Standard Operating Procedure (SOP)

MANAGEMENT OF HIGH COST MEDICINES

SETTING Trustwide

FOR STAFF For staff who prescribe high cost medicines and divisional budget managers

ISSUE To provide the appropriate control of high cost medicines, with the necessary commissioning, financial, and governance arrangements in place.

Background

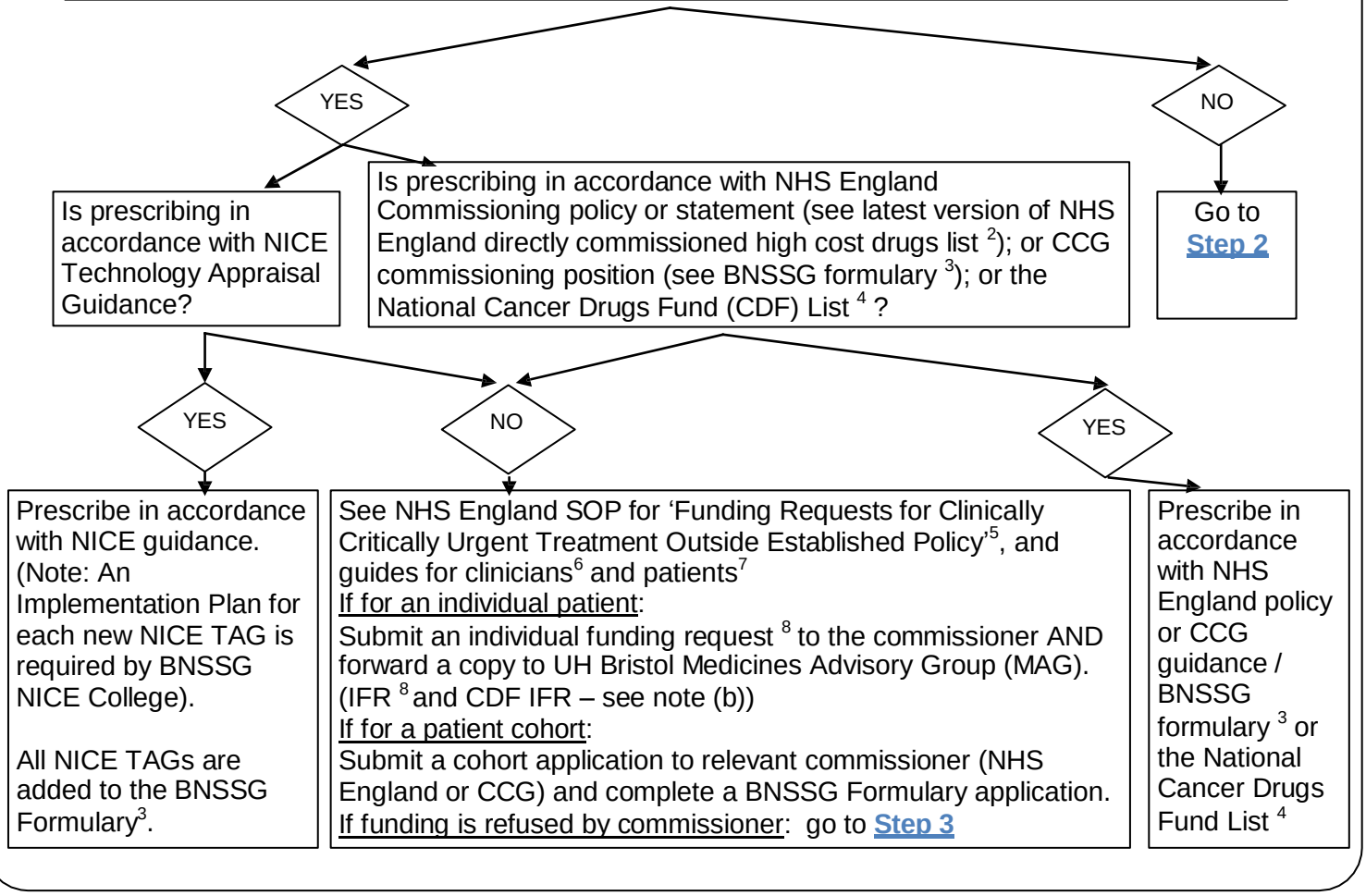
A medicine is considered to be "high cost" when:

- It is incorporated on the 'high cost drugs' list (drugs excluded from the national tariff as defined by HSCIC / Monitor / NHS England [1]) and / or the NHS England high cost list 'Medicines not reimbursed through national prices and directly commissioned by NHS England'.[2]
- Also, in the context of the following flow chart:
  Where a single patient's treatment will cost over £2,000 per annum, or the total anticipated divisional expenditure will exceed £10,000 per annum.

