Policy for Approving
Primary Care Prescribing Rebate Schemes

Version: 4.0

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Version History

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0.1	20/11/13	Joanne Fitzpatrick, Head of Medicines Optimisation	Initial draft presented to Medicines Optimisation Group for comments	MOG
0.2	03/01/14	Joanne Fitzpatrick, Head of Medicines Optimisation	Updated following comments from Medicines Optimisation Group	
0.3	20/01/14	Joanne Fitzpatrick, Head of Medicines Optimisation	Updated checklist following comments from Andrew Pepper, Chief Finance officer	Chief Finance Officer
1.0	22/02/14	Joanne Fitzpatrick, Head of Medicines Optimisation	Approved by Integrated Governance committee	IGC
1.1	26/05/16	Carly Day, Primary Care Medicines Optimisation	Document review. Updated to include information on PrescQIPP; Rebate	IGC

		Lead	Approval Scheme Approval Process appendix; minor additions	
2.0	16/06/2016	Joanne Fitzpatrick, Head of Medicines Optimisation	Approved at Integrated Governance Committee	IGC
2.1	14//05/2018	Carly Day, Primary Care Medicines Optimisation Lead	Addition of criteria for locally offered Rebates; other minor changes	Head of Medicines Optimisation
2.2	29/05/2018	Joanne Fitzpatrick, Head of Medicines Optimisation	Oversight of minor changes and update of terminology	IGC
3.0	21/06/2018	Carly Day, Primary Care Medicines Optimisation Lead	Approved at Integrated Governance Committee	IGC
3.1	20/05/2020	Carly Day, Primary Care Medicines Optimisation Lead	Review of policy; update web links; addition of consideration of schemes less than 2 year duration; addition of invoice payment terms; other minor changes to terminology	QPG
4.0	23/07/2020	Carly Day, Primary Care Medicines Optimisation Lead	Approved at Quality, Performance and Governance Committee	CCG website / CCG intranet

Contents **Page**

1. Introduction

The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism by which the Department of Health and Social Care (DHSC) working with the Association of the British Pharmaceutical Industry (ABPI) 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. This is a non-contractual voluntary agreement.

The PPRS does not apply to devices or nutritional products; nor does it apply to generic medicines where cost tends to be controlled by their Drug Tariff agreed pricing.

Information on the current scheme can be accessed via: https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access

The view of the Department of Health expressed in the consultation document on value based pricing is 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.

In light of this, a number of manufacturers / pharmaceutical companies have established 'rebate schemes' for drugs used in primary care to support the NHS QIPP (efficiencies) agenda. Under the terms of such a scheme, the NHS is charged the Drug Tariff price or the Dictionary of Medicines and Devices (dm+d) listed price for primary care prescriptions dispensed and the manufacturer then provides a rebate to the primary care organisation based on an agreed discount price verified by ePACT2 data.

Most schemes are straight discounts that are not volume based, whilst others have varying discount rates available dependent upon the volume of drug prescribed. The rebate value within each discount scheme is 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 pharmaceutical company and CCG. It is important for NHS Wakefield CCG to have in place, a policy to support the evaluation and approval of rebate schemes to ensure that schemes are only signed off when they provide good value for money to the public purse and the scheme's terms are in line with the organisation's vision, values, policies and procedures.

The CCG's policy provides transparency in its process for considering and entering into rebate scheme agreements. 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. Scope of the Policy

This policy applies to NHS Wakefield CCG and 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 those on work experience placements.

4. Duties / Accountabilities and Responsibilities

The Primary Care Medicines Optimisation Lead will be responsible for assessing schemes against the principles outlined in section 2 (Purpose). The "Rebate Scheme Decision Form" in Appendix B will be used to record the assessment against the principles and to provide a recommendation to the Head of Medicines Optimisation; Lay Member and Chief Financial Officer.

The Head of Medicines Optimisation, Lay Member and Chief Financial Officer are responsible for checking and signing the Rebate Scheme Decision Form to confirm whether they do or do not support the recommendation made by the Primary Care Medicines Optimisation Lead as outlined on the form.

The Chief Financial Officer is responsible for final approval of rebate agreements on behalf of NHS Wakefield CCG. The Head of Medicines Optimisation is the authorised signatory for rebate agreements.

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

The Quality, Performance & Governance Committee is responsible for the formal approval of this policy.

5. Principles for Assessing Rebate Schemes

The following will be used to determine the suitability of taking a rebate scheme to NHS Wakefield CCG for consideration and ratification:

5.1 Product Related

- There should be a demonstrable clinical need for the product.
- All products should normally be recommended for prescribing in Wakefield and be listed on local Acute Trust formularies where appropriate.

