NHS
Staffordshire and Stoke-on-Trent
Integrated Care Board

Approving and Managing Primary Care Pharmaceutical Rebate Schemes Policy

Policy Folder & Policy Number	Commissioning
Version:	V2
Ratified by:	Staffordshire & Stoke-on-Trent CCGs Governing Body in Common
Date ratified:	28/10/2021
Name of originator/author:	Claire Dearden Medicines Optimisation Delivery Manager Amin Mitha, Head of Medicines Optimisation
Name of responsible committee/individual:	Finance & Performance
Date approved by Committee:	26/10/2021
Date issued:	01/11/2021
Review date:	Three years from issue date unless significant changes are required
Date of first issue	13/11/2019
Target audience:	Organisation wide

CONSULTATION SCHEDULE

Name and Title of Individual	Groups consulted	Date Consulted
Paul Winter Deputy Director of Corporate Services & Governance	Governance Team	December 2019 V1.0
	Joint Medicines Optimisation Group	13/11/2019 V1.0
	Pharmaceutical Rebate Task and Finish group	28/09/2021 V1.1
Samantha Bostock RSM UK Risk Assurance Services LLP		21/07/2022 V2

APPROVALS & RATIFICATION SCHEDULE

Name of Committee approving Policy	Date
Finance & Performance Committee / v1.0	28th January 2020
Finance & Performance Committee / v1.1	26th October 2021
Staffordshire & Stoke-on-Trent CCGs Governing Body in Common / v1.1	28th October 2021

VERSION CONTROL

Version	Version/Description of amendments	Date	Author/amended by
1	First draft	13/11/19	Amin Mitha Claire Dearden
1.1	Second version CFO- changed to Deputy Director of Finance – Commissioning and Financial Management JMOG changed to Pharmaceutical Rebate Task and Finish group Appendix A updated with RAG rating on administration time involved and outcome log	11/08/21	Claire Dearden
2	Adapted for use of the ICB Finance Job role titles changed	July 2022	Claire Dearden

Impact Assessments – available on request

	Stage	Complete	Comments
Equality Impact Assessment	Stage 1 Approved	01/04/2019	
Quality Impact Assessment			Not applicable confirmed by Quality Team 24/09/19
Privacy Impact Assessment			Not applicable

Contents

1. Introduction

Primary care pharmaceutical rebate schemes (PCPRS) are contractual arrangements offered by pharmaceutical companies or third-party companies, which offer financial rebates on GP prescribing expenditure for branded medicine(s) and other products. Such schemes are offered as a matter of course to Clinical Commissioning Groups/ Integrated Care Board by the pharmaceutical industry as a means to introduce new drugs into the NHS, or more simply as a tool to increase/ establish market share of existing/new medicine(s).

This policy provides a framework for managing PCPRS in a legal and ethical way. It forms the basis of the process that Staffordshire and Stoke-on-Trent (SSOT) Integrated Care Board (ICB) use to evaluate rebate schemes so that they are only signed off where they provide good value for money to the public purse and the scheme's terms are in line with organisation vision, values, policies, and procedures. The policy also provides assurance that the ICB is transparent in its process for considering these schemes.

2. Scope

This policy should be used in conjunction with the following policies which have been adopted by the ICB:

- Gifts and Hospitality Policy
- Commercial sponsorship Policy
- Anti- fraud and Anti- bribery Policy
- Business Ethics Policy
- Prime Financial Policies and Scheme of Delegation (Policy No 4.27)
- Records Management Policy
- Conflicts of Interest Policy

3. Principles for Assessing Rebate Schemes

3.1. Overarching Principles

It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS. However, within the NHS there is general acceptance by commissioners and providers alike that on occasions there are commercial barriers for manufacturers to change the published price, and so instead they prefer to use the rebate scheme as a way of reducing the effective price of a medicine available for use in the NHS.

The acceptance of a scheme should not constrain existing local decision-making processes or formulary development. This is in line with Dept of Health document (gateway reference 14802) on Strategies to Achieve Cost-Effective Prescribing (2010). This states that the following principles should underpin local strategies:

- The decision to initiate treatment or change a patient's treatment regime should be based on up-to-date best clinical evidence or guidance, e.g., from the National Institute for Health and Clinical Excellence (NICE) or other authoritative sources.

- Health professionals should base their prescribing decisions on individual assessments of their patients' clinical circumstances, e.g., patients whose clinical history suggests they need a particular treatment should continue to receive it.

- The individual patient (and their guardian or carer where appropriate) should be informed about the action being taken and suitable arrangements should be made to involve the patient, ensuring they have an opportunity to discuss a proposed switch of medicines, and to monitor the patient following any switch.

- Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money.

- Schemes should be reviewed whenever relevant NICE or alternative guidance are updated. (See section 5.4)

- Scheme terms will be published on the SSOT ICB website.

3.2. Good Practice Principles

In addition to ensuring that particulars of a PCPRS do not contravene the overarching principles mentioned above, SSOT ICB will adopt the following good practice principles when deciding whether it participates in a PCPRS or not:

3.3. Product Related

PCPRS will only be considered for those medicines which are already commissioned and included in the local formulary and its place in a care pathway has already been established through normal SSOT ICB Governance.