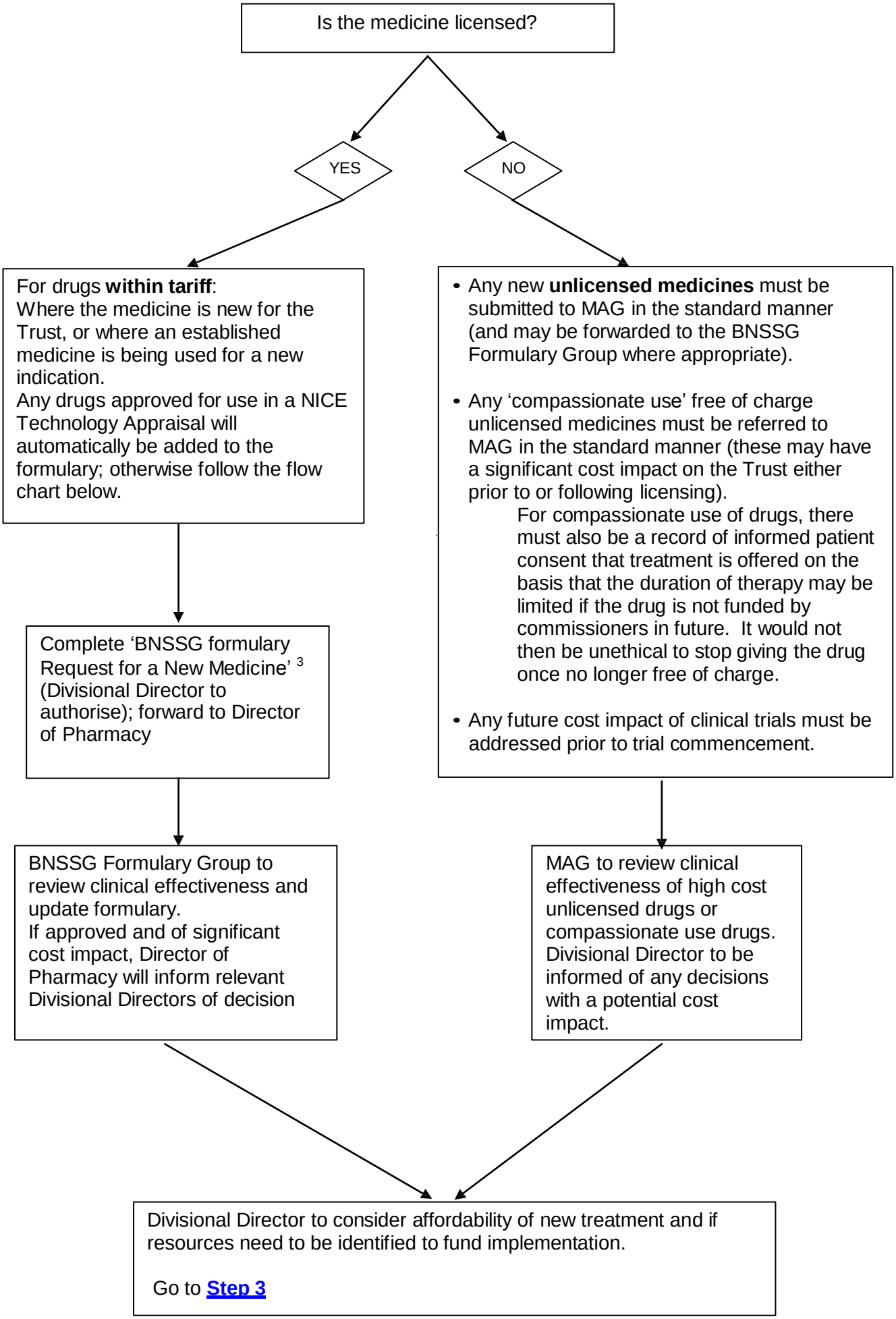
The following flow diagram outlines the Trust process for addressing both the clinical effectiveness and affordability of high cost medicines.
Any new high cost medicines (whether licensed or unlicensed) that are required in an emergency situation must be referred to the relevant Divisional Director and Director of Pharmacy - See note (a)

Step 1

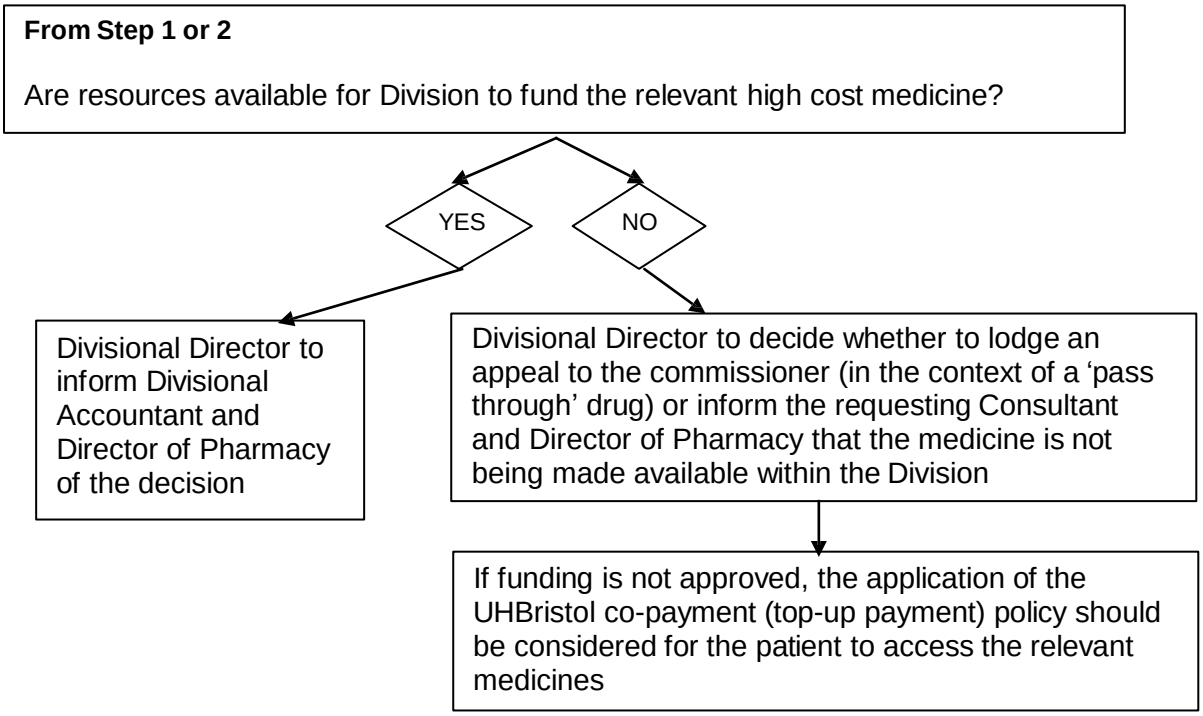
Is the drug **outside tariff**? ie a 'pass through' drug incorporated on the 'high cost drugs list' (drugs excluded from the national tariff as defined by HSCIC / Monitor / NHS England [1]) and / or the NHS England high cost drugs list 'Medicines not reimbursed through national prices and directly commissioned by NHS England' [2], and / or is cancer chemotherapy (which is all outside tariff).



Step 2


Is the medicine licensed?
YES
NO
For drugs **within tariff**:
Where the medicine is new for the Trust, or where an established medicine is being used for a new indication.
Any drugs approved for use in a NICE Technology Appraisal will automatically be added to the formulary; otherwise follow the flow chart below.
Complete 'BNSSG formulary Request for a New Medicine' [3] (Divisional Director to authorise); forward to Director of Pharmacy
BNSSG Formulary Group to review clinical effectiveness and update formulary.
If approved and of significant cost impact, Director of Pharmacy will inform relevant Divisional Directors of decision
• Any new **unlicensed medicines** must be submitted to MAG in the standard manner (and may be forwarded to the BNSSG Formulary Group where appropriate).
• Any 'compassionate use' free of charge unlicensed medicines must be referred to MAG in the standard manner (these may have a significant cost impact on the Trust either prior to or following licensing).
For compassionate use of drugs, there must also be a record of informed patient consent that treatment is offered on the basis that the duration of therapy may be limited if the drug is not funded by commissioners in future. It would not then be unethical to stop giving the drug once no longer free of charge.
• Any future cost impact of clinical trials must be addressed prior to trial commencement.
MAG to review clinical effectiveness of high cost unlicensed drugs or compassionate use drugs. Divisional Director to be informed of any decisions with a potential cost impact.
Divisional Director to consider affordability of new treatment and if resources need to be identified to fund implementation.
Go to Step 3

Step 3



Note (a): Where there is an urgent requirement, the Director of Pharmacy (or deputy) will obtain from the Divisional Director (or deputy) the approval for progressing with treatment on an 'at risk' basis.

