NHS
Leeds Clinical Commissioning Groups Partnership

Policy for the review, acceptance and monitoring of rebate schemes offered by the pharmaceutical industry

Version:	Version 6
Ratified by:	Leeds Health Commissioning & System Integration Board
Date Ratified:	25 January 2018
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Name of responsible committee/individual:	Senior Management Team and Board
Date issued:	26 January 2018
Review date:	26 January 2021
Target audience:	Medicines management Finance Governance Quality Senior Management Team

1. Introduction

The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism by which the Department of Health ensures that the NHS has access to branded medicines at a reasonable price. The PPRS balances setting reasonable prices for the NHS against delivering a fair return for the pharmaceutical industry so that investment and innovation in pharmaceuticals is incentivised.

The PPRS does not apply to devices or nutritional products; nor does it apply to generic medicines whose prices tend to be controlled by their Drug Tariff agreed pricing.

The view of the Department of Health expressed in the consultation document on value based pricing is that the existing PPRS does not promote innovation or access to medicines, as the freedom of companies to set the price of new drugs results in the NHS often paying high prices which are not justified by the benefits of the drug and/or of having to restrict access to the drug.

A number of manufacturers have established 'rebate schemes' for drugs used in primary care to support the NHS QIPP agenda. The NHS is charged the Drug Tariff price for primary care prescriptions dispensed, then the manufacturer provides a rebate to the primary care organisation based on an agreed discount price and verified by ePACT data.

Primary care rebate schemes (PCRS) are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular branded medication. These schemes usually reimburse organisations retrospectively with an agreed percentage discount of the total amount of a particular branded medication prescribed and dispensed. PCRS, underpinned by robust assessment and governance procedures, can lead to significant cost savings. This policy describes how the Leeds CCGs will adopt and implement good practice recommendations to ensure a clear and transparent process for the review, acceptance and monitoring of PCRS.

Some schemes are straight discounts and are not volume based, whilst others have varying discount rates available dependent upon the volume of drug prescribed. The discount schemes are confidential to the NHS enabling manufacturers to maintain a higher price in global markets.

2. Purpose and scope

This policy is designed to ensure that any PCRS that are adopted deliver financial benefits to the CCG and:

- are in the best interests of patients
- do not adversely influence prescribing behaviour
- do not adversely affect other parts of the local health community

The NHS faces a significant challenge in achieving efficiency savings. PCRS can contribute to reduce primary care prescribing costs which can be re-invested into service development and quality improvement work or off set against prescribing budget. It has been reported that at least 30% of CCGs accept PCRS, with potential savings of up to £100,000 in some localities.

Pharmaceutical companies offer PCRS for a number of reasons:

- Pharmaceutical prices are often set by the European office of multinational companies
- Reference pricing – advertised prices in the UK may affect prices in other countries.
- This may mean that a price set centrally is not competitive in the UK
- To manage this through competition law, companies have the option to discount to the purchaser.
- This is managed retrospectively as a rebate to the NHS statutory body purchasing at a local level.

There are examples of similar schemes running within the NHS, such as:

- Patient access schemes. These usually relate to high cost specialist drugs, which NICE has approved, allowing for the drug to be prescribed for a patient at a cheaper cost for a specified period of time.
- Hospital and dispensing doctors can negotiate prices for medication direct with the manufacturers, either on a local or national level.

There are some concerns regarding PCRS in relation to legislation such as the Bribery Act, Competition Act and Public procurement law. There are also concerns around:

- potentially creating incentives to prescribe drugs with PCRS
- undermining the Pharmaceutical Price Regularity Scheme - a voluntary agreement to control the prices of branded drugs sold to the NHS
- financial governance and audit requirements
- administrative burden of the schemes

The legal status of rebate schemes has been reviewed by a number of organisations. The London Primary Care Medicines Use and Procurement QIPP Group sought legal advice on such schemes in 2012. Based on this advice, this Group recommended a set of good practice principles for primary care organisations to use to facilitate robust scrutiny and identification, adoption and implementation of PCRS. This policy incorporates those good practice principles.

3. General principles

Before entering into a PCRS with a pharmaceutical industry partner, all proposals will be rigorously tested against clear criteria to ensure that they are in the best interests of both patients and the CCG. All proposals will be treated equally and decisions made will need to stand up to scrutiny if questioned:

- Any drug where a PCRS is offered will only be considered by Leeds CCGs which has been reviewed by Leeds Area Prescribing Committee (LAPC) and a recommendation given as to the traffic light classification. The recommendation made by LAPC will take into account the clinical need and safety for the medicines and its place in the care pathway. Black light drugs and those classified for safety reasons will not be considered. LAPC is made up of doctors, pharmacists and nurses from the whole Leeds health economy and includes a lay patient representative.

