

# POLICY ON PRIMARY CARE REBATE SCHEMES (PCRS)

## DECEMBER 2016

<b>Authorship :</b>	Laura Angus NHS Vale of York CCG, Lead Pharmacist
<b>Reviewing Committee(s) :</b>	Audit Committee
<b>Date :</b>	23 August 2016, 22 September 2016, 28 September 2016, 26 September 2019
<b>Approval Body :</b>	Audit Committee
<b>Approved Date :</b>	22 September 2016
<b>Review Date :</b>	March 2021
<b>Equality Impact Assessment :</b>	Yes
<b>Sustainability Impact Assessment :</b>	Yes
<b>Related Policies</b>	<ul style="list-style-type: none"> <li>• Sponsorship Policy</li> <li>• Business Conduct Policy</li> <li>• Local Anti-Fraud, Bribery and Corruption Policy</li> <li>• Freedom of Information Policy</li> <li>• Conflict of Interests Policy</li> </ul>
<b>Target Audience :</b>	Governing Body and its Committees and Sub-Committees and CCG Staff
<b>Policy Reference No. :</b>	FIN04
<b>Version Number :</b>	V1.5

## POLICY AMENDMENTS

Amendments to the Policy will be issued from time to time. A new amendment history will be issued with each change.

New Version Number	Issued by	Nature of Amendment	Approved by and Date	Date on Intranet
1.0	NHS Vale of York CCG Prescribing Team	New Policy	Quality and Finance Committee 22 September 2016	29 September 2016
1.1	NHS Vale of York CCG Prescribing Team	Flow chart for approval now includes Quality and Finance Committee – see 6.2 and Appendix 3.		
1.2	HaRD MMT	Amendment to terms, flowchart, appendix 3 and narrative when affected by appendix 3 changes		
1.3	HaRD MMT	Incorporation of contracting team into process	Finance and Performance Committee 26 January 2017	14 March 2017
1.4	HaRD MMT	Incorporation of communications team into process, review of flowchart	This amendment approved by Audit Committee 26 April 2017	09 May 2017
1.5	NHS Vale of York CCG Prescribing Team	Amendments to terms and flowchart. Removal of Finance and Performance Committee from the process.	This amendment approved by Audit Committee 26 September 2019	

To request this document in a different language or in a different format, please contact NHS Vale of York CCG on :

01904 555 870

or

[valeofyork.contactus@nhs.net](mailto:valeofyork.contactus@nhs.net)

## Table of Contents

<b>1. INTRODUCTION</b>	<b>4</b>
<b>2. POLICY STATEMENT</b>	<b>4</b>
<b>3. IMPACT ANALYSES</b>	<b>4</b>
3.1. EQUALITY	4
3.2. SUSTAINABILITY	4
3.3. SCOPE	4
<b>4. POLICY PURPOSE/AIMS &amp; FAILURE TO COMPLY</b>	<b>4</b>
<b>5. PRINCIPLE LEGISLATION AND COMPLIANCE WITH STANDARDS</b>	<b>5</b>
5.1. LEGAL ADVICE	5
5.2. OVERARCHING PRINCIPLES	5
5.3. GOOD PRACTICE PRINCIPLES FOR PRIMARY CARE REBATE SCHEMES	5
5.4. INTERFACE WITH THE PHARMACEUTICAL INDUSTRY	7
5.5. CONTRACTS	7
5.6. ACCOUNTABILITY	8
5.7. CONFLICT OF INTERESTS	8
5.8. INFORMATION GOVERNANCE	8
5.9. SHARING OF INFORMATION WITH PRESCRIBERS AND OTHER STAKEHOLDERS	8
5.10. THE FREEDOM OF INFORMATION ACT 2000	9
5.11. FREEDOM OF INFORMATION REQUESTS	9
5.12. USE OF REBATES	9
<b>6. ROLES &amp; RESPONSIBILITIES</b>	<b>9</b>
6.1. MEDICINES MANAGEMENT TEAM PHARMACIST	9
6.2. CONTRACTING TEAM	9
6.3. CHIEF FINANCE OFFICER	10
6.4. AUDIT COMMITTEE	10
<b>7. POLICY IMPLEMENTATION</b>	<b>10</b>
<b>8. TRAINING &amp; AWARENESS</b>	<b>10</b>
<b>9. MONITORING &amp; AUDIT</b>	<b>10</b>
9.1. MONITORING & ACCOUNTABILITY	10
<b>10. POLICY REVIEW</b>	<b>10</b>
<b>11. REFERENCES</b>	<b>10</b>
<b>12. ASSOCIATED POLICIES</b>	<b>11</b>
<b>13. CONTACT DETAILS</b>	<b>11</b>
<b>14. APPENDIX 1: EQUALITY IMPACT ANALYSIS FORM</b>	<b>12</b>
<b>15. APPENDIX 2: SUSTAINABILITY IMPACT ASSESSMENT</b>	<b>16</b>
<b>16. APPENDIX 3 OPERATING PROCEDURES</b>	<b>21</b>