Note (b): IFR application forms [8] may be obtained from the Director of Pharmacy. A Cancer Drugs Fund IFR application (ICDFR) is by a separate process and must be submitted directly on-line via BlueTeq.

1. https://improvement.nhs.uk/resources/national-tariff-1719/ Annex A Tab 13b
2. https://www.england.nhs.uk/wp-content/uploads/2017/04/nhs-england-drugs-list-v12.pdf
3. http://www.bnssgformulary.nhs.uk/
4. http://www.england.nhs.uk/ourwork/pe/cdf/
5. http://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/06/ccu-pub-doc-11062015.pdf
6. How do I reach a decision about treatment for my patient? http://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/06/how-to-reach-decision-trtmnt-pats.pdf
7. Individual funding requests – A guide for patients and service users http://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/06/individl-fund-reqts-info-pats.pdf
8. NHS England IFR form – http://www.england.nhs.uk/commissioning/policies/gp/

University Hospitals Bristol NHS
NHS Foundation Trust

M4: Policy for Prescribing of Medicines Used Outside the Scope of a Product Licence

Document Data	
Subject:	Procedural Documents
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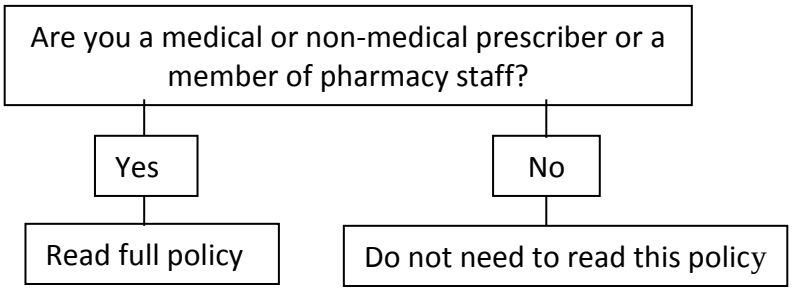
Document Abstract
Whenever possible, prescribing of medicines should be for indications for which the medicine is licensed. However, there are clinical situations when the use of unlicensed medicines or use of medicines outside the terms of the licence i.e. 'off-label' may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence. This policy lists the type of situations when an unlicensed medicine may be used and details the prescriber's responsibility to the patient in assessing the patient's needs for alternatives to the use of an unlicensed medicine and ensuring that the patient is fully aware of the use of an unlicensed medicine.

Who should read this document?



[1] Divide number of words (2532) by 240 for average reading time and add 25% for specialist content.

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
17.01.13	2	Director of Pharmacy	Major	Review, update and re-format into new approved trust format.
May 2016	3	Director of Pharmacy	Minor	Review and Update.

Table of Contents

1. Introduction

1.1 Whenever possible, prescribing of medicines should be for indications for which the medicine is licensed. However, there are clinical situations when the use of unlicensed medicines or use of medicines outside the terms of the licence i.e. 'off-label' may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence. Such practice is particularly common in certain areas of medicine: for instance, in paediatrics where difficulties in the development of age-appropriate formulations means that many medicines used in children are used off-label or are unlicensed.

1.2 Healthcare professionals may regard it necessary to prescribe or advise on the use of an unlicensed medicine (through the 'specials' regime when no licensed suitable alternative is available, or when a medicine is prepared in a pharmacy by, or under the supervision of, a pharmacist), or the use of a licensed medicine outside the terms defined by the licence e.g. outside defined indications, doses, routes of administration, contrary to listed warnings or use in pregnancy.

1.3 Unlicensed or Off label use commonly includes the use of:

a) A medicine by its licensed route, to treat a disease not included in its licensed indications, or to treat a patient group not included in these licence specifications.

b) A medicine by an unlicensed route or in a manner not included in the data sheet recommendations.

c) An unlicensed medicine, in the absence of any suitable licensed formulation.

1.4 In each of these situations, the prescriber should be fully aware that his/her professional responsibility is increased. The prescriber has a duty to take reasonable care and act in a manner consistent with the practice of a responsible body of his/her peers of similar professional standing.

1.5 The Trust indemnity cover applies to any clinicians who prescribe in such a responsible manner. Practice in any other way may result in the prescriber being personally accountable for any injury caused to the patient. (Advice on the use of medicines in unlicensed indications may be obtained from the pharmacy).

1.6 Licensed medicines must therefore be prescribed, and administration of these medicines undertaken according to the Summary of Product characteristic recommendations, unless the patient has special needs that are not met by this course of action.

1.7 Medical and non-medical independent prescribers and supplementary prescribers acting in accordance with the clinical management plan are permitted to prescribe unlicensed or off label medicines providing that they are acting within the boundaries of their individual clinical competence; the professional codes and ethics of their statutory bodies; and the prescribing policies of UHBristol.

1.8 The responsibility that falls on healthcare professionals when prescribing an unlicensed medicine or a medicine off-label may be greater than when prescribing a licensed medicine within the terms of its licence. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label. These risks may include: adverse reactions, low product quality; or discrepancies in product information or labelling (e.g. absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports, and

potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use).

2. Purpose and Scope

2.1 The purpose of this policy is to identify the scenarios when an unlicensed medicine is most likely to be used and to define the prescriber's responsibilities in the use of an unlicensed medicine.

3. Definition

3.1 *Licensed medicine*

(a) A licensed medicine is a medicine that holds a marketing authorisation or product licence. A marketing authorisation or product licence defines a medicine's terms of use: its Summary of Product Characteristics outlines, among other things, the indication(s), recommended dose(s), contraindications, and special warnings and precautions for use on which the licence is based, and it is in line with such use that the benefits of the medicine have been judged to outweigh the potential risks. Furthermore, a licensed medicine has been assessed for efficacy, safety, and quality; has been manufactured to appropriate quality standards, and when placed on the market is accompanied by appropriate product information and labelling.

3.2 *Unlicensed medicine*

(a) An unlicensed medicine is a medicine which either;

i. Does not hold a marketing authorisation in the UK.

ii. Is a 'special'; that is a medicine that is specially manufactured or imported to the order of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber for the treatment of an individual patient. (MHRA, https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials).

(b) The term unlicensed medicine is often used to indicate off-label use of a licensed medicine.

