Primary Care Rebate Scheme Policy

June 2020

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Description of Amendment(s):	Clarity on responsibilities and reporting arrangements Equality Impact Assessment completed	
This policy will impact on:	Planning & Commissioning Committee Integrated Audit & Governance Committee	
Policy Area:	Commissioning	
Version No:		
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	Planning & Commissioning Committee	05/06/2020
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Consultation:	Commissioning and Medicines Optimisation Teams	

Primary Care Rebate Scheme
Policy

1. Introduction

The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism by which the Department of Health 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.

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

A number of manufacturers have established 'rebate schemes' for drugs used in primary care to support the NHS QIPP agenda. 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 increasingly being offered to Clinical Commissioning Groups (CCGs) 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).

An equality impact assessment has been carried out on this policy and is attached at Appendix 5. As a result of performing the 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. In considering any rebate scheme consideration will be given to potential equality impacts.

2. Scope

This policy applies to Hull CCG and all of its employees, members of the CCG, Co-opted members, members of the Governing Body and its committees and employees of North of England Commissioning Support providing services to the CCG, who must comply with the arrangements outlined in this policy. The policy should be used in conjunction with the following policies:

- Standing Financial Orders and Instructions
- Commercial sponsorship policy

3. Policy Purpose & Aims

Rebate agreements usually take the form of legal agreements between the manufacturer and CCG. It is important that Hull 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 scheme's terms are in line with organisation vision, values, policies and procedures and to ensure that the CCG 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 the CCG and a clear process for approving and scrutinising agreements.

4. IMPACT ANALYSIS / REGULATIONS

4.1. Equality

The CCG is committed to designing and implementing services, policies and measures that meet the diverse needs of its population and workforce, ensuring that no individual or group is disadvantaged.

In developing and applying this policy, the CCG will have due regard to the need to eliminate unlawful discrimination, promote equality of opportunity, and foster good relations between people of diverse groups, in particular on the grounds of the following characteristics protected by the Equality Act (2010); age, disability, gender, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, and sexual orientation, in addition to offending background, trade union membership, or any other personal characteristic.

Please see Appendix 5 for the full equality impact assessment and findings.

4.2. Bribery Act 2010

NHS Hull Clinical Commissioning Group has a responsibility to ensure that all staff are made aware of their duties and responsibilities arising from The Bribery Act 2010. It is therefore, extremely important that staff adhere to this and other related policies and documentation (as detailed on the CCG's website) when considering whether to offer or accept gifts and hospitality and/or other incentives.

If fraud, bribery and corruption are particularly relevant to a policy, e.g. where the policy covers payments, claims, contracts or financial transactions where an individual or company could make a gain and/or cause a loss to the CCG the section should be headed Counter Fraud, Bribery and Corruption and should include a cross reference to the Counter Fraud, Bribery and Corruption Policy.

Please see Appendix 4 for full details.

4.3. General Data Protection Regulation (GDPR)

The CCG is committed to ensuring that all personal information is managed in accordance with current data protection legislation, professional codes of practice and records management and confidentiality guidance. More detailed information can be found in the CCGs Data Protection and Confidentiality and related policies and procedures.

5. NHS CONSTITUTION

With respect to this policy the CCG supports the Principles of the NHS Constitution.

6. ROLES / RESPONSIBILITIES / DUTIES

Chief Finance Officer

- Provides oversight of all aspects of this policy to ensure organisational compliance.

- Provides regular reports to the Integrated Audit and Governance Committee.
- Maintaining a secure record of all rebate schemes approved.

CCG Prescribing Lead

- Ensures this policy is adhered to in all decisions relating to acceptance or refusal of rebates.

North of England Commissioning Support Medicines Optimisation Team

- Ensures this policy is adhered to in all decisions relating to acceptance or refusal of rebates.
- Ensures rebates are claimed in a timely fashion.
- Implement and monitors implementation of all rebate schemes.
- Prepares an annual report of all rebate schemes.

Planning & Commissioning Committee

- Considers and reviews any new rebate offers.
- Provides a recommendation to Integrated Audit and Governance Committee including a summary of the clinical discussion that took place in reaching the recommendation.
- Considers and reviews any offers of rebate extensions.
- Provides a recommendation in relation to rebate extensions to Integrated Audit and Governance Committee including a summary of the clinical discussion that took place in reaching the recommendation.