## **1. Introduction**

1.1 A number of manufacturers have established 'rebate schemes' for products used in primary care. Under the terms of such a scheme, the NHS is charged the Drug Tariff price for primary care prescriptions dispensed, the manufacturer then provides a rebate to the primary care organisation based on an agreed discount price and verified by ePACT data. Such schemes are being offered to Clinical Commissioning Groups by the pharmaceutical industry in relation to named products

## **2. Policy Statement**

2.1 NHS Vale of York Clinical Commissioning Group aspires to the highest standards of corporate behaviour and responsibility. It is the role of NHS Vale of York Clinical Commissioning Group to manage the local medicines bill, to ensure the most clinically appropriate, cost effective and safe use of medicines across the locality.

## **3. IMPACT ANALYSES**

### **3.1. Equality**

3.1.1. As a result of performing the screening analysis, the policy does not appear to have any adverse effects on people who share Protected Characteristics and no further actions are recommended at this stage. The results of the screening are attached.

### **3.2. Sustainability**

3.2.1. A Sustainability Impact Assessment has been undertaken. One positive impact was identified within the twelve sustainability themes. The results of the assessment are attached.

### **3.3. Scope**

3.3.1. This policy applies to NHS Vale of York Clinical Commissioning Group and all of its employees, members of the CCG, co-opted members, members of the Governing Body and its committees. All must comply with arrangements outlined in this policy.

3.3.2. The scope of this document is to establish a policy to define the criteria for acceptance or refusal of rebates.

## **4. POLICY PURPOSE / AIMS AND FAILURE TO COMPLY**

4.1 General Rebate agreements usually take the form of legal agreements between the manufacturer and Clinical Commissioning Group. It is important that NHS Vale of York Clinical Commissioning Group has a policy to support evaluation and sign off of rebate schemes to ensure that each scheme is only signed off if it provides good value for money to the public purse and its terms are in line with organisation vision, values, policies and procedures and to ensure that NHS Vale of York Clinical Commissioning Group is transparent in its process for considering these schemes. This policy provides a framework for managing rebates in a legal and ethical way. The principles outlined in this policy document allow for the objective evaluation of schemes submitted to NHS Vale of York Clinical Commissioning Group and a clear process for approving and scrutinising agreements.

## 5. PRINCIPLE LEGISLATION AND COMPLIANCE WITH STANDARDS

### 5.1. Legal Advice

5.1.1. Legal advice sought by the London Procurement Partnership (LPP) concluded that primary care rebate schemes are not unlawful and are within the powers of Clinical Commissioning Groups to agree to, provided they meet certain requirements. The detailed legal advice obtained by the London Procurement Partnership has been shared within the NHS<sup>1</sup>. It is accepted that NHS Vale of York Clinical Commissioning Group may wish to take further legal advice on any point identified on the content of any particular scheme prior to entering into any agreement.

### 5.2. Overarching Principles

5.2.1. It is preferable for pharmaceutical companies to supply products to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS. Any products should only be agreed for use within a rebate scheme if it is believed to be appropriate for a defined cohort of patients within a population. It is important that all patients continue to be treated as individuals, and acceptance of a scheme should not constrain existing local decision making processes or formulary development. This is in line with DH document (gateway reference 14802) on Strategies to Achieve Cost-Effective Prescribing (2010)<sup>2</sup>. 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 prescribed [product], and to monitor the patient following any switch;
- Prescribers should be able to make their choice of [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.
- Scheme details ie: date of commencement, company and item involved should be published on the Clinical Commissioning Group's website.

### 5.3. Good Practice Principles for Primary Care Rebate Schemes

5.3.1. The detailed content of primary care rebate schemes offered to primary care organisations will differ between schemes. Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources. These Good Practice Principles can help the Clinical Commissioning Group in assessing these schemes, the Clinical Commissioning Group will need to be assured that the schemes offered do not breach any other UK legislation, in particular, reimbursement for pharmaceutical services according to the Drug Tariff, duty to comply with the DH's controls on pricing

NHS Vale of York Clinical Commissioning Group  
POLICY ON PRIMARY CARE REBATE SCHEMES (PCRS)  
made under the 2006 Act, the Medicines Act, the Human Medicines Regulations 2012,  
the Bribery Act, EU law and the public law principles of reasonableness and fairness  
(see section 5.1 – Legal Advice - above).

