Policy for Approving Primary Care Prescribing Rebate Schemes

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Based on:
Former Greater Huddersfield CCG and North Kirklees CCG Policy v2 – approved October 2020

Version	Date	Author	Status/Approval Body	Circulation
0.1	March 2021	Rizwana Anwar/Sylvia Adams	Updated for Kirklees CCG and to meet the requirements of the Accessible Information Standard	CCG Website
1.1	July 2021	Rizwana Anwar/Sammi Hall	Amendments made to section 3.F regarding Vitamins. Amendments made to flow chart Appendix B.	Lindsay Greenhalgh Head of Medicines Optimisation
1.2	July 2021	Lindsay Greenhalgh	Title changed to Head of Medicines Optimisation, from Head of Medicines Management, Appendix c changed to remove Chief Financial Officers signature. Clinical lead changed to Dr Edara from Dr Rehman	

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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 manufacturer's 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, and then the manufacturer provides a rebate to the primary care organisation based on an agreed discount price and verified by ePACT2 data.

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

Rebate agreements usually take the form of legal agreements between the manufacturer and CCG. It is important that Kirklees CCG has a policy to support evaluation and sign off of rebate schemes to ensure that schemes are only signed off where they provide good value for money to the public purse and the schemes terms

are in line with organisation vision, values, policies and procedures and also to ensure that the CCG is transparent in the process for considering these schemes.

The principles outlined in this policy document allow for the objective evaluation of schemes submitted to the CCG and for a clear process for approving and scrutinising agreements.

NHS Kirklees CCG also subscribe to the PrescQIPP NHS programme which created the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board. PrescQIPP is a not for profit Community Interest Company (CIC) that supports commissioners deliver medicines Optimisation improvements. The primary output of the board is an assessment, summarising the recommendations for any rebate scheme submitted to them.

Each Board Assessment will also include a Red, Amber or Grey status depending on the outcome of the assessment stage. The classification of the three colours is as follows:

Grey: Scheme considered; no significant reservations

Amber: Scheme considered; not fully appropriate

Red: Scheme considered; Inappropriate

Ideally schemes will have been through the PrescQIPP assessment and will have a grey or amber status in addition to meeting all the CCG's principles.

3. Principles for Assessing Rebate Schemes

The following will be used to determine the suitability of taking a Rebate Scheme to Kirklees CCG for consideration and ratification:

Product Related

a. There should be a demonstrable clinical need for the product.
b. All products should normally be recommended for prescribing in Kirklees and be listed on local acute Trusts formulary where appropriate.

c. Products should not:

i. Be included in the CCG's 'Do not prescribe list' or the DROP-list from PrescQIPP.

ii. Be included in the NHSE lower value medicines guidance as not suitable for routine prescribing in primary care.

iii. Have a negative decision by NICE.

d. There shall be no directive for health professionals to prescribe a specific product, solely because a Primary Care Rebate Scheme (PCRS) is in place. Prescribing decisions should be made on assessments of an individual patient's clinical circumstances. The impact of a rebate scheme is a secondary consideration.

e. Any medicine considered under a Primary Care Rebate Scheme (PCRS) must be licensed in the UK. Where there is more than one licensed indication for a medicine, a scheme should not be linked to a particular indication for use.

f. Any device or nutritional supplement considered under a PCRS should be included within the relevant chapter of the Drug Tariff.

g. Vitamins, which are classed as food supplements, should only be included if they are recommended for use by NHS Kirklees CCG for a defined indication.

h. Rebate schemes promoting unlicensed or off label uses will not be entered into. All recommendations for use of a medicine within a PCRS must be consistent with the Marketing Authorisation of the medicine in question.

i. Consistent savings must be achievable across all pack sizes where applicable.

Rebate Scheme Related

j. The administrative burden to the CCG of setting up and running the scheme must be factored into assessment of likely financial benefit of the scheme.

k. Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement.

l. Primary care rebate schemes encouraging exclusive use of a particular brand of product will not be entered into. Where specific brand prescribing is required due to the nature of the product e.g. Glucose Testing strips or some specific drugs (e.g. modified release products), then an increase in that particular product usage may be seen but individual patient need must be the driver.
m. Primary care rebate schemes are not appropriate for medicines in Category M and some medicines in Category A of the Drug Tariff. This is due to the potential wider impact on community pharmacy reimbursement.
n. The primary care rebate scheme will not be directly linked to requirements to increase market share or volume of prescribing. It is recognised that an increase in market share may be a consequence of the primary care rebate scheme. This principle may be waived if the scheme is available as a result of a formal open tender.
o. A volume based scheme should only be agreed if clinically appropriate. However, the administrative burden of monitoring such a scheme should be carefully considered.
p. Schemes offered should ideally have been through the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board assessment process and must have achieved a ‘Grey’ or ‘Amber’ status.
q. Rebate Schemes with a RED status will not be considered.
r. Rebate Schemes which have not been through the PrescQIPP process will be assessed against the CCG principles and if the scheme meets all requirements, it may be considered for acceptance.
s. Short term rebate schemes (less than 2 years) will not normally be considered. It is expected that the reduced price should be available to the CCGs over an extended period of time.

Information and Transparency

t. The primary care rebate scheme will not preclude the CCG from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so.

u. There will be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT2 data.

v. Primary care rebate schemes will not be entered into that requires provision of patient specific data.

w. Primary care rebate schemes will be subject to Freedom of Information (FOI) requests. Advice will be sought from the CCG's FOI lead as to what information should be shared.

x. The CCG will publish a list of the schemes it participates in on the CCG website. The full terms of the scheme may not be published depending on the nature of the rebate scheme contract. A redacted contract may be available from the pharmaceutical company depending on the nature of the individual rebate scheme contract.

4. Freedom of Information

The 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. The CCG benefits from many of these schemes through the prices charged to them 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.

The 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. Duties / Accountabilities and Responsibilities

Duties within organisation

The CCG's Head of Medicines Optimisation will be responsible for assessing scheme against the principles outlined in section 3 above. The "Rebate Scheme Decision Form" in Appendix C will be used to record the assessment against the principles and to provide a recommendation to the Chief Financial Officer.

Responsibilities for approval

The Chief Financial Officer is responsible for final approval of rebate agreements on behalf of the CCG.

The CCG's Audit Committee will be presented with a copy of the "Rebate Scheme Decision Form" at the next committee meeting for scrutiny.

6. Public Sector Equality Duty

The 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.

The CCG has considered the general legal duty required by the Equality Act 2010 and does not consider it necessary to carry out an EIA on this policy as it does not have an impact on patients, carers, staff or the wider community.

7. Bribery Act 2010

The CCG follows good NHS business practice as outlined in the Conflicts of Interest Policy and has robust controls in place to prevent bribery as outlined in the Anti-Fraud, Bribery Policy. Due consideration has been given to the Bribery Act 2010 in the development of this policy document and it is felt that the Bribery Act is particularly relevant to this policy. CCG staff should be aware that they cannot make any promises to participants regarding influencing changes to future policies or CCG decisions in return of their support and engagement.

It should be noted that the Act makes bribery a criminal offence and there are four offences:

- bribing, or offering to bribe, another person
- requesting, agreeing to receive, or accepting a bribe
- bribing, or offering to bribe, a foreign public official
- failing to prevent bribery

All individuals should be aware that in committing an act of bribery they may be subject to a penalty of up to 10 years imprisonment, an unlimited fine, or both. They may also

expose the organisation to a conviction punishable with an unlimited fine because the organisation may be liable where a person associated with it commits an act of bribery.

8. Scope of the Policy

This policy applies to all employees, members of the CCG, co-opted members and members of the Governing Body and its committees who must comply with the arrangements outlined in this policy.

9. Monitoring Compliance with the Document

The CCG's Audit Committee will monitor compliance with the policy. The finance report presented to Audit Committee will list any rebate schemes considered and whether the CCGs have agreed to sign up to the scheme or not.

Copies of Appendix C will be maintained for all schemes formally considered by the CCG and will be available for audit if necessary.

10. Arrangements for Review

This policy will be reviewed two years after the date of authorisation. The policy may be reviewed sooner if there is a change in legislation or new national guidance.

11. Dissemination

This policy will be shared with all members of the Senior Management Team. It will be published on the CCG's intranet and internet sites.

12. References

The following policies were used as the basis of this policy

Ethical Framework for Considering Rebate Agreements from Pharmaceutical, Nutrition and Device Companies. Greater Manchester Commissioning Support Unit. 2013.

Principles and Legal Implications of Primary Care Rebate Schemes. London Procurement Programme. 2012.

Primary Care Rebate Schemes. Health Service Journal. 2013

Freedom of Information Act Awareness Guidance No. 5. Information Commissioner's Office. 2008.

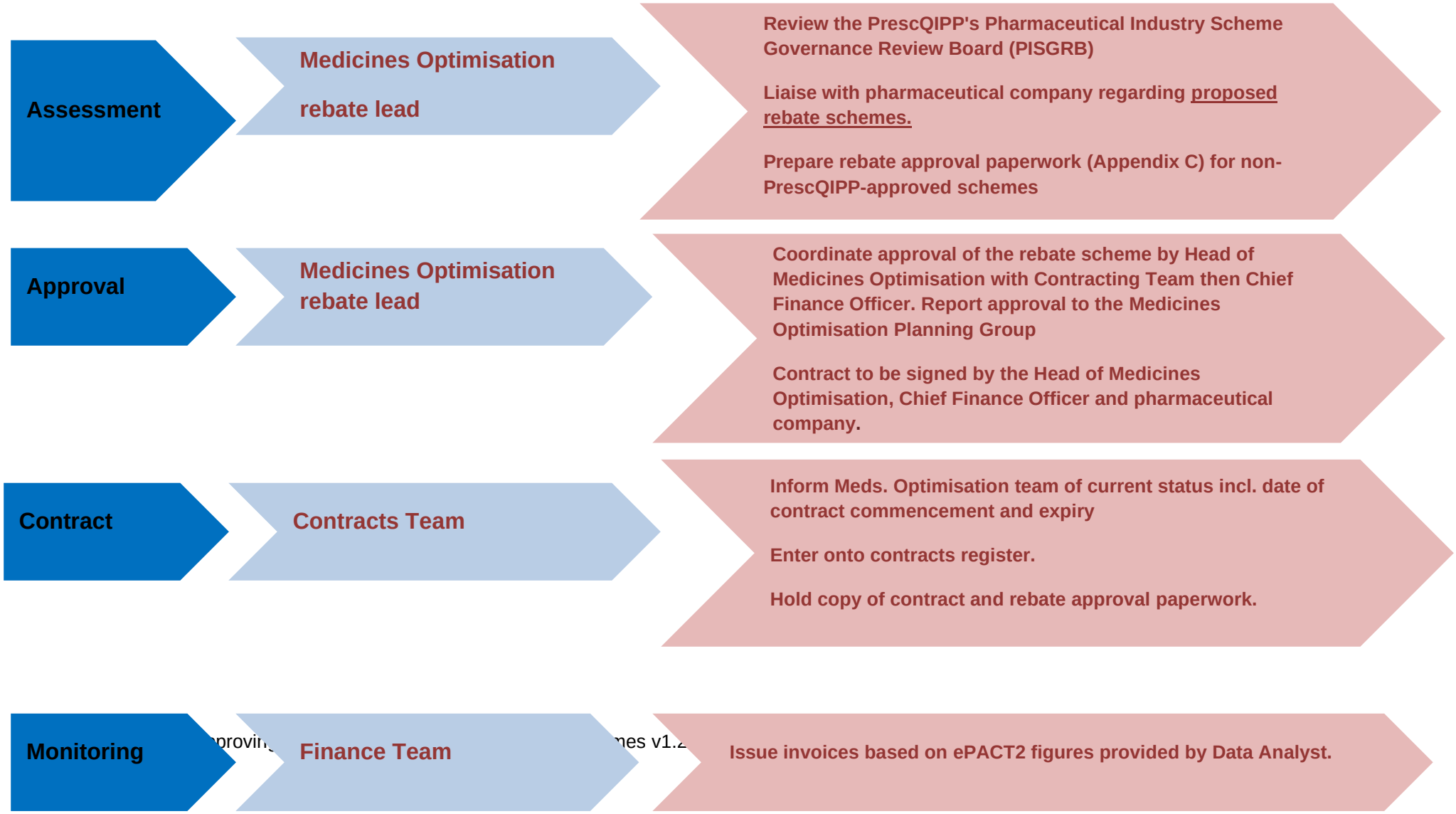
http://www.ico.org.uk/for_organisations/guidance_index/~/media/documents/library/Freedom_
of_Information/Detailed_specialist_guides/AWARENESS_GUIDANCE_5_V3_07_03_08.ashx

Appendix A – Key Stakeholders Consulted in the Development of the Policy Document

Stakeholders name and designation	Date feedback requested	Detail of feedback received	Date feedback received	Action taken
Medicines Strategy Group	23 August 2013	Agreed with the ethical principles outlined. Minor amendments suggested.	3 September 2013	Feedback incorporated into principles
Chief Financial Officer	10 September 2013	Agreed principles and discussed approval process options	10 September 2013	Incorporated into policy
Audit Committee Chair	25 September 2013	Agreed with principles and suggested approval process for schemes	25 September 2013	Incorporated into the policy
Senior Management Team	15 October 2013	Requested more specific information to be provided on managing FOI requests. Equality Duty Information updated	22 October 2013	Policy updated
Audit Committee	13 November 2013	Suggested Audit Committee received information on schemes considered through the Finance Report	13November 2013	Policy Updated

SMT	17 September 2020	Governing Bodies for final sign off	17 September 2020	Feedback received. New information added from PrescQIPP and process updated
Governing Bodies	14 October 2020	Suggested adding information in regarding the Bribery Act and monitoring to be undertaken through Audit Committee not Governing Bodies. Titles of the meds management team amended on flow chart	14 October 2020	Policy amended to reflect the changes

Appendix B - Rebate Scheme Approval Process



Appendix C - Rebate Scheme Decision Form *Confidential*

Product	
Company	
Contact Details	

Question	**Yes/No**
Is product listed on CCG/Acute Trust Formulary (as either a brand or generic)?	
Is the product listed on the PrescQIPP DROP list or 'Do Not Prescribe List?	
Does the product have a negative decision from NICE?	
Is there any requirement(s) for a directive or guideline to be given to health care professionals to prescribe the specific product?	
Is it a licensed medicine in the UK?	
Is the rebate scheme designed to increase off label use of the drug?	
Is the product is a device or nutritional supplement within the current Drug Tariff?	
If the product is a vitamin and classed as a food supplement is it recommended for use in Kirklees CCG?	
Does the rebate scheme require exclusive use of a specific brand? See principles re: caveats for specific product categories.	
Is the product contained in Category A or M of the Drug Tariff?	
Is the rebate scheme is linked directly to a requirement for an increase in market share or volume of prescribing?	
Does the rebate scheme prevent consideration of other schemes?	

Is there any requirement to submit additional information beyond the volume of prescribing of the product?	
Is there any requirement to collect patient specific data?	
No. of years scheme is available? (Is it ≥2 years?)	
Does the rebate scheme have PrescQIPP Board Assessment? What is the status (Grey, Amber, or Red)	
If the scheme has not been assessed by PrescQIPP, does the scheme meet all requirements of the CCG principles?	
Estimated potential savings (per annum)?	
Have any other contractual or legal issues been identified during the evaluation? (outlined below)	
Further information	
Outline:	

• *Estimated administrative burden* • *Any legal or contractual issues uncovered* • *Governance issues* • *Freedom of Information issues* • *Any other pertinent issues*	
Recommendation	
Rationale	
Evaluation carried out by (Name, Title & Date)	
Checked by (Name, Title & Date)	

CCG Decision

I do/do not support the decision to agree to this primary care rebate scheme

Name:

Signed: Date:

Head of Medicines Optimisation

I do/do not support the decision to agree to this primary care rebate scheme

Name:

Signed: Date:

Chief Financial Officer/Deputy Chief Officer