NHS
Vale of York
Clinical Commissioning Group

BRANDED MEDICINES PRESCRIBING POLICY

SEPTEMBER 2016

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Approval Body	Governing Body
Approved date:	29th September 2016
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Equality Impact Assessment	Completed
Sustainability Impact Assessment	Completed
Related Policies	Prescribing Policy for Primary Care Providers Branded-Generic Medicines Prescribing Policy
Target Audience:	Primary Care Providers
Policy Reference No:	PRE05
Version Number:	V0.2

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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 & Date	Date on Intranet
0.1	NHS Vale of York Clinical Commissioning Group Prescribing Team	New Policy		
0.2	NHS Vale of York Clinical Commissioning Group Prescribing Team	Changes to section 5.4 regarding offering a private prescription, in line with updated guidance from LMC	Laura Angus 02.08.18	

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1. INTRODUCTION

1.1. NHS Vale of York Clinical Commissioning Group wants to commission the best treatments for local patients and wants the right clinician to have responsibility for those treatments – please see the document 'How we commission medicines'. We want patients to have access to medicines which improve the quality of their care, that have demonstrated cost effectiveness and are safe.

1.2. NHS Vale of York Clinical Commissioning Group is keen to ensure that only treatments that are clinically effective and provide a clear health benefit to patients are prescribed on NHS prescriptions. This is to ensure that NHS Vale of York Clinical Commissioning Group resources provide interventions with a proven health gain for the population. Therefore NHS Vale of York Clinical Commissioning Group prioritise resources based on evidence of the clinical effectiveness and safety of treatments, their cost effectiveness, and on which interventions provide the best health outcomes.

1.3. In 2016-17 NHS Vale of York Clinical Commissioning Group estimates there is more than £150,000 of potential annual savings from changing patients from unnecessary brand prescribing to generic prescribing. Patients who unreasonably demand branded prescribing are reducing NHS resources for other health services.

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 clinical appropriate, cost effective and safe use of medicines across the locality. The policy represents best practice and supports the requirement of the NHS to make best use of NHS resources.

3. IMPACT ANALYSES

Equality

3.1. 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.

Sustainability

3.2. A Sustainability Impact Assessment has been undertaken. Four positive impacts were identified within the twelve sustainability themes. The results of the assessment are attached.

Scope

3.3. This policy applies to Primary Care Providers within the NHS Vale of York Clinical Commissioning Group boundaries. NHS Vale of York Clinical Commissioning Group recommends that all must comply with the arrangements outlined in this policy, as it is best practice and supports the use of the requirement of the NHS to make the best use of NHS resources.

3.4. The document applies to primary care healthcare professionals who prescribe; this may be general practitioners or non-medical prescribers.

3.5. The scope of this document is to establish a policy for prescribers on the rationale for generic and branded prescribing within the NHS Vale of York Clinical Commissioning Group area and to detail the basis on which exceptions are considered appropriate.

4. POLICY PURPOSE/AIMS & FAILURE TO COMPLY

4.1. NHS Vale of York Clinical Commissioning Group is keen to ensure that only treatments that are clinically effective and provide a clear health benefit to patients are prescribed on NHS prescriptions. This is to ensure that NHS Vale of York Clinical Commissioning Group resources provide interventions with a proven health gain for the population. Therefore NHS Vale of York Clinical Commissioning Group prioritise resources based on evidence of the clinical effectiveness and safety of treatments, their cost effectiveness, and on which interventions provide the best health outcomes. All other treatments should be considered as less suitable for prescribing on NHS prescription. This supports GMC guidance *'You must make good use of the resources available to you'.*

5. PRINCIPLE LEGISLATION AND COMPLIANCE WITH STANDARDS

5.1. When and why is generic prescribing appropriate?

- Generic prescribing is the preferred option in the vast majority of cases, on the grounds of cost and ability to source drugs as generic prescribing allows pharmacists to choose from a range of procurement options.
- Within NHS Vale of York Clinical Commissioning Group where generic prescribing is more cost effective than brand prescribing prescribers should NOT prescribe brands unless exceptions detailed in section 5.5 of this policy 'when is branded prescribing justified'.
- The licensing process for medicines assures bioequivalence between brands and therefore on scientific grounds (with a few notable exceptions – see section 5.5), there is no reason why a patient should not be switched from a branded product to the generic equivalent.
- There is little robust evidence that switching between different manufacturers of the generic product is clinically significant.

- Initiating generic prescribing from the outset removes the need for future review of repeats when brand patents expire and enables cost benefits to be realised faster.
- Prescribers should avoid referencing a specific salt within their prescription, as this may lead to a requirement for a brand to be dispensed e.g.: amlodipine rather than amlodipine besilate / maleate and this may incur unnecessary cost, with no additional clinical value.

5.2. Prescribers should use this information to reinforce the stance of generic prescribing with patients who demand branded options.

5.3. It is NHS Vale of York Clinical Commissioning Group policy that all prescriptions should be prescribed generically unless the exceptions described below apply. Should legitimate clinical needs require a brand then the brand should be provided on the NHS. Prescribers should be sure that the clinical needs are legitimate and where patients state a generic is not 'as good' or causes unexpected adverse effects should report this to the MHRA[1].

5.4. If a patient requests a particular branded product and does not have a legitimate clinical need, despite local NHS policy to prescribe generically, the prescriber can only offer an NHS prescription, and cannot offer a private prescription.

5.5. **When is branded prescribing justified? (Exceptions)**

Branded Prescribing is appropriate for:

- True clinical hypersensitivity to any of the excipients in particular product (which applies to branded products also). Such cases tend to be rare and should not have a significant impact on generic prescribing rates.
- Narrow therapeutic index drugs e.g. phenytoin, carbamazepine, ciclosporin and lithium
- Certain modified or extended release products e.g. MR diltiazem, nifedipine, mesalazine
- When there are formulation differences between medicines e.g. transdermal strong opioids are available as fentanyl matrix brand (suitable to be cut) and fentanyl reservoir brands (unsuitable for cutting)
- Certain administration devices e.g. salbutamol dry power inhalers have rather different mechanisms of deployment
- Products of the same drug but with different bioavailability Qvar® v Clenil® beclometasone inhalers
- Multiple ingredient products: oral contraceptives / hormone replacement therapy and emollients
- Difference licensed indications of the same product e.g. Cymbalta®/ Yentreve® (duloxetine)
- Biological rather than chemical medicines e.g.: erythropoietin

6. Branded Generics

6.1. A branded generic is the brand name given to a drug that is bioequivalent to the original (innovator) brand, but once the original brand name has come off patent it is marketed under another company's brand name, not the generic name.

6.2. It is NHS Vale of York Clinical Commissioning Group policy to use branded generics where appropriate, notably when the medicine should be prescribed by brand, as detailed in section 5.5 of this policy, in line with the UKMI guidance (modified release preparations, combination products etc.) and when the use of the branded generic is more cost-effective than the generic equivalent. Many other factors are considered in the selection of branded generic products and these are detailed in a separate policy – Branded Generic Prescribing Policy.

7. Actions

7.1. Prescribers should not provide patients with two prescriptions (i.e. one for a branded product on private prescription and the generic equivalent on FP10) as this is not considered to be safe practice.

7.2. Practices should aim for generic prescribing rates in excess of 80% - the current national average. Less than 0.5% of a practice prescribing budget should represent potential generic savings.

7.3. Prescribers should continue with generic prescribing as routine with the clinical exceptions detailed.

7.4. Practice Prescribing leads should monitor their practice's Top 20 Generic Savings (available from NHS Business Services Authority Information Services Portal) to support NHS Vale of York Clinical Commissioning Group's cost efficiency programme and ensure all prescribers are aware of and implement this guidance

7.5. Practices should use Clinical Decision Support Software provided by NHS Vale of York Clinical Commissioning Group to support decision making when prescribing e.g. OptimiseRx

7.6. NHS Vale of York Clinical Commissioning Group GP Prescribing lead and Lead Pharmacist will investigate practice achievement less than expected and where necessary discuss this with the Council of Representatives.

8. ROLES & RESPONSIBILITIES

Role

8.1. The Lead Pharmacist is responsible for the policy content

8.2. Primary Care Organisations within the NHS Vale of York Clinical Commissioning Group boundaries are responsible for implementing the content of the policy.

9. POLICY IMPLEMENTATION

9.1. 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.
- The policy will be brought to attention of Primary Care Organisations within NHS Vale of York Clinical Commissioning Group

10. TRAINING & AWARENESS

10.1. 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.

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

11. MONITORING & AUDIT

Monitoring & Accountability

11.1. The Lead Pharmacist will be reviewing the impact of the policy on an annual basis.

12. POLICY REVIEW

12.1. 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.

13. REFERENCES

- Medicines and Healthcare Products Regulatory Agency MHRA https://www.gov.uk/report-problem-medicine-medical-device
- UKMI. (2013, 09). *Which medicines should be considered for brand-name prescribing in primary care?*
- Electronic medicines compendium. https://www.medicines.org.uk/emc/
- The community pharmacy - A guide for general practitioners and practice staff (July 2013)

14. ASSOCIATED POLICIES

- Prescribing Policy for Primary Care Providers
- Branded-Generic Medicines Prescribing Policy

15. CONTACT DETAILS

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

16. APPENDIX 1: EQUALITY IMPACT ANALYSIS FORM

1.	Title of policy/ programme/ service being analysed
	Branded Medicines Prescribing Policy
2.	Please state the aims and objectives of this work.
	NHS Vale of York Clinical Commissioning Group is keen to ensure that only treatments that are clinically effective and provide a clear health benefit to patients are prescribed on NHS prescriptions. This is to ensure that NHS Vale of York Clinical Commissioning Group resources provide interventions with a proven health gain for the population. Therefore NHS Vale of York Clinical Commissioning Group prioritise resources based on evidence of the clinical effectiveness and safety of treatments, their cost effectiveness, and on which interventions provide the best health outcomes. The policy defines when prescribers should use branded and generic medicines.
3.	Who is likely to be affected? (e.g. staff, patients, service users)
	Patients
4.	What sources of equality information have you used to inform your piece of work?
	Affects the entire population The policy has been on the website for 6 weeks for comments, thoughts and feedback from the public – none received. The policy has been sent to Healthwatch York to circulate for comments, thoughts and feedback – none received.
5.	What steps have been taken ensure that the organisation has paid due regard to the need to eliminate discrimination, advance equal opportunities and foster good relations between people with protected characteristics

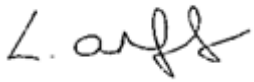
	The policy has been on the website for 6 weeks for comments, thoughts and feedback from the public – none received. The policy has been sent to Healthwatch York to circulate for comments, thoughts and feedback – none received.
6.	Who have you involved in the development of this piece of work?
	Primary Care Organisation representatives, Local Medical Committee representatives, Strategy and Assurance Manager, NHS Vale of York Clinical Commissioning Group, Healthwatch York, Public feedback sought via website.
7.	What evidence do you have of any potential adverse or positive impact on groups with protected characteristics? Do you have any gaps in information? 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 Clinical Commissioning Group 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	

Sign off

Name and signature of person / team who carried out this analysis Laura Angus Lead Pharmacist, NHS Vale of York Clinical Commissioning Group 
Date analysis completed 27th September 2016
Name and signature of responsible Director Dr Shaun O'Connell GP Lead for Planned Care and Prescribing, NHS Vale of York Clinical Commissioning Group 
27th September 2016

18. 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	Branded Medicines Prescribing Policy
What is the main purpose of the document	NHS Vale of York Clinical Commissioning Group is keen to ensure that only treatments that are clinically effective and provide a clear health benefit to patients are prescribed on NHS prescriptions. This is to ensure that NHS Vale of York Clinical Commissioning Group resources provide interventions with a proven health gain for the population. Therefore NHS Vale of York Clinical Commissioning Group prioritise resources based on evidence of the clinical effectiveness and safety of treatments, their cost effectiveness, and on which interventions provide the best health outcomes. The policy defines when prescribers should use branded and generic medicines.
Date completed	27th September 2016
Completed by	Laura Angus

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		
	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		

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 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?	n/a		
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?	n/a		
Procurement	Will it promote greater efficiency of resource use?	1	Makes best use of NHS resources by seeking to ensure prescribing is safe, evidence based, clinically appropriate and cost-effective	
	Will it obtain maximum value from pharmaceuticals and technologies (medicines management, prescribing, and supply chain)?	1	Makes best use of NHS resources by seeking to ensure prescribing is safe, evidence based, clinically appropriate and cost-effective	
	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		

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?
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?	1	Public feedback sought via website – no feedback received	
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?	1	Makes best use of NHS resources by seeking to ensure prescribing is safe, evidence based, clinically appropriate and cost-effective	

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 deliver integrated care, that co-ordinate different elements of care more effectively and remove duplication and redundancy from care pathways?	n/a		