5.3.2. NHS Vale of York Clinical Commissioning Group will adopt the following principles when deciding whether to participate in a PCRS or not:

#### 5.3.2.1. Product Related

- PCRS will only consider a product that is on the York and Scarborough Joint Formulary.
- The price of the product will be considered but this consideration will be secondary to the clinical need for the medicine and its place in established pathways.
- Health professionals should always base their prescribing decisions primarily on assessments of the individual patient's clinical circumstances.
- The Clinical Commissioning Group will not consider or promote unlicensed or 'off-label' uses of products as part of a PCRS. Furthermore, a PCRS for a drug or product must be linked to total use of that 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.
- All recommendations for use of a product within a PCRS must be consistent with the UK Marketing Authorisation of the product in question, i.e. the PCRS should only advocate the use of a drug in line with the data sheet / Specific Product Characteristics (SPC) for the drug in question.
- Consideration should be given as to whether an increase in the use of the item would be in line with the NHS Vale of York Clinical Commissioning Group's clinical direction for that item.
- When NICE actively does not recommend a product that product will not be considered under a PCRS.
- Any product rejected by the NHS Vale of York Clinical Commissioning Group Medicines Commissioning Committee will not be considered under a PCRS.
- PCRS are not appropriate for products in Category M and some in Category A of the Drug tariff because of potential wider impact on community pharmacy reimbursement. Advice should be sought from the senior member of the Medicines Management Team\* for any Category A products.
- (\*the Medicines Management Team is hosted by Harrogate and District Clinical Commissioning Group and is a shared service across the North Yorkshire CCGs)

#### 5.3.2.2. Rebate Scheme Related

- Any and all decision making processes will be clinically-led and involve all appropriate stakeholders, including patients where appropriate.
- PCRS should not be linked directly to requirements to increase market share or volume of prescribing
- Rebate schemes should be approved through robust local governance processes that include review of appropriateness by a senior member of the Medicines Management Team, including Prescipp evaluation if available, a review of the contract by the contract team and final approval by the Chief Finance Officer – see Appendix 3 -Primary Care Rebate Scheme Approval Process Flow Chart
- A minimum threshold of £250 saving per annum should be applied as a part of determining whether the rebate is appropriate to take to a committee. The Medicines Management Team will consider whether rebates with a higher value are appropriate.

- There is a clear requirement for suppliers to promote products in an ethical manner to prescribing practitioners within the Clinical Commissioning Group. In order to ensure prescribing practitioners are not influenced by PCRS agreements they should not be discussed, referred to or promoted in any way by suppliers.
- 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.
- PCRS 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.

#### **5.4. Interface with the Pharmaceutical Industry**

- 5.4.1. The Clinical Commissioning Group must be able to demonstrate that all suppliers wishing to offer rebates are provided with equal access. When appointments to discuss a rebate offer are requested, the supplier should be provided with a copy of this policy. Meetings to discuss rebates should be attended by a senior member of the Medicines Management Team.
- 5.4.2. Suppliers should not make guideline or formulary positioning conditional to any rebate offer. Equally, the Clinical Commissioning Group must not offer or expect any favourable positioning of a product with respect to the local formulary in return for a rebate offer. To avoid misunderstandings, meetings pertaining to rebates must not consider formulary or guidelines status, positioning relative to competitor products or any other actions resulting from the rebate offer. This includes the execution of any medicines change programmes by the Clinical Commissioning Group. Suppliers must not discuss any potential joint working arrangements, medical education goods and services, sponsorship offers or patient support programmes. Exceptions are where these elements are explicitly part of the commercial offer and are included in a legal contract.
- 5.4.3. In the event of the above not being adhered to in a meeting, the meeting must be terminated immediately and the incident reported to the Accountable Officer and Chair of the Audit Committee to ascertain appropriate action.

#### **5.5. Contracts**

- 5.5.1. NHS Clinical Commissioning Group Chief Finance Officer and the contracting team must ensure that a formal written contract is in place, signed by both parties to ensure:
  - The terms of the scheme are clear
  - Legal protection is maximised.
- 5.5.2. 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.
- 5.5.3. PCRS 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.

5.5.4. PCRS agreements should include a clause stating the time frame from the date the scheme contract is signed by the Vale of York Clinical Commissioning Group eg: the start of the next calendar month.

