NHS
Coventry and Warwickshire
Integrated Care Board

Policy for Managing Rebates on Prescribed Products in Primary Care

Reference Number:	This will be applied to all new ICB-wide PPSs by the Governance and Corporate Affairs Team and will be retained throughout its life span.
Version:	Version 2.0
Name of responsible Committee and date approved or recommended to Integrated Care Board Board:	Audit Committee
Date approved by the Integrated Care Board (if applicable):	1 July 2022
Next Review Date:	1 April 2025
Expiry Date:	1 October 2025
Name of author and title:	Natasha Jacques, Medicines Optimisation Lead Pharmacist -Primary Care
Name of reviewer and title:	Altaz Dhanani, Deputy Director of Medicines Optimisation
Department:	Corporate Office

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.
01 July 2022	V2	The policy has been amended with key changes to the following; • Addition of scope • Addition of responsibilities • Addition of definitions • Removal of the requirement for the scheme to have received a positive assessment from PrescQIPP. This has been replaced with a detailed assessment proforma (rebate consideration form) to complete for each rebate. • Addition of section on decision making • Addition of related policies • Addition of relevant legislation and guidance	Deputy Director of Medicines Optimisation

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1. Introduction

NHS Coventry and Warwickshire Integrate Care Board ('the ICB') has approved the implementation of prescribing rebate schemes as a means of QIPP savings. This includes helping to prioritise the resources of the medicines optimisation team under the pressures of QIPP and financial turnaround. Retrospective rebates are increasingly being offered by suppliers of products prescribed on FP10 in primary care. This allows suppliers the commercial flexibility to achieve the following:

- Offer NHS organisations a lower price without adjusting list price. This prevents parallel trade and maintains the UK list price as a European reference point.
- Develop a commercial approach specific to individual organisations or groups of organisations.

The concept of rebating is established for some aspects of prescribing, for example, oral nutrition and some secondary care Patient Access Schemes. Manufacturers of new premium price, potentially high-volume medicines are also offering rebates to the NHS which could result in significant cost avoidance or greater access for patients. Rebating is also accepted as normal practice in other countries.

While there are no legal barriers per se, the way in which rebates are handled within an organisation is an important consideration. Risks vary from an organisational 'discomfort' with the concept of rebates to serious breach of European Competition Laws or the Bribery Act. There are, however, potentially significant opportunities to improve the efficient use of the prescribing budget and facilitate access to valuable products for patients. This policy outlines the principles and processes for decision making which will ensure that rebate schemes adhere to the values of the ICB and correspondingly, do not influence clinical decision making.

2. Scope

This policy applies to any member of staff or contractor who work with or for Coventry and Warwickshire ICB who consider sponsorships or rebates from any third party providing the NHS with clinical support. This includes but is not limited to pharmaceutical companies or other organisations providing medications, training, or other services to NHS Trusts within the ICB.

3. Purpose

Rebate agreements usually take the form of legal agreements between the manufacturer and the ICB. It is important that the ICB 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 ICB 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 ICB and for a clear process for approving and scrutinising agreements.

4. Responsibilities

i. All Staff

- Ensure they are familiar with this policy and guidance for working with third party organisations, and with the Standards of Business Conduct ICB Policy
- Comply with professional codes of conduct and guidance for working, including the policies regarding gifts offered to them from third parties
- Declare any conflicts of interest to the legal team, including any gifts offered (accepted or not accepted)

ii. Medicines Management, Legal, Finance, and Governance Teams

- Evaluate all proposed schemes
- Ensure all representatives of the pharmaceutical industry are compliant with the ABPI Code of Practice
- Address any contentious issues or conflicts of interest presented by any proposed schemes
- Monitor Compliance with the policies of any approved schemes
- Maintain the integrity of any approved schemes by ensuring knowledge of rebates is kept separate from prescribing duties
- Assess the evidence base for the medicines, using multiple reliable sources and not relying solely on the pharmaceutical industries evidence.

5. Definitions

ePACT: Electronic Prescribing Analysis and Cost Tool

Pharmaceutical Price Regulation Scheme (PPRS): A policy which balances fair price for the NHS and profit for the pharmaceutical companies, to ensure that the NHS has access to branded medicines for a reasonable price whilst incentivising investment into research in the pharmaceutical sector.

PrescQIPP is a community interest company (a type of social enterprise) that operates on a 'not for profit' basis for the benefit of NHS patients, commissioners and organisations.

