

# **BNSSG Joint Formulary Group (JFG)**

## **Terms of Reference**

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### **1. Introduction**

A local formulary is 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 Medicines Practice guideline MPG1 'Developing and updating local formularies 2014).

The BNSSG Joint Formulary (JF) is a local formulary that is a joint venture across the care system, and recognises the needs of primary, community and secondary care and the impact that drug choice in one sector can have on the others. The BNSSG Joint Formulary Group (JFG) is the committee with responsibility for promoting appropriate, safe, rational, evidence based and cost effective use of medicines and prescribable medical devices 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 aims to cover prescribing across the BNSSG Health community (approximately 1,000,000 population) (FP10 prescriptions, Acute trust prescriptions, FP10 (HP) prescriptions, FP10D dental prescriptions and recommendations made to GPs e.g. in out-patient letters)

The JFG has delegated responsibility from all BNSSG organisations with regards to the formulary. The JFG has no delegated responsibility for resource allocation. Decisions made by the JFG are intended to guide clinical decisions.

### **2. Membership and Responsibilities**

The JFG is a decision- making group within the remits outlined within the terms of reference, and therefore organisations will need to delegate responsibility to their representative members.

Each member of the JFG has core Roles and Responsibilities:

- Commit to regular attendance to ensure consistency and equity of decision making.

- Hold delegated responsibility to their representative members.
- Declare conflicts of interest as required at each meeting.
- Undertake work as necessary between meetings including reading papers in advance of the meetings.
- Participate in the discussions around the New Drug Requests and Shared Care Protocols.
- Ensure decisions made are consistent and equitable in line with the decision making and ethical framework (see section 7)
- Take decisions from JFG back to individual organisations and promote the formulary within them.
- Ensure agreed actions are followed up and reported back to the group
- To provide a period of 3 month's notice on the decision to step down from the Group to enable replacement and retain quoracy

The list of roles and responsibilities are not exhaustive and members may be asked to support other roles as materialise

Organisation	Job Title	Additional Roles and Responsibilities
BNSSG Public Health	Public Health Consultant	<ul style="list-style-type: none"> <li>• Chair the JFG meetings</li> <li>• If unable to attend, to organise a deputy</li> <li>• Introduce applicants</li> <li>• Ensure decision criteria used by JFG for appraising NDRs are explicitly discussed to ensure transparency and consistency of decision making.</li> </ul>
BNSSG ICB	Deputy Director (Medicines Optimisation)	<ul style="list-style-type: none"> <li>• Hold budgetary responsibility for Primary Care Prescribing budget and the PbR excluded non-NICE, CCG commissioned budget.</li> </ul>
	Principal Pharmacist-BNSSG system	<ul style="list-style-type: none"> <li>• Support the Formulary Leads with formulary related issues as they arise.</li> <li>• Deputise for Deputy Director (Medicines Optimisation) where necessary.</li> </ul>
	Interface Pharmacists (Formulary Leads)	<ul style="list-style-type: none"> <li>• Manage and co-ordinate the NDRs pre and post meeting</li> <li>• Liaise with primary care application applicants</li> <li>• Secretary for the Meetings</li> <li>• Liaise with applicants prior to and after meetings</li> <li>• Inform applicants of the outcome of the application</li> <li>• Update the Formulary Website</li> <li>• Be responsible for formal minutes and action logs of the meetings.</li> <li>• Ensure appropriate communication of decisions upwards through the Governance structure.</li> </ul>
	Clinical Lead(s) for Prescribing	<ul style="list-style-type: none"> <li>• Provides primary care clinical perspective</li> <li>• Engages with other GPs where needed.</li> <li>• Provides clinical support to Formulary Leads where necessary.</li> </ul>
University Hospitals Bristol and Weston NHS Foundation Trust (UHBW)	Senior Pharmacist	<ul style="list-style-type: none"> <li>• Coordinate the NDRs within the trust, ensuring it is received by the interface pharmacist 6 weeks prior to the next meeting.</li> <li>• Ensure internal organisational governance processes have been adhered to prior to the meeting.</li> </ul>