5.5.5. Freedom of Information requirements (see section 5.14 - Information Governance) should be discussed with the manufacturer before a commissioner enters into any agreement with them and should be contained in the contract.

## **5.6. Accountability**

5.6.1. The Medicines Management Team will be responsible for assessing schemes against the principles outlined in section 5 above. The 'Rebate Scheme Decision Form' (Appendix 3) will be used to record assessment against the principles and provide a recommendation to the Chief Finance Officer, who is responsible for final approval of rebate agreements on behalf of NHS Vale of York Clinical Commissioning Group.

## **5.7. Conflict of Interests**

5.7.1. NHS Vale of York Clinical Commissioning Group acknowledges that there is a potential conflict of interest with signing up to rebates in primary care with the GPs being both the prescribers and the commissioners and that PCRS could be seen to undermine national pricing agreements between the Department of Health and industry. However, measures have been taken to ensure that NHS Vale of York Clinical Commissioning Group enters into rebate schemes that have been independently assessed as being appropriate, so that the NHS can benefit from the cost-efficiencies that the schemes offer. Full rebate scheme paperwork will be provided to the audit committee, where no clinicians will be present, ensuring no potential for conflict of interest. This policy should be read in conjunction with NHS Vale of York Clinical Commissioning Group's Conflicts of Interest Policy.

## **5.8. Information Governance**

5.8.1. NHS Vale of York Clinical Commissioning Group 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. NHS Vale of York Clinical Commissioning Group will publish its policy for accepting rebate agreements under policies along with the list of products for which rebate agreements exist on its publically available website.

5.8.2. Whilst manufacturers often attempt to impose requirements for confidentiality that would restrict NHS Vale of York Clinical Commissioning Group from disclosing the existence and level of any discount to any third party, NHS Vale of York Clinical Commissioning Group recognise that such agreements are likely not to be in the interests of the NHS. This is on the basis both that it will compromise the ability of NHS Vale of York Clinical Commissioning Group to evaluate whether it is obtaining the best possible terms and that in the medium to longer term it is likely to lead to price inflation.

5.8.3. NHS Vale of York Clinical Commissioning Group will ensure that all PCRS agreements meet the requirements of the Data Protection Act, and patient confidentiality must never be compromised.

## **5.9. Sharing of Information with prescribers and other stakeholders**



5.9.1. 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.

## **5.10. The Freedom of Information Act 2000**

5.10.1. The Freedom of Information Act 2000 provides the right of public access to information held by public authorities. The main principle behind freedom of information legislation is that people have a right to know about the activities of public authorities, unless there is a good reason for them not to. This may be described as a presumption or assumption in favour of disclosure. The NHS Vale of York Clinical Commissioning Group fully supports the principle of openness and accountability.

5.10.2. There may be occasions where specific information requested is considered to be exempt under Section 43 'Commercial Interests' of the Freedom of Information Act. Some information appertaining to rebate agreements may meet the criteria advised by the Information Commissioner's Office as being 'Commercial in Confidence.' This exemption would only be applied where the information requested would be considered to prejudice the commercial interests of the company to which it relates. This would be decided on a case by case basis.

## **5.11. Freedom of Information Requests**

5.11.1. NHS Vale of York Clinical Commissioning Group supports the principle that openness should be the norm in public life. Any decision from the Information Commissioners Office to disclose information must be adhered to.

## **5.12. Use of Rebates**

5.12.1. It is vital that any funds received by NHS Vale of York Clinical Commissioning Group as part of a rebate are managed in a transparent, legal and ethical way. As a rebate, the funds will initially and primarily be returned to the CCG prescribing budget as a credit to expenditure. The finance team will report on any spending plans, redistribution of funds and control of destination budgets. Audit Committee will have oversight of any spending plans, redistribution of funds and destination budgets.

5.12.2. No one individual should be in a position to benefit personally from the level of rebate received by NHS Vale of York Clinical Commissioning Group.

5.12.3. PCRS should not be linked to any current or future prescribing incentive schemes, indicative prescribing budget arrangements or prescribing gain share agreements.

# **6. ROLES AND RESPONSIBILITIES**

## **6.1. Medicines Management Team Pharmacist**

6.1.1. The Medicines Management Team ensures that this policy is adhered to in all decisions relating to acceptance or refusal of rebates.

## **6.2. Contracting Team**

6.2.1. The contracting team will ensure that the contract complies with the NHS Vale of York CCG contract standards and make the Chief Financial Officer aware of their views.