3.3 *Off-label use of a licensed medicine*

(a) Off label use of a licensed medicine is the use of a licensed medicine outside the scope of its product licence. This may be in an unlicensed patient group e.g. the use in a child when the medicine is licensed for adults only, or the use of a different dose, route or for a different indication to that detailed in the marketing authorisation.

4. Duties, Roles and Responsibilities

4.1 *Director of Pharmacy*

(a) The Director of Pharmacy will ensure that all unlicensed medicines issued by pharmacy are issued in accordance with the pharmacy standard operating procedures for dispensing unlicensed medicines.

4.2 *Prescribers*

(a) Prior to prescribing an unlicensed medicine, prescribers will be satisfied that an alternative licensed medicine will not meet the patient's needs.

(b) Prior to prescribing an off-label medicine, prescribers will be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative.

(c) Before prescribing an unlicensed medicine or using a medicine off-label, prescriber's will:

i. Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to show its safety and efficacy

ii. Take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up

iii. Record the medicine prescribed and, where common practice is not being followed, the reasons for prescribing this medicine. Record the fact that you have informed the patient that the medicine is not licensed or being used off label.

(d) Prescribers will:

i. Give patients, or those authorising treatment on their behalf, sufficient information about the proposed treatment, including known serious or common adverse reactions, to enable them to give informed consent. Where current practice supports the use of a medicine outside the terms of its licence, it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients or carers require or which they may see as relevant.

ii. Explain the reasons for prescribing a medicine off-label or prescribing an unlicensed medicine where there is little evidence to support its use, or where the use of a medicine is innovative

4.3 *Pharmacy Staff*

(a) Pharmacy staff are responsible for the accuracy and quality of the preparation when a medicine has been specially prepared for a patient.

(b) Pharmacy staff are responsible for accurately dispensing an unlicensed medicine in accordance with pharmacy department standard operating procedures.

4.4 *All Healthcare professionals*

(a) Healthcare professionals have a responsibility to help monitor the safety of medicines in clinical use through submission of suspected adverse drug reactions to the MHRA and CHM via the Yellow Card Scheme. Such reporting is equally important for unlicensed medicines or those used off-label as for those that are licensed.

5. Policy Statement and Provisions

5.1 *Use of licensed medicines outside the scope of a product licence (off-label use)*

(a) In circumstances where the patient category or disease is not included in the product licence, the prescriber is responsible for the clinical effects of the medicine. He/she must therefore be fully aware of this responsibility and consider the benefits and risks before prescribing.

(b) If the benefits of using a product outside the scope of the licence are appreciable, this may be the more appropriate practice.

(c) If there is good published data on dosage and efficacy of a medicine in a required situation, it may be prescribed outside the scope of its product licence. In this situation, the General Practitioner may be asked to assume prescribing responsibility. The GP may request prescribing information and guidance in such circumstances and the resulting communication should be undertaken speedily to avoid inconvenience to patients.

(d) Prescriptions must always be clear and complete, hence must provide specific details of the administration of a medicine. For example, for intravenous infusions, the dose, infusion fluid, volume, rate and route must be specified. In circumstances where the prescriber wishes to administer the drug outside the scope of the licence, he/she must again consider the benefits and risks prior to prescribing and will be responsible for the clinical effects of the preparation.

5.2 *Use of Unlicensed Medicines*

(a) Where a licensed equivalent is available, it should be used unless the patient's requirements are not met by the use of the licensed product.

(b) Where a licensed product is unavailable although the ingredients are recognised as standard. In such circumstances, the pharmacy may prepare or purchase unlicensed preparations, for example:

i. Re-formulating licensed drugs into a different pharmaceutical presentation to aid administration to specific patient groups (e.g. oral suspensions for paediatric patients).
ii. Developing novel formulations using recognised pharmaceutical ingredients to treat specialist patient groups (e.g. individually prepared topical dermatology formulations).

(c) The prescriber should consider that supplies of unlicensed medicines may not be consistent or guaranteed, particularly if the unlicensed medicines has to be specifically imported for use.

5.3 *Where novel formulations of unconventional ingredients are required*

(a) Occasionally, novel formulations may be purchased or developed locally for individual patients which contain unconventional ingredients (i.e. they do not appear in a current Pharmacopoeia). Where such therapy may be regarded as research, proposals to prescribe

such medicines must be submitted to the Research Ethics Committee, prior to use in patients.

(b) In circumstances where a prescriber considers the use of such novel formulations is essential and urgent, informed written consent must be obtained from the patient or guardian.

(c) As with other unlicensed medicine use, the manufacturer is responsible for the accuracy and quality of preparation and the prescriber is responsible for the clinical effects of the preparation.

5.4 *Compassionate Use of medicines prior to marketing authorisation*

(a) On some occasions, new medicines are made available for individual patients on a compassionate basis, often prior to receiving a marketing authorisation in the United Kingdom.

(b) This poses an ethical dilemma, and it has been agreed that the compassionate use of such drugs would be ethical as long as the patient was offered treatment and gave informed consent for that treatment on the basis that the duration of therapy may be limited. It would not then be unethical to stop giving the drug once it was no longer free, if no funding had been agreed.

6. Standards and Key Performance Indicators

6.1 *Applicable Standards*

(a) Prescribers will consider the suitability of available licensed products before deciding to prescribe an unlicensed medicine.

(b) Prescribers will assume increased responsibility for the clinical action of the medicine when they have prescribed an unlicensed medicine.

6.2 *Measurement and Key Performance Indicators*

(a) Only the following staff groups will prescribe unlicensed medicines:

Doctors, dentists, nurse independent prescribers, pharmacist independent prescribers, optometrist independent prescribers and supplementary prescribers acting in accordance with the clinical plan.

7. References

MHRA. Informal consultation paper on the review of unlicensed medicines. Accessed on 18/12/12. Available at http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/Othermedicinesconsultations/CON046465

MHRA. Medicines that do not need a license (exemptions from licensing). Accessed on 18/12/12. Available at http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Medicinesthatdonotneedalicence/index.htm

8. Associated Documentation

8.1 Pharmacy department unlicensed medicines standard operating procedure.

8.2 Patient Information Leaflet. Use Of Unlicensed Medicines Supplied By The Pharmacy Production Department

8.3 Patient Information Leaflet. The Use Of Unlicensed Medicines And Medicines For Unlicensed Conditions Information For Patients And Carers

8.4 Patient Information Leaflet. The Use Of Unlicensed Medicines And Medicines For Unlicensed Indications Information For Older Children

9. Appendix A – Monitoring Table for this Policy

9.1 The agreed aspects of the policy, including the standards and KPIs will be monitored every 24 months and tabled as an agenda item at Medicines Governance Group.