- Products should not:
    - Be included in the NHS England items which should not be routinely prescribed in primary care programmes (Low Priority Prescribing Programme) https://www.england.nhs.uk/medicines-2/items-which-should-not-be-routinely-prescribed/ or those additional items that are not routinely commissioned by NHS Wakefield CCG
    - Have a negative decision by NICE Technology Appraisals

- 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.

- PCRS 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.

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

5.2 Rebate Scheme Related

- PrescQIPP is a Community Interest Company operating on a 'not for profit' basis for the benefit of NHS patients, commissioners and organisations. Their Pharmaceutical Industry Scheme Governance Review Board assesses any rebate scheme for clinical, financial and contractual issues to support CCGs in addressing the risk of perverse incentives from such schemes. Only schemes with a positive outcome after assessment will be considered by NHS Wakefield CCG.

- Consideration will be given to rebates offered directly to NHS Wakefield CCG where the product is already the preferred evidence-based choice locally and newer versions of the medicine have since been introduced at a lower cost to the NHS. To consider this offer the following criteria must be met:
    - The drug company advises it is not in a position to lower the cost price to the NHS (due to medicines pricing in the UK and export to the EU and the implications this may have on the supply chain) AND
    - The majority of prescribing locally is for this product AND
    - Switching existing prescribing to the more cost-effective alternative medicine would be best avoided in the interest of patients

- 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.

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

- PCRS 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, and choice where appropriate, must be the driver.

- PCRS are not appropriate for medicines in Category M of the Drug Tariff. This is due to the potential wider impact on community pharmacy reimbursement.

- The PCRS 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 PCRS. 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.

- Previously, short term rebate schemes (less than 2 years) have not normally been considered as it was expected that the reduced price should be available to the CCG over an extended period of time. However, as rebate agreements stipulate a termination period for both the company and the CCG, in essence each scheme could be considered to be for as long as this period of notice. Therefore schemes of 12 months duration will be considered.

- In line with NHS standard payment terms, drug companies will have 30 days from the date of the invoice to pay the CCG. If a company cannot offer this within its standard terms and conditions then rationale will be sought and the CFO will make a decision based on the information provided as to whether this is agreeable.

5.3 Information and Transparency

- The PCRS 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 pharmaceutical company any data other than volume of use **or** the total Net Ingredient Cost as derived from ePACT2 data.

- PCRS will not be entered into that require provision of patient specific data.

- PCRS 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. Some pharmaceutical companies provide a redacted version of the agreement to facilitate the efficiency for CCGs in responding to FOIs.

6. Freedom of Information

NHS Wakefield CCG 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. 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. NHS Wakefield CCG benefits from many of these schemes through the prices charged to it for tariff-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.

NHS Wakefield 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.

Most rebate scheme providers offer a redacted version of the agreement to support the CCG in dealing with FOIs efficiently. The redacted version omits only the rebate value.

7. Public Sector Equality Duty

NHS Wakefield 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.

8. Monitoring Compliance with the Document

The NHS Wakefield CCG Audit Committee will monitor compliance with the policy.

The Audit Committee will be provided with a completed Rebate Scheme Decision Form (Appendix B) for scrutiny for each scheme agreed.

9. Arrangements for Review

This policy will be routinely reviewed every two years or sooner if the need arises. The Primary Care Medicines Optimisation Lead and Head of Medicines Optimisation are responsible for reviewing this policy.

10. Dissemination

This policy will, following ratification by the Quality, Performance & Governance Committee, be shared with Heads of Service and Executive team for further dissemination as necessary.

The policy will be published on both NHS Wakefield CCG intranet and internet sites.

11. References

The following documents were used as the basis of this policy:

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

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

http://www.lpp.nhs.uk/media/43744/Primary-Care-Rebate-Schemes-Principles-NHS-London-Procurement-Partnership.pdf

