

Rebate Schemes Policy

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POLICY AMENDMENTS

Amendments to the Policy will be issued from time to time. A new amendment history will be issued with each change.

New Version Number	Issued by	Nature of Amendment	Approved by & Date	Date on Intranet
0.1	Deputy Director of Finance – Financial Accounting & Reporting	First version of the policy	<ul style="list-style-type: none">• Medicines Management Board 20th January 2021• Audit Committee: 23rd February 2021	

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1.0 Introduction

A number of pharmaceutical companies have established 'rebate schemes' for drugs prescribed in primary care. It is recognised that such rebates are now a recurrent element of both the CCG's QIPP agenda and its overall ability to balance spend against its resource allocation.

The NHS operates a single drug tariff pricing mechanism for primary care prescriptions it dispenses, which means that local pricing arrangements cannot be entered into. Pharmaceutical companies then offer rebate schemes to CCGs, sometimes nationally or sometimes more targeted to specific localities.

A rebate scheme is a confidential contractual agreement between the manufacturer and the CCG. Under the agreement the CCG receives funding from the manufacturer when its member GP practices prescribe a specific drug. Some schemes offer a straight forward rebate pricing mechanism, such as a set price per packet or dose. However some schemes are much more complex in nature involving stepped pricing and ceiling & floor limits.

2.0 Purpose

The purpose and objectives of this policy are to protect the CCG along with its member GP practices, service users, staff and other stakeholders, as well as the assets of the CCG, whilst ensuring delivery of its strategic and corporate objectives.

Rebate agreements usually take the form of legal agreements between the manufacturer and the CCG. The aim of this policy is to provide a framework for managing rebates in a legal and ethical way to ensure 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 and to ensure the CCG is transparent in its process for considering these schemes. The principles outlined in this policy document allow for the objective evaluation of schemes submitted to the CCG and a clear process for approving and scrutinising agreements.

3.0 Definitions / Explanation of Terms

Rebate: 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 medicine(s).

4.0 Scope of the Policy

The policy applies to NHS North Yorkshire CCG and all its employees and must be followed by all those who work for the organisation, including the Governing Body, those on temporary or honorary contracts, secondments, pool staff, contractors and students.

The policy should be used in conjunction with the following policies:

- Standing Financial Orders and Instructions

- CCG Commercial Sponsorship Policy

Failure to comply with this policy would be considered to be a breach of the terms and conditions of employment and may result in the matter being treated as a disciplinary offence under the CCG's disciplinary procedure.

5.0 Duties / Accountabilities and Responsibilities

Accountable Officer

- Ensures the CCG has an appropriate policy in place

Chief Finance Officer

- Provides oversight of all aspects of this policy to ensure organisational compliance
- Ensures agreed governance arrangements are in place for decision
- Provides regular reports to the Finance, Performance, Commissioning & Contracting Committee
- Is authorised to sign rebate agreements of behalf of the CCG
- Ensures rebates are claimed in a timely fashion.

CCG Prescribing Lead

- Ensures this policy is adhered to in all decisions relating to acceptance or refusal of rebates.

Head of Service - Medicines Management

- Review offered rebate schemes in line with criteria detailed within section 11 of this policy, including consideration of external reviews, for example those carried out by PrescQIPP.
- Provide an appraisal and recommendation to the contracts and finance teams and the Chief Finance Officer.
- Regularly review the rebate scheme register, held on the CCG's website, for accuracy

Head of Service – Management Accounting & Contracting

- Review the rebate offer prior to sign off by the Chief Finance Officer.

Head of Service – Financial Accounting & Reporting

- Reclaim rebate funding from the administrator of the scheme.

Responsibilities for Approval

The Finance, Performance, Commissioning & Contracting Committee is responsible for the approval of rebate schemes.

The Audit Committee is responsible for the approval of this policy.

6.0 Rebate Scheme Policy Requirements

It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms which do not create an additional administrative burden to the NHS. 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 DH 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. Scheme terms, including details of relevant therapeutic evaluations underpinning the scheme, should be published on the CCG's website.

6.1 Good Practice Principles for Rebate Schemes

The detailed content of rebate schemes offered to CCGs 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 the CCG in assessing these schemes. 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 DH's controls on pricing made under the 2006 Act
- The Medicines Act

- The Human Medicines Regulations 2012
- The Bribery Act
- EU law and the public law principles of reasonableness

The CCG will also adopt the following principles when deciding whether to participate in a rebate scheme or not.

