Bedfordshire, Luton and Milton Keynes Integrated Care Board

Commissioning Policy on Risk Sharing/Patient Access Schemes for Medicines

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Document Control	
Document Owner:	Chief Primary Care Officer
Document Author(s):	Commissioning Lead Pharmacist
Directorate:	Primary care
Approved By:	The Board of the Integrated Care Board
Date of Approval:	01-07-2022
Date of Next Review:	01-07-2024
Effective Date:	01-07-2022

Version Control			
Version	**Date**	**Reviewer(s)**	**Revision Description**
Final v1.0	01-07-2022	The Board of the Integrated Care Board	Adopted approved policy
v 1.1	27-09-2023	BLMK Area Prescribing Committee	To reflect the retirement of the Regional Medicines Optimisation Committee (RMOC) Free of Charge (FOC) Policy and substitution with the National Policy that replaced it.

Implementation Plan

Development and Consultation:	The following individuals were consulted and involved in the development of this document: ▪ As this is a well-established policy, during the alignment of policies across Bedfordshire, Luton & Milton Keynes, the members of the legacy Area Prescribing Committees were consulted during the last ratification of the document in November and December 2020 i.e. Milton Keynes Prescribing Advisory Group and the Bedfordshire and Luton Joint Prescribing Committee. ▪ The minor update to the policy made in September 2023 reflects the retirement of the RMOC Free of Charge Policy and substitution with the National Policy that replaced it. BLMK Area Prescribing Committee reviewed *and approved* the update
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: ▪ None required; however the Commissioning Lead Pharmacists are available to answer questions relating to this Policy on request.
Monitoring:	Monitoring and compliance of this document will be carried out via: ▪ The Integrated Care Board (ICB) Commissioning/Medicines Optimisation teams will monitor compliance of providers to this policy. ▪ The ICB Contracting team will monitor compliance of providers to any criteria laid out in any Patient Access/Risk-Sharing Schemes agreed by the ICB, including financial aspects.
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: ▪ Free of charge (FOC) medicines schemes – national policy recommendations for local systems

References:	The following articles were accessed and used to inform the development of this document: • Holdstock, RA, Local Risk Sharing Schemes, A briefing paper to Clinical Priorities Group, Suffolk Primary Care Trust. • British Oncology Pharmacy Association; Cancer Network Pharmacists Forum; Position Statement on 'Risk Sharing Schemes in Oncology', May 2008. • House of Commons Health Select Committee on Top-Up fees, Report of Session 2008-09, 30th April 2009. • Risk Sharing Schemes for Drugs which are not subject to NICE Technology Appraisal Guidance, Briefing Paper to Bedfordshire and Luton Joint Prescribing Committee, September 2009. • Interim, process for advising on the feasibility of implementing a patient access scheme, NICE, September 2009. Free of charge (FOC) medicines schemes – National policy recommendations for local systems, v3 August 2023

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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.

2.0 Scope

2.1 The purpose of this policy is to define the position of the ICB in relation to Risk-Sharing/Patient Access Schemes for medicines. It is required that all providers to the ICB will comply with this policy.

2.2 This policy applies, as appropriate, to:

2.2.1 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).

2.2.2 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).

2.2.3 All ICB Providers.

3.0 Definitions

3.1 This section provides staff members with an explanation of terms used within this policy.

3.2 **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.

3.3 **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.**

4.0 Policy Statement

4.1 This policy applies 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 PAS.

4.2 All policies, practices and procedures are constantly checked against equality legislative requirements and best practices to ensure that no person is treated less favourably on the grounds of their race, gender, religion, disability, age, sexual orientation and religion or belief.

4.3 The ICB will ensure that reasonable adjustments (such as interpretation and translation, hearing loops, British Sign Language) are made available, should these be needed to ensure that patients are fully informed about the policy and its implications.

4.4 The ICB will not support nationally agreed Patient Access Schemes for medicines, as defined within this policy, unless they are associated with a positive NICE Technology Appraisal Guidance.

4.5 The ICB will not support 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 (v3, August 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 policy and the FOC policy recommendations.

4.6 See appendix 3 for background information, including advantages and disadvantages of risk-sharing/Patient Access Schemes.

5.0 Roles and Responsibilities

5.1 All Commissioned Providers to the ICB are required to adhere to this Policy. Before entering into any local risk-sharing schemes, providers should seek agreement from the ICB.

5.2 The ICB Medicines Optimisation Team will ensure that any applications from Trusts to enter into Risk-Sharing/Patient Access Schemes comply with this policy.

5.3 The Contracting Teams will ensure that any applications from providers to enter into Risk-Sharing/Patient Access Schemes are referred to the ICB Medicines Optimisation Team.

5.4 See also Implementation – Monitoring.

The following have specific responsibilities in relation to this policy.

5.5 **The Bedfordshire Luton and Milton Keynes Area Prescribing Committee –** to approve the policy

5.6 **The Board -** to ratify the policy

NHS
Bedfordshire, Luton and Milton Keynes
Integrated Care Board

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:	**Commissioning Policy on Risk Sharing/Patient Access Schemes for Drugs**
Date of assessment:	07/08-2023
Screening undertaken by:	Commissioning Lead Pharmacist (based on 2018 assessment by the BCCG Equality and Diversity Manager – see below)

Equality Impact Assessment

This policy requires that association with a NICE Technology Appraisal Guidance (TA) is required in order to support national Patient Access Schemes for drugs and that local risk-sharing schemes for drugs will be considered when they are in accordance with a positive NICE TA or the CCG has assessed and already prioritised the drug treatment for funding. This requirement is not likely, in itself, to have an adverse impact on a patient because of their having one of the protected characteristics. However, there could be an indirect effect that the requirement of having, or not having, a positive NICE TA has on determining who gets certain treatments. Whilst this policy doesn't specify treatments it could mean that some people who do share a protected characteristic could affected. It will be important to monitor the use of the policy to see if there is an indirect adverse impact on patients who share a protected characteristic. Where the CCG accepts risk share in the absence of a NICE positive TA it will be important to monitor if that process is used in particular by patients who share a protected characteristic. As agreed with Paul Curry, Equality and Diversity manager on 8th May 2018

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	No	

impairment which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities.		
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 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.	No	
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	No	

sex, the opposite sex, to both sexes or none.		
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 – this policy has been in place since 2009		
Has potential disadvantage for some groups been identified which require mitigation?		
Yes / **No –** (If there are significant impacts and issues identified a full Equality / Quality Impact Assessment (EQIA) must be undertaken.)		

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 blmkicb.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:	**Commissioning Policy on Risk Sharing/Patient Access Schemes for Drugs**
Date of assessment:	07/08/2023
Screening undertaken by:	Commissioning Lead Pharmacist

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.	Yes / **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.	Yes / **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.	Yes / **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.	Yes / **No**
5.	**Will the policy result in organisations or people having access to information they do not currently have access to?**	Yes / **No**
6.	**Will the policy result in an organisation using information it already holds or has access to, but for a different purpose?**	Yes / **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.	Yes / **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)	Yes / **No**
9.	**Will the policy result in the collection of additional information about individuals in addition to what is already collected / held?**	Yes / **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.	Yes / **No**

Appendix 3 - Background Information to support Policy 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.