Integrated Audit and Governance Committee

- Monitors the Compliance and Effectiveness of this Policy
- Receives and considers recommendations from Planning and Commissioning Committee
- Approves or declines rebate offers or rebate extension offers
- Receives an annual report summarising the Primary Care Rebate schemes entered by the CCG – this to include financial information in relation to the rebate
- Ensures publication of decisions on the CCG website in relation to rebates
- Final decision of the CCG whether or not to approve a rebate scheme would be made on a case by case basis and in the light of an appraisal of the evidence to support the benefit to residents for whom the CCG is responsible for.

7. Implementation

Implementation of the policy will be overseen by the CCG Prescribing Lead. The Planning & Commissioning Committee will consider and review rebate offers and the Integrated Audit & Governance Committee will monitor the compliance and effectiveness of the policy.

8. Training and Awareness

Members of the Planning and Commissioning Committee and Integrated Audit and Governance Committee will be made aware of the policy requirements in reviewing any rebate offers and monitoring compliance and effectiveness of the policy.

9. Monitoring and Effectiveness

The effectiveness of this Policy will be monitored through the record of all approved schemes and annual report.

10. Legal Advice

There have been concerns raised by some CCGs on the lack of clarity on whether such schemes are allowed under the current regulations. The London Primary Care Medicines Use and Procurement QIPP group as part of the London Procurement Partnership agreed that it was unclear whether these schemes were allowed within the current regulations and sought legal opinion from DAC Beechcroft LLP.

In conclusion, legal opinion states that primary care rebate schemes are not unlawful and are within the powers of CCGs to agree to, provided they meet certain requirements. The detailed legal advice obtained by the London Procurement Partnership has been shared within the NHS and it is acknowledged that Hull CCG will seek further legal advice on any point identified. (Detailed legal advice from DAC Beechcroft[1] is available from North of England Commissioning Support Medicines Optimisation team).

The CCG may wish to take legal advice on the content of any particular scheme prior to entering into any agreement.

11. 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. Any medicine 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)[2]. This states that the following principles should underpin local strategies:

i. 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;

ii. 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;

iii. 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;

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

v. Schemes should be reviewed whenever relevant NICE or alternative guidance are updated.

vi. Scheme terms, including details of relevant therapeutic evaluations underpinning the scheme, should be published on the CCG's website.

12. Good Practice Principles for Primary Care Rebate Schemes

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 CCG in assessing these schemes, the CCG 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 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 3 – Legal Advice - above).

Hull CCG will adopt the following Principles when deciding whether to participate in a PCRS or not:

12.1. Product Related

- PCRS will only be considered for those medicines which are already commissioned and included in the joint Hull and East Riding joint formulary, and its place in a care pathway has already been established through normal CCG Governance, i.e. Planning and Commissioning Committee, Integrated Audit and Governance Committee, Hull and East Riding Prescribing Committee (HERPC).
- The price of a medicine 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 their individual patients' clinical circumstances. The impact of a rebate scheme is a secondary consideration.
- The CCG will not consider or promote unlicensed or 'off-label' uses of medicines as part of a PCRS. Furthermore, a PCRS 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.
- All recommendations for use of a medicine within a PCRS must be consistent with the UK Marketing Authorisation of the medicine in question, i.e. the PCRS should only advocate the use of the drug in line with the data sheet/Specific Product Characteristics (SPC) for the drug in question.
- Medicines not recommended by NICE will not be considered under a PCRS
- PCRS 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 Medicines Optimisation Team for any Category A products.

12.2. 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 Medicines Management Committee/Area Prescribing Committee (or equivalent) approval, involving both primary and secondary care and Director level approval.
- 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.

13. Interface with Pharmaceutical Industry

The CCG 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. Any meetings to discuss rebates should be attended by a senior member of the Medicines Optimisation Team and the GP Prescribing Lead.

Suppliers should not make guideline or formulary positioning conditional to any rebate offer. Equally, the CCG 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 CCG. Suppliers must not discuss any potential joint working arrangements, medical education goods and services, sponsorship offers or patient support programmes. An exception is where these are explicitly part of the commercial offer and are included in a legal contract

In the event of the above not being adhered to in a meeting, the meeting must be terminated immediately and an incident report completed.

14. Contracts

A senior member of the Medicines Optimisation Team and Chief Finance Officer/Deputy Chief Finance Officer 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

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.

Freedom of Information issues (see section 11 – Information Governance) should be discussed with the manufacturer before a commissioner enters into any agreement with them and should be contained in the contract.

