

## **Position Statement: Risk Sharing and Patient Access Schemes (PAS) for Medicines**

Bedfordshire, Luton and Milton Keynes Integrated Care Board (ICB) supports equitable, evidence-based access to medicines while ensuring responsible stewardship of NHS resources.

The purpose of this statement is to define the position of the ICB in relation to Risk Sharing and Patient Access Schemes (PAS) for medicines (see definitions below).

The position statement applies, where appropriate, to:

- Any patient who is the responsibility of Bedfordshire, Luton and Milton Keynes ICB where the ICB has commissioning responsibility for the provision of the medicine which is the subject of the local risk-share or national Patient Access Scheme (PAS).
- All ICB staff members, including Ordinary Members of the Board of the ICB, involved in policy-making processes, whether permanent, temporary or contracted-in under a contract for service (either as an individual or through a third-party supplier).
- All ICB Providers.

### **Position Statement:**

BLMK ICB will not support:

- Nationally agreed Patient Access Schemes for medicines, as defined within this position statement, unless they are associated with a positive NICE Technology Appraisal Guidance.
- Local risk-sharing schemes for medicines unless they are in accordance with a positive NICE Technology Appraisal Guidance or the ICB has assessed and already prioritised the drug treatment for funding. The local risk-sharing schemes will be considered by the ICB on an individual basis, including an assessment of the associated risks and benefits to include any guidance provided by the PrescQIPP Pharmaceutical industry scheme governance review board and in accordance with the Free of charge (FOC) medicines schemes – National policy recommendations for local systems (last updated, November 2023).

There are established frameworks in place in England to enable access to medicines without charge. These are the Medicines and Healthcare products Regulatory Agency (MHRA) [Early Access to Medicines Scheme](#) (EAMS) and the European Medicines Agency (EMA) access for [compassionate use](#) in certain scenarios. These are out of the scope of this position statement and the FOC policy recommendations.

## Roles and Responsibilities in Relation to the Position Statement

- All commissioned providers must **adhere to this position statement**.
- Providers must **seek prior agreement from the ICB** before entering into any local risk-sharing scheme.
- The **ICB Medicines Optimisation Team** will:
  - Review applications from Trusts for Risk Sharing and Patient Access Schemes
  - Ensure compliance with this position statement
- The **ICB Contracting Team** will:
  - Ensure all provider applications are appropriately referred to the Medicines Optimisation Team

## Appendix 1: Definitions

**Patient Access Schemes (PAS):** - Schemes proposed by a pharmaceutical company and agreed between the Department of Health (with input from the National Institute for Health and Care Excellence (NICE) via the Patient Access Schemes Liaison Unit) and the pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. These are nationally agreed schemes and are mandatory when associated with positive NICE Technology Appraisal Guidance.

**Risk Sharing Schemes:** - Local schemes proposed by a pharmaceutical company and agreed between the Trust/ICB and the pharmaceutical company in order to improve the cost-effectiveness of a medicine. **N.B. A number of Pharmaceutical Companies are terming local schemes as Patient Access Schemes.**

## Appendix 2: Background Information to Support Position Statement

When a medicine first comes on to the market there is usually insufficient data (for example, on long-term outcome) for the medicine to be assessed by NICE. This means that there can be a delay in patients being offered these medicines, especially if they are expensive. The pharmaceutical industry has developed risk sharing schemes as a way of overcoming this barrier. These schemes can also mean that the pharmaceutical industry maintains a global market price whilst meeting the NICE threshold for price per QALY (Quality-Adjusted Life Year).

Risk Sharing Schemes are a specific way of reducing the overall cost of a medicine for a specific disease through a special agreement with the manufacturer. The risk element of these schemes involves a sharing of the financial risk between the NHS and participating pharmaceutical companies.

Risk-sharing schemes may be agreed locally between the pharmaceutical company and the ICB/Trust or nationally agreed between the pharmaceutical company and the Department of Health (with input from NICE). Such national risk-sharing schemes have been re-termed patient access schemes by the Department of Health and are mandatory when associated with a positive NICE Technology Appraisal.

There are a number of advantages and disadvantages to Risk-sharing/Patient Access Schemes:

### Advantages of Risk-Sharing/Patient Access Schemes

- Earlier access to medicines; especially high cost ones, which may benefit patients.
- The outcome of treatment will be in the public domain, increasing accessible information on the medicine.
- May encourage close working between the NHS and the pharmaceutical industry which could benefit patients further.
- Reduced financial risk for NHS organisations.

### Disadvantages of Risk-Sharing/Patient Access Schemes

- Financial costs may be incurred by the ICB and Acute Trust which will not be paid by the manufacturer including:
  - The service that patients receive whilst receiving the medicine e.g. out-patient appointments and in-patients stays, staff and equipment used to administer and monitor the medicine.
  - Financial cost of providing administrative, auditing and governance support.
  - Costs associated with assessing the schemes, particularly as the schemes proposed to date are not consistent in nature.
- Increased financial risk to NHS organisations.
- Increased inconsistency in medicines funded between ICBs.
- There are possible implications for patient confidentiality as data is transferred between the hospital, ICB and pharmaceutical industry.
- There will be increased pressure on decision making processes as risk-shares are often only offered where the cost-effectiveness of treatments is low or borderline.

### References

- [Free of charge \(FOC\) medicines schemes – national policy recommendations for local systems](#)

Version	Author	Purpose/Change	Date
1.0	Medicines Optimisation Team	New document (replaces v2.0 of the previous policy of the same name, approved August 2024)	March 2026