Product Related:

- Rebate schemes will only consider a medicine that is already commissioned and included in the CCG's joint formulary, and its place in a care pathway has already been established through the CCGs Quality and Clinical Governance Committee or the North Yorkshire Area Prescribing Committee or equivalent.
- 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.
- The CCG will not consider or promote unlicensed or 'off-label' uses of medicines as part of a rebate scheme. Furthermore, a rebate scheme for a drug or product must be linked to total use of that drug or product 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 rebate scheme must be consistent with the UK Marketing Authorisation of the medicine in question, i.e. the rebate scheme should only advocate the use of the drug in line with the data sheet / Specific Product Characteristics (SPC) for the drug in question.
- Medicines with a current negative recommendation by NICE will not be considered.
- Any product rejected by the North Yorkshire Area Prescribing Committee (or equivalent) will not be considered.
- Rebate schemes are not appropriate for medicines in Category M and some medicines in Category A of the Drug tariff because of the potential wider impact on community pharmacy reimbursement. Advice should be sought from the Strategic Lead Pharmacist for any Category A products.

Rebate Scheme Related:

- Any and all decision making processes will be clinically-led and involve appropriate stakeholders, including patients where appropriate.

- Rebate schemes should not be linked directly to requirements to increase market share or volume of prescribing
- Rebate schemes should be approved through robust local governance processes that include early stage approval by the CCG's Medicines Management Team.
- The administrative burden to the NHS of setting up and running the scheme must be factored into the 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 data.
- 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.
- 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.

6.2 Interface with the Pharmaceutical Industry

The CCG 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 Management Team.

Suppliers should not make guideline or formulary positioning conditional to any rebate offer. Equally, the CCG 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 or any other actions resulting from the rebate offer. This includes the execution of any medicines change programmes by the CCG. 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.

In the event of the above not being adhered to in a meeting, the meeting must be terminated immediately and the incident reported to the Chief Finance Officer to ascertain appropriate action.

6.3 Contracts

The CCG Head of Medicines Management and 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 (see 7.2, 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 below) should be discussed with the manufacturer before a commissioner enters into any agreement with them and should be contained in the contract.

6.4 Information Governance

The CCG supports the principles of transparency enshrined in the Freedom of Information Act. Rebate schemes 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.

Whilst manufacturers often attempt to impose requirements for confidentiality that would restrict the CCG from disclosing the existence and level of any discount to any third party, the CCG recognise that such agreements are likely not to be in the interests of the NHS. This is on the basis both that it will compromise the ability of the CCG to evaluate whether it is obtaining the best possible terms and that in the medium to longer term it is likely to lead to price inflation.

The CCG will ensure that all rebate scheme agreements meet the requirements of the Data Protection Act, and patient confidentiality must never be 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 CCG 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.

The CCG supports the principle of openness about its activities. Any decision from the Information Commissioners Office to disclose information must be adhered to.

7.0 Public Sector Equality Duty

NHS North Yorkshire CCG aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

In developing this policy an Equality Impact Analysis (EIA) has been undertaken. As a result of the analysis, the policy, project or function does not appear to have any adverse effects on people who share *Protected Characteristics* and no further actions are recommended at this stage.

8.0 Consultation

This Policy has been reviewed by the Medicines Management Team and the Finance Team prior to approval by the Audit Committee.

9.0 Training

Training needs will be identified via the annual appraisal process and training needs analysis.

10.0 Monitoring Compliance with the Document

The CCG will monitor compliance with this policy through the internal audit programme.

11.0 Arrangements for Review

The policy and procedure will be reviewed at least every two years by the CCG in conjunction with managers, and Trade Union representatives if appropriate, with changes made as required and the outcome published. Where review is necessary due to legislative change, this will happen immediately.

The Finance, Performance, Commissioning and Contracting Committee has delegated responsibility for monitoring and reviewing the policy and will report any concerns to the Governing Body.

12.0 Dissemination

All staff will be made aware of the policy via the CCG's Internet.

Staff directly impacted by this policy, such as the Medicines Management Team and the Finance Team, will be provided with a copy of the policy.

Awareness of reviewed and amended policies will be through the CCG staff newsletter.

13.0 Associated Documentation

The policy should be used in conjunction with the following policies:

