NHS
Bradford District and Craven
Clinical Commissioning Group

Primary Care Rebate Schemes (PCRS) for Prescribing

Policy and Procedure

Version History

V.	Date	Author	Amendments	Circulation
V0.1	June 2020	Claire Kilburn, Senior Head of Medicines Management	Full review and update for NHS BD&C CCG; updated to include NHSE Low Priority Prescribing as an exemption.	Senior Head of Medicines Optimisation, Head of Corporate Governance
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1. Introduction

A number of manufacturers have established 'rebate schemes' for medicinal products and devices used in primary care. Under the terms of such a scheme, the NHS is charged the Drug Tariff price for primary care prescriptions dispensed, the manufacturer then provides a rebate to the primary care organisation based on an agreed discount price and verified by ePACT 2 data. Such schemes are being offered to Clinical Commissioning Groups (CCGs) by the pharmaceutical industry in relation to named products.

Legal opinion based on DAC Beachcroft LLP's advice to the London Procurement Partnership states that primary care rebate schemes are lawful and are within the powers of CCGs to agree to, provided they meet certain requirements (as outlined in this policy). From a Freedom of Information request in February 2012 (the most recent information available), 59% of English Primary Care Trusts and Acute Trusts engaged in rebate schemes.

Any medicine should only be agreed for use within a rebate scheme if it is believed to be appropriate for a defined cohort of patients within a population. It is important that all patients continue to be treated as individuals, and acceptance of a scheme should not constrain existing local decision making processes or formulary development. This is in line with the Department of Health's document (Gateway Reference 14802) on Strategies to Achieve Cost-Effective Prescribing (2010)[2]. This states that the following principles should underpin local strategies:

i. *The decision to initiate treatment or change a patient's treatment regime should be based on up-to-date best clinical evidence or guidance, e.g. from the National Institute for Health and Clinical Excellence (NICE) or other authoritative sources;*

ii. *Health professionals should base their prescribing decisions on individual assessments of their patients' clinical circumstances, e.g. patients whose clinical history suggests they need a particular treatment should continue to receive it;*

iii. *The individual patient (and their guardian or carer where appropriate) should be informed about the action being taken and suitable arrangements should be made to involve the patient, ensuring they have an opportunity to discuss a proposed switch of medicines, and to monitor the patient following any switch;*

iv. *Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money;*

v. *Schemes should be reviewed whenever relevant NICE or alternative guidance are updated.*

vi. *The CCGs will publish a list of the schemes they participates in on the CCG website, however the full terms of the scheme may not be published depending on the nature of the rebate scheme contract.*

2. Scope

This policy applies to NHS Bradford district and Craven Clinical Commissioning Group and all of its employees, in particular the finance team and employees of the medicines optimisation Team. All must comply with arrangements outlined in this policy.

Where an individual fails to comply with this policy disciplinary action may be taken or the individual removed from office.

3. Associated Documentation

This policy should be considered in conjunction with:

- Standing Financial Instructions
- Policy on the Offer and Receipt of Gifts, Hospitality and Sponsorship Policy
- Conflicts of Interest and Business Conduct Policy
- Counter-fraud, Bribery and Corruption Policy

Pharmaceutical and Related Industries Joint Working Policy

4. Aims and Objectives

Rebate agreements usually take the form of legal agreements between the manufacturer and CCGs. This aim of this policy is to provide a framework for managing rebates in a legal and ethical way.

5. Policy Statement

NHS Bradford district and Craven Clinical Commissioning Group will operate rebate schemes in a manner that ensures that:

- each scheme is only signed off if it provides good value for money to the public purse and its terms are in line with organisational vision, values, policies and procedures
- the CCG is transparent in its process for considering these schemes
- clear process for approving and scrutinising agreements is in place that is independent from formulary and prescribing decisions.

6. Definition

A rebate scheme is a confidential contractual agreement between the manufacturer and commissioner offering a rebate of part of the cost of a specified product, or products based on usage. Most schemes offer straight percentage discounts but some more complex versions may be offered.

7. Duties, Responsibilities, Roles and Accountability

7.1 Chief Finance Officer

- Provides oversight of all aspects of this policy to ensure organisational compliance
- Provides regular reports to the Finance and Performance Committee (FPC)
- Is authorised to sign rebate agreements of behalf of the CCG
- Ensures rebates are claimed in a timely fashion.