15. Accountability

North of England Commissioning Support Medicines Optimisation Team and GP Prescribing Lead will be responsible for assessing schemes against the principles outlined in section 5 above. The "Rebate Scheme Decision Form" in Appendix 2 will be used to record the assessment against the principles and to provide a recommendation to the Planning & Commissioning Committee which is responsible for reviewing the rebate scheme in order to make a decision and provide a recommendation to the CCG Integrated Audit and Governance Committee including a summary of the clinical discussion in reaching the recommendation.

The CCG Integrated Audit and Governance Committee will be presented, at the next committee meeting, with a copy of the "Rebate Scheme Decision Form" and details of the clinical discussions and recommendations, for scrutiny and final approval of the rebate agreements on behalf of Hull CCG whilst balancing the public interest. Where an extension to a rebate scheme is offered on the same terms as the original scheme, and the scheme is still of benefit to the population, the scheme can be extended and the Planning and Commissioning and Integrated Audit and Governance Committees will be informed of the extension. Where an extension to a rebate scheme is offered on different terms the full process for consideration of the scheme should be followed.

An annual report will be submitted to the CCG Integrated Audit and Governance Committee summarising the Primary Care Rebate Schemes entered by the CCG including relevant financial information.

16. Information Governance

Hull 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.

Whilst manufacturers often attempt to impose requirements for confidentiality that would restrict the CCG from disclosing the existence and level of any discount to any third party, the CCG 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 the CCG 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.

The CCG will ensure that all PCRS agreements meet the requirements of the Data Protection Act, and patient confidentiality must never be compromised

16.1. Sharing of Information with prescribers and other stakeholders

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.

16.2. Freedom of Information Requests

Any Decision from the Information Commissioners Office to disclose information must be adhered to.

17. Use of Rebates

It is vital that any funds received by the CCG as part of a rebate are managed in a transparent, legal and ethical way. Oversight for any spending plans, redistribution of funds and control of destination budgets will be provided by the Integrated Audit and Governance Committee.

No one individual should be in a position to benefit personally from the level of rebate received by the CCG.

Examples of unacceptable practice:
• A GP LES for diabetes is funded by an insulin rebate. The higher the rebate payment, the more funds available for the LES.
• The medicines management team create a budget for special projects. All rebates are paid into this budget and the team can use this for short term posts.

Example of acceptable practice:
• A diabetes 'invest to save' project is approved by the CCG. The business case includes an investment which is offset by a rebate scheme. The projected savings are in line with analysis of appropriate use and the project funding is secure even if rebate savings are not fully realised. Any surplus is not automatically allocated to the project.

18. Policy Review

This policy will be reviewed by a period of no longer than 2 years as stated or in response to any relevant changes in local and/or national policies and guidance, whichever is sooner.

19. References

[1] London Procurement Programme Legal Response from DAC Beachcroft LLP – Personnel Communication
[2] Department of Health. Strategies to Achieve Cost-Effective Prescribing (2010)

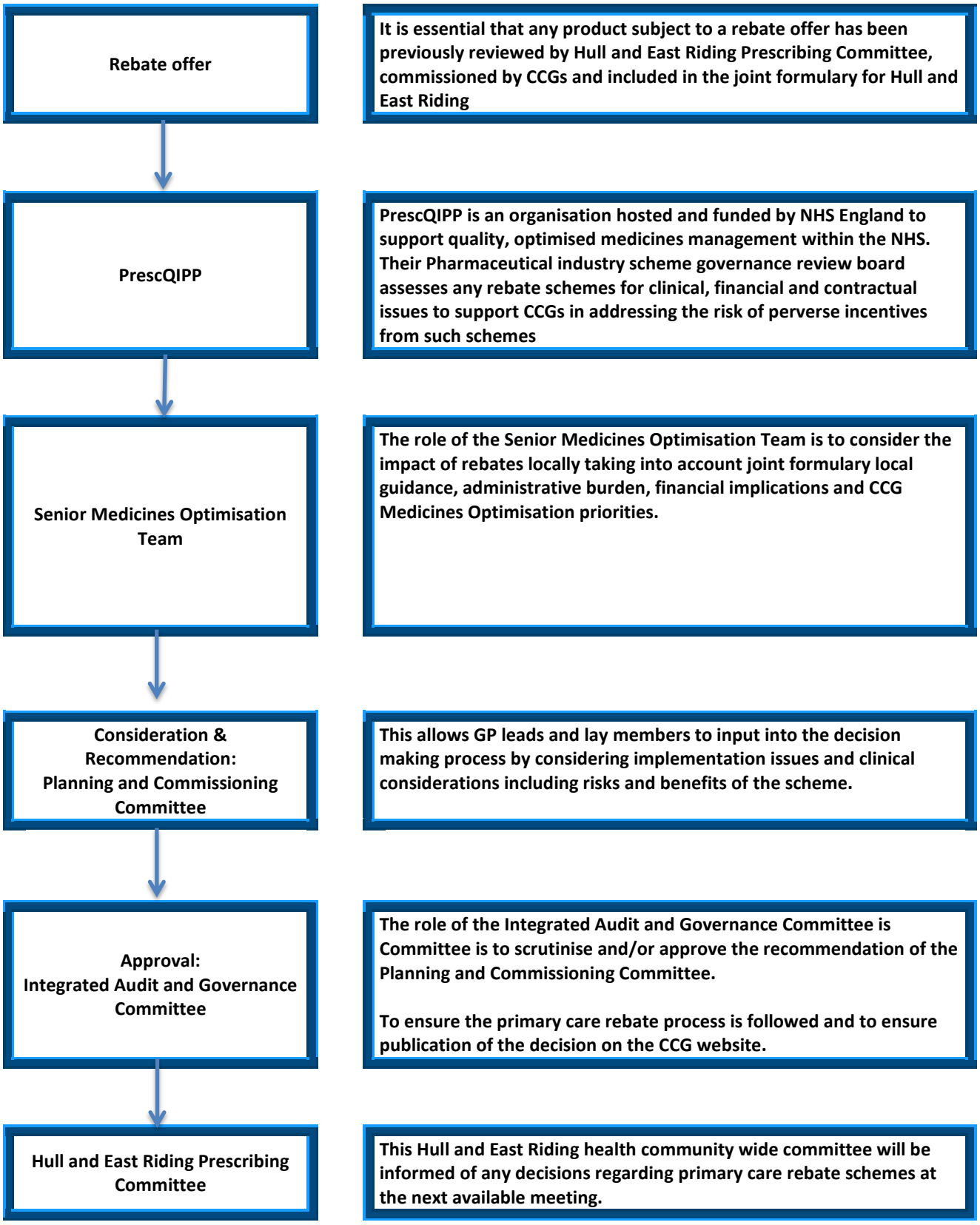
20. Associated Documents

The following were used as the basis of this policy;

- Principles and Legal Implications of Primary Care Rebate Schemes. London Procurement Programme. 2012.
- Ethical Framework for Considering Rebate Agreements from Pharmaceutical, Nutrition and Device Companies. Greater Manchester Commissioning Support Unit. 2013.
- PrescQIPP Pharmaceutical Industry Scheme Governance Review Board. 2014.

Appendix 1

Primary Care Rebate Scheme Approval Process


Rebate offer
It is essential that any product subject to a rebate offer has been previously reviewed by Hull and East Riding Prescribing Committee, commissioned by CCGs and included in the joint formulary for Hull and East Riding
PrescQIPP
PrescQIPP is an organisation hosted and funded by NHS England to support quality, optimised medicines management within the NHS. Their Pharmaceutical industry scheme governance review board assesses any rebate schemes for clinical, financial and contractual issues to support CCGs in addressing the risk of perverse incentives from such schemes
Senior Medicines Optimisation Team
The role of the Senior Medicines Optimisation Team is to consider the impact of rebates locally taking into account joint formulary local guidance, administrative burden, financial implications and CCG Medicines Optimisation priorities.
Consideration & Recommendation: Planning and Commissioning Committee
This allows GP leads and lay members to input into the decision making process by considering implementation issues and clinical considerations including risks and benefits of the scheme.
Approval: Integrated Audit and Governance Committee
The role of the Integrated Audit and Governance Committee is Committee is to scrutinise and/or approve the recommendation of the Planning and Commissioning Committee.
To ensure the primary care rebate process is followed and to ensure publication of the decision on the CCG website.
Hull and East Riding Prescribing Committee
This Hull and East Riding health community wide committee will be informed of any decisions regarding primary care rebate schemes at the next available meeting.

Appendix 2 Primary Care Rebate Scheme Decision Form *Confidential*

Product	
Manufacturer	
Contact Details	

Brief details of rebate scheme	

Assessment Criteria	**Yes/NO**
Is the product listed in the Joint CCG/HEYHT Formulary?	**Yes/NO**
Does the product have a negative decision from NICE?	**Yes/NO**
Is there a requirement for a directive or guideline to be given to health care professionals to prescribe the specific product?	**Yes/NO**
If the product is a medicine, is it licensed in the UK?	**Yes/NO**
Is the rebate scheme designed to increase off label use of the drug?	**Yes/NO**
If the product is a device or nutritional supplement is it contained in the current Drug Tariff?	**Yes/NO**
If the product is a vitamin and classed as a food supplement, is it recommended for use in Hull CCG?	**Yes/NO**
Does the rebate scheme require exclusive use of a specific brand?	**Yes/NO**
Is the product contained in Category A or M of the Drug Tariff?	**Yes/NO**
Is the rebate scheme linked directly to a requirement for an increase in market share or volume of prescribing?	**Yes/NO**
Does the rebate scheme prevent consideration of other schemes?	**Yes/NO**
Is there a requirement to submit additional information beyond the volume of prescribing of the product?	**Yes/NO**
Is there a requirement to collect patient specific data?	**Yes/NO**
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 Hull population per annum)?	
Have any other contractual or legal issues been identified during the evaluation?	**For CCG completion. Freedom of Information is included in the attached copy of the rebate contract agreement**
Further information: **For Example** • **Administrative Burden** • **Governance issues** • **Freedom of information issues**	

• **Any other Pertinent issues**
Recommendation:
Rationale:
Evaluation carried out by **(Name, Title, Date)**
Reviewed by **(Name, Title, Date)**

Appendix 3

Planning and Commissioning Committee (PCC) Decision

The Committee does/does not support the decision to agree to this primary care rebate scheme

Date:

Signed by:

Title: PCC Chair

Name:

Signature:

Title: Lay Person

Name:

Signature:

Title: Chief Finance Officer

Name:

Signature:

Date sent to Integrated Audit and Governance Committee (IAGC):

Final IAGC Approval

Date:

The IAGC does/does not approve the decision to agree to this primary care scheme.

Title: IAGC Chair

Name:

Signature:

Appendix 4

Bribery Act 2010:

Under the Bribery Act 2010, it is a criminal offence to:

- Bribe another person by offering, promising or giving a financial or other advantage to induce them to perform improperly a relevant function or activity, or as a reward for already having done so; and
- Be bribed by another person by requesting, agreeing to receive or accepting a financial or other advantage with the intention that a relevant function or activity would then be performed improperly, or as a reward for having already done so.
- Failure to prevent bribery; The Bribery Act also introduced a corporate offence for a relevant commercial organisation (the CCG) to bribe another person intending (1) to obtain or retain business, or (2) to obtain or retain an advantage in the conduct of business. The only defence available to the CCG against Bribery Act offences would be to prove that it had adequate procedures in place designed to prevent persons associated with it from undertaking any of the conduct outlined above.

These offences can be committed directly or by and through a third person and, in many cases, it does not matter whether the person knows or believes that the performance of the function or activity is improper.

It is therefore, extremely important that staff adhere to this and other related policies and documentation (as detailed on the CCG's website) when considering whether to offer or accept gifts and hospitality and/or other incentives.

If fraud, bribery and corruption are particularly relevant to a policy, the section should be headed Anti-fraud, Bribery and Corruption and should include a cross reference to the Local Anti-fraud, Bribery and Corruption Policy. The following wording should also be included:
'If an employee suspects that fraud, bribery or corruption has taken place, they should ensure it is reported to the Local Counter Fraud Specialist (LCFS) and/or to NHS Counter Fraud Authority (NHSCFA) as follows:

- LCFS, AuditOne, Kirkstone Villa, Lanchester Road Hospital, Lanchester Road, Durham, DH1 5RD. Tel: 0191 4415936; Email: counterfraud@audit-one.co.uk or ntawnt.counterfraud@nhs.net
- The CCG's Chief Finance Officer,
- NHSCFA, 0800 028 40 60 (powered by Crimestoppers)
- Online: https://cfa.nhs.uk/reportfraud.

For further information see http://www.justice.gov.uk/guidance/docs/bribery-act-2010-quick-start-guide.pdf. If you require assistance in determining the implications of the Bribery Act please contact the LCFS on the details above.