NHS
Calderdale
Clinical Commissioning Group

Policy for Approving Primary Care Prescribing Rebate Schemes

Policy Ref: 017

Version No/Status:	2.0 /Final
Responsible Committee:	Finance and Performance Committee
Date Approved	25 October 2018
Author:	Medicines Management Teams
Responsible Lead:	Head of Primary Care Quality and Improvements
Review Update:	October 2021

Acknowledgments to Kirklees CCG for the development of this policy

Version History

Version	Date	Author	Document Status	Commentary: (document development / approval)	Circulation
0.1	16.10.13	Eric Power	Draft	Final version of CCCG rebate policy	Medicines Advisory Group
0.2	17.4.14	Helen Foster	Draft	Revised policy in line with comments from CCCG Corporate and Governance Manager	Corporate and Governance manager
0.3	29.04.14	Helen Foster	Draft	Added new Equality form following input from Equality and Diversity Associate	Equality and Diversity Associate
1.0	15.05.14	Helen Foster	Final	Approved by Audit Committee	Staff/ Website
1.1	23.08.18	Nicola Booth	Draft	Reviewed and amendments proposed	MAG
1.2	2.10.18	Nicola Booth	Draft	EQIA reviewed and template replaced by Project Coordinator, equality specialist (Service Improvement)	Kym Brearley

1.3	25.10.18	Nicola Booth	Final Draft		F and P Committee
2.0	26.10.18	Nicola Booth	Final Version	Approved by Finance and Performance Committee	Staff/ Website

Contents

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. This is verified by ePACT 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 Calderdale CCG has a policy 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 and also to ensure that 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 for a clear process for approving and scrutinising agreements.

NHS Calderdale CCG also subscribes to the PrescQIPP NHS programme which created the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board. PrescQIPP is a not for profit 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 CCCG for consideration and ratification:

3.1 Product Related

- There should be a demonstrable clinical need for the product.

- All products should normally be recommended for prescribing in Calderdale and be listed in the Calderdale primary care formulary or Calderdale and Huddersfield NHS Foundation Trust formulary where appropriate.

- Products should not:

    - Be included in the CCCG ‘Do not prescribe list’ or the DROP-list from PrescQIPP (which has replaced the Area Prescribing Committee ‘Grey List’)
    - Be included in the NHSE Lower value medicines guidance as not suitable for routine prescribing in primary care
    - Have a negative decision by NICE

- 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.

- 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.

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

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

- Rebate schemes for 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.
- Consistent savings must be achievable across all pack sizes where applicable.

3.2 Rebate Scheme Related

- 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.

- 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.

- Rebate Schemes with a RED status will not be considered.

- 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.

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

- 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.

- 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.
- 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 a change in formulary locally, but this will not be linked to a requirement of a rebate scheme. This

principle may be waived if the scheme is available as a result of a formal open tender.

- A volume based scheme should only be agreed if clinically appropriate. However, the administrative burden of monitoring such a scheme should be carefully considered.

- Short term rebate schemes (less than 2 years) will not routinely be considered. It is expected that the reduced price should be available to the CCG over an extended period of time.

3.3 Information and Transparency

- It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms that do not create an additional administrative burden to the NHS.

- 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.

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

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

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

- Calderdale CCG will publish a list of the schemes it participates in on the CCG website. The full terms of each scheme will not be published. A

redacted contract may be available depending on the nature of the individual rebate scheme contract.

4 Duties / Accountabilities and Responsibilities

4.1 Duties within organisation

The CCG's Medicines Management Team will be responsible for assessing schemes 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/Deputy Chief Officer.

4.2 Responsibilities for approval

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

4.3 CCG Medicines Advisory Group

The CCG Medicines Advisory Group (MAG) will not be consulted on rebate schemes to be adopted by the CCG, unless there is a need for clinical opinion. In this case the rebate scheme will be discussed at the next MAG meeting. MAG members will be presented with a copy of the completed "Rebate Scheme Decision Form" in advance of the meeting, along with the clinical issue to be discussed. A record of any email scrutiny and minutes of the relevant MAG meeting will be retained in line with the CCG's Records Management and Information Lifecycle Policy.

5. Public Sector Equality Duty

Calderdale 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.

6. Scope of the Policy

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

7. Monitoring Compliance with the Document

The Calderdale Medicines Management Team will monitor compliance with the policy.

8. Arrangements for Review

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

9. Dissemination

This policy will be shared with all members of the Senior Management Team.

It will be published on both the CCG intranet and website.

10. 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)

11. Appendices

A – Key stakeholders consulted

B – Equality impact assessment

C – Rebate scheme form

Appendix A - Key Stakeholders Consulted/Involved in the Development of the Policy Document

Stakeholders name and designation	Date feedback requested	Detail of feedback received	Date feedback received	Action taken
Medicines Advisory Group	26.9.13	Agreed with the ethical principles outlined. No amendments suggested.	Discussed at meeting, no further feedback received	None required
Corporate and Governance Manager	6.3.14	Some small amendments to align with Calderdale processes	27.3.14	Incorporated into policy
Sarah Mackenzie-Cooper, Senior Associate Equality and Diversity	17.4.14	Agreed policy has no observed impact on patients. Advised use of different Equality Impact Assessment form	24.4.14	Completed new form
Medicines Advisory Group	Meeting 23.8.18	Agreed with the ethical principles outlined as before. Suggested amendments to role of MAG in rebates – restrict to if clinical	Discussed at meeting, feedback re role of MAG accepted.	Incorporated into updated policy.

Stakeholders name and designation	Date feedback requested	Detail of feedback received	Date feedback received	Action taken
		issues are noted rather than the need to retrospectively inform MAG of all rebates.		
Kym Brearley	Email 1.10.18	Reviewed EQIA – newer template used, otherwise no amendments	Email 2.10.18	New form used in policy.

Appendix B - Equality Impact Assessment

Title of policy:

Policy for approving primary care prescribing rebate schemes

Names and roles of people completing the assessment

Helen Foster, Medicines Management Lead, Nicola Booth, Medicines Management Pharmacist

Date assessment started/completed/reviewed

First completed 29.4.14
Reviewed 3.8.18

1. Outline

Give a brief summary of the policy

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.

2. **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

Analysis of impact

Characteristics	Are there any likely impacts? Are any groups going to be affected differently? Please describe.	Are these negative, positive or neutral?	What action will be taken to address any negative impacts or enhance positive ones?
Age	No impact	Neutral	N/A
Disability	No impact	Neutral	N/A
Gender reassignment	No impact	Neutral	N/A
Marriage and civil partnership	No impact	Neutral	N/A
Pregnancy and maternity	No impact	Neutral	N/A
Race	No impact	Neutral	N/A
Religion or belief	No impact	Neutral	N/A
Sex	No impact	Neutral	N/A
Sexual orientation	No impact	Neutral	N/A
Carers	No impact	Neutral	N/A
Other relevant group	No impact	Neutral	N/A
Human Rights	No impact	Neutral	N/A
Health Inequalities	No impact	Neutral	N/A

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

Not applicable

4. Monitoring, Review and Publication

How will the impact and effectiveness of the actions be monitored/reviewed and by whom?

Assessment via the Medicines Advisory Group will be scheduled for 3 years after ratification of policy

When will this EQIA be reviewed and by whom?

This will be reviewed by the Medicines Management Team and Equality Team at the time the policy is reviewed.

Lead Officer: Helen Foster
Review Date: 3.8.2018

5. Sign off

Equality Lead:
Kym L Brearley, Project Co-ordinator, equality specialist (Service Improvement - PMO)
02/10/2018

Director:
Date approved:

Once complete please forward to the Equality lead, Kate Bell in order to provide an audit trail for governance purposes.

Appendix C - Rebate Scheme Decision Form *Confidential*

Product:

Company:

Contact Details

Question	Yes	No	Pass
Is product listed on CCG/acute Trust Formulary CCG?			
Is product listed on CCG/acute Trust Formulary Trust?			
Is the product listed on the PrescQIPP DROP list or CCG 'Do not Prescribe List?			
Does the product have a negative decision from NICE?			
Are there requirements for a directive or guideline to be given to health care professionals to prescribe the specific product?			
If the product is a medicine, is it licensed in the UK?			
Is the rebate scheme 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 the product is a vitamin and classed as a food supplement, is it recommended for use in Calderdale 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 linked directly to a requirement for an increase in market share or volume of prescribing?			
Does the rebate scheme prevent consideration of other schemes?			

Question	Yes	No	Pass
Is there a requirement to submit additional information beyond the volume of prescribing of the product?			
Is there a requirement to collect patient specific data?			
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?			

Number of years scheme is available? Is it > 2 years?)

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 and Date)

Checked by (Name, Title and Date)

CCG Decision

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

Signed: Date:

Medicines Management Lead

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

Signed: Date:

Chief Financial Officer/Deputy Chief Officer