### **6.3. Chief Finance Officer**

- 6.3.1. The Chief Finance Officer provides oversight of all aspects of this policy to ensure organisational compliance as well as:
- Provides regular reports to the Audit Committee.
  - Is authorised to sign the rebate decision tool and rebate agreements of behalf of the CCG
  - Ensures rebates are claimed in a timely fashion.

### **6.4. Audit Committee**

6.4.1. The Audit Committee monitors the compliance and effectiveness of this policy.

### **6.5. Communications Team**

6.5.1. The communications team is responsible for publishing adopted rebate scheme to the Vale of York CCG website.

## **7. POLICY IMPLEMENTATION**

7.1 Following approval by the Governing Body, the policy will be published on NHS Vale of York Clinical Commissioning Group's website and will be available to staff on the organisation's intranet.

7.2 The policy will be brought to attention of NHS Vale of York Clinical Commissioning Group employees, Governing Body and its Committees and Sub-Committees.

## **8. TRAINING AND AWARENESS**

8.1 This policy will be published on the NHS Vale of York Clinical Commissioning Group's website and will be available to staff on the organisation's intranet.

8.2 Any queries relating to the policy should be directed to the Lead Pharmacist, NHS Vale of York Clinical Commissioning Group

## **9. MONITORING AND AUDIT**

### **9.1. Monitoring and Accountability**

9.1.1. The Lead Pharmacist and Chief Finance Officer will review the impact of the policy on an annual basis.

## **10. POLICY REVIEW**

10.1 This policy will be reviewed within 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.

## **11. REFERENCES**

1) [Principles and Legal Implications of Primary Care Rebate Schemes. London Procurement Programme, 2012.](#)

- 2) Ethical Framework for Considering Rebate Agreements from Pharmaceutical, Nutrition and Device Companies. Greater Manchester Commissioning Support Unit, 2013.
- 3) PrescQIPP Pharmaceutical Industry Scheme Governance Review Board, 2014

## 12. ASSOCIATED POLICIES

- Sponsorship Policy
- Business Conduct Policy
- Local Anti-Fraud, Bribery and Corruption Policy
- Freedom of Information Policy
- Conflicts of Interest Policy

## 13. CONTACT DETAILS

Laura Angus

Lead Pharmacist

Tel: 01904 555870

Email: [valeofyork.contactus@nhs.net](mailto:valeofyork.contactus@nhs.net)

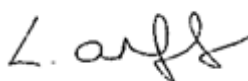
NHS Vale of York Clinical Commissioning Group, West Offices, Station Rise, York. Y01 6GA

## 14. APPENDIX 1: EQUALITY IMPACT ANALYSIS FORM

1.	Title of policy/ programme/ service being analysed
	Policy on Primary Care Rebate Schemes (PCRS)
2.	Please state the aims and objectives of this work.
	General Rebate agreements usually take the form of legal agreements between the manufacturer and Clinical Commissioning Group. It is important that NHS Vale of York Clinical Commissioning Group has a policy to support evaluation and sign off of rebate schemes to ensure that each scheme is only signed off if it provides good value for money to the public purse and its terms are in line with organisation vision, values, policies and procedures and to ensure that NHS Vale of York Clinical Commissioning Group is transparent in its process for considering these schemes. This policy provides a framework for managing rebates in a legal and ethical way. The principles outlined in this policy document allow for the objective evaluation of schemes submitted to NHS Vale of York Clinical Commissioning Group and a clear process for approving and scrutinising agreements.
3.	Who is likely to be affected? (e.g. staff, patients, service users)
	Internal policy document
4.	What sources of equality information have you used to inform your piece of work?
	N/A
5.	What steps have been taken ensure that the organisation has paid <u>due regard</u> to the need to eliminate discrimination, advance equal opportunities and foster good relations between people with protected characteristics
	The analysis of equalities is embedded within the CCG's Committee Terms of Reference and project management framework.
6.	Who have you involved in the development of this piece of work?
	NHS Vale of York CCG Senior Management Team CCG Audit Committee CCG Medicines Management Team CCG Governance Team
7.	What evidence do you have of any potential adverse or positive impact on groups with protected characteristics? N/A Do you have any gaps in information? N/A Include any supporting evidence e.g. research, data or feedback from engagement activities
	There is nothing in the policy that does not support equality and diversity in accordance with the CCG Equality and Diversity Strategy.

