NHS
Leeds
Clinical Commissioning Group

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

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Target audience:	Medicines Optimisation Finance Contracts Clinical Governance Quality Team Corporate Governance Executive Management Team

1. Introduction

The voluntary scheme for branded medicines pricing and access (Voluntary Scheme) came into force on 1 January 2019, following expiry of the Pharmaceutical Price Regulation Scheme 2014 (2014 PPRS). The parties to the Voluntary Scheme are:
• the Department of Health and Social Care (Department), acting on behalf of the UK Government and the governments of Scotland, Wales and Northern Ireland;
• NHS England, legally referred to as the National Health Service Commissioning Board (NHS England);
• The Association of the British Pharmaceutical Industry (ABPI); and
• Manufacturers or suppliers of Branded Health Service Medicines that have joined the Voluntary Scheme (Scheme Members)

The Department of Health and Social Care (representing the UK Government, and the governments of Scotland, Wales and Northern Ireland), NHS England and the Association of the British Pharmaceutical Industry recognise the importance of collaboration between the public and private sectors in delivering improved health gains from medicines in the national health service across the United Kingdom (NHS), and in supporting the pharmaceutical industry in the United Kingdom so that it can continue to innovate now and in the future.

A number of manufacturers have established 'rebate schemes' for drugs used in primary care to support the NHS Quality, Innovation, Productivity and Prevention (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 NHS Leeds CCG 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 the 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 2019 voluntary scheme for branded medicines pricing and access (Voluntary 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.

PrescQIPP is an organisation hosted by NHS England to support quality, optimised medicines management within the NHS. Their Pharmaceutical Industry Scheme Governance Review Board assesses some rebate schemes for clinical, financial and contractual issues to support CCGs in addressing the risk of incentives from such schemes.

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 NHS Leeds CCG if it 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 rebate schemes will not be circulated to prescribers, but NHS Leeds CCG will publish the acceptance of PCRS from pharmaceutical companies on its website.

- Any products which have a negative decision from NICE Technology Appraisals will not be considered by NHS Leeds CCG.

- Any medicine considered under a PCRS must be licenced in the UK. NHS Leeds CCG will not accept any rebate schemes for unlicensed or off-licence uses. For products with more than one indication the PCRS should not be linked to a particular indication.

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

- Any PCRS offered that encourages exclusive use of a particular drug will not be considered by NHS Leeds CCG.

- NHS Leeds CCG 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 and to maximise legal protection.
- All negotiations around a scheme should be expressed as being "subject to contract" i.e. not binding until the formal contract has been signed by both parties.

- NHS Leeds CCG will not accept any PCRS unless it includes a right to terminate on notice with a sensible notice period. (Usually no more than 6 months).

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

- Products contained in Category M of the Drug Tariff are not appropriate for PCRS. Some products within Category A of the Drug Tariff should be carefully considered due to the potential wider impact on community pharmacy reimbursement. Any Category A products should be reviewed by a Commissioning Pharmacist.

- Food supplements and devices offered under PCRS should be included in the relevant Drug Tariff chapter and already be recommended for use by NHS Leeds CCG.

- Consistent cost saving should be achievable across all pack sizes where applicable.

- Any financial gains received as a result of accepting PCRS:
    - Will not contribute to the NHS Leeds CCG Prescribing Engagement Scheme freed up resources.
    - Will be used to offset against non-recurrent costs for service/treatment improvement projects identified and supported and agreed by NHS Leeds CCG.
    - Will be used to address any unexpected shortfall in primary care prescribing costs.

- In the cases where a PCRS is agreed, NHS Leeds CCG 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

NHS 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.

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.

NHS 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:

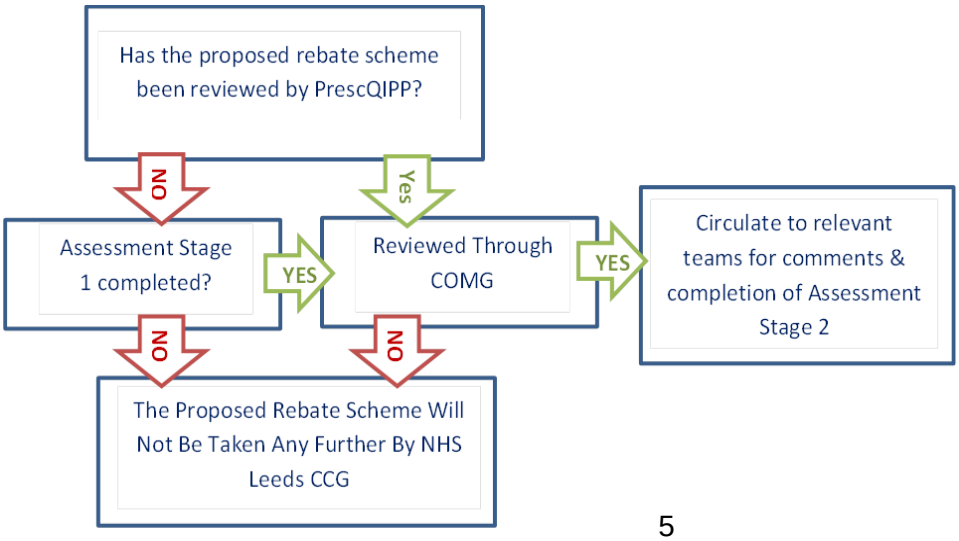
Stage 1 - initial screening
Stage 2 - detailed assessment

Stage 1

This initial screening will be undertaken by a Pharmacist or Pharmacy Technician in the Medicines Commissioning Team for NHS Leeds CCG, using the Stage One Screening Questionnaire in Appendix 1.