7.2 Medicines Optimisation Team

- Review offered rebate schemes in line with criteria detailed within section 8 of this policy, including consideration of external reviews, for example those carried out by PrescQIPP.
- Provides an appraisal and recommendation to the contracts and finance team and Chief Finance Officer.
- Ensures this policy is adhered to in all decisions relating to acceptance or refusal of rebates.

7.3 Contracts and Finance Team

- The contracts team will review the rebate offer prior to sign off by the Chief Finance Officer.
- The finance team will reclaim rebate monies from the administrator of the scheme.

7.4 Finance and Performance Committee

- Approves this policy.
- Monitors compliance with and the effectiveness of this policy.
- Receives reporting on approved rebate schemes on an annual basis.

8. Principles for Primary Care Rebate Schemes (PCRS)

The detailed content of primary care rebate schemes offered to primary care organisations will differ between schemes. Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources. These Good Practice Principles can help NHS Bradford district and Craven Clinical Commissioning Group in assessing these schemes and the CCG will need to be assured that the schemes offered do not breach any other UK legislation, in particular, reimbursement for pharmaceutical services according to the Drug Tariff, duty to comply with the Department of Health's controls on pricing made under the 2006 Act, the Medicines Act 1968, the Human Medicines Regulations 2012, the Bribery Act 2010, EU law and the public law principles of reasonableness and fairness.

NHS Bradford district and Craven Clinical Commissioning Group will adopt the following principles when deciding whether to participate in a PCRS or not:

8.1. Product Related

- PCRS will only consider a medicine that is:

a. Already commissioned and included in a local joint formulary, and its place in a care pathway established by NHS Bradford district and Craven Clinical Commissioning Group.

b. Not currently included within the formulary but high levels of established use is likely to continue.

- The price of a medicine will be considered but this consideration will be secondary to the clinical need for the medicine and its place in established pathways.

- Health professionals should always base their prescribing decisions primarily on assessments of the individual patient's clinical circumstances. The impact of a rebate scheme is a secondary consideration.

- NHS Bradford district and Craven Clinical Commissioning Group will not consider or promote unlicensed or 'off-label' uses of medicines as part of a PCRS. Furthermore, a PCRS for a drug or product must be linked to total use of that drug and not limited to particular indications for which that drug can be used, and in line with the Specific Product Characteristics (SPC) for the drug in question.

- All recommendations for use of a medicine within a PCRS must be consistent with the UK Marketing Authorisation of the medicine in question, i.e. the PCRS should only advocate the use of the drug in line with the data sheet/Specific Product Characteristics (SPC) for the drug in question

- Medicines not recommended by NICE,
or medicines that form part of NHS England items which should not be routinely prescribed in primary care programme (Low Priority Prescribing) will not be considered under a PCRS.

- Any product rejected by the Area Prescribing Committee (APC), Joint Formulary Committee or Regional Medicines Optimisation Committee will not be considered under a PCRS.

- PCRS are not appropriate for medicines in Category M and some medicines in Category A of the Drug tariff because of potential wider impact on community pharmacy reimbursement. Advice should be sought from the Senior Head of Medicines Optimisation for any Category A products.

8.2 Rebate Scheme Related

- PCRS should not be linked directly to requirements to increase market share or volume of prescribing. A volume based scheme should only be agreed if clinically appropriate, and the administrative burden of monitoring such a scheme should be carefully considered.

- Rebate schemes should be approved through robust local governance processes that include the review and recommendation by the Medicines optimisation team and final approval by the Chief Finance Officer.

- There is a clear requirement for suppliers to promote products in an ethical manner to prescribing practitioners within NHS Bradford district and Craven

Clinical Commissioning Group. In order to ensure prescribing practitioners are not influenced by PCRS agreements they should not be discussed, referred to or promoted in any way by suppliers.

- The administrative burden to the NHS of setting up and running the scheme must be factored into assessment of likely financial benefit of the scheme. Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement. There will be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT 2 data.

8.3 Interface with the pharmaceutical industry

NHS Bradford district and Craven Clinical Commissioning Group must be able to demonstrate that all suppliers wishing to offer rebates are provided with equal access. When appointments to discuss a rebate offer are requested, the supplier should be provided with a copy of this policy. Meetings to discuss rebates should be attended by a senior member of the medicines optimisation team.