Disability People who are learning disabled, physically disabled, people with mental illness, sensory loss and long term chronic conditions such as diabetes, HIV)	Consider building access, communication requirements, making reasonable adjustments for individuals etc
N/A	
Men and Women	Consider gender preference in key worker, single sex accommodation etc
N/A	
Race or nationality People of different ethnic backgrounds, including Roma Gypsies and Travelers	Consider cultural traditions, food requirements, communication styles, language needs etc.
N/A	
This applies to all age groups. This can include safeguarding, consent and child welfare	Consider access to services or employment based on need/merit not age, effective communication strategies etc.
N/A	
Trans People who have undergone gender reassignment (sex change) and those who identify as trans	Consider privacy of data, harassment, access to unisex toilets & bathing areas etc.
N/A	
Sexual orientation This will include lesbian, gay and bi-sexual people as well as heterosexual people.	Consider whether the service acknowledges same sex partners as next of kin, harassment, inclusive language etc.
N/A	
Religion or belief Includes religions, beliefs or no religion or belief	Consider holiday scheduling, appointment timing, dietary considerations, prayer space etc.

N/A	
Marriage and Civil Partnership Refers to legally recognised partnerships (employment policies only)	Consider whether civil partners are included in benefit and leave policies etc.
N/A	
Pregnancy and maternity Refers to the pregnancy period and the first year after birth	Consider impact on working arrangements, part-time working, infant caring responsibilities etc.
N/A	
Carers This relates to general caring responsibilities for someone of any age.	Consider impact on part-time working, shift-patterns, options for flexi working etc.
N/A	
Other disadvantaged groups This relates to groups experiencing health inequalities such as people living in deprived areas, new migrants, people who are homeless, ex-offenders, people with HIV.	Consider ease of access, location of service, historic take-up of service etc
N/A	

<b>Sign off</b>
Name and signature of person / team who carried out this analysis Laura Angus Lead Pharmacist 
Date analysis completed 12 August 2016

Name and signature of responsible Director  
Dr Shaun O'Connell  
GP Lead for Prescribing and Planned Care



Date analysis was approved by responsible Director  
12 August 2016

## 15. APPENDIX 2: SUSTAINABILITY IMPACT ASSESSMENT

Staff preparing a policy, Governing Body (or Sub-Committee) report, service development plan or project are required to complete a Sustainability Impact Assessment (SIA). The purpose of this SIA is to record any positive or negative impacts that this is likely to have on sustainability.

Title of the document	Policy on Primary Care Rebate Schemes (PCRS)
What is the main purpose of the document	General Rebate agreements usually take the form of legal agreements between the manufacturer and Clinical Commissioning Group. It is important that NHS Vale of York Clinical Commissioning Group has a policy to support evaluation and sign off of rebate schemes to ensure that each scheme is only signed off if it provides good value for money to the public purse and its terms are in line with organisation vision, values, policies and procedures and to ensure that NHS Vale of York Clinical Commissioning Group is transparent in its process for considering these schemes. This policy provides a framework for managing rebates in a legal and ethical way. The principles outlined in this policy document allow for the objective evaluation of schemes submitted to NHS Vale of York Clinical Commissioning Group and a clear process for approving and scrutinising agreements.
Date completed	12 August 2016
Completed by	Laura Angus, Lead Pharmacist

Domain	Objectives	Impact of activity Negative = -1 Neutral = 0 Positive = 1 Unknown = ? Not applicable = n/a	Brief description of impact	If negative, how can it be mitigated? If positive, how can it be enhanced?
Travel	Will it provide / improve / promote alternatives to car based transport?	n/a		



Domain	Objectives	Impact of activity Negative = -1 Neutral = 0 Positive = 1 Unknown = ? Not applicable = n/a	Brief description of impact	If negative, how can it be mitigated? If positive, how can it be enhanced?
	Will it support more efficient use of cars (car sharing, low emission vehicles, environmentally friendly fuels and technologies)?	N/A		
	Will it reduce 'care miles' (telecare, care closer) to home?	N/A		
	Will it promote active travel (cycling, walking)?	N/A		
	Will it improve access to opportunities and facilities for all groups?	N/A		
	Will it specify social, economic and environmental outcomes to be accounted for in procurement and delivery?	?		
Procurement	Will it stimulate innovation among providers of services related to the delivery of the organisations' social, economic and environmental objectives?	N/A		
	Will it promote ethical purchasing of goods or services?	?		
Procurement	Will it promote greater efficiency of resource use?	?		

