICS) (depending on the level of funding required).

	APC recommendations will be reported to Trust Drug and Therapeutics Committees (or equivalent) within BLMK. As representatives from these Trusts participate in the APC decision-making process, it is expected that the APC decisions will be adopted by Providers within BLMK. Decisions made by the APC are arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the APC guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
Equality and Diversity	The BLMK APC commits to have due regard to Equality, Inclusion and Human Rights considerations in its decision-making process and this is included in the Ethical Framework used by the Committee. (See appendix 1)
Appeals Process	The BLMK APC is willing to re-consider recommendations made if new significant drug information on efficacy, safety or cost is provided to the Committee. If an appeal against a recommendation is made on the basis that due process has not been followed, this will be referred to the Hertfordshire and West Essex Area Prescribing Committee (HWE APC) for consideration. The HWE APC will not re-review the evidence presented but will consider if due process has been followed. It will be for the BLMK APC to reconsider its recommendations (or otherwise) in the light of any HWE APC recommendations about the process followed.
Document history	Version 5, Approved May 2023

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Appendix 1

Bedfordshire, Luton and Milton Keynes (BLMK) Area Prescribing Committee (APC) Assessment against Ethical and Commissioning Principles

Treatment assessed (Month and Year):
APC Recommendation TBC post meeting
1) Clinical Effectiveness *e.g. according to national guidelines…*
2) Cost Effectiveness *e.g. most appropriate and cost- effective products have been recommended*
3) Needs of the community *e.g. prevalence and incidence of disease being treated?*
4) **Equity & Equality Impact Assessment** (see also embedded additional information including factsheet below to aid completion of this section) Consider whether this decision of the APC will have an impact for patients or staff in regard to Equality, Inclusion and Human Rights legislation. Such impacts (negative) could include: • Restriction of a drug which could benefit those with certain conditions[1,2] Where the implementation of the decision of the BLMK APC may impact on one or more equality group differently to others, a full equality impact assessment may need to be completed as advised by the BLMK Equality and Diversity Lead. Equality Impact Assessment Factsheet **Protected Characteristics (under the Equality Act 2010):** Age; Disability; Gender reassignment; Marriage & Civil Partnership (in employment only); Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual orientation; carers; other identified groups. [1] NB Equality and Diversity is only one part of an assessment of the new drug/indication. [2] It should be noted that where the BLMK APC is following national guidance, these have been developed with consultation and are required to have been subject to Equality Analysis and Due Regard.
Please state whether the decision will have an impact: Yes ☐ *If **YES,** the proposal is likely to impact patients or staff. Please set out those impacts and any mitigations that have been identified in the section below. Examples include a process where the needs of exceptional cases can be met.* No ☐ ***NO**, please state that the decision has been reviewed with regard to Equality, Inclusion and Human Rights and no issues have been identified in the section below.*
Provide rationale for impact assessment: *Should a significant impact be identified a full EQIA should be completed*
5) Need for healthcare (incorporates patient choice and exceptional need) *e.g. are there alternative therapies available or is this a completely new treatment option?*

6) Policy drivers: *e.g. relevant local or national guidance*
7) Disinvestment: • *How will this medicine help to address local health priorities?* • *By using this medicine, what disinvestment in other medicines, interventions and services may be possible?* • *How much would this save?* • *Affordability considerations?* • *Will this medicine help to address local health priorities?*
8) Environmental impact of decision (if applicable)