QIPP: Quality, Innovation, Productivity, and Prevention

Rebate Agreement: Legal arrangement between the ICB and Pharmaceutical company, whereby the ICB will be granted a refund on a specific medication. This may include a straight discount or a volume-based scheme.

Rebate Scheme: A scheme under which the NHS is charged the drug tariff price for medications dispensed, then the manufacturer issues a rebate to the primary care provider based on an agreed price and data reported from ePACT

Staff: Any and all employees of the Coventry and Warwickshire ICB, including but not exclusive to temporary staff, agency workers and locum staff, Contractors, Governors, and clinical leads.

Straight Rebate: A discount value is calculated the same for each item dispensed, regardless of overall quantity

Volume-based Rebate: Discount value is variable depending on how many items overall are dispensed.

6. Principles for Assessing Rebate schemes

The Medicines Management team will use the Rebate Scheme Consideration Form (Appendix 1) to undertake the assessment of each rebate scheme. This will be used to determine the suitability of taking a rebate scheme to the ICB for consideration and ratification. The following will be used to determine the suitability of taking a rebate scheme for consideration and ratification:

- The main beneficiary must be the patient.
- The purpose of any rebate schemes must be to minimise the ICB's expenditure of its prescribing budget, and any income received from a rebate should be used solely for that purpose.
- Appendix 1: Rebate Scheme Consideration form, must be used when a scheme is being considered.

i. Product Related

- There should be a demonstrable clinical need for the product.
- All products should normally be recommended for prescribing in the ICB and be listed on local Acute Trust formularies where appropriate.
- Any medicine considered under a Primary Care Rebate Scheme 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 Primary Care Rebate Scheme should be included within the relevant chapter of the Drug Tariff
- Vitamins, which are classed as food supplements, should be only those recommended for use by the ICB
- PCRS 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.

ii. Products should not:

- Be included in the Area Prescribing Committee's 'blacklist' that is in operation across Coventry & Warwickshire
- 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.
- A Primary Care Rebate Scheme promoting unlicensed or off label uses will not be entered into. All recommendations for use of a medicine within a Primary Care Rebate Scheme must be consistent with the Marketing Authorisation of the medicine in question.

iii. Rebate Scheme Related

- Any scheme must be offered by the manufacturer and not initiated by the ICB or primary care provider.
- The administrative burden to the ICB 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.
- A volume-based scheme should only be agreed if clinically appropriate. However, the administrative burden of monitoring such a scheme should be carefully considered.
- PrescQipp Pharmaceutical Industry Scheme Governance Review Board assesses some rebate schemes for clinical, financial and contractual issues to support ICB in addressing the risk of perverse incentives from such schemes. Rebate schemes that have been assessed by PrescQipp are preferred, however other schemes will be considered provided the same level of governance can be demonstrated within the scheme.

iv. Schemes should not:

- Short term rebate schemes (less than 1 year) will not normally be considered. It is expected that the reduced price should be available to the ICB over an extended period of time.
- Primary Care Rebate Schemes (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 then an increase in that particular product usage may be seen but individual patient need, and choice where appropriate, must be the driver.
- 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.

- Any rebate scheme must not financially advantage any member of ICB or Primary care staff, practice member, or individual prescriber.
- Any rebate scheme must not bring about any conflict of interest.

7. Decision making

- Rebate schemes will be subject to review using Appendix 1 by the Medicines Optimisation Team
- The Deputy Director of Medicines Optimisation is responsible for deciding if the rebate scheme will be put forward for approval by the ICB's Senior Management Team.
- Once agreed, the ICB Contract Signature Authorisation Form will be completed for final approval by the Chief Financial Officer or nominated deputy.

8. Information and Transparency

- The PCRS will not preclude the ICB 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.
- 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 ICB FOI lead as to what information should be shared.
- Any scheme which requires the details of the PCRS to be kept confidential must not be entered into. All information regarding PCRS will be publishable by the ICB.
- PCRS must not require the provision of information to the manufacturer about competitor products.

9. Freedom of Information

The ICB 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.

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 publicly 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 publicly available and are the subject of confidentiality clauses. The ICB currently benefits from many of these schemes through the prices charged to it for Payment by Results 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 ICB 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.

10. Accountability

The Head of Medicines Optimisation will be responsible for assessing schemes against the principles outlined in section 6 above and to provide a recommendation to the Chief Finance Officer/Deputy Chief Finance Officer with accountability for primary care prescribing, who is responsible for final approval of rebate agreements.