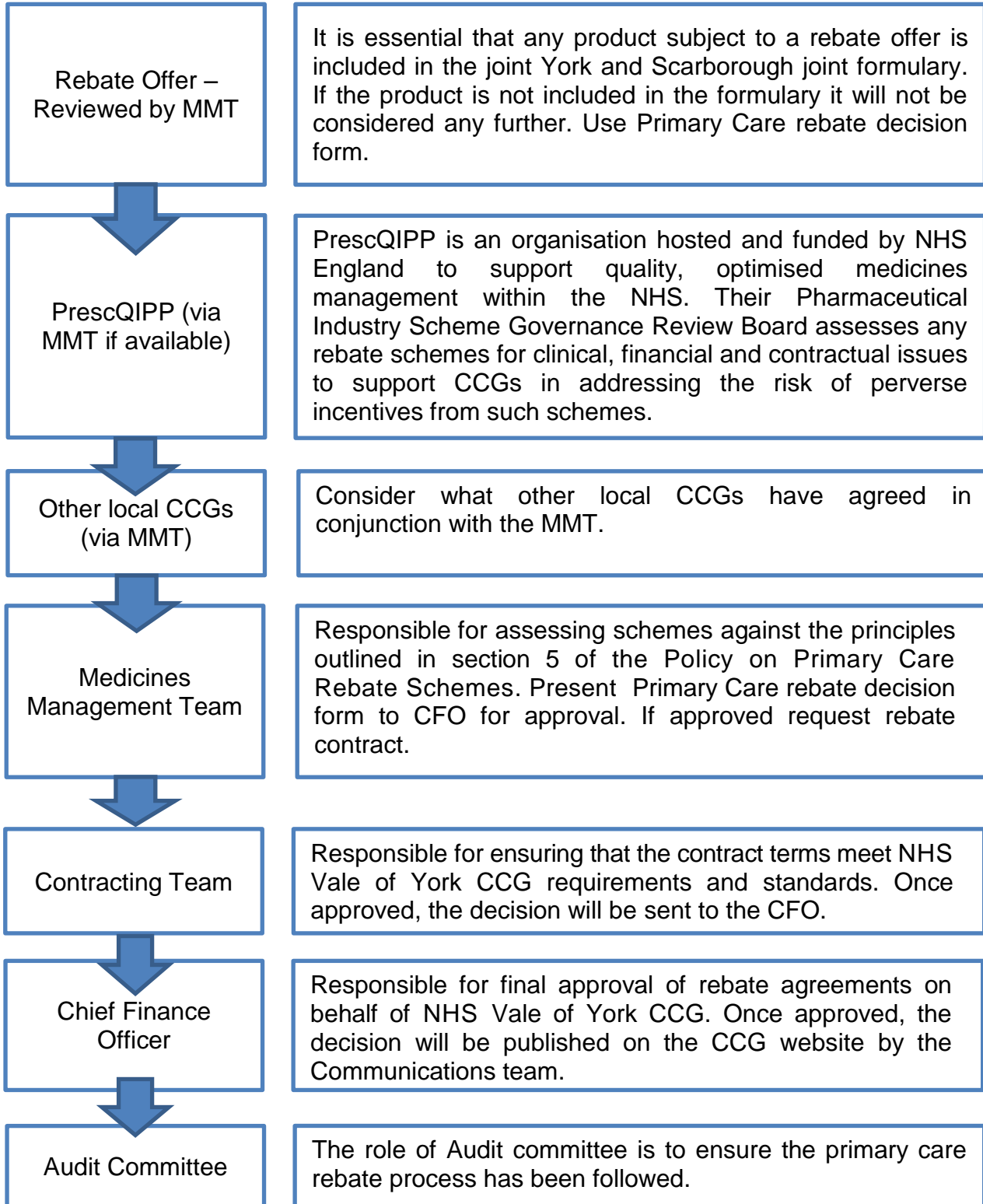
Domain	Objectives	Impact of activity Negative = -1 Neutral = 0 Positive = 1 Unknown = ? Not applicable = n/a	Brief description of impact	If negative, how can it be mitigated? If positive, how can it be enhanced?
	Will it obtain maximum value from pharmaceuticals and technologies (medicines management, prescribing, and supply chain)?	1	It is important that NHS Vale of York Clinical Commissioning Group has a policy to support evaluation and sign off of rebate schemes to ensure that each scheme is only signed off if it provides good value for money to the public purse and its terms are in line with organisation vision, values, policies and procedures and to ensure that NHS Vale of York Clinical Commissioning Group is transparent in its process for considering these schemes. This policy provides a framework for managing rebates in a legal and ethical way. The principles outlined in this policy document allow for the objective evaluation of schemes submitted to NHS Vale of York Clinical Commissioning Group and a clear process for approving and	N/A

Domain	Objectives	Impact of activity Negative = -1 Neutral = 0 Positive = 1 Unknown = ? Not applicable = n/a	Brief description of impact	If negative, how can it be mitigated? If positive, how can it be enhanced?
	Will it support local or regional supply chains?	N/A		
	Will it promote access to local services (care closer to home)?	N/A		
	Will it make current activities more efficient or alter service delivery models	N/A		
Facilities Management	Will it reduce the amount of waste produced or increase the amount of waste recycled? Will it reduce water consumption?	N/A		
Workforce	Will it provide employment opportunities for local people?	N/A		
	Will it promote or support equal employment opportunities?	N/A		
	Will it promote healthy working lives (including health and safety at work, work-life/home-life balance and family friendly policies)?	N/A		
	Will it offer employment opportunities to disadvantaged groups?	N/A		
Community Engagement	Will it promote health and sustainable development?	N/A		
	Have you sought the views of our communities in relation to the impact on sustainable development for this activity?	N/A		
Buildings	Will it improve the resource efficiency of new or refurbished buildings (water, energy, density, use of existing buildings, designing for a longer lifespan)?	N/A		

Domain	Objectives	Impact of activity Negative = -1 Neutral = 0 Positive = 1 Unknown = ? Not applicable = n/a	Brief description of impact	If negative, how can it be mitigated? If positive, how can it be enhanced?
	Will it increase safety and security in new buildings and developments?	N/A		
	Will it reduce greenhouse gas emissions from transport (choice of mode of transport, reducing need to travel)?	N/A		
	Will it provide sympathetic and appropriate landscaping around new development?	N/A		
	Will it improve access to the built environment?	N/A		
Adaptation to Climate Change	Will it support the plan for the likely effects of climate change (e.g. identifying vulnerable groups; contingency planning for flood, heat wave and other weather extremes)?	N/A		
Models of Care	Will it minimise 'care miles' making better use of new technologies such as telecare and telehealth, delivering care in settings closer to people's homes?	N/A		
	Will it promote prevention and self-management?	N/A		
	Will it provide evidence-based, personalised care that achieves the best possible outcomes with the resources available?	N/A		
	Will it deliver integrated care, that co-ordinate different elements of care more effectively and remove duplication and redundancy from care pathways?	N/A		

**16. APPENDIX 3 OPERATING PROCEDURES**

**PRIMARY CARE REBATE SCHEME APPROVAL PROCESS**  
**PRIMARY CARE REBATE SCHEME DECISION FORM**



**PRIMARY CARE REBATE SCHEME DECISION FORM – To be completed by a Senior Member of the Medicines Management Team**

**\*CONFIDENTIAL\***

MMT Code	
Product	
Manufacturer	
Contact Details	
Brief details of rebate scheme	

Assessment Criteria	Yes / No
If the product is a medicine, is it licensed in the UK?	
The product does not have a negative decision from NICE?	
Is the product listed in the joint CCG/ Trust formulary with a GREEN, AMBER or RED status?	
The contract does not include any requirement for a directive guideline to be given to health care professionals to prescribe the specific product?	
In the event that prescribing of the rebate item(s) increases, would this be in line with the CCG formulary and guidance for that item?	
The rebate scheme is not designed to increase off label use of the product?	
If the product is a device or nutritional supplement is it contained in the current Drug Tariff?	
If it is not a medicine, it has not been excluded from use within primary care?	
If the product is a vitamin and classed as a food supplement, is it recommended for use in NHS Vale of York CCG?	
The rebate scheme does not require exclusive use of a specific brand?	
The product is not contained in Category A or M of the Drug Tariff?	
The rebate scheme is not linked directly to a requirement for an 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?	
Is there a break clause present in the contract (length)?	

**Other considerations:**

PrescQIPP Pharmaceutical Industry Scheme Governance Board assessment			
No. of years scheme is available? (Is it >2 years?)			
Estimated potential savings (per patient and for NHS Vale of York population per annum)?	£ /pt/annum	£ /Vale of York/annum	Over the threshold £250?
Have any other contractual or legal issues been identified during the evaluation?			

<b>Further information</b> <i>For example :</i> <ul style="list-style-type: none"> <li>• <i>Administrative burden</i></li> <li>• <i>Governance issues</i></li> <li>• <i>Freedom of Information issues</i></li> <li>• <i>Any other pertinent issues</i></li> </ul>
<b>Recommendation</b>
<b>Rationale</b>
<b>Evaluation carried out by (Name, Title and Date )</b>
<b>Reviewed by (Name, Title and Date)</b>

NHS Vale of York CCG **does / does not** support the decision to agree to this primary care rebate scheme

<b>Title</b>	<b>Name</b>	<b>Signature</b>	<b>Date</b>
CCG Chief Finance Officer			

Date sent to Audit Committee: