NHS
Warwickshire North
Clinical Commissioning Group

NHS
Coventry and Rugby
Clinical Commissioning Group

Policy for Approving Pharmaceutical Industry Rebate Schemes

VERSION CONTROL

Version:	1.0
Ratified by:	Governing Body Meetings in Common
Date ratified:	Warwickshire North CCG – 9 May 2018 Coventry and Rugby CCG – 17 May 2018
Name of originator/author:	Altaz Dhanani - Head of Medicines Optimisation
Name of responsible committees:	Audit Committees
Date issued:	17 May 2018
Review date:	May 2021

VERSION HISTORY

Date	**Version**	**Comment / Update**
9 May 2018	1.0	Approved by Warwickshire North CCG Governing Body
17 May 2018	1.0	Approved by Coventry and Rugby CCG Governing Body

Contents

1.0 Introduction

The CCG 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 CCG and correspondingly, do not influence clinical decision making.

2.0 Purpose

Rebate agreements usually take the form of legal agreements between the manufacturer and CCG. It is important that both Coventry & Rugby CCG and Warwickshire North 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 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.

3.0 Principles for Assessing Rebate schemes

The following will be used to determine the suitability of taking a rebate scheme to Coventry & Rugby and Warwickshire North CCGs 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 Coventry & Rugby and Warwickshire North CCGs and be listed on local Acute Trust formularies where appropriate.

- Products should not:
    - Be included in the Area Prescribing Committee's 'black List' 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.

- 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.

- 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.

3.2 Rebate Scheme Related

- 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. 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 Coventry & Rugby and Warwickshire North CCGs.

- 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 and some medicines in Category A 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.

- 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 CCG over an extended period of time.

3.3 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 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 CCG FOI lead as to what information should be shared.

4.0 Freedom of Information

Coventry & Rugby and Warwickshire North CCGs support 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 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. Coventry & Rugby and Warwickshire North CCGs currently benefits from many of these schemes through the prices charged to it 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.

Coventry & Rugby and WN 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.

5.0 Accountability

The Head of Medicines Optimisation will be responsible for assessing schemes against the principles outlined in section 3 above and to provide a recommendation to the Chief Finance Officer.

The Chief Finance Officer is responsible for final approval of rebate agreements on behalf of Coventry & Rugby and Warwickshire North CCGs.

6.0 Compliance Monitoring

The Audit Committee will monitor compliance with the policy.

The PMO will monitor rebate schemes on the basis that they relate to the CCGs QIPP.