Unlicensed medicines will be included when audits of prescribing standards are completed in line with chapter 2 of the medicines code, the prescribing policy.

10. Appendix B – Dissemination, Implementation and Training Plan

10.1 The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Director of Pharmacy
This document replaces existing documentation:	Yes
Existing documentation will be replace by:	Superseding existing document and removal from DMS
This document is to be disseminated to:	All prescribers, medical and non-medical
Training is required:	No

Plan Elements	Plan Details
The Training Lead is:	N/A

Additional Comments

11. Appendix C – Document Checklist

11.1 The checklist set out in the following table confirms the status of 'diligence actions' required of the 'Document Owner' to meet the standards required of University Hospitals Bristol NHS Foundation Trust Procedural Documents. The 'Approval Authority' will refer to this checklist, and the Equality Impact Assessment, when considering the draft Procedural Document for approval. All criteria must be met.

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
Title	The title is clear and unambiguous:	Y
	The document type is correct (i.e. Strategy, Policy, Protocol, Procedure, etc.):	Y
Content	The document uses the approved template:	Y
	The document contains data protected by any legislation (e.g. 'Personal Data' as defined in the Data Protection Act 2000):	N
	All terms used are explained in the 'Definitions' section:	Y
	Acronyms are kept to the minimum possible:	Y
	The 'target group' is clear and unambiguous:	Y
	The 'purpose and scope' of the document is clear:	Y
Document Owner	The 'Document Owner' is identified:	Y
Consultation	Consultation with stakeholders (including Staff-side) can be evidenced where appropriate:	Y
	The following were consulted:	Medicines Governance Group members and prescriber representatives
	Suitable 'expert advice' has been sought where necessary:	Y

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
Evidence Base	References are cited:	Y
Trust Objectives	The document relates to the following Strategic or Corporate Objectives:	N/A
Equality	The appropriate 'Equality Impact Assessment' or 'Equality Impact Screen' has been conducted for this document:	Y
Monitoring	Monitoring provisions are defined:	Y
	There is an audit plan to assess compliance with the provisions set out in this procedural document:	Y
	The frequency of reviews, and the next review date are appropriate for this procedural document:	Y
Approval	The correct 'Approval Authority' has been selected for this procedural document:	Y

Bristol CCG
South Gloucestershire CCG
North Somerset CCG

North Bristol NHS Trust
University Hospitals Bristol NHS Foundation Trust
Weston Area Health NHS Trust

Bristol, North Somerset, South Gloucestershire (BNSSG) Joint Formulary Group

TERMS OF REFERENCE

September 2016

Overview

A local formulary has been defined as 'the output of processes to support the managed introduction, utilisation or withdrawal of healthcare treatments within a Health Economy, service or organisation' (NICE Good Practice Guidance 1 'Developing and updating local formularies 2012). The BNSSG Joint Formulary (JF) is a local formulary that is a joint venture across the primary and secondary care interface, and recognizes the needs of primary and secondary care and the impact that drug choice in one sector can have on the other. In compiling and amending the formulary consultation is undertaken in primary care with GPs and other relevant healthcare professionals and in secondary care with the relevant specialists.

The BNSSG Joint Formulary Group (JFG) aims to promote optimal use of medicines to improve patient outcomes, promote medicines management guidance and resource decision making to the best effect for the health of the local population. The BNSSG JFG develops, manages and produces the local formulary which is evidence based, considers clinical and cost-effectiveness and reflects the needs of the local population and local affordability. It covers all prescribing across the BNSSG Health community (approximately 900,000 population) (FP10 prescriptions, Acute trust prescriptions, FP10 (HP) prescriptions, FP10D dental prescriptions and recommendations made to GPs e.g. in out-patient letters). Obtaining agreement across the interface between primary and secondary care and the subsequent prescribing within the JF promotes a seamless approach to prescribing which will benefit all patients who require medicines, and reduces the need for switching programs.

It is hoped that the Joint Formulary will cover 80-90% of prescribing across primary and secondary care, although it is recognised that there will be instances where prescribing outside of the formulary will be necessary e.g. new patients registering with a practice on a non-formulary drug, specialised usage of a drug within secondary care. Where a specialist needs to prescribe a drug outside the formulary and is requesting for example a GP to take over prescribing responsibility the specialist should explain why a non-formulary product is required. There are additional processes within individual trusts that should be followed when prescribing non-formulary medicines, for one-off patients.

The BNSSG JFG along with the BNSSG NICE College has a vital role in meeting the agenda outlined in Innovation Health and Wealth (Department of Health, December 2011). The DH publication 'Creating Change - IHW One Year On' (published December 2012) specifies that:

> "NHS organisations should demonstrate their commitment to implement each element of the Comply or Explain regime, and we shall set out compliance in the NHS Standard Contract. There are four elements to Comply or Explain:
>
> - automatic inclusion of positive NICE Technology Appraisals on local formularies in a planned way that supports safe and clinically appropriate practice;
> - publication of local formularies;
> - tracking of adoption of NICE Technology Appraisals through the Innovation Scorecard; and
> - support to overcome the system barriers to implementation of NICE Technology Appraisal guidance and other guidance through the NICE Implementation Collaborative."

Decisions made by the JFG are intended to guide clinical decisions. They are not intended to inhibit an individual clinician's responsibility to treat patients as they deem necessary.

Decisions are made by consensus of the group present; all decisions are circulated to members of the group not present to allow comment on decisions made. When a meeting is not quorate this process is followed to allow all members of the group to comment on the decisions reached.

1. Purpose

a. To promote optimal use of medicines in BNSSG to improve patient outcomes
b. To develop, update and maintain the BNSSG JF.
c. To manage and update the BNSSG JF website.
d. To manage all new medicine applications to the JF
e. To gain implementation assurance by reviewing audits undertaken within primary and secondary care and providing feedback to the organisations.
f. To manage the Traffic Light Status (TLS) of formulary medicines
g. To co-ordinate and sign off Shared Care Protocols (SCPs) for those medicines that have been given amber status i.e. medicines appropriate for specialist initiation, that maybe continued by primary care under appropriate written guidance.
h. To develop the BNSSG formulary e.g. to include paediatrics.
i. To undertake an annual horizon scanning process to determine those new drugs in the pipeline that will have a potential impact on the JF within a given financial year.