Organisation	Job Title	Additional Roles and Responsibilities
		<ul style="list-style-type: none"> <li>• Support Interface Pharmacist in liaising with applicants where needed.</li> <li>• To be responsible for actions relating to their Trust.</li> <li>• To ensure decisions are communicated and embedded in practice at their Trust.</li> <li>• Ensure that the appropriate Division is aware of the application and that the application is signed off.</li> </ul>
	Clinician Representative from UHBW (Consultant)	<ul style="list-style-type: none"> <li>• Provides secondary care clinical perspective</li> <li>• Engages with other clinicians in Trust where needed.</li> <li>• To ensure decisions are communicated and embedded in practice at their Trust.</li> </ul>
	Senior paediatric Pharmacist from BRCH	<ul style="list-style-type: none"> <li>• Coordinate the paediatric NDRs within the trust, ensuring the initial NDR is received by the interface pharmacist 6 weeks prior to the next meeting.</li> <li>• Support Interface Pharmacist in liaising with applicants where needed.</li> <li>• To provide expertise on applications for children and interpret whether any adult applications should also be applicable to children.</li> <li>• To be responsible for actions relating to within their Trust.</li> <li>• To ensure that decisions are communicated and promoted at their Trust.</li> <li>• Ensure that the appropriate Division is aware of the application and that the application is signed off.</li> </ul>
	Clinician Representative from BRCH (Paediatric Consultant)	<ul style="list-style-type: none"> <li>• Engages with other clinicians in Trust where needed.</li> <li>• To ensure that decisions are communicated and embedded in practice at their Trust.</li> <li>• Provides secondary care clinical perspective</li> </ul>
North Bristol NHS Trust (NBT)	Formulary Pharmacist (or other senior pharmacist)	<ul style="list-style-type: none"> <li>• Coordinate the NDRs within the trust, ensuring it is received by the interface pharmacist 6 weeks prior to the next meeting.</li> <li>• Ensure internal organisational governance processes have been adhered to prior to the meeting.</li> <li>• Support Interface Pharmacist in liaising with applicants where needed</li> <li>• To be responsible for actions relating to their Trust.</li> <li>• To ensure that decisions are communicated and promoted at their Trust.</li> <li>• Ensure that the appropriate Division is aware of the application and that the application is signed off.</li> </ul>
	Clinician Representative from NBT (Consultant)	<ul style="list-style-type: none"> <li>• Provides secondary care clinical perspective</li> <li>• Engages with other clinicians in Trust where needed.</li> </ul>

Organisation	Job Title	Additional Roles and Responsibilities
		<ul style="list-style-type: none"> <li>To ensure that decisions are communicated and promoted at their Trust.</li> </ul>
Primary Care provider	GP or Non-Medical Prescriber	<ul style="list-style-type: none"> <li>Provides primary care clinical perspective</li> <li>Engages with other GPs where needed.</li> </ul>
Avon and Wiltshire Mental Health Trust (AWP)	Formulary Pharmacist	<ul style="list-style-type: none"> <li>Provide Mental Health Provider clinical perspective</li> <li>Link in with BNSSG formulary pharmacists where appropriate</li> <li>Ensure that the BNSSG and AWP formularies align as closely as possible.</li> </ul>

Members of the Committee should send a nominated deputy to the meeting. These individuals must be able to operate with full authority over any issue arising at the meeting.

Members should give 3 month's notice of resignation from the Committee to enable timely replacement of the resigning member and allow continuity of membership.