SSOT ICB will consider PCPRS for products that are not medicines but used in medical conditions such as devices and nutritional products provided these products meet requirements of relevant national and local clinical guidelines. These products should be available for prescribing as per the Drug Tariff.

The price of a medicine or product will be considered but this consideration will be secondary to the clinical need for the medicine/product and its place in established pathways.

SSOT ICB will not consider or promote unlicensed, or ‘off-label’ uses of medicines as part of a PCPRS. Furthermore, a PCPRS must be linked with a drug and not limited to particular indications for which that drug can be used, and in line with the Specific Product Characteristics (SPC) for the drug in question.

PCPRS for medicines or products not recommended by NICE and not approved by the local formularies will not be entered into.

PCPRS are not appropriate for medicines in Category M and some medicines in Category A of the Drug tariff, because of the potential wider impact on community pharmacy reimbursement. Advice should be sought from the Head of Medicines Optimisation for any Category A medicines.

Products should be available through normal supply channels and not require special procurement or place extra financial burden on community pharmacies when trying to acquire the necessary stock.

3.4. Rebate Scheme Related

PrescQIPP Pharmaceutical Industry Scheme Governance Review Board (PRISGB) regularly assesses pharmaceutical schemes on financial and contractual basis, and regarding any clinical implications. SSOT ICB will consider any PRISGB assessments in its decision-making process.

PCPRS should not be linked directly to requirements to increase market share or volume of prescribing.

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

All negotiations around a scheme should be expressed as being "subject to contract" i.e., not binding until the formal contract has been signed by both parties.

SSOT ICB will not enter into any PCRS which precludes them from considering any other schemes subsequently offered by manufacturers of competitor drugs/products, should they wish to do so. These PCRS should all be considered using the same criteria.

All PCRS agreements must meet the requirements of the Data Protection Act, General Data Protection Regulation and patient confidentiality must never be compromised.

Individual contracts will contain details of any confidentiality agreements, but such agreements must not preclude the sharing of information, including discounts and scheme details, within the wider NHS.

PCPRS agreements should include a right to terminate on notice (i.e., without having to have any reason for doing so) with a sensible notice period e.g., three or six months. The need for exit criteria and an exit strategy should be considered before a scheme is agreed. It is essential to allow flexibility to respond to emergence of significant new clinical evidence, or significant changes in market conditions. A shorter notice period should be agreed in these circumstances

4. Roles and Responsibilities

Director of Operational Finance

- Provides oversight of all aspects of this policy to ensure organisational compliance.
- Is authorised to sign contract of behalf of the ICB. (See section 5.1)

Deputy Director of Corporate Services & Governance

- Provides governance and corporate oversight for this policy.

Head of Medicines Optimisation

- Ensures that due process is followed for assessment of new schemes and renewal of any existing schemes.
- Ensures this policy is adhered to in all decisions relating to acceptance or refusal of PCPRS.

- Provides pharmaceutical oversight for this policy.

Medicines Optimisation Delivery Manager

- Key contact for all PCPRS agreements.
- Monitoring (see section 5.4).
- Preparation of PCPRS application papers.
- The Medicines Optimisation Delivery Manager will be accountable for operational management of the process for approving PCPRS, from identification through to implementation and review of PCPRS agreements.

Medicines Optimisation Data Analyst

- Ensures rebates are claimed in a timely fashion.

ICB Finance Team / Shared business service

- Ensures rebates are claimed and invoiced in a timely fashion.

Pharmaceutical Rebate Task and Finish group

Assesses rebate schemes against the policy principles and makes recommendations.

Attendance (or nominated deputes for Medicine Head of Medicines Optimisation, Deputy Director of Corporate Services & Governance and Director of Operational Finance):

- Director of Operational Finance.
- Deputy Director of Corporate Services & Governance.
- Head of Medicines Optimisation.
- Medicines Optimisation Delivery Manager.
- Lay Member; and
- Clinical Primary Care Representative.

5. Process for the Assessment, Approval and Management of Rebate Schemes

5.1. Assessment and Approval

- The Head of Medicines Optimisation and the Medicines Optimisation Delivery Manager will ensure that contractual papers and briefing summaries on PCPRS are tabled at Pharmaceutical Rebate Task and Finish group meetings in timely manner.

- Conflicts of interest will be declared and noted in the minutes of the meeting.

- Pharmaceutical Rebate Task and Finish group will assess any PCPRS on offer in line with principles stated above (An assessment form for this purpose is attached in Appendix A).

- The Director of Operational Finance will be responsible for approving and signing the contracts based on recommendation from the Pharmaceutical Rebate Task and Finish group.

5.2. Use of Rebate Income

Oversight for any spending plans, redistribution of funds and control of destination budgets will be provided by the Director of Operational Finance. Generally, the rebate income is used to offset any financial deficit in the prescribing budget.