2. Membership

Each member of the JFG has core Roles and Responsibilities:
- Participate in the discussions around the NDRs and SCPs
- To promote the formulary within their individual organisation

Core Members

Organisation	Job Titles	Additional Roles and Responsibilities
Bristol Clinical Commissioning Group (CCG)	Head of Medicines Management	• Hold budgetary responsibility for Primary Care Prescribing budget and the PbR excluded non-NICE, CCG commissioned budget.
	Interface Pharmacists – Formulary Lead	• Manage and co-ordinate the NDRs pre and post meeting • Liaise with primary care application applicants • Secretary for the Meetings • Invite applicants along to the meetings • Inform applicants of the outcome of the application • Update the Formulary Website
	GP representative	
North Somerset CCG	Head of Medicines Management	• Hold budgetary responsibility for Primary Care Prescribing budget and the PbR excluded non-NICE, CCG commissioned budget.

	GP representative	
South Gloucestershire CCG	Head of Medicines Management	• Hold budgetary responsibility for Primary Care Prescribing budget and the PbR excluded non-NICE, CCG commissioned budget.
	GP representative	
University Hospitals Bristol NHS Foundation Trust (UHB)	Principal Pharmacist	• Coordinate the NDRs within the trust, ensuring the initial NDR is received by the interface pharmacist 6 weeks prior to the next meeting. • Liaise with applicants ensuring they know when their application will be discussed and the outcome of the discussion. • Ensure that the appropriate Division is aware of the application and that the application is signed off.
	Medicines Information Pharmacist	• Co-ordinate the NDRs within the trust, ensuring the initial NDR is received by the interface pharmacist 6 weeks prior to the next meeting. • Liaise with applicants ensuring they know when their application will be discussed. • Ensure that the appropriate Division is aware of the application and that the application is signed off.
	Clinical Representative from Medicines Advisory Group	
North Bristol NHS Trust (NBT)	Formulary Pharmacist	• Co-ordinate the NDRs within the trust, ensuring the initial NDR is received by the interface pharmacist 6 weeks prior to the next meeting. • Liaise with applicants ensuring they know when their application will be discussed. • Ensure that the appropriate Division is aware of the application and that the application is signed off.
	Clinician representative from the Drugs and Therapeutics Committee	
Weston Area Health Trust (WAHT)	Deputy Chief Pharmacist	• Co-ordinate the NDRs within the trust, ensuring the initial NDR is received by the Interface Pharmacist 6 weeks prior to the next meeting. • Liaise with applicants ensuring they know when their application will be discussed. • Ensure that the appropriate division is aware of the application and that the application is signed off.
	Clinician representative from the Drugs and Therapeutics Committee	

Bristol City Council, on behalf of BNSSG local Public Health	Public Health Consultant	• Chair the JFG meetings • If unable to attend, to organise a deputy • Introduce applicants • Inform applicants of decisions
	Clinical Effectiveness Research Lead	• Aid in the critical appraisal work required for some NDR applications

Welcome to attend and papers also circulated to

The minutes of the meetings will also be sent to other individuals for information. The individuals are welcome to attend any meetings that are relevant to their clinical practice.

Organisation	**Job Titles**
University Hospitals Bristol NHS Foundation Trust	Director of Pharmacy
North Bristol NHS Trust	Director of Pharmacy
Weston Area Health Trust	Chief Pharmacist
NHS England, Area Team	Specialised Commissioning Pharmacist
Avon and Wiltshire Mental Health Trust (AWP)	Chief Pharmacist Formulary Pharmacist
St Peters Hospice	Pharmacist
Bristol Community Health	Pharmacist
Sirona Care and Health	Pharmacist
North Somerset Community Partnership	Pharmacist

Notes to membership

A meeting will be quorate if there are at least **five** members present including:

3 pharmacist members (at least one CCG and one secondary care) and 2 medical representatives (at least one should be from one primary care and one from secondary care). If not quorate, the Formulary Lead will determine if the meeting should proceed, securing active endorsement of any decisions ex-committee from a quorate group of members.

Members of the JFG are responsible for representing their peers, fully participating in the activities of the group and communicating back to those that they represent. All members will actively promote the BNSSG Joint Formulary.

In the event of a participant being unable to attend a meeting, the member should nominate an appropriate deputy to represent them. The member should notify the chair of any deputies.

3. Frequency / meeting arrangements

Frequency
The BNSSG JFG will meet every 6 weeks (8 meetings per year) with the meetings lasting 3 hours. The venue will alternate between South Plaza, North Bristol NHS Trust and North Somerset.

Meeting arrangements
The agenda and papers (including the completed New Drug Request (NDR) applications) will be circulated no less than 5 working days before each meeting. Completed NDRs will need to be sent to the Formulary Lead no later than 30 working days before each meeting. NDRs not received within this timescale will be deferred.

The Formulary Lead will be responsible for executive duties to the review group and ensuring agreed actions are recorded and implemented.

Applicants are expected to attend the JFG meeting to present their New Drug Request wherever possible in order that they are able to answer any questions that the group may have. Failure to attend may mean that the application has to be deferred until the next meeting. All NDRs should be completed fully, and may be rejected if they are incomplete.

4. Declaration of Interests

Members of the JFG will be asked to make Declarations of Interests. This will be in the form of an annual declaration by completing a form held by the BNSSG Joint Formulary Pharmacist. In addition, at the beginning of each meeting the Chair will ask any attendees to declare any additional interests. The JFG will decide what, if any effect such a declaration will have on the deliberations of the meetings and decide appropriate action.

Where the chair of the BNSSG JFG has made a declaration that could have an effect on the deliberations he/she will pass the chair to the Joint Formulary Pharmacist or a nominated acting chair.

5. Terms of Reference

Representing a collaborative approach between primary and secondary care:

5.1. To develop, update and maintain a Joint Formulary that is evidence based, considers clinical and cost-effectiveness and reflects the needs of the local population and local affordability.

5.2. To manage all new drug applications to the BNSSG JF. A centralised approach will ensure a reduction in duplication of work within the area and local clinicians will have a consistent set of medicines to prescribe from. A decision at the JFG is applicable to all member organisations of the JF.

5.3. To consider new drug applications only if the expected cohort is greater than 5 per year across BNSSG, in accordance with NHS England. Interim Commissioning Policy: Individual funding requests April 2013 Reference : NHSCB/CP/03

5.4. Reviewing information contained within the formulary in accordance with new evidence or guidance received, for example, guidance and guidelines received

by the National Institutive for Health and Clinical Excellence (NICE) and National Service Frameworks

5.5. To discuss, agree and sign-off Shared Care Protocols for drugs assigned amber status within BNSSG.

5.6. To monitor the implementation and adherence to the formulary through audit.

5.7. To adopt positive NICE Technology Appraisals within the 90 day window post NICE publication.

5.8. To consider drugs that are included on the NICE TAG program only if the TAG is expected to be published in over 6 months' time, and the delay would negatively impact the local populations health outcomes

5.9. Keeping the formulary up to date is a key function of the BNSSG Joint Formulary Group. The addition and removal of drugs will be considered as chapters of the Joint Formulary are reviewed and, on request, when new information becomes available.

