GENERIC MEDICINES (Non-Innovator Brand)
PRESCRIBING POLICY

First issued by/date	Issue Version	Purpose of Issue/Description of Change	Planned Review Date
August 2018	1.0	Promoting generic prescribing whenever possible	August 2020

Named Responsible Officer	Approved by Committee	Date
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Policy file: **General Policy**	**Impact Assessment Screening Complete -** **Full impact Assessment Required - No**	**Policy No.**

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1. Introduction

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.

The licensing process for medicines assures bioequivalence between brands and therefore on scientific grounds (with a few exceptions, see section 4), there is no reason why a patient should not be switched from a branded product to the generic equivalent. There is also 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. As such, prescribers are encouraged to prescribe medicines by their generic name as they are generally considerably less expensive, thereby freeing up NHS resources to fund other treatments and front-line services.

The British National Formulary (BNF) recommends that where non-proprietary (generic) titles are listed, they should be used in prescribing. This enables any suitable product to be dispensed, thereby saving delay to the patient and sometimes expense to the health service. The only exception is where there is a demonstrable difference in clinical effect between each manufacturer's version of the formulation, making it important that the patient should always receive the same brand; in such cases, the brand name or the manufacturer should be stated[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. Within NHS Wirral Clinical Commissioning Group, where branded-generic prescribing is more cost effective than generic prescribing, branded-generic products are preferred.

2. SCOPE OF THIS POLICY

2.1 This policy sets out NHS Wirral Clinical Commissioning Group's approach to ensure that prescribing of medication is generic (with the exceptions listed in section 4). It also supports prescribers in implementing this decision. Please see appendix 1 for sample patient letter.

2.2 This policy will ensure equity of service for all residents of the Wirral and will support the management of patient expectations when prescribed generic medicines from a GP practice or other NHS services.

2.3 This policy applies to all services and all prescribers contracted by or delivered by the NHS across NHS Wirral CCG including:

- GP Practices
- Out of hours and extended hours providers
- Acute Hospitals
- Out-Patient Clinics

- NHS Community Providers
- Independent providers
- Community pharmacies

2.4 This policy applies to all patients (adults and children) who are registered with a Wirral GP practice (permanent or temporary resident) or who access an NHS service in the Wirral.

3. Actions

It is NHS Wirral Clinical Commissioning Group's policy that all prescriptions should be prescribed generically unless the exceptions described below apply. Should 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 at https://yellowcard.mhra.gov.uk.

Consistency in prescribing behaviour is paramount to ensure that this policy is implemented fairly across NHS Wirral.

4. Exceptions to Generic Prescribing

4.1 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® vs 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.

The UK Medicines Information (UKMI) service have published a document entitled "*Which medicines should be considered for brand-name prescribing in primary care?*" This was updated in November 2017[2]. See Appendix 2

4.2 Branded Generics

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.

It is NHS Wirral Clinical Commissioning Group policy to use branded generics where appropriate, when the use of the branded generic is more cost-effective than the generic equivalent. ScriptSwitch guides prescribers where this is appropriate.

References

1.Guidance on prescribing (accessed on 27/2/18)
https://bnf.nice.org.uk/guidance/guidance-on-prescribing.html

2.UK Medicines Information (UKMi). Which medicines should be considered for brand-name prescribing in primary care? (accessed on 27/2/18) https://www.sps.nhs.uk/wp-content/uploads/2017/12/UKMi_QA_Brand-name_prescribing_Update_Nov2017.pdf

Appendix 1

Sample Patient Letter

Dear xxxxx

NHS Wirral CCG has recently approved a policy that relates to the prescribing of generic medicines. The policy requires the practice to switch patients from branded medicines to the equivalent generic medicine in line with national guidelines. This will allow cost effective and evidence-based healthcare to be consistently implemented in all GP practices in the area and will release significant savings that will be used locally for other NHS front line services.

The NHS Wirral CCG generic medicines policy requires practices to implement the guidance in the British National Formulary which states:
"Where non-proprietary ('generic') titles are given, they should be used in prescribing. This will enable any suitable product to be dispensed, thereby saving delay to the patient and sometimes expense to the health service."

You have previously been prescribed [insert brand drug name and strength]

You will now be prescribed [insert generic drug name and strength]

Your new generic medicine contains the same quantity of active ingredients as the branded medicine that you have previously received from the practice.
Your new medication may appear different to your previous medication but still contains exactly the same active ingredient in the same amount.

If you have any queries relating to the change in your prescription, please contact [insert practice contact].

If you remain unhappy with the NHS Wirral CCG generic medicines policy you should contact NHS Wirral CCG directly on 0151 541 5380.

UKMi - Medicines that should be considered for brand-name prescribing in primary care. Please see full document for further information and references - https://www.sps.nhs.uk/wp-content/uploads/2017/12/UKMi_QA_Brand-name_prescribing_Update_Nov2017.pdf

BNF Chapter	Drug or drug class	Reason for considering brand-name prescribing
1	Mesalazine oral preparations	The BNF states there is no evidence that any one oral preparation of mesalazine is more effective than another; however, delivery characteristics of mesalazine preparations may vary [4]. If switching to a different brand of mesalazine, advise the patient to report any changes in symptoms [16].
2	Diltiazem MR preparations > 60mg	Different versions of diltiazem MR preparations containing more than 60mg may not have the same clinical effect [4].
	Nifedipine MR preparations	Different versions of nifedipine MR preparations may not have the same clinical effect [4].
3	Dry powder inhalers	Patient familiarity with one brand is important; instructions for use vary between preparations and patient training is required [8]. Generic prescribing of inhalers should be avoided as this can lead to people with asthma being given an unfamiliar inhaler device with resultant problems of usage and compliance [17].
3	Theophylline MR preparations	Theophylline has a narrow therapeutic index and bioavailability differs between brands of oral MR theophylline. Patients should be maintained on the same brand [4, 17]. If a prescription for an oral theophylline MR preparation does not specify a brand name, the pharmacist should contact the prescriber and agree the brand to be dispensed [4].
3	Aminophylline MR preparations	Aminophylline has a narrow therapeutic index and bioavailability differs between brands. Patients should be maintained on the same brand [4]. If a prescription for an oral aminophylline MR preparation does not specify a brand name, the pharmacist should contact the prescriber and agree the brand to be dispensed [4].
3	Beclometasone dipropionate- containing CFC-free pressurised metered dose inhalers	Beclometasone dipropionate CFC-free pressurised metered-dose inhalers are not interchangeable and should be prescribed by brand name; Qvar has extra-fine particles, is more potent than traditional beclometasone dipropionate CFC-containing inhalers, and is approximately twice as potent as Clenil Modulite [4,18].
3	Adrenaline (epinephrine) pre-filled syringes	Patient familiarity with one brand is important; instructions for use vary between preparations and patient training is required [8]. To ensure patients receive the auto-injector device that they have been trained to use, prescribers should specify the brand to be dispensed [4].
4	Lithium preparations	Lithium has a narrow therapeutic index and preparations vary widely in bioavailability. Changing the preparation requires the same precautions as initiation of treatment [4].
4	Buprenorphine patches	Buprenorphine patches are available as 72-hourly, 96-hourly and 7-day formulations [4,9]. Brand name prescribing is recommended to reduce the risk of confusion and error in dispensing and administration [9,19].
4	Fentanyl patches	Fentanyl patches are available as matrix and reservoir formulations. Reservoir patches must not be cut because damage to the rate-limiting membrane can lead to a rapid release of fentanyl resulting in overdose [9]. If the prescriber intends the patch to be cut (NB: unlicensed and not

		recommended by the MHRA) then the prescription must specify a brand of matrix formulation patch. Brand name prescribing is recommended to reduce the risk of confusion and error in dispensing and administration [9,19].
4	Methylphenidate MR preparations	Methylphenidate MR preparations contain both immediate-release (IR) and MR methylphenidate. The proportion of IR and MR methylphenidate differs between brands; different preparations may not have the same clinical effect [4].
4	Morphine oral MR preparations	Oral morphine MR preparations are available in 12-hourly and 24- hourly formulations. Dosage requirements should be reviewed if the brand of morphine MR is altered [4]. The pharmacokinetic profiles of MR products differ; to minimise the risk of mistakes, it is best to keep individual patients on the same MR brand [9]. Including the brand name on the prescription and dispensing label will aid in identification of the correct formulation to be dispensed or administered [20].
4	Oxycodone oral MR preparations	Oral oxycodone MR preparations are available in 12-hourly and 24-hourly formulations [4]. Brand-name prescribing is recommended to reduce the risk of confusion and error in dispensing and administration [9,21].
4	Tramadol oral MR preparations	Oral tramadol MR preparations are available as 12-hourly or 24- hourly formulations [4]. Brand-name prescribing is recommended to reduce the risk of confusion and error in dispensing and administration [9].
4	Antiepileptic drugs (when used for epilepsy)	The MHRA has classified antiepileptic drugs (AEDs) into three categories of risk, based primarily on their therapeutic index and physiochemical characteristics (in particular solubility and permeability across membranes) to help healthcare professionals decide whether it is necessary to maintain continuity of a specific manufacturer's product [22]: **Category 1:** Specific measures are necessary to ensure consistent supply of a particular product (which could be either a branded product or a specified manufacturer's generic product). **Category 2:** NB: By default, this category includes all AEDs not listed in categories 1 or 3. The need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with patient and/or carer. It is necessary to consider clinical factors such as seizure frequency, treatment history and the potential implications for the individual of having a breakthrough seizure. **Category 3:** Therapeutic equivalence between branded and generic products (and between generics) can be assumed. For these drugs, it is usually unnecessary to ensure that patients are maintained on a specific manufacturer's product unless there are specific reasons such as patient anxiety and risk of confusion or dosing errors. The MHRA acknowledges factors other than therapeutic equivalence are important. Differences between products (e.g. product name, packaging, appearance and taste) may be perceived negatively by patients or carers and may lead to dissatisfaction, anxiety, confusion, dosing errors and reduced adherence. Difficulties for patients with autism, learning disability or mental health problems should be considered [15]. NICE recommends consistent supply (of the same brand, or the same generic preparation), for patients with seizure disorders, unless the

		prescriber, in consultation with the patient and their family or carers, considers this not to be a concern [23]. (For individual antiepileptic agents, see below.)
4	Carbamazepine	MHRA Category 1 (see 'Antiepileptic drugs' above)
4	Ethosuxamide	MHRA Category 3 (see 'Antiepileptic drugs' above)
4	Gabapentin	MHRA Category 3 (see 'Antiepileptic drugs' above)
4	Lacosamide	MHRA Category 3 (see 'Antiepileptic drugs' above)
4	Levetiracetam	MHRA Category 3 (see 'Antiepileptic drugs' above)
4	Phenobarbital	MHRA Category 1 (see 'Antiepileptic drugs' above)
4	Phenytoin	MHRA Category 1 (see 'Antiepileptic drugs' above)
4	Pregabalin	MHRA Category 3 (see 'Antiepileptic drugs' above) NHS guidance effective from July 2017 advises pregabalin can be prescribed generically for all indications [14]. Previous guidance issued in March 2015 recommended pregabalin be prescribed by brand name as far as reasonably possible, when used for neuropathic pain [12,13]. That guidance has now been withdrawn.
4	Primidone	MHRA Category 1 (see 'Antiepileptic drugs' above)
4	Tiagabine	MHRA Category 3 (see 'Antiepileptic drugs' above)
4	Vigabatrin	MHRA Category 3 (see 'Antiepileptic drugs' above)
6	Insulins	Patient familiarity with one brand is important; instructions for use vary between preparations and patient training is required [8].
8	Mycophenolate (when used to prevent transplant rejection)	Switching between a brand and generic formulation, or between generic formulations, should be initiated only by a transplant specialist [24].
8	Ciclosporin (when used to prevent transplant rejection)	Ciclosporin must be prescribed and dispensed by brand name. Patients should be stabilised on a particular brand of oral ciclosporin because switching between formulations without close monitoring may lead to clinically important changes in blood- ciclosporin concentration [25]. Switching between a brand and generic formulation, or between generic formulations, should be initiated only by a transplant specialist [24].
8	Tacrolimus (when used to prevent transplant rejection)	Inadvertent switching between oral tacrolimus products has been associated with reports of toxicity and graft rejection. To ensure maintenance of therapeutic response when a patient is stabilised on a particular brand, oral tacrolimus products should be prescribed and dispensed by brand name only [26]. Switching between a brand and generic formulation, or between generic formulations, should be initiated only by a transplant specialist [24].
13	Preparations for skin and scalp conditions containing multiple ingredients	To aid identification where products contain multiple ingredients [11]. Also, potency of topical corticosteroid preparations is a result of the formulation as well as the corticosteroid [4].