5.3. Information Governance

- Contracts will be held in accordance with the Records Management Policy.
- There will be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.
- SSOT ICB 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 (FOI). The ICB will publish its policy for accepting rebate agreements along with the list of products for which rebate agreements exist on its public facing website.
- As part of the FOI process any decision from the Information Commissioners Officer to disclose information will be adhered to.
- SSOT ICB will ensure that all PCRS agreements meet the requirements of the Data Protection Act and the General Data Protection Regulation.

5.4. Monitoring

- The Medicines Optimisation Delivery Manager will ensure that rebates are being processed at agreed intervals.
- The Head of Medicines Optimisation and the Medicines Optimisation Delivery Manager will conduct annual review of the schemes considering factors such as any recent relevant clinical guidance, entry of a new product or any other relevant clinical developments.
- The Medicines Optimisation Delivery Manager will liaise with the pharmaceutical companies on review of schemes which are due to expire within three months. To obtain a contract renewal which will be signed by Director of Operational Finance.

6. Policy Development

6.1. Equality and Diversity

This policy has been assessed in relation to having due regard to (1) the public sector equality duty (PSED) three aims, dropping down from the Equality Act 2010 to: eliminate discrimination, harassment victimisation; advance equality of opportunity; and foster good relations", (2) The Health & Social Care Act 2012 re evidencing showing due regard to reducing health inequalities between the people of England.

6.2. Legal Advice

Legal advice was sought by the London Procurement Partnership in 2012 to address the issue of legality of PCPRS. The conclusion of legal scrutiny was that although it was not unlawful for primary care organisations to enter PCPRS agreements, it was important that policies and procedures were in place to allow for robust scrutiny and identification, adoption, and implementation of rebates schemes. On the back of legal advice and consultation with stakeholders the London Primary Care Medicines Use and Procurement QIPP Group produced guidance for primary care commissioning organisations on principles and legal implications to consider when drawing up a policy on dealing with rebates. PISGRB has also produced similar guidance considering the legal advice. This policy is in line with guidance produced by the aforementioned organisations.

6.3. Stakeholder Engagement

The Pharmaceutical Rebate Task and Finish Group is a multidisciplinary group and has considered, amended, and endorsed this policy.

7. Approval and Ratification process for the Policy

- Pharmaceutical Rebate Task and Finish group.
- Finance and Performance Committee; and
- Ratified by the Staffordshire & Stoke-on-Trent CCGs Governing Body in Common.

8. Policy review

This policy will be reviewed by a period of no longer than three years as stated or in response to any relevant changes in local and/or national policies and guidance, whichever is sooner.

9. References

Principles and Legal Implications of Primary Care Rebate Schemes 2012. London Procurement Partnership.
http://www.lhttp://www.lpp.nhs.uk/page.asp?fldArea=2&fldMenu=6&fldSubMenu=7&fldKey=271pp.nhs.uk/page.asp?fldArea=2&fldMenu=6&fldSubMenu=10&fldKey=252

Strategies to Achieve Cost-effective Prescribing. DH Gateway Reference 14802.
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_120213.pdf

Principles of Governance of Primary Care Rebates for Commissioners
https://www.prescqipp.info/media/3638/principles-of-governance-of-primary-care-rebates-for-commissioners.pdf

Appendix A: Primary Care Pharmaceutical Rebate Scheme Assessment Template

Date assessed by Pharmaceutical Rebate Task and Finish group:

Product:

Potential value of the rebate:

1. Is the product in the local formularies? What is the status of the product in the formulary?
2. For non-formulary products: (a) is the product commonly used? (b) is the product backed by any national and professional clinical guidelines?
3. What is the Drug Tariff status for the product?
4. Is the product available through normal wholesaler and pharmacy channels?
5. Has the product been assessed by the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board? If so, what was the recommendation?
6. Does the scheme require increase in volume of prescribing or market share?
7. Does the scheme prohibit in any way use of competitor products or require affording any special status to the scheme product? Consider any contract clauses that impose restrictions on the ICB entering any future schemes?
8. What data must be submitted as part of the scheme to claim the rebate?
9. What are the contractual exit arrangements for both parties? Are these arrangements acceptable?
10. Are there sufficient details to support FOI enquiries?
11. Does the contract allow for communication to all relevant stakeholders?
12. Does the scheme meet requirements of the General Data Protection Regulation?
13. How much administration is required to manage the scheme?

RAG rating	Detail	Cost/hours
Green -limited resources needed	Third party company or pharma company generates prescribing data and pays straight into ICB bank account.	4hrs per quarter - £80 = £320 per year
Amber 1 – some resources needed	Third party company or pharma company generates prescribing data – ICB inform Finance to invoice	6hrs per quarter - £120= £480 per year
Amber 2– some resources needed	ICB generates prescribing data, checks with company and company pays straight into ICB bank account	8hrs per quarter - £160= £640 per year
Red -extensive resources needed	ICB generates prescribing data, checks with company, and then informs Finance to invoice	15hrs per quarter - £300= £1200 per year Plus, finance ICB time

Financial threshold vs time	Financial threshold £3,000	RAG rating for this agreement	*To be completed*

Copy of the contracts: *PDF or word documents to be embedded here*

Overall decision and comments

Corporate and Governance approval	
Finance approval	
Medicines Optimisation approval	
Date of meeting	xxx/xx/xxxx