### Welcome to attend and papers also circulated to

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

Organisation	Job Titles
University Hospitals Bristol & Weston NHS Foundation Trust (UHBW)	Director of Pharmacy (Bristol)
University Hospitals Bristol & Weston NHS Foundation Trust (UHBW)	Chief Pharmacist (Weston)
North Bristol NHS Trust	Director of Pharmacy
NHS England, Area Team	Specialised Commissioning Pharmacist
Local Hospices (St Peters, Charlton Farm Childrens Hospices)	Lead Pharmacist
Sirona Care and Health (SCH)	Lead Pharmacist
Childrens and Adolescent Mental Health Services (CAMHS)	Clinician
HMPs within BNSSG area (Ashfield, Bristol, Eastwood Park and Leyhill)	Lead Pharmacist

Other persons may be invited to attend to enable the Committee to discharge its functions effectively. The committee will also invite guests to attend, to present information and/or provide the expertise necessary for the committee to fulfil its responsibilities.

## 4. Administration

A named administrator from BNSSG ICB will be responsible for the provision of administrative support to the Committee and they will ensure that minutes of the meeting are accurately produced and agreed with members.

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 Leads no later than 6 weeks before each meeting. NDRs not received within this timescale will be deferred. The Formulary Leads 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 will be rejected if they are incomplete. The application should have relevant Divisional Manager and Divisional Clinical Director support. Required information is included in the New Drug Request application form available from the Joint Formulary Group website: <https://remedy.bnssg.icb.nhs.uk/formulary-adult/formulary-process-and-paperwork/joint-formulary-paperwork/> . Where a NICE Technology Appraisal decision is expected within the next 12 months, applications for these drugs will not be accepted by JFG.

If there is a cost implication to the ICB by implementing the use of the drug i.e. additional investment is required beyond delegated limits, the committee will pass the recommendation to the relevant commissioning or Trust board/forum for prioritisation and financial approval.

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. Quoracy

For meetings which concern adult agenda items only, the meeting will be quorate with the attendance of the seven members below:-

- The Chair or delegated deputy
- Three regular members from BNSSG ICB Medicines Optimisation team to include two Medicines Optimisation Pharmacists from the ICB **and** a GP Clinical lead or other primary care physician
- Three regular members from acute provider Trusts to include two Pharmacists from acute provider Trusts (UHBW, NBT) **and** a named consultant

For meetings which concern paediatric agenda items, the meeting will be quorate with the attendance of the above plus:-

- A paediatric medical representative from BRCH
- A paediatric senior pharmacist representative from BRCH

The aim will be to reach consensus without the need to resort to a vote. A decision put to a vote at the meeting shall be determined by the vote of the quorate membership (see above) including the chair.

If the meeting is not quorate, the Chair will determine if the meeting should proceed and the interface pharmacists will secure active endorsement of any decisions post-meeting.

For meetings held virtually which are not quorate, active endorsement of any decisions will be sought post-meeting by email. The quorate membership will be required to confirm their agreement by email within the specified time frame. Decisions will not be approved until all the quorum has responded. Active response required.

In the event of a participant being unable to attend a meeting, the member should nominate an appropriate deputy to represent them. The deputy must be approved by their organisation to hold delegated decision making powers. The member should notify the chair of any deputies.

### **Extra-ordinary virtual decision making**

An extra-ordinary virtual JFG decision may be made if the following criteria are met:

- a. There is an urgent Formulary issue that cannot wait until the next scheduled JFG meeting and
- b. this issue is supported by an urgent clinical need and
- c. the decision is required to maintain and/or improve health, reduce risk and prevent harm to patients and
- d. the expedited Formulary decision has been requested to improve the patient pathway within the local healthcare system.

This will be co-ordinated by the Interface Pharmacists.

Representation of this virtual group must include Directors of Pharmacy for NBT and UHBW, Deputy Director Medicines Optimisation, GP Prescribing Lead, JFG Consultant representative and JFG Chair. In the event of absence, a Deputy must be used.

Responses from all the members (or Deputies) of the virtual group listed above must respond within the timeframe given. Non-response will be followed up by the BNSSG ICB Interface team.

In usual circumstances, urgent use of a medicine for an individual patient should be managed through local organisational governance processes.

**Decision making when a member of the committee leaves and there is a resulting delay to replacement.**

If a vacancy in membership of the committee is not immediately replaced and there is a delay, every best effort will be made to find an interim representative by the respective stakeholder organisation.

If the title of the member of the committee is essential to a meeting being quorate and there is no interim representative, the JFG may agree the decisions despite non-quoracy providing that the JFG is assured:

1. that the correct formulary processes have been followed,
2. that the correct stakeholders have been involved in the application,
3. that the applicants have attended the meeting,
4. that there are representatives from the organisation(s) from which the application is made,
5. that there are no objections to the decisions made in the meeting,

If any objections to a decision are made, these must be taken to the next JFG for discussion and agreement.

This process may only be followed in exceptional circumstances to allow continuity of decision making. Any objections to the decision will require a delay and re-consideration with quorate membership with interim representation if required.

## 6. Meetings

The BNSSG JFG meet on average every 6-7 weeks. Meetings will alternate between adults only and adults and children combined. The running time of the meeting will vary but will average 3 hours.

All member organisations must commit to regular attendance at 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.

## 7. Guiding Principles

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. In order to maintain consistency of decision making, for all new drug applications, the JFG will consider it against the criteria below, based on the NICE Guidance MPG1: Developing and updating local formularies, 2014. Each of these points should be discussed and minuted for each New Drug Applications.

### Decision Criteria used by JFG for NDR

- Patient safety
- Clinical effectiveness
- Cost effectiveness or resource impact
- Strength of evidence
- Place in therapy relative to available treatments
- National guidance and priorities
- Local health priorities
- Equity of access
- Environmental Impact

These criteria align with the BNSSG Ethical Framework Principles for decision making (Appendix 3) as below.

Ethical Framework Principle	JFG decision criteria
Principle 1- Rational	This will be covered by ensuring the group take into account patient safety, clinical effectiveness and strength of evidence.
Principle 2- Inclusive	This will be covered by ensuring the group take into account equity of access and national guidance and priorities.
Principle 3- Take account of the value we will get	This will be covered by ensuring the group take into account cost effectiveness and place in therapy relative to available treatments. Whilst the JFG does not manage the drug budget or make decisions on purely financial grounds, the group will take into account the cost effectiveness of any new treatment in comparison to the cost effectiveness of existing or alternate treatments.
Principle 4- Transparent and open to scrutiny	This will be covered by ensuring the decisions made by the group and the reasons behind them are clearly communicated and there is a robust appeals process (See Appendix 2)
Principle 5- Promote health for both individuals and the community	This will be covered by ensuring that the group take into account both national guidance and priorities and local health priorities.

## 8. Roles and Responsibilities

The main roles and responsibilities of the Committee are:

1. To develop, update and maintain the BNSSG JF by:
  - a) Managing all new medicine and applications for devices prescribable on FP10s, to the JF, making recommendations consistent with the BNSSG Ethical Framework (Appendix 3)
  - b) Managing the Traffic Light Status (TLS) of formulary medicines including approved NICE Technology Appraisals within the 90 day implementation period and reviewing the TLS of existing drugs when applications to do so are received.
  - c) Approving Shared Care Protocols (SCPs) for amber medicines which have been co-ordinated by the CCG Interface team with direct communication and collaborative working with all relevant stakeholders.



- d) Acknowledging the chapter review process of the BNSSG Joint Formulary, drawing on appropriate specialists in key areas, in accordance with an agreed work plan.
- e) Considering and acting on relevant outputs from national bodies such as National Institute for Health and Care Excellence (NICE), Regional Medicines Optimisation Committees (RMOC) and Medicines and Healthcare Regulatory Agency (MHRA).
- f) Ensuring that cohorts of patients of Exceptional Funding Requests are identified, through this panel, and that steps are taken to support a JFG NDR for these.
- g) Undertaking 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.
- h) Acknowledge any Early Access to Medicines Schemes (EAMS) and Free Stock Schemes which have been managed by the High Cost Drugs STP as per the BNSSG EAMS and Free Stock policy.

2. Encourage and evaluate compliance with the formulary by:

- a) Preventing and assisting in the resolution of issues relating to medicine provision at the interfaces of care.
- b) Monitoring the implementation and adherence to the formulary through audit and suggesting appropriate action.
- c) Communicating recommendations and outputs effectively to all relevant member and stakeholder organisations and encourage implementation.
- d) Providing the annual report for the JFG to provide assurance to the CCGs and Provider Trusts.

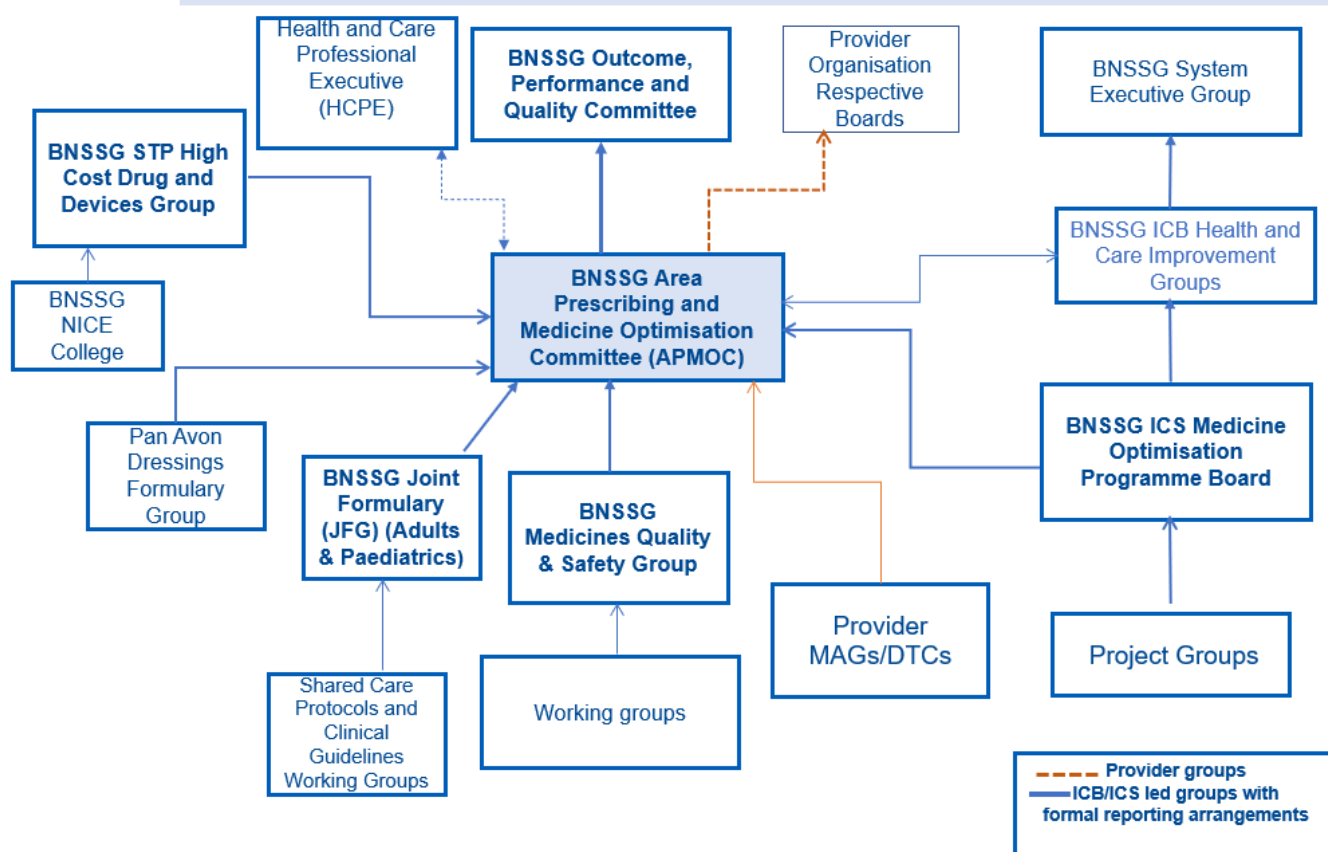
## 9. Governance Structure and Reporting Requirements

The Joint Formulary Group reports to and makes recommendations on the suitability of medicines for prescribing to the Area Prescribing and Medicines Optimisation Committee (APMOC) on behalf of BNSSG. Decisions made by the JFG are communicated to the local acute trusts DTCs by the Pharmacist representatives from those Trusts (NBT D&TC, UHBW Bristol MAG) The ICB will also communicate relevant decisions to other stakeholders e.g primary care. Decisions will need to be taken to the relevant commissioning group/Trust forum for agreement if they involve significant financial impact on existing system budgets.

Requires new allocated resource or significant shift in resource – responsibility of JFG to highlight resource requirement on system budgets.

Shared Care Protocols will be worked up with relevant parties outside of the group before they can come to JFG for final approval.

## BNSSG ICS Medicine Optimisation Governance Structure



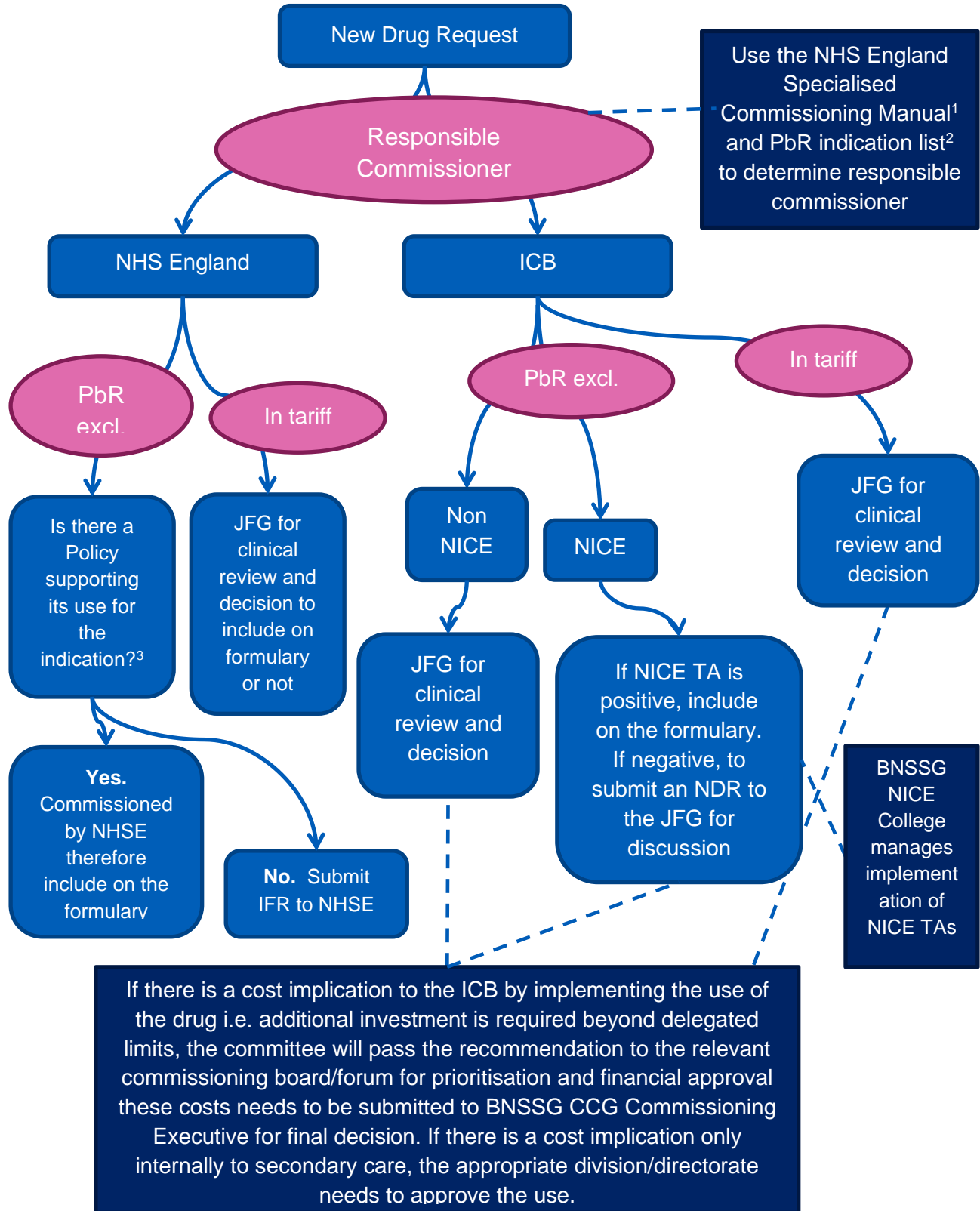
### 9. Date to review these Terms of Reference

These terms of reference will be reviewed annually to coincide with publication of the JFG Annual Report.

Version	Date	Author/Reviewer	Comment
V1	17/7/2020	Emily Knight	
V2	15/12/2021	Sasha Beresford	Updated to include extra-ordinary virtual decision making
V3	09/01/2023	Sasha Beresford/ Anna Durbin	Update following group feedback and discussion
V4	17/04/2023	Sasha Beresford/ Anna Durbin	Updated to incorporate JFG feedback from 31.1.23 meeting and Colm feedback from email

Appendices

**Appendix 1 BNSSG JF Process for managing the introduction of New Drugs**



1. NHS England Manual for Prescribed Specialised Services 2018/19 <https://www.england.nhs.uk/wp-content/uploads/2017/10/prescribed-specialised-services-manual.pdf>
2. Indications for NHS England drugs list version13 <https://www.england.nhs.uk/wp-content/uploads/2018/03/nhs-england-drugs-list-v13.pdf>
3. NHS England Specialised Services Clinical Reference Groups <https://www.england.nhs.uk/commissioning/spec-services/npc-crg>

## Appendix 2 BNSSG JF 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. This should be discussed at the next available meeting.

### 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:
  - 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 Commissioning Policy: Individual Funding Request, Reference NHSCD/CP/03, November 2017

## **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 Optimisation Pharmacist
- 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 (JFGRP) only. They will not attend the review meeting.

None of these members should have been involved in the application prior to the JFGRP. 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 JFGRP will examine all the papers considered by the JFG, the reasons for the decision and the grounds of the appeal. The JFGRP will examine the process followed by the JFG and the decision made by the JFG. The JFGRP will examine the issues raised in the grounds for the appeal and the tests set out above. The JFGRP 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 JFGRP 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 JFGRP 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.

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If any of these apply, the JFGRP 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 Commissioning Policy: Individual Funding Request, Reference NHSCD/CP/03, November 2017

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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 JFGRP shall uphold the decision of the JFG.

### **Outcome from the JFG Review Panel**

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

The JFGRP will inform the applicant and JFG of the outcome of the JFGRP 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 JFGRP 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.

## Appendix 3 BNSSG Ethical Framework



### Ethical Framework for Decision-Making

22 January 2019



Shaping better health

Updated: May 2023, BNSSG Joint Formulary Group

Approved: BNSSG Joint Formulary Group

Review Date: 3 years from approval, or in light of new requirements, whichever is sooner.