Suppliers should not make guideline or formulary positioning conditional to any rebate offer. Equally, NHS Bradford district and Craven Clinical Commissioning Group must not offer or expect any favourable positioning of a product with respect to the local formulary in return for a rebate offer. To avoid misunderstandings, meetings pertaining to rebates must not consider formulary or guidelines status, positioning relative to competitor products, links to any medicines switch programmes or any other actions resulting from the rebate offer.

Suppliers must not discuss any potential joint working arrangements, medical education goods and services, sponsorship offers or patient support programmes. Exceptions are where these elements are explicitly part of the commercial offer and are included in a legal contract (i.e. these elements must have been specified in writing in advance of any meetings to discuss rebates schemes).

In the event of the above not being adhered to in a meeting, the meeting must be terminated immediately and the incident should be reported to the Chief Finance Office to ascertain appropriate action. The CCG may also report their complaint to the Director of the Prescription Medicines Code of Practice Authority (PMCPA) at complaints@pmcpa.org.uk if deemed appropriate.

8.4 Contracts

The NHS Bradford district and Craven Clinical Commissioning Group Chief Finance Officer must ensure that a formal written contract is in place, signed by both parties to ensure:

- The terms of the scheme are clear
- Legal protection is maximised.

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.

PCRS agreements should include a right to terminate on notice (i.e. without having to have any reason for doing so) with a sensible notice period e.g. three or six months. The need for exit criteria and an exit strategy should be considered before a scheme is agreed. It is essential to allow flexibility to respond to emergence of significant new clinical evidence, or significant changes in market conditions. A shorter notice period should be agreed in these circumstances.

Freedom of Information issues (see section 8.6 – Information Governance) should be discussed with the manufacturer before a commissioner enters into any agreement with them and should be contained in the contract.

8.5 Conflicts of Interest

NHS Bradford district and Craven Clinical Commissioning Group acknowledges that there is a potential conflict of interest with signing up to rebates in primary care with the GPs being both the prescribers and members of the Clinical Commissioning Group and that PCRS could be seen to undermine national pricing agreements between the Department of Health and industry.

This policy will ensure that NHS Bradford district and Craven Clinical Commissioning Group enters into rebate schemes that have been independently assessed as being appropriate, so that the NHS can benefit from the cost-efficiencies that the schemes offer.

NHS Bradford district and Craven Clinical Commissioning Group will ensure that any formulary decisions are not influenced by the availability or acceptance of a rebate scheme through clear separation of these decision making processes.

PCRS will not be linked to any current or future prescribing incentive schemes, indicative prescribing budget arrangements or prescribing gain share agreements.

8.6 Information Governance

NHS Bradford district and Craven Clinical Commissioning Group supports the principles of transparency enshrined in the Freedom of Information Act. PCRS often contain confidentiality clauses which may restrict what information may be disclosed under Freedom of Information. NHS Bradford district and Craven Clinical Commissioning Group will publish its policy for accepting rebate agreements along with the list of products for which rebate agreements exist on its publically available website.

Whilst manufacturers often attempt to impose requirements for confidentiality that would restrict NHS Bradford district and Craven Clinical Commissioning Group from disclosing the existence and level of any discount to any third party, NHS Bradford district and Craven Clinical Commissioning Group recognise that such agreements are likely not to be in the interests of the NHS and will therefore not accept such terms.

NHS Bradford district and Craven Clinical Commissioning Group will ensure that all PCRS agreements meet the requirements of the Data Protection Act, and patient confidentiality is never compromised.

The Freedom of Information Act 2000 provides the right of public access to information held by public authorities. The main principle behind freedom of information legislation is that people have a right to know about the activities of public authorities, unless

there is a good reason for them not to. This may be described as a presumption or assumption in favour of disclosure. The NHS Bradford district and Craven Clinical Commissioning Group fully supports the principle of openness and accountability.

There may be occasions where specific information requested is considered to be exempt under section 43 “Commercial Interests” of the Freedom of Information Act. Some information appertaining to rebate agreements may meet the criteria advised by the Information Commissioner’s Office as being “Commercial in Confidence”. This Exemption would only be applied where the information requested would be considered to prejudice the commercial interests of the company to which it relates. This would be decided on a case by case basis.

NHS Bradford district and Craven Clinical Commissioning Group supports the principle openness about its activities. Any decision from the Information Commissioners Office to disclose information must be adhered to.

8.7 Sharing of Information with Prescribers and Other Stakeholders

Individual contracts will contain details of any confidentiality agreements but such agreements must not preclude the sharing of information, including discounts and scheme details, within the wider NHS.

8.8 Use of Rebates

It is vital that any funds received by the CCG as part of a rebate are managed in a transparent, legal and ethical way. As a rebate, the funds will initially and primarily be returned to the CCG prescribing budget as a credit to expenditure.

Oversight for any spending plans, redistribution of funds and control of destination budgets will be provided by the Chief Finance Officer.

No one individual will be in a position to benefit personally from the level of rebate received by the CCG.

9 Dissemination, Implementation and Training

Once approved this policy and procedure will be:

- Shared with Contracting, Finance and Medicines Optimisation Team.
- Published on all of NHS Bradford district and Craven Clinical Commissioning Group websites.

Any queries relating to the policy should be directed to the Medicines optimisation team.

10 Review and Monitoring

Monitoring Criteria	Methodology	Frequency of Monitoring	Responsible Officer (s)	Reporting Committee
Content of Policy	Review to ensure all content still relevant	Bi-annually	Senior Head of Medicines Optimisation and Senior Governance Manager	Finance and Performance Committee
Approved Schemes	Report on schemes approved in year.	Annually	Senior Head of Medicines Optimisation	Finance and Performance Committee
Adherence	Audit rebate schemes in place to ensure still appropriate	Annually	Senior Head of Medicines Optimisation	Finance and Performance Committee
Cost / Benefit Analysis	Review of benefits received from rebate schemes versus estimated costs of administration	Annually	Senior Head of Medicines Optimisation	Finance and Performance Committee

This document will be reviewed after 2 years or in response to any relevant changes in local and/or national policies and guidance, whichever is sooner.

11 Public Sector Equality Duty

The Equality Act 2010 includes a general legal duty to:

- Eliminate unlawful discrimination, harassment victimisation and any other conduct prohibited under the Act
- Advance quality of opportunity between people who share a protected characteristic and people who do not share it

- Foster good relations between people who share a protected characteristic and people who do not have it

The protected characteristics are:

- Age
- Disability
- Gender reassignment
- Marriage or civil partnership
- Pregnancy and maternity
- Race
- Religion or belief
- Sex
- Sexual orientation

Public bodies have to demonstrate due regard to the general duty. This means active consideration of equality must influence the decisions reached that will impact on patients, carers, communities and staff.

It is no longer a specific legal requirement to carry out an Equality Impact Assessment on all policies, procedures, practices and plan but, as described above, the CCG does need to be able to demonstrate it has paid due regard to the general duty.

The policy establishes how NHS Bradford district and Craven Clinical Commissioning Group will ensure a framework for managing rebates in a legal and ethical way that complies with recommended practice and which is independent from clinical prescribing decisions. It is not believed that this policy will impact on or affect differently or adversely any of the groups with protected characteristics.

