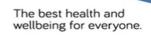


BRANDED-GENERIC MEDICINES PRESCRIBING POLICY

SEPTEMBER 2016

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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
1.0	NHS Vale of York Clinical Commissioning Group Prescribing Team	New Policy	Clinical Executive Committee – 29 September 2016	13 October 2016

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or

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CONTENTS

1.	INTRODUCTION	4
2.	POLICY STATEMENT	4
3.	IMPACT ANALYSES	4
4.	POLICY PURPOSE/AIMS & FAILURE TO COMPLY	5
5.	PRINCIPLE LEGISLATION AND COMPLIANCE WITH STANDARDS	5
6.	ROLES & RESPONSIBILITIES	7
7.	POLICY IMPLEMENTATION	7
8.	TRAINING & AWARENESS	8
9.	MONITORING & AUDIT	8
10.	POLICY REVIEW	
11.	REFERENCES	8
12.	ASSOCIATED POLICIES	8
13.	CONTACT DETAILS	8
14.	APPENDIX 1: EQUALITY IMPACT ANALYSIS FORM	9
16.	APPENDIX 2: SUSTAINABILITY IMPACT ASSESSMENT	14

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. A branded-generic is the brand name given to a dug 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.
- 1.4. In 2016-17 NHS Vale of York Clinical Commissioning Group estimates there are more than £1 million of potential annual savings from changing all appropriate patients from generic prescribing to branded-generic prescribing for specific branded-generic 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 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 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 branded-generic prescribing within the NHS Vale of York Clinical Commissioning Group area and to detail the basis on which branded-generic products are selected.

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. It is policy of NHS Vale of York Clinical Commissioning Group to use branded-generics where appropriate as detailed below.
- 5.2. When and why is branded-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. Please refer to Branded Medicines Prescribing Policy.

However, certain branded-generic products are more cost-effective for NHS Vale of York Clinical Commissioning Group than the equivalent generic

products. Within NHS Vale of York Clinical Commissioning Group where branded-generic prescribing is more cost effective than generic prescribing branded-generic products are preferred if they meet the following criteria:

- The branded-generic drug is suitable for inclusion in the local <u>York and Scarborough formulary.</u>
- The branded-generic is a medicine that should be prescribed by a brand name, in line with <u>UKMI guidance</u> on 'which medicines should be considered for brand name prescribing in primary care'. This includes inhalers, controlled drugs and modified-release preparations. Please refer to 'Branded Medicine Prescribing Policy' for further information.
- The list price for the branded-generic product is more cost-effective than the generic equivalent price as listed in the NHS Drug Tariff.
- The cost savings achieved by actively switching to the branded-generic medicine exceeds a specified threshold; the threshold will be determined annually by NHS Vale of York Clinical Commissioning Group.
- The branded-generic is equivalent in bioavailability, release profile and licensed indications as the generic version. The licensing process for medicines assures bioequivalence between brands, generic and branded-generics and therefore on scientific grounds there is no reason why a patient should not be switched from a generic to a branded-generic equivalent.
- There is sufficient information on the branded-generic in the <u>British National Formulary</u> or via the Summary Product Characteristics data sheet for the product (accessed via the <u>Electronic Medicines Compendium</u>).
- The branded-generic is listed on the prescriber's clinical system.
- The Medicines Management Team have determined that the manufacturer of the branded-generic can guarantee supplies and that Community Pharmacies and Dispensing Practices can obtain the branded-generic product from usual supply routes/wholesalers
- The Medicines Management Team have confirmed that the price of the branded-generic will remain competitive (i.e. lower than the generic equivalent) for a minimum of 2-years
- The branded-generic product is not in Category M of the NHS Drug Tariff
- The total number of new branded-generic products recommended by NHS Vale of York Clinical Commissioning Group per annum for active switching does not exceed 20. The agreed list will be determined annually by NHS Vale of York Clinical Commissioning Group. Branded switches that do not exceed the threshold for active switching and/or are classed as historic branded-generic switches (used prior to current financial year) will be added to the NHS Vale of York Clinical Commissioning Group's choice of Clinical Decision Support Software (currently Optimise Rx).
- NHS Vale of York Clinical Commissioning Group are responsible for supporting Primary Care Providers to actively complete the any brandedgeneric switches and the switches will be completed in-line with a switch protocol.
- All selected branded-generic products will be loaded on to the NHS Vale of York Clinical Commissioning Group's choice of Clinical Decision

- Support Software (currently Optimise Rx) to support prescribers select the correct option.
- NHS Vale of York Clinical Commissioning Group recommend writing in the directions field 'the same active ingredient as <generic>' to support prescriber's in identifying the branded-generic products.
- If a prescriber wishes to prescribe an alternative branded-generic product to the products selected by NHS Vale of York Clinical Commissioning Group it is recommended that the same considerations as detailed above are considered, the branded-generic must be as cost-effective as the NHS Vale of York Clinical Commissioning Group recommended brandedgeneric. The Medicines Management Team can provide advice on the suitability of alternative branded-generic products in-line with this policy.

6. Actions

- 6.1. NHS Vale of York Clinical Commissioning Group will communicate the list of medicines that should be prescribed as branded-generics (in line with this policy) to Primary Care Organisations in the locality.
- 6.2. Prescribers are requested to support and implement the use of branded-generics as outlined in this policy.
- 6.3. 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
- 6.4. 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.

7. ROLES & RESPONSIBILITIES

Role

- 7.1. The Lead Pharmacist is responsible for the policy content
- 7.2. Primary Care Organisations within the NHS Vale of York Clinical Commissioning Group boundaries are responsible for implementing the content of the policy.

8. POLICY IMPLEMENTATION

- 8.1. 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

9. TRAINING & AWARENESS

- 9.1. 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.
- 9.2. Any queries relating to the policy should be directed to the Lead Pharmacist, NHS Vale of York Clinical Commissioning Group

10. MONITORING & AUDIT

Monitoring & Accountability

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

11. POLICY REVIEW

11.1. 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.

12. REFERENCES

- <u>UKMI. (2013, 09). Which medicines should be considered for brand-name prescribing in primary care?</u>
- Electronic medicines compendium. https://www.medicines.org.uk/emc/
- Branded generics Good Practice Guide. PrescQIPP Bulletin 141 May 2016

13. ASSOCIATED POLICIES

- Prescribing Policy for Primary Care Providers
- Branded Medicine Prescribing Policy

14. CONTACT DETAILS

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Y01 6GA

15. APPENDIX 1: EQUALITY IMPACT ANALYSIS FORM

1.	Title of policy/ programme/ service being analysed
	Branded-Generic 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.
	This policy defines when prescribers should use branded-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 <u>due regard</u> to the need to eliminate
	discrimination, advance equal opportunities and foster good relations between people with protected
	characteristics

received.	The policy has been sent to Healthwatch York to circulate for comments, thoughts and feedback – none					
6. Who have you involved in the develop	oment of this piece of work?					
	atives, Local Medical Committee representatives, Strategy and Assurance Commissioning Group, Healthwatch, Public feedback sought via website					
characteristics? Do you have any gaps in information Include any supporting evidence e.g. There is nothing in the policy that doe Commissioning Group Equality and D Disability People who are learning disabled, physically disabled, people with mental illness, sensory loss and long term	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					
chronic conditions such as diabetes, HIV)	chronic conditions such as diabetes, HIV)					
N/A						
Men and Women	Consider gender preference in key worker, single sex accommodation etc					
N/A	N/A					
Race or nationality People of different ethnic backgrounds, including Roma Gypsies and Travelers	eople of different ethnic backgrounds, language needs etc.					
N/A	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.
ı/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 bisexual 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

17. 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-Generic 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-generic medicines.
Date completed	27 th September 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		
	Will it support more efficient use of cars (car sharing, low emission vehicles, environmentally friendly fuels and technologies)?	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 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?	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	

Domain	Objectives Will it support local or regional supply chains?	Impact of activity Negative = -1 Neutral = 0 Positive = 1 Unknown = ? Not applicable = n/a 0	Brief description of impact Policy considers impact of use of branded generics on Community Pharmacies and Dispensing Practices – neutral impact due to criteria specified in section 5.2	If negative, how can it be mitigated? If positive, how can it be enhanced?
	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		

Domain	Objectives Have you sought the views of our	Impact of activity Negative = -1 Neutral = 0 Positive = 1 Unknown = ? Not applicable = n/a	Brief description of impact Public feedback sought via website – no comments received	If negative, how can it be mitigated? If positive, how can it be enhanced?
	communities in relation to the impact on sustainable development for this activity?		Commente 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		
	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		

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