The Chief Finance Officer or deputy is responsible for final approval of rebate agreements on behalf of the ICB.

11. Compliance Monitoring

The Audit Committee will monitor compliance with the policy.

The Medicines Optimisation Team will monitor rebate schemes on the basis that they relate to the ICBs QIPP.

12. Related Policies

Standards of Business Conduct Policy

Fraud, Bribery, and Corruption Policy

13. Relevant Legislation/Guidance

Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry

Equality Act 2010

Freedom of information Act 2000

NHS Birmingham and Solihull ICB Policy for Joint working with the pharmaceutical industry, commercial sponsorship and primary care prescribing rebate schemes 2019

NHS Greater Manchester Joint Commissioning Team Policy for the Ethical Framework for considering Rebate Applications from Pharmaceutical, Nutrition, and Device companies 2019

NHS Terms and conditions of Service 2018

14. Equality Impact Assessment (EIA)

Policy/Service	Policy for managing rebates on prescribed products in Primary	**Person completing EIA**	Natasha Jacques – Arden & GEM CSU
Date of EIA	March 2022	**Accountable ICB Lead**	Altaz Dhanani

Aim of Work	The Public Sector Equality Duty (PSED) requires us to eliminate discrimination, advance equality of opportunity, and foster good relations with protected groups. This EIA assesses the impact of the policy on protected groups.

Protected Group	Likely to be a differential impact?	Protected Group	Likely to be a differential impact?
Age	No	**Race**	No
Disability	No	**Religion or belief**	No
Gender reassignment	No	**Sex**	No
Marriage and civil partnership	No	**Sexual orientation**	No
Pregnancy and maternity	No		

Describe any potential or known adverse impacts or barriers for protected/vulnerable groups and what actions will be taken (if any) to mitigate. If there are no known adverse impacts, please explain.

The impact of this policy has been discussed at length by the Coventry and Warwickshire Joint Policy Development group and all protected characteristics and Human Rights values given due regard and only patient demographic issues that could impact on individual risk and/or clinical effectiveness were taken into account when reaching a decision.

Since ICBs operate within finite budgetary constraints the policies detailed in this document make explicit the need for the ICB to prioritise resources and provide interventions with the greatest proven health gain.

The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.

The impact of this policy has been considered against all protected characteristics and human rights principles; the review identified the protected characteristics of age, disability and pregnancy/maternity as most likely to be affected by the policy where certain cohorts within these groups may be exempt from prescription payments.

Please summarise where further action is required and when the projects/decision will be reviewed.
The policy will be reviewed as and when new evidence or guidance is published and by no longer than three years after ratification by the ICB Board.

Appendix 1

Rebate Scheme Consideration Form

Product: ……..

Company Name: ……..

Contact details: ……

……..

Product:

Question (Grey shading suggests less suitability)	Yes	No
Is the product listed on the ICB/Trust formulary?		
Is the product licenced for use in the UK?		
Is the product listed in the Drug Tariff?		
Is the product listed in category A or M of the Drug Tariff?		
Does the product have a negative decision from NICE?		
Is the product listed on the APC blacklist?		
If the product is a vitamin or food supplement, is it recommended for use in Coventry and Warwickshire ICB?		
Is there a requirement for a directive or guideline for health care professionals to prescribe the product?		
Is the scheme designed to increase off-label use of the product?		

Scheme:

Question (Grey shading suggests less suitability)	Yes	No
Is the company a member or the ABPI?		
Does the scheme require exclusive use of a specific brand?		
Is the rebate scheme directly linked to an increase in volume of prescribing or increase in market share?		
Is the rebate scheme PrescQIPP approved?		
Does the scheme prevent consideration of other schemes?		
Does the scheme require collection of patient specific information?		
Is there a requirement for more information beyond the volume of product prescription?		
Is more information required than that derived from ePACT??		
Is the scheme available for ONE year or more?		
Does the scheme place any unacceptable obligations on the ICB?		
Does the scheme affect FOI requests or how FOI requests are handled?		
Are there any penalty clauses?		
Can the ICB exit the arrangement without penalty?		

Could the scheme be considered anti-competitive?		
Does the scheme limit the ICBs freedom in any way?		
Does the scheme limit communication with stakeholders?		

Clinical Suitability:
Estimated Potential savings:
Any issues or concerns identified during evaluation?
Further information:
Recommendation:
Rationale:
Completed by: …… **Date:……**