Any PCRS which have been reviewed by PrescQIPP and have no significant reservations will not require a review through assessment stage 1. These schemes will go to review through assessment stage 2, subject to review by Commissioning of Medicines Group (COMG). Rebate schemes which have not been reviewed by PrescQIPP must be reviewed through assessment stage 1 and COMG before final review at stage 2.

PCRS which are deemed to have not fulfilled stage 1 will be rejected and the relevant Pharmaceutical Company will be informed by email.
The initial screening process is outlined below:



Stage 2

All PCRS that have satisfactory passed the Stage 1 screening process will be assessed by;-

- Head of Medicines Commissioning/or their representative
- Finance representative
- Corporate Governance team representative
- Clinical Governance representative
- Quality team representative
- Governing Body Lay member
- Principal Medical Advisor for the Medicines Commissioning Team or deputy
- Medical Director or deputy

For PCRS which have been reviewed by PrescQIPP the scheme pack will be emailed to the above teams for comments and completion of assessment Stage 2 – each team should complete their section on the questionnaire. Schemes which have not been reviewed by PrescQIPP assessment Stage 1 and details of the scheme will be emailed to the relevant teams. The Medicines Commissioning Team is responsible for the circulation of any proposed rebate schemes to each team after review through COMG.

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 Chief Finance Officer.

The contract will be forwarded to the contracts team for entry onto the contracts register. A copy of the contract and approval paperwork should be held by the contracts team.

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 Commissioning 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 NHS Leeds CCG Medicines Commissioning Team. If any unexpected effects on prescribing trends are seen this will be reported to the NHS Leeds CCG Commissioning of Medicines Group (COMG).

Any changes in prescribing practice which necessitates the cessation of a PCRS will be brought to the attention of the Chief Finance Officer and the Medical 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.

NHS
Leeds
Clinical Commissioning Group

Stage 1 screening questionnaire

To be completed by a Pharmacist / Pharmacy Technician in the Medicines Commissioning Team

Product	
Manufacturer	
Name and role of Medicines Commissioning representative undertaking the screening.	
Date of initial offer/approach	
Assessment criteria	Yes / No
Is the product licensed in the UK?	
Does the product not have a negative decision from NICE?	
Does the product have a traffic light classification on Leeds formulary?	
Does the PCRS not require a change to prescribing to fulfil the requirements?	
Does the PCRS not require exclusive use of a specific brand?	
Does the contract not require a directive guideline to be given to health care professionals?	
Is the product not being used off-licence?	
If the product is a device or nutritional supplement is it contained in the current Drug Tariff?	
If the product is a vitamin and classed as food supplement is this recommended for use by NHS Leeds CCG?	
Is the product not contained in category A or M of the Drug Tariff?	
The PCRS will not have an adverse effect on any other providers?	
There is not a requirement to submit additional information beyond prescribing of the product? (e.g. patient specific data)	
Number of years the scheme is available? (is it >2 years?)	
Progress to stage 2?	YES / NO (All answers should be YES to proceed to Assessment stage 2)
Date completed	

NHS
Leeds
Clinical Commissioning Group

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		
A representative from each team should answer the necessary questions and add any further comments in their relevant teams section below	**Y/N/ value**	**Additional comments**
Medicines Commissioning Team		
Has the stage 1 screening questionnaire been completed and approval granted by COMG?		Only progress this stage if the screening questionnaire is positive.
Is there a fixed term to which the organisation has to agree to participate on the scheme?		
Is there an agreed exit strategy written into the agreement?		
Additional comments		
Finance Team		
What is the estimated value of the potential financial benefit?		
Does the scheme require significant NHS resource to realise the benefits, can a financial value be attributed to this?		

Is the benefit (both financial and non-financial) achievable?		
Is the estimated financial value assessed against the overall current spend and resource required to realise the benefit, a significant benefit to the organisation? i.e. Does it represent value for money?		
Additional comments		
Corporate Governance Team		
Are there any potential conflicts of interest and if so, have appropriate arrangements been identified to manage these?		
Additional comments		
Clinical Governance Team		
Will the PCRS have any impact on patient choice (of product/medication)? If yes, is this positive or negative? If negative, what is being done to mitigate the impact?		
Will the PCRS have any impact on patient experience? If yes, is this positive or negative? If negative, what is being done to mitigate the impact?		
Additional comments		
Quality Team		
Is the PCRS likely to directly (or indirectly) discriminate against any particular client/patient groups in terms of limiting choice and accessibility?		
Additional Comments		
Medical Director or Deputy		
Comments		
Principal Medical Advisor for Medicines Commissioning Team		

Comments		
Governing Body Lay Member		
Comments:		

NHS
Leeds
Clinical Commissioning Group

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	Medicines Commissioning Team	
Date assessment started/completed	12/12/19	12/12/19

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.

Will the proposal have a disproportionate impact on:	**Yes or No** *Please select from the list below*
People with one or more protected characteristics?	No
Patient Experience	No
Patient Safety	No
Clinical Effectiveness	No
Staffing within the service area or the wider workforce?	No
result in change noticeable to patients or carers?	No
be likely to result in political, consumer champion or media interest or has already had significant public interest?	No
impact those eligible to access the service e.g. by changing referral criteria/method of access/ where or when it will be delivered?	No
Project lead	Keegan Hutchinson/ Kim Mooring
Programme Quality Lead	Sharon Moore
Programme Equality Lead	Sharon Moore
Programme Lead	Jo Alldred