5.9.1. Reviewing chapters of the BNSSG Joint Formulary, drawing on appropriate specialists in key areas, in accordance with an agreed work plan.

5.9.2. To review all feedback and information collated and recommend appropriate changes to the chapter.

5.10. Promoting the BNSSG Joint Formulary within the BNSSG Health Community.

5.11. Advising on the implementation of the BNSSG Joint Formulary within both primary and secondary care.

5.12. Evaluating non-formulary prescribing and suggesting appropriate action.

5.13. To support and maintain links with Specialised Commissioning Area Pharmacists.

5.14. To provide the annual report for the JFG to provide assurance to the CCGs and Provider Trusts.

5.15. To act upon MHRA Drug Safety alerts and Summary of Product Characteristics (SPC) changes with the formulary

5.16. Zero cost or free stock. Prior to NICE publication zero cost or free stock programs will not influence the local medicines governance arrangements through the BNSSG Joint Formulary Group and BNSSG NICE College; local BNSSG organisational policies on working with the pharmaceutical industry will followed.

5.17. Management of EAMs

Recruitment time in to the EAMS may be limited prior to licensing. The JFG may not be able to consider the impact of the EAMS in a timely manner for patients to benefit from treatment. In order to be responsive to this innovation the EAMS approval process should be followed:

1) BNSSG EAMS notification form to be completed and submitted the Interface Pharmacists, Bristol CCG.
2) Form circulated by Interface Pharmacists to HoMMs (or Deputy HoMMs)
3) HoMMs acknowledge sight of EAMS and highlight any considerations for future planning.
4) Once acknowledgement of the EAMS has been received from all the BNSSG HoMMs (or Deputy) the Interface Pharmacists will approve and notify the relevant acute Trust.

5.18. Horizon-scan for new medicines likely to have an impact on the local Health Economy for the next financial year.

5.19. Ensure that cohorts of patients of Individual Funding Requests are identified, through this panel, and that steps are taken to support a JFG NDR for these 3.

6. Guiding Principles

All member organisations must commit to regular attendance at review meetings, as continuity and balance of input into decision-making is of the utmost importance. Nominated deputies should be identified and empowered, wherever possible, to ensure that a balanced complement of members is always present.

Meetings should encourage open, honest and challenging debate. Decisions should be reached by consensus. Once a decision has been finalised a corporate view will be presented and maintained.

7. Reporting requirements

The JFG will report to individual CCGs, partnership boards and appropriate Trust governance groups.

The Joint Formulary Group is a decision making body on behalf of BNSSG. Decisions made by the JFG are communicated to the local acute trusts D&TCs (NBT D&TC, UHB MAG, Weston D&TC) and the BNSSG D&TC for information only. Applications only need to be taken further to the CCG boards if they involve significant financial impact.

The JFG will produce an annual report, agreed in the group and signed by the Chair, to demonstrate that proceedings are appropriate and subject to adequate governance.

Minutes will be circulated within 10 working days of each meeting and will be submitted to the CCG boards, and the Secondary Care D&TCs/MAGs for information.

8. Date to review these Terms of Reference

Annual review of Terms of Reference to coincide with publication of JFG Annual Report.

[redacted]
Formulary Lead - Interface Pharmacist NHS Bristol

Reviewed [redacted] Interface Pharmacist) [redacted] 2016

Appendix 1

BNSSG Joint Formulary process for review of a Joint Formulary Group (JFG) decision

There are two possible routes that the applicant can take to request a review of a BNSSG Joint Formulary Group decision:
1. Reconsideration of the application with further relevant information
2. Appeal the decision

1. Reconsideration

If the applicant believes that there is further relevant information that was not considered by the JFG, they may ask the JFG to reconsider the application specifically in the light of this information.

2. Appeal

Grounds for requesting an appeal

The applicant can make a request to the JFG Review Panel to review the decision made. The request should be made within 21 days of being informed of the decision.

The request for review must set out the grounds on which the JFG decision is being challenged. The JFG Review Panel shall consider whether:

- The process followed by the JFG was consistent with the agreed decision making processes of the JFG.
- The decision reached by the JFG: o was taken following a process which was consistent with the agreed processes of the JFG
    - had taken into account and weighed all relevant evidence.
    - had not taken into account irrelevant factors
    - indicated that the members of the JFG acted in good faith
    - was a decision which a reasonable Formulary decision making body was entitled to reach.

• In the event that JFG Review Panel consider that there was any procedural error in the decision of the JFG, the JFG Review Panel shall next consider whether there was any reasonable prospect that the JFG may have come to a different decision if the JFG had not made the procedural error.

If the JFG Review Panel considers that there was no reasonable prospect of the JFG coming to a different decision then the JFG Review panel shall approve the decision notwithstanding the procedural error.Based on the NHS Commissioning Board Interim Commissioning Policy: Individual Finding Request April 2013 Reference NHSCB/CP/03 Page 2 of 5 NHS Bristol CCG April 2013

However, if the JFG Review Panel considers there was a reasonable prospect that the JFG may have come to a different decision if the JFG had not made the procedural error, the JFG Review Panel shall require the JFG to reconsider the decision.

Membership of the JFG Review Panel

A CCG Clinical Lead plus two others from the clinicians listed below to include one representative of the submitting organisation:

- Medicines Management Pharmacist (Bristol South Gloucestershire or North Somerset)
- Director of Pharmacy (UHB, NBT, WAHT)
- GP/Secondary care consultant

A member of the JFG will present the new drugs application in context to the Joint Formulary to the JFG Review Panel only. They will not attend the review meeting.

None of these members should have been involved in the application prior to the JFG Review Panel. The panel will be quorate if all three members are in attendance and decisions will be reached by consensus.

Purpose of the JFG Review Panel

The JFG Review Panel will examine all the papers considered by the JFG, the reasons for the decision and the grounds of the appeal. The JFG Review Panel will examine the process followed by the JFG and the decision made by the JFG. The JFG Review Panel will examine the issues raised in the grounds for the appeal and the tests set out above. The JFG Review Panel will not consider new information or receive oral representation. If there is significant new information, not previously considered by the JFG, it will be considered as set out under 'Reconsideration'.