- Standing Financial Orders and Instructions
- CCG Commercial sponsorship policy

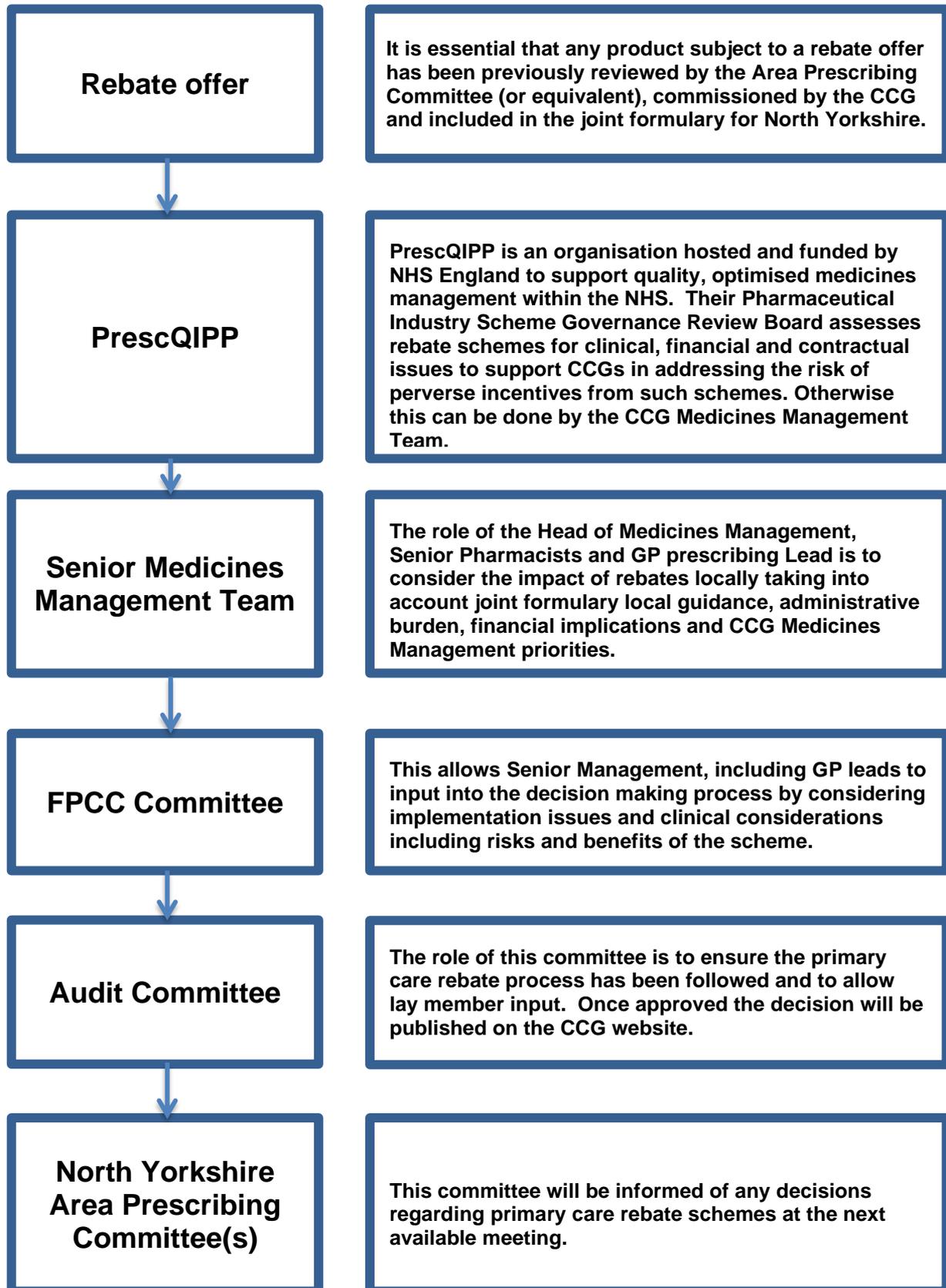
14.0 References

None

15.0 Appendices

1. Rebate scheme approval process
2. Rebate scheme decision form

Primary Care Rebate Scheme Approval Process



Confidential

Primary Care Rebate Scheme Decision Form *Confidential*
Primary Care Rebate Scheme Decision Form

Product	Product brand names (generic name), form and strength(s)
Manufacturer	Company name
Contact Details	Name of individual, email and phone number, on behalf of; Company name Company address Phone: <u>+44 xxx</u>

Brief details of rebate scheme	Product brand names (generic name), form and strength(s):				
	Description e.g. straight forward rebate per tablet prescribed in North Yorkshire CCG.				
	Product	Pack size	NHS list price	Rebate value	Rebated price
	Brand, strength + form				

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?	
Is the product listed in the CCG and/or a trust (HDFT/ST/YDH/TEWV) 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 NY CCG?	
The rebate scheme does not require exclusive use of a specific brand?	
The product is not contained in Category A (seek advice) or M (exclude) 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	
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Governance Board assessment		
How many years is the scheme available? (Is it >2 years?)	e.g. Expires 31 st Dec 2022	
Estimated potential savings (per patient and for NY population per annum)?	e.g. £14.00/patient/28days £182.50/patient/year	e.g. Approx £120k/year (based on Q3 19/20 use)
Have any other contractual or legal issues been identified during the evaluation?	Responses to FOI requests must be approved by the company before disclosure.	
Further information: <ul style="list-style-type: none"> • Administrative burden: • Governance issues: • Freedom of Information issues: • Any other pertinent issues: 		
Recommendation:		
Rationale:		
Evaluation carried out by:		
Reviewed by:		

FPCC Committee Decision:

The Committee does/does not support the decision to agree to this primary care rebate scheme.

Title	Name	Signature	Date
FPCCC Chair			
CCG Chief Finance Officer			

Date sent to Audit committee by MMT: