PrescQIPP Community Interest Company

Branded generic medicines

This bulletin focuses on the prescribing of branded generic medicines in primary care. It looks at the saving opportunities available and provides some principles to apply if considering branded generics during formulary reviews.

Recommendations

Recommending branded generic prescribing and inclusion of these medicines in local formularies can be a cost saving proposition for commissioning organisations. Savings may be possible, for example, for Category C items and when brand prescribing is required (see attachment 1), however consider these principles before proceeding:

- Prescribing Category M branded generics could affect the competition that drives down prices in the generics market and could drive up costs to the NHS.
- The impact of including a branded generic in the formulary could create a large demand for the product over a very short period of time, especially if several commissioners switch at the same time; therefore supply could potentially be limited.
- GP practices should be informed of formulary decisions involving branded generics and of any stock issues that arise, e.g. via newsletters.
- Community pharmacies and GP dispensing practices will need to be involved in, and informed of, the formulary decisions and may need to be provided with information on how to access these branded generics. This may be different from their normal supply routes. They may incur additional expenses obtaining them, which are directly charged back to the NHS by Out of Pocket Expenses claims.
- Check which wholesalers stock the branded generic recommended and if they have the capacity to supply the quantities required.
- Notify and engage with relevant pharmaceutical companies to reduce risks to the supply chain due to an increased demand for the branded generic medicine.
- Check that the bioavailability and the release profiles of the branded generic are interchangeable/ equivalent to the innovator medicine (or the medicine currently recommended by the commissioner). This is because a wide range of branded generics are available as modified or sustained release preparations.
- Check if there is sufficient information available for prescribers relating to the branded generic medicine. Is it included in the British National Formulary (BNF)? Does it have a readily accessible Summary of Product Characteristics (SPC)? Check the branded generic SPC to ensure the indications are equivalent to the innovator medicine (or the medicine currently recommended by the commissioner).
- Check that the branded generic is listed on the prescriber's clinical system to allow the chosen product to be prescribed correctly.
- The prices of branded generic medications may change frequently. Check if the pharmaceutical company gives a price guarantee for the branded generic. If not, this could mean a need for regular reviews to ensure the most cost-effective recommendations.

Background

Many medicines have at least two different names:[1-3]

- The brand (trade or innovator) name – This is the name given to a pharmaceutical product by the manufacturer who created the medicine. The use of this name is reserved exclusively to the original manufacturer as opposed to the generic name.
- The generic name – This is the approved name of the active ingredient in the medicine and used for marketing after the expiry of patent or other exclusivity rights.

Pharmaceutical companies take out exclusive rights (patents) on each new drug they discover. If a company has a patent on a drug, only that company can market it under their brand name once it has been granted a licence. Once the patent expires, other manufacturers can market generic versions. The generic versions will be the same as the branded medicine because they contain the same active ingredients.[1]

In the UK there are strict quality controls before a product licence is granted for branded or generic versions of medicines. This means that a generic or branded version of the same medicine will be of the same quality and have the same action. Generic medicines often cost far less than the branded versions and so are cheaper for the NHS.[1,2]

Brand names may also be used for generic products; they are then often called “branded generics”. These brand names are different from innovator brand names. Many different branded generic products of the same medicine can be on the market in a country along with the original branded product.[3]

Branded generics are different to ghost generics. Ghost generics are items prescribed generically with the manufacturers name stated.[4] When an item is prescribed generically, the dispenser is reimbursed at the price in the Drug Tariff; but when a manufacturer is stated, the reimbursement price is usually more expensive.[5] This problem mainly occurs with SystmOne, so PrescQIPP has a prescribing report and searches to support identifying patients who may have inadvertently been prescribed a generic with the manufacturers name stated in brackets.

Reimbursement and the Drug Tariff

The Drug Tariff outlines what will be paid to dispensing contractors for NHS services provided. This is for reimbursement of the cost of the medicines, appliances etc. which have been supplied against an NHS prescription or for remuneration. It also sets out what they are paid as part of the dispensing contract for fees/allowances.[6] The price used to reimburse a dispensing contractor for the medicine or appliance they dispense depends on whether the prescribed product is a branded or generic medicine. When a medicine is prescribed by brand name, the reimbursement is based on the manufacturer’s list price for the prescribed product.[7] The 2019 voluntary scheme for branded medicines pricing and access is a non-contractual voluntary agreement between the Department of Health and Social Care (DHSC) and the Association of the British Pharmaceutical Industry (ABPI) to keep the branded medicine bill affordable for the NHS through a cap in growth of branded sales.[8] Although the prices to the NHS of these branded products can be high, pharmacists often make a loss on dispensing them, because the reimbursement price is lower than the purchase price.[7]

Part VIIIA of the Drug Tariff contains the basic NHS reimbursement prices for medicines prescribed generically. It includes most of the commonly prescribed products. Part VIIIA is further divided into categories A, C, and M:[6,9]

Category A

Category A includes popular generics, which are widely available. The price is determined by the Secretary of State for Health and based on a weighted average of the list prices from two wholesalers and two generic manufacturers.[6,9] Some examples of Category A medicines include: isosorbide dinitrate 10mg and 20mg tablets (56), paracetamol 120mg/5ml oral suspension paediatric (500ml) and beclometasone 0.025% cream and ointment (30g).[6]

Category C

Category C items are not readily available as a generic, the price is based on a particular brand, manufacturer or supplier.[6,9] Some examples of Category C medicines include: calamine lotion (Thornton & Ross Ltd), fluticasone/salmeterol inhalers CFC free (Seretide Evohaler), diltiazem 90mg modified-release capsules (Adizem-SR).[6] For certain medicines in Category C it is advisable to prescribe by the brand name, for example inhalers. This will ensure patients are supplied the correct inhaler device they are familiar with. Prescribers should specify the brand to be dispensed for certain modified-release preparations, as they may not have the same clinical effect between different brands. As these are in Category C the dispensing contractors will be paid based on the brand listed. Branded generics can offer a cost saving alternative for some Category C items if the cost is cheaper than the brand that the Drug Tariff price is based on (see attachment 1 for some examples). Branded generics could also be considered for items where the brand should be specified for new patients. If the patient is stabilised on a certain brand then switching to a branded generic may not be suitable, however if drug characteristics such as bioavailability, release profile and indication(s) of the branded generic are interchangeable/equivalent then this could be considered with caution, but may require specialist input and additional monitoring.

Category M

Category M includes medicines that are readily available. The DHSC calculates the price based on information submitted by manufacturers.[6,9] Some examples of Category M medicines include: ramipril capsules, metformin tablets and amoxicillin capsules.[6]

Prescribing medicines by generic rather than brand name can improve cost-effectiveness and is encouraged. There are some circumstances in which continuity of the same product is important for patient safety and prescribing a specific manufacturer's product (brand or generic) is preferred. These include:[10]

- Drugs where there is a difference in bioavailability between brands of the same medicine, particularly if the medicine has a narrow therapeutic index.
- Where modified-release preparations are not interchangeable.
- Where there are important differences in formulation between brands of the same medicine.
- Where administration devices (e.g. inhaler or self-injection) have different instructions for use and patient familiarity with one product is important.
- Where the product is a biological rather than chemical entity.
- Where products contain multiple ingredients and brand-name prescribing aids identification.
- Where there are differences in licensed indications.

Some examples of medicines which should be prescribed by a specific manufacturer's product include: adrenaline pre-filled syringes, aminophylline, buprenorphine patches, carbamazepine, ciclosporin, fentanyl patches, lithium, methylphenidate MR, morphine MR, mycophenolate, phenytoin, tacrolimus and theophylline.[10]

For new patients, branded generics could be a cost effective choice of treatment for products where the brand needs to be specified e.g. modified release products. For patients already stable on a certain brand then switching to a branded generic should be considered with caution. Drug characteristics such as bioavailability, release profile and indication(s) of the branded generic would need to be considered and specialist input and additional monitoring maybe required.

Discount deduction

Contractors are reimbursed for the medicines they dispense each month by the NHS Business Services Authority (NHSBSA), less an amount of discount deduction or 'clawback'. The 'clawback' amount is calculated according to a discount deduction scale (DDS) shown in the Part V of the Drug Tariff and is

based on the monthly value of medicines dispensed (Net Ingredient Cost or NIC) for each contract. It is possible to work out from the DDS (Part V of the Drug Tariff) what the deduction rate will be for a given value of standard discount rate products dispensed. The value of zero discount-rated products dispensed is not considered when calculating the discount deduction rate. Currently the average level of discount deduction across all products is approximately 8%.[6,11]

The potential cost of branded generics for the NHS, dispensing contractors and patients

Category M is of the greatest interest to prescribers, commissioners and dispensing contractors, because it includes the majority of generic medicines that are prescribed in primary care.[7] It is the principal price adjustment mechanism to ensure delivery of the retained margin, guaranteed as part of the Community Pharmacy contractual framework and is used to set the reimbursement prices of over 500 medicines.[12]

The community pharmacy sector will receive £2.592 billion per year from 2019/20 to 2023/24. Of the annual sum, £800 million is to be delivered as retained buying margin. This is the profit pharmacies can earn on dispensing drugs through cost effective purchasing. The £800m retained margin element is a target that the DHSC aim to deliver by adjusting the reimbursement prices of drugs in Category M of the Drug Tariff. The delivery of margin to pharmacy is carefully monitored by the Pharmaceutical Services Negotiating Committee (PSNC) and the DHSC. Where they identify that the delivery rate of margin to community pharmacy will under, or over deliver on the £800 million target, the DHSC will re-calibrate Category M Drug Tariff prices to bring the margin delivery rate back on track.[12]

Category M prices are set to include an element of purchase profit so reimbursement prices may be higher than manufacturer's list prices.[13] Although most generic medicines in Category M are the most cost effective way of prescribing that medicine, at times manufacturers reduce the price of their branded product to one that is cheaper than the equivalent generic product listed in Category M. This is done to promote market share of the branded product.[7] Sometimes to save money, some commissioners may encourage the prescribing of, and switching patients to a specific branded generic.[7,13] Such a policy and formulary inclusion may deliver some short term local cost savings to the commissioner's drugs budget, but the savings are often unsustainable by the manufacturer, and will ultimately end up costing more for the NHS.[7]

When medications are prescribed generically, pharmacies seek to obtain the best available generics prices. This will drive down the prices being charged by wholesalers, manufacturers and in turn the Drug Tariff reimbursement prices and costs for the NHS. Prescribing Category M branded generics profoundly affects the competition that drives down prices in the generics market and acts to drive up costs to the NHS.[13]

Branded generic drug manufacturers sell their brands into the market at prices that include the costs of their marketing efforts with commissioners and prescribers. These costs are not incurred by "true" generic manufacturers. They are able to list prices lower than those of the equivalent generic drug because they are not contributing, or contributing at minimal level, to the delivery of the agreed level of purchase profit that is part of the contractual framework funding. The contribution that is missing is consumed by marketing costs and the branded generic manufacturer's own profits. When recommending Category M branded generics, pharmacy contractors are required to purchase branded products for which there is little or no discount, but the discount reduction is still applied when the prescription is priced by NHS Prescription Services. Consequently the items may be reimbursed at less than cost price to the pharmacy.[13]

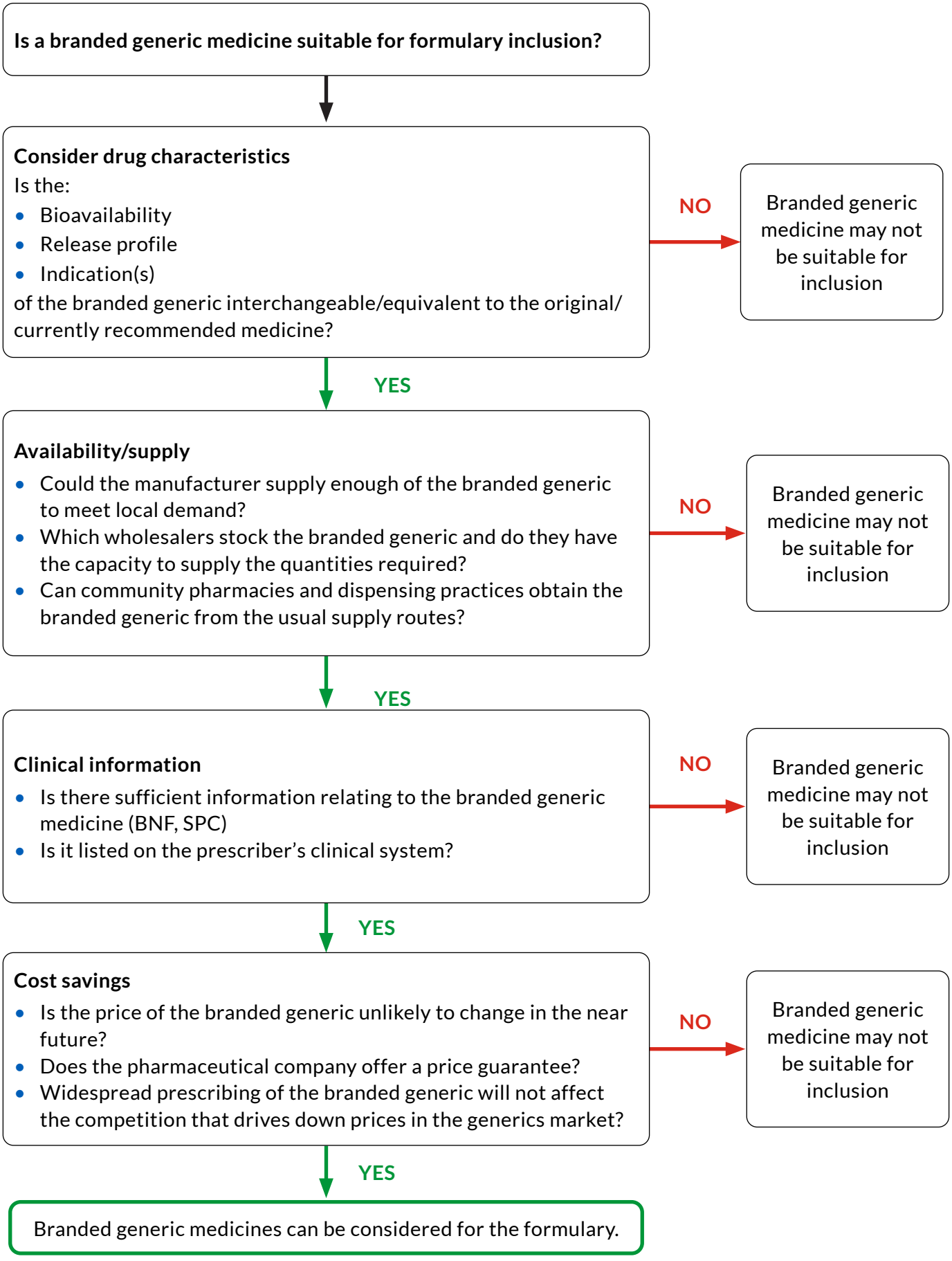
Although branded generics may not be suitable as an alternatives to Category M generic medications, they can offer a cost saving alternative for some Category C items (see attachment 1 for some examples). Category C items are not readily available as a generics and their price is based on a particular brand, manufacturer or supplier.[6,9] If the cost of the branded generic is cheaper than the brand that the

Drug Tariff price is based on, then saving opportunities are available. Branded generics could also be considered for items where a particular brand should be specified. This would be suitable for new patients, but may require caution for patients stabilised on a certain brand.

When considering branded generics for inclusion in a local formulary, commissioners should follow an assessment process to ensure they would be suitable. Figure 1, on the next page, demonstrates some important points to consider.

Community pharmacies and GP dispensing practices may have to order the branded generics from a

Figure 1: Flow chart to illustrate an assessment process of branded generic medicines for inclusion in formularies



different supplier than normal. This may incur additional expenses which can be claimed back as Out of Pocket Expenses. Out of Pocket Expenses includes costs such as postage and packaging, handling and the cost of phone calls to manufacturers or suppliers to order products.[14]

Summary

Recommending branded generic prescribing and inclusion of these medicines in local formularies can produce cost saving for commissioners. Branded generics can be considered for some Category C items and medications where the brand should be specified. Caution is required for patients stabilised on a certain brand, specialist involvement and increased monitoring may be needed if switching is being considered, whereas newly initiated patients could be prescribed a branded generic.

Commissioners should follow an assessment process when considering branded generics for inclusion in a local formulary. An important point to consider is whether the pharmaceutical company gives a price guarantee for the branded generic as prices can change frequently which means regular reviews are required to ensure the most cost-effective medicines are recommended.

Recommending a branded generic can create a large demand over a very short period of time, especially if several commissioners switch at the same time, potentially this could limit supply. If commissioners are considering recommending a branded generic, they should check which wholesalers stock the branded generic and with the relevant pharmaceutical companies to reduce risks to the supply chain due to an increased demand for the branded generic. Community pharmacists and GP dispensing practices should be informed about how to access the recommended branded generic as this might not be from their usual supplier. This can result in extra charges obtaining the product which is charged to the NHS as Out of Pocket Expenses.

Many branded generic medicines are modified or sustained release preparations, so commissioners should check the bioavailability and the release profiles are interchangeable/equivalent to the original medicine or the medicine currently recommended. Ensure there is sufficient information available for prescribers on the recommended branded generic. Is the branded generic in the BNF? Does it have a SPC? Is it listed on the prescribers' clinical system? It is important that prescribers have access to enough information, to satisfy themselves that the chosen product is prescribed correctly and appropriately.

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Additional PrescQIPP resources

Briefing Implementation tools	https://www.prescqipp.info/our-resources/bulletins/bulletin-290-branded-generic-medicines/

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