- To reduce the effect of influencing prescribing inadvertently. The details of rebates schemes will not be circulated to prescribers, but Leeds CCGs will publish the acceptance of PCRS from pharmaceutical companies on their web site and will include the company name and drug, however total value for the rebates received will be included in the CCG accounts which is available publically.

- Any Medicine considered under a PCRS must be licenced in the UK. Leeds CCGs will not accept any rebate schemes for unlicensed or off-licence uses.

- All PCRS offered to Leeds CCGs will be reviewed by the assessment process outlined below to ensure a robust process that follows Leeds CCGs governance procedures.

- Any PCRS offered that encourages exclusive use of a particular drug will not be accepted by Leeds CCGs.

- Leeds CCGs will only accept PCRS where there is a formal contract that is signed by both parties to ensure:

  - That the terms of the scheme are clear,
  - To maximise legal protection.

- Leeds CCGs will not accept any PCRS unless it includes a right to terminate on notice with a sensible notice period (usually no more than 3 months).

- Leeds CCGs will only accept PCRS that require submission of volume of use level data available from EPACT relating to the drug the rebate scheme refers to. Leeds CCGs will not provide market share data for competitors' products or patient identifiable data. Patient confidentiality will be maintained at all times.

- Any financial gains received as a result of accepting PCRS:
  - Will not contribute to the Leeds CCGs CCG Prescribing engagement scheme freed up resources.
  - Will be used to offset against non-recurrent costs for service/treatment improvement projects identified and supported by Leeds CCG's Medicines Optimisation Team's, which have been approved by the senior management team (SMT).
  - Will be used to address any unexpected shortfall in primary care prescribing costs.

- In the cases where a PCRS is agreed, Leeds CCGs will ensure that the agreement entered in to states that the pharmaceutical company that is offering the PCRS will not use our engagement in the scheme to promote their company's activities that are related to this agreement, or in any other promotional activity for their benefit.

4. Freedom of Information

Leeds CCG supports the principles of transparency enshrined in the Freedom of Information Act. Rebate agreements often contain confidentiality clauses which may restrict what information may be disclosed under Freedom of Information. The CCG will publish its policy for accepting rebate agreements along with the list of products for which rebate agreements exist on its publically available website.

Section 43 of the Freedom of Information Act sets out an exemption from the right to know if:

• The information requested is a trade secret, or
• Release of the information is likely to prejudice the commercial interests of any person. (A person may be an individual, a company, the public authority itself or any other legal entity.)

The UK is a reference pricing country for pharmaceutical and medical device products and any change to publically available UK prices can impact on the international profitability of pharmaceutical and medical device companies. Pharmaceutical and medical device companies often consider their pricing structures to be trade secrets and there are precedents within the NHS in restricting access to pricing information for these products.

NICE negotiates a number of patient access schemes as part of the NICE Technology Appraisal programme. The details of the products that are available to the NHS under a patient access scheme (or discount scheme) are published on the NICE website. The commercial and operational details of the individual schemes are not made publically available and are the subject of confidentiality clauses. Greater Huddersfield CCG benefits from many of these schemes through the prices charged to it for PbR excluded drugs.

Section 43 is a qualified exemption. That is, it is subject to the public interest test which is set out in section 2 of the Act. Where a public authority is satisfied that the information requested is a trade secret or that its

release would prejudice someone's commercial interests, it can only refuse to provide the information if it is satisfied that the public interest in withholding the information outweighs the public interest in disclosing it.

Leeds CCG will consider all Freedom of Information requests on rebate agreements on their individual merits taking into account the public interest and whether the release of information will prejudice other parties to the agreements.

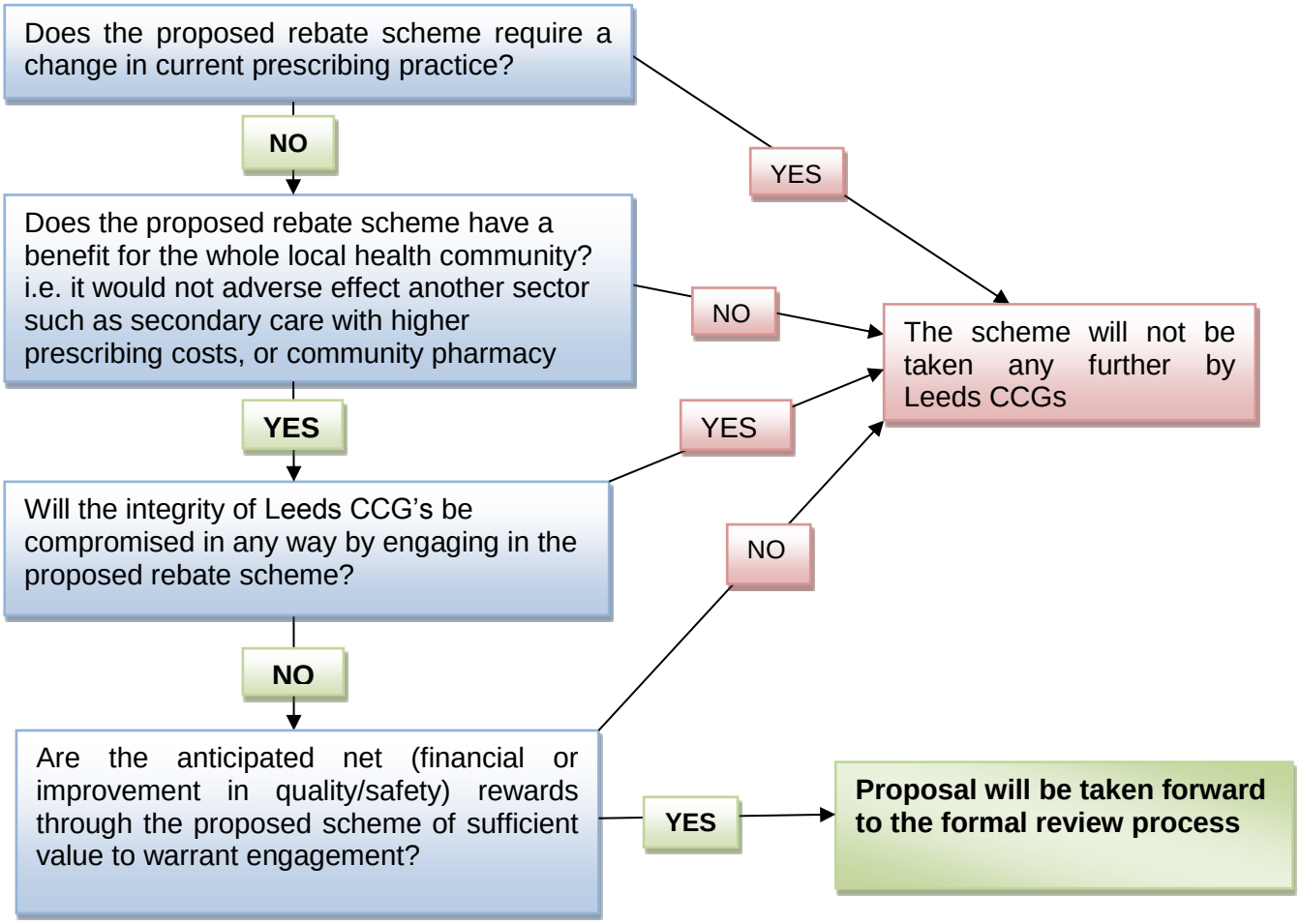
5. Assessment process

The assessment process will be in 2 stages:

Stage 1 - initial screening (outlined overleaf)
Stage 2 - detailed assessment

Stage 1

The initial screening process is outlined below:



This initial screening will be undertaken by the Head of Medicines Optimisation, for Leeds CCG, using the Stage One screening questionnaire in Appendix 1.

On satisfactory completion of stage one all PCRS proposals will go to stage 2 of the process. PSRC which are deemed to have not fulfilled stage 1 will be rejected and the relevant Pharmaceutical Company will be informed by email.

Stage 2

All PCRS that have satisfactory passed the Stage 1 screening process will be assessed by a review panel consisting of;-

- Head of Medicines Optimisation/or their deputy
- Finance representative
- Governance team representative
- Quality team representative
- Lay member

- Prescribing lead GP
- GP non-exec member
- Medical director or deputy

All PCRS will be assessed against the Stage 2 assessment template in Appendix 2.

If the PCRS is accepted to be taken forward then the pharmaceutical company will be contacted and arrangements will be made for the contract to be signed by the Director of Finance.

6. Monitoring, compliance and effectiveness

Once the PCRS has been signed, the prescribing data will be collected as outlined in the contract by the Medicines Optimisation team and submitted to the pharmaceutical company, if required.

Once PCRS have been agreed, prescribing trends of the drugs involved will be monitored on a quarterly basis to detect any unexpected effects on prescribing trends. This will be undertaken by Leeds CCG medicines optimisation team. If any unexpected effects on prescribing trends are seen this will be reported to the Leeds CCG Senior management team. A summary of all PCRS that been offered to Leeds CCG will be submitted to SMT, together with the outcomes every 6 months.

Any changes in prescribing practice which necessitates the cessation of a PCRS will be brought to the attention of the director who signed the original agreement or the clinical director and the pharmaceutical company offering the PCRS will be notified as soon as possible following the agreed exit strategy. An example where this may be necessary is when a drug may be withdrawn off the market due to safety concerns.

Appendix 1

Stage 1 screening questionnaire

Pharmaceutical company offering the scheme and representative.	
Name of Medicines Optimisation representative undertaking the screening.	
Brand of drug PCRS refers to	
Date of initial offer/approach	
Does the proposed rebate scheme fulfil all the general principles outlined in the Leeds CCG policy on receiving and handling PCRS?	Yes / No
If No - outline which general principle(s) the PCRS does not fulfil.	
If Yes – Progress to stage 2	
Date result fed back to Pharmaceutical company.	
Date completed	

Appendix 2

Stage 2 detailed assessment questionnaire

PCRS review questionnaire		
Date of review panel		
Names and designation of review panel		
Pharmaceutical Company		
Product(s)		
Brief outline of proposal		
	Y/N/ value	**Additional comments**
1. Has the stage 1 screening questionnaire been completed?		Only progress this stage if the screen questionnaire is positive.
2. Has place in therapy been agreed? Or is it subject to review Only those agreed will be taken forward		
3. Has this product been given a traffic light drug?		
4. What is the current volume of use?		
5. Will this increase or decrease?		
6. What is the anticipated financial benefit (£)?		

7. If tied into volume what increase in volume would we need to achieve in order to achieve cost benefit vs use of currently used therapies?		
8. What would be the impact on other products currently being used +/- , and would this be beneficial to patients?		
9. What is the impact on partner organisations, such as secondary care and community pharmacy?		
10. How would the scheme be administered?		
11. What data would the organisation need to share with the pharmaceutical company supplier in order to quantify current / future product usage and time commitment?		
12. Is there a fixed term to which the organisation has to agree to participate on the scheme?		
13. Is there an agreed exit strategy written into the agreement?		
14. Impact on supply chain, including risk of failure of supply of available product		

Outcome of panel

Agree to take forwards Y/N

Leeds Clinical Commissioning Groups Partnership

Appendix 3

Equality Impact Assessment

Title of the guidance	Policy for approving primary care prescribing rebate schemes	
Names and roles of people completing the assessment	Heather Edmonds – Head of Medicines Optimisation	
Date assessment started/completed	5.7.17	5.7.17

1. Outline	
Give a brief summary of the guidance	The policy provides a transparent framework to support evaluation and approval of rebate schemes to ensure that schemes are only approved where they provide good value for money to the public purse and the schemes' terms are in line with the organisation's vision, values, policies and procedures
What outcomes do you want to achieve	The objective evaluation of schemes submitted to the CCG and a clear process for approving and scrutinising agreements.

4. Analysis of impact

This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to; eliminate unlawful discrimination; advance equality of opportunity; foster good relations

	Are there any likely impacts? Are any groups going to be affected differently? Please describe.	**Are these negative or positive?**	**What action will be taken to address any negative impacts or enhance positive ones?**
Age	N		
Carers	N		
Disability	N		
Sex	N		
Race	N		
Religion or belief	N		
Sexual orientation	N		
Gender reassignment	N		
Pregnancy and maternity	N		
Marriage and civil partnership	N		

Other relevant group	N		
If any negative/positive impacts were identified are they valid, legal and/or justifiable? Please detail.	NA		

5. Monitoring, Review and Publication			
How will you review/monitor the impact and effectiveness of your actions	Assessment via the Medicines Optimisation Group will be scheduled for 2 years after ratification of policy		
Lead Officer	Heather Edmonds	**Review date:**	TBA

6. Sign off			
Lead Officer			
Director		**Date approved:**	