

Commissioning Policy on Risk Sharing/Patient Access Schemes for Drugs

June 2018

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Responsibility:	All Commissioned Providers and relevant CCG Staff should adhere to this policy.
Effective Date:	<i>June 2018</i>
Review Date:	<i>June 2021</i>
Reviewing/Endorsing committees	<i>Prescribing Committee, Bedfordshire Clinical Commissioning Group, 5 June 2018.</i>
Date Ratified by Executive Team	<i>28 June 2018</i>
Version Number	3
Related Documents	<ul style="list-style-type: none"> 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.

POLICY DEVELOPMENT PROCESS

Names of those involved in policy development

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Names of those consulted regarding the policy approval

Date	Name	Designation	Email
1/5/18	All members of the CCG Medicines Optimisation Team		
15/18	All members of the CCG Prescribing Committee		
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Committee where policy was discussed/approved/ratified

Committee/Group	Date	Status
BCCG Prescribing Committee	5 June 2018	Endorsed
BCCG Executive Team	28 June 2018	Ratified

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 be 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

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1. Executive Summary

- The CCG will not support nationally agreed Patient Access Schemes for drugs, as defined within this policy, unless associated with a positive NICE Technology Appraisal Guidance.
- The CCG will not consider supporting local risk-sharing schemes for drugs unless they are in accordance with a positive NICE Technology Appraisal Guidance or the CCG has assessed and already prioritised the drug treatment for funding.

2. Introduction

When a drug first comes on to the market there is usually insufficient data (for example, on long-term outcome) for the drugs to be assessed by NICE. This means that there can be a delay in patients being offered these drugs, 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.

Risk Sharing Schemes are a specific way of reducing the overall cost of a drug 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 CCG/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, are included in the current (2014) Pharmaceutical Price Regulation Scheme 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 drugs; especially high cost ones, which may benefit patients.
- The outcome of treatment will be in the public domain, increasing accessible information on the drug.
- 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 CCG and Acute Trust which will not be paid by the manufacturer including:-
 - The service that patients receive whilst receiving the drug e.g. out-patient appointments and in-patients stays, staff and equipment used to administer and monitor the drug.
 - 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 drugs funded between CCGs
- There are possible implications for patient confidentiality as data is transferred between the hospital, CCG 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.

3. Purpose

The purpose of this policy is to define the position of the CCG in relation to Risk-Sharing/Patient Access Schemes for Drugs.

It is required that all providers to the CCGs will comply with this policy.

4. Definitions

The following definitions apply in this policy:

Patient Access Schemes:- Schemes proposed by a pharmaceutical company and agreed between the Department of Health (with input from NICE via the Patient Access Schemes Liaison Unit) and the pharmaceutical company in order to improve the cost-effectiveness of a drug 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/CCG and the pharmaceutical company in order to improve the cost-effectiveness of a drug . **N.B. A number of Pharmaceutical Companies are terming local schemes as Patient Access Schemes.**

5. Responsibilities

- All Commissioned Providers to the CCG are required to adhere to this Policy. Before entering into any local risk-sharing schemes, Providers should seek agreement from then CCG.
- The CCG Medicines Optimisation Team will ensure that any applications from Trusts to enter into Risk-Sharing/Patient Access Schemes comply with this policy.
- The Contracting Teams will ensure that any applications from providers to enter into Risk-Sharing/Patient Access Schemes are referred to the CCG Medicines Optimisation Team.
- See also Section 9 – Monitoring.

6. The Commissioning Policy

- This policy applies to any patient who is the responsibility of Bedfordshire Clinical Commissioning Group [“the CCG”] where the CCG has commissioning responsibility for the provision of the drug which is the subject of the local risk-share or national PAS.
- 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.
- The CCG 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.
- The CCG will not support nationally agreed Patient Access Schemes for drugs, as defined within this policy, unless they are associated with a positive NICE Technology Appraisal Guidance.
- The CCG will not support local risk-sharing schemes for drugs unless they are in accordance with a positive NICE Technology Appraisal Guidance or the CCG has assessed and already prioritised the drug treatment for funding. The Local risk-sharing schemes will be considered by the CCG 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.

7. Development process

This policy has been in place for several years, first as an NHS Bedfordshire Policy and then a slightly updated NHS Bedfordshire and Luton Cluster Policy (ratified 6 November 2012), then as a BCCG Policy April 2013, updated in June 2015. The current document replaces the 2015 BCCG Policy and is effective from June 2018.

8. Training Requirements

None

9. Monitoring

- The CCG Commissioning/Medicines Optimisation teams will monitor compliance of providers to this policy.
- The CCG Contracting team will monitor compliance of providers to any criteria laid out in any Patient Access/Risk-Sharing Schemes agreed by the CCG, including financial aspects.

10. References

- 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.

- The Pharmaceutical Price Regulation Scheme 2014, Department of Health and The Association of the British Pharmaceutical Industry, December 2013.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf.
- 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.