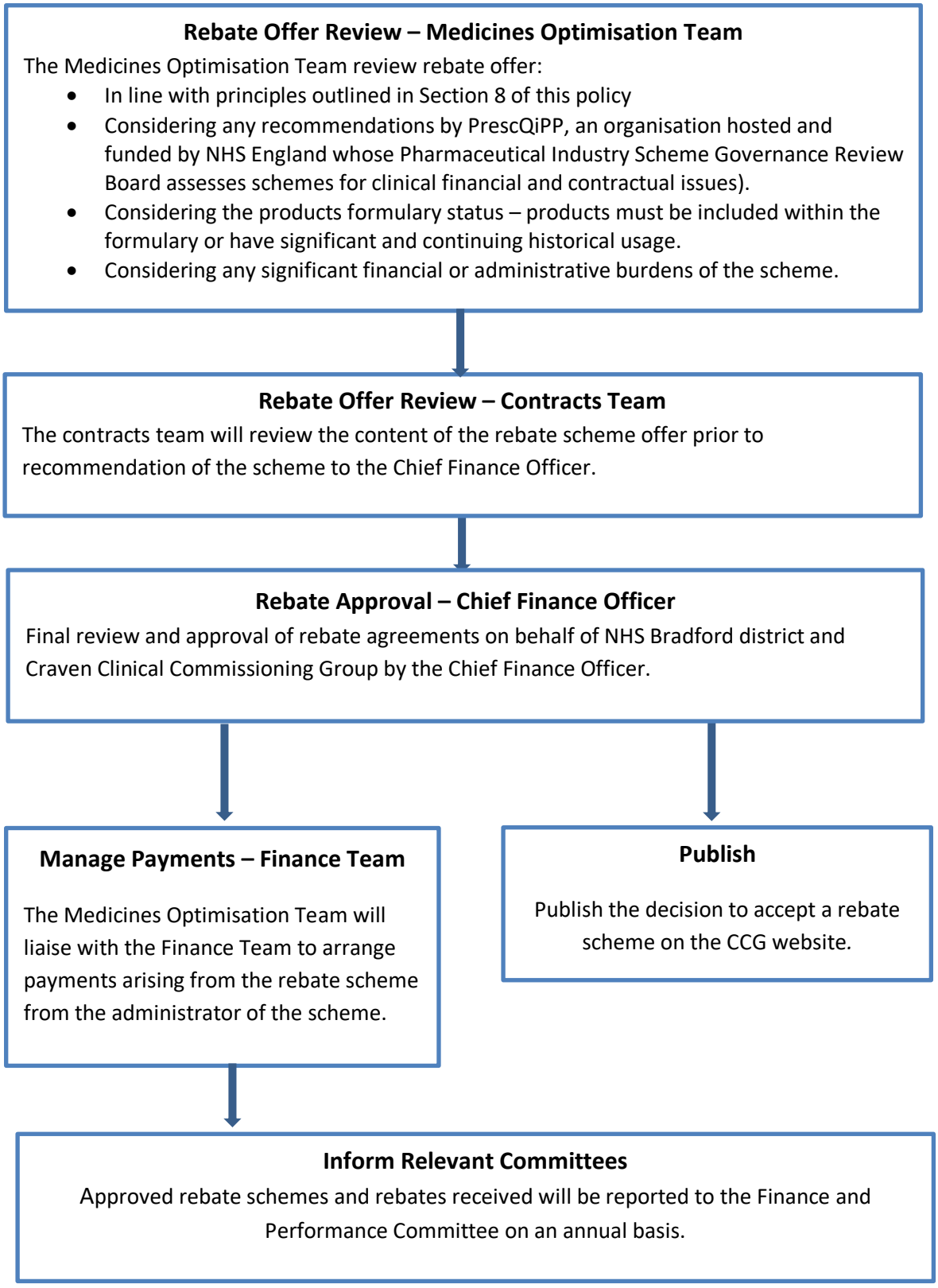
12 References

1. London Procurement Programme Legal Response from DAC Beachcroft LLP – Personnel Communication.

2. Department of Health. Strategies to Achieve Cost-Effective Prescribing (2010)

Appendix 1

Procedure for Assessing and Approving Rebate Schemes



Appendix 2

Primary Care Rebate Scheme Decision Form

Product	
Manufacturer	
Contact Details	

Brief details of rebate scheme	

Assessment Criteria	**Yes/No**
If the product is a medicine, is it licensed in the UK?	
The product does not have a negative decision from NICE, and is not on NHSE's list of Items which should not be Routinely Prescribed in Primary Care?	
Is the product listed in the joint Formulary?	
The contract does not include any requirement for a directive or guideline to be given to health care professionals to prescribe the specific product?	
The rebate scheme is not designed to increase off label use of the drug?	
If the product is a device or nutritional supplement is it contained in the current Drug Tariff?	
If it is not a medicine, it has not been excluded from use within primary care?	
If the product is a vitamin and classed as a food supplement, is it recommended for use in NHS Bradford district and Craven CCG?	
The rebate scheme does not require exclusive use of a specific brand?	
The product is not contained in Category A or M of the Drug Tariff?	
The rebate scheme is not linked directly to a requirement for an increase in market share or volume of prescribing?	
The rebate scheme does not prevent consideration of other schemes?	
There is no requirement to submit additional information beyond the volume of prescribing of the product?	
There is no requirement to collect patient specific data?	

Other Considerations:

PrescQIPP Pharmaceutical Industry Scheme Governance Board assessment		
No. of years scheme is available? (Is it >2 years?)		
Estimated potential savings (per patient and for the CCGs populations per annum)?		
Have any other contractual or legal issues been identified during the evaluation?		
Further information		

Recommendation
Rationale
Evaluation carried out by
Reviewed by (Name, Title & Date)

Rebate Scheme Approval

Title	Name	Signature	Date
Senior Head of Medicines Optimisation			
Senior Contracts Manager			
Chief Finance Officer			