The JFG Review Panel will be able to reach one of two decisions:

- To uphold the decision reached by the JFG
- To refer the case back to the JFG with detailed points for reconsideration

In the event that the JFG Review Panel consider that either:

- The decision may not have been consistent with the ToR of the JFG

OR

- The JFG may not have taken into account and weighted all the relevant evidence

OR

- The JFG may have taken into account irrelevant factors

OR

- The JFG may have reached a decision which a reasonable Formulary decision making body was not entitled to reach.

If any of these apply, the JFG Review Panel shall refer the matter to the JFG if they consider that there is a reasonable prospect that the application will be approved by the JFG when it reconsiders. Based on the NHS Commissioning Board Interim Commissioning Policy: Individual Finding Request April 2013 Reference NHSCB/CP/03 Page 3 of 5 NHS Bristol CCG April 2013

If the JFG Review Panel considers that, notwithstanding their decision on the procedure adopted by the JFG, there is no reasonable prospect that the decision would have been different; the JFG Review Panel shall uphold the decision of the JFG.

Outcome from the JFG Review Panel

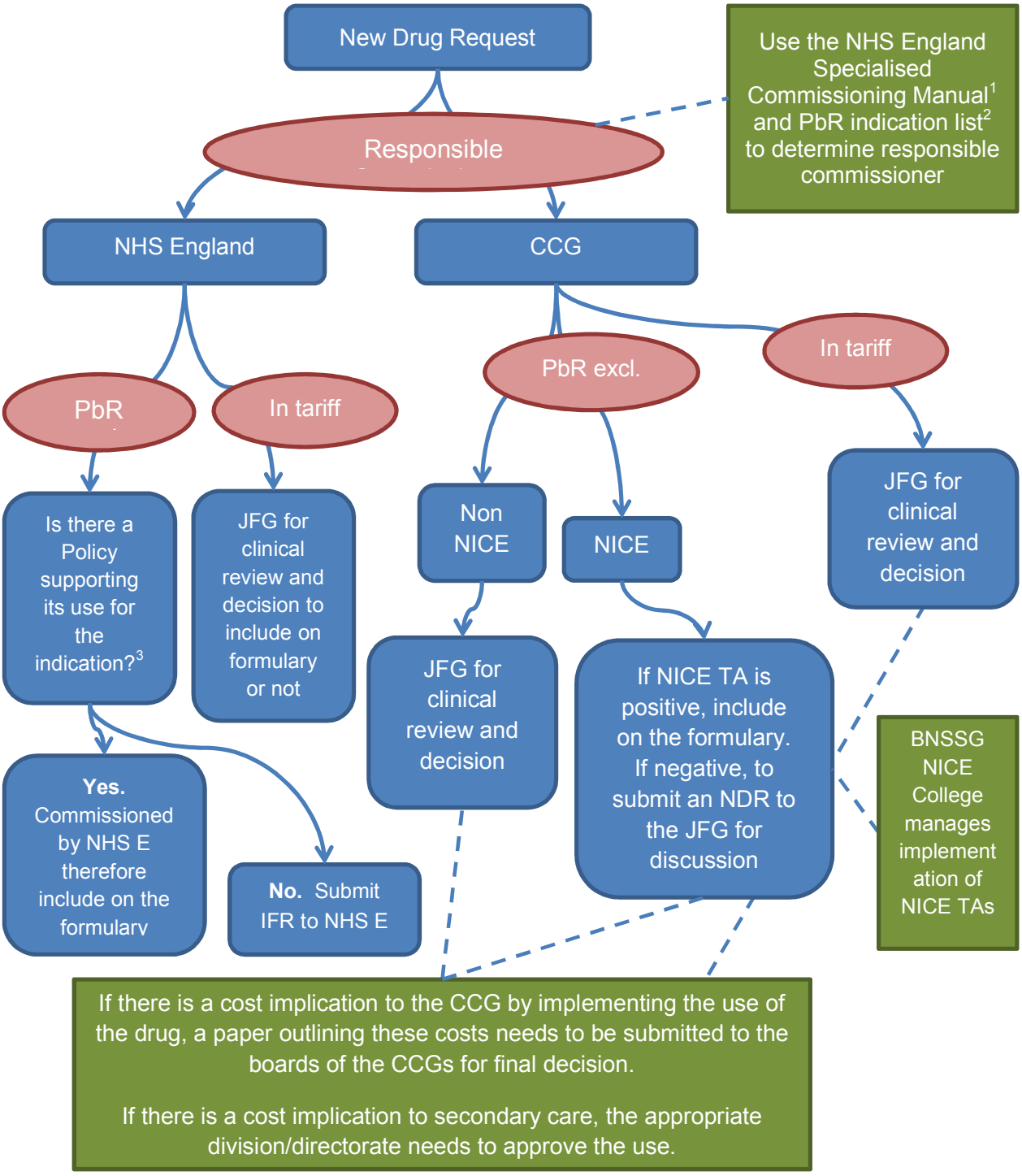
The outcome of the JFG Review Panel will be either to uphold the decision of the JFG or to refer back to the JFG for reconsideration.

The JFG Review Panel will inform the applicant and JFG of the outcome of the JFG Review Panel within 1 week. Reasons given should only refer to the basis on which the original decision was made.

If the original JFG decision is upheld, then the applicant will be informed that there are no further routes of appeal.

If the JFG Review Panel determines that the JFG needs to reconsider the new drug application, the JFG will reconsider the application at the next scheduled meeting. The JFG will reconsider its decision and in doing so will formally address the detailed points raised by the JFG Review Panel. The JFG is not bound to change its decision as a result of the case being referred for reconsideration but if it confirms its original decision, then clear reasons must be given for not agreeing to the new drug application.

BNSSG JF Process for managing the introduction of New Drugs



1. NHS England Manual for Prescribed Specialised Services 2016/17 https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-may16.pdf
2. Indications for NHS England drugs list https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2014/06/nhse-drugs-list-v10.pdf
3. NHS England Specialised Services Clinical Reference Groups https://www.england.nhs.uk/commissioning/spec-services/npc-crg

Appendix 3

Notification of EAMS in BNSSG

For Trust completion:

Name of Trust *(tick as appropriate)*	NBT		UHB		WAHT	
Name of EAMS (include MHRA PAR link)						
Define patient cohort criteria for use						
Define number of patients						
Define number of patient involved in clinical trial for this drug						
Applicant: (Consultant)						
Supported by: (Director of Pharmacy)						

For CCG completion:

Name of CCG	**Bristol**		**NS**		**SG**	
Comments						
Acknowledged by (name and role)						
Date						

Interface Pharmacist use only:						
Date received from Trust						
Date returned from CCG	Bristol		NS		SG	
Date CCGs approve EAMS						