3. Primary Care Rebate Schemes. Health Service Journal. 2013

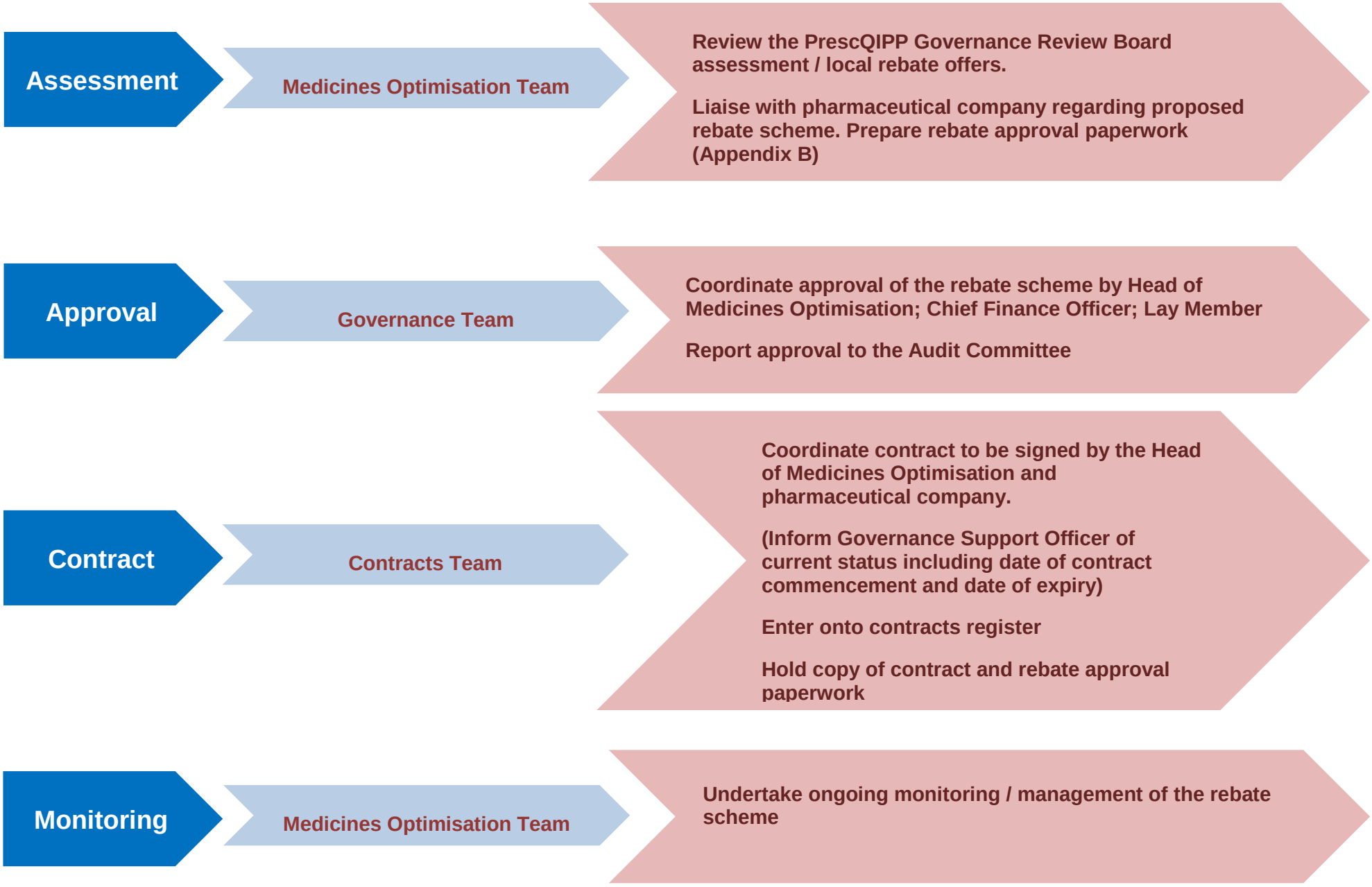
4. The Information Commissioner's Office guide to freedom of information

https://ico.org.uk/for-organisations/guide-to-freedom-of-information/

12. Appendices

A Rebate Scheme Approval Process
B Rebate Scheme Decision form

Appendix A - Rebate Scheme Approval Process



Appendix B - Rebate Scheme Decision Form *Confidential*

Product	
Company	
Contact Details	

Has the scheme been assessed by the PrescQIPP Governance Review Board?	**Yes/No**
If no, does the scheme fit the locally agreed criteria for being suitable option?	**Yes/No**
Provide a brief summary of the final score; comments and overall status (attach copy of assessment if available):	

Question (if any are ticked 'no' then the scheme is less suitable for rebate authorisation)	**Yes/No**
Is product listed on CCG/Acute Trust Formulary?	
The product is not included in the NHS England Low Priority Prescribing Programme or on the drugs not routinely commissioned locally list?	
The product does not have a negative decision from NICE?	
There is no requirement 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?	
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 the product is a vitamin and classed as a food supplement, is it recommended for use in Wakefield CCG?	
The rebate scheme does not require exclusive use of a specific brand? See principles re: caveats for specific product categories.	
The product is not contained in Category A or M of the Drug Tariff?	
Confirm that the rebate scheme is not linked directly to a requirement for an	

Appendix B - Rebate Scheme Decision Form *Confidential*

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?	

Estimated potential savings (per patient **and** for Wakefield population 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)	

Appendix B - Rebate Scheme Decision Form *Confidential*

CCG Decision

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

Signed: Date:

Name: Title: Head of Medicines Optimisation

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

Signed: Date

Name: Title: Chief Financial Officer

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

Signed: Date

Name: Title: Lay Member

Date sent to Audit committee: