Framework for Managing Medicines across the Nottinghamshire Integrated Care System

Document Purpose	To define the process which will apply within the Nottinghamshire Health Community for clarifying the clinical and prescribing responsibilities for individual medicines
Version	6.0
Title	Framework for Managing Medicines across the Nottinghamshire Health Community
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Approval Date	May 2023
Approving Committee	Nottinghamshire Area Prescribing Committee
Review Date	May 2026
Groups/Staff Consulted	NHS Nottingham and Nottinghamshire ICB Sherwood Forest Hospitals NHS Foundation Trust Nottinghamshire Healthcare NHS Trust Nottingham University Hospitals NHS Trust Nottinghamshire Local Medical Committee
Target Audience	All prescribers across primary and secondary care
Circulation List	NHS Nottingham and Nottinghamshire ICB Sherwood Forest Hospitals NHS Foundation Trust Nottinghamshire Healthcare NHS Trust Nottingham University Hospitals NHS Trust Nottinghamshire Local Medical Committee
Superseded documents	Framework for Managing Medicines across the Nottinghamshire Health Community version 5

1. Introduction

This document is intended to define the process which will apply within the Nottinghamshire ICS for clarifying the clinical and prescribing responsibilities for individual medicines.

The purpose of the Nottinghamshire Area Prescribing Committee (APC) is:

- To establish a collective strategic approach to prescribing and medicines management issues across the Nottinghamshire ICS, in relation to the safe, clinical and cost-effective use of medicines.

- To approve policy on prescribing and medicines management issues at the interface between Primary and Secondary Care and identify associated resource implications for consideration by the commissioning organisations.

- To ensure robust governance arrangements are in place for the effective delivery of medicine policy within a framework of the whole patient care pathway.

- To provide guidance on these issues for commissioners and providers within the ICS.

For further information on the roles and responsibilities of the Nottinghamshire APC please see *Nottinghamshire Area Prescribing Committee Terms of Reference*

2. Scope

This guideline is applicable to all healthcare professionals providing NHS services in the Nottinghamshire ICS or delivering NHS services outside the area to citizens registered with a GP practice within Nottingham and Nottinghamshire.

Legal responsibility for prescribing lies with the prescriber who signs the prescription; this includes the correct completion of the prescription and full or shared clinical responsibility for the treatment of the patient.

GPs, as independent contractors, have the right to decline to take clinical and prescribing responsibilities for a patient on their medical list who is being treated elsewhere, but the reason for this action must be documented. However it may be inappropriate for a GP to refuse to take clinical and prescribing responsibilities for an individual medicine, where:

- Shared care protocols or guidance for that medicine have become common practice and where shared care protocols or supporting prescribing guidance include adequate support, education, and information as approved by the Nottinghamshire APC.

- The prescribing of that medicine within Primary Care has become common practice.

Where a dispute arises over this, advice will be sought from the Nottinghamshire APC in conjunction with the Nottinghamshire LMC (or other representative organisation). The ICB GP prescribing leads may be asked to support the GP(s) and/or Specialist only after local resolution has failed.
It is essential that patients' treatment does not suffer while decisions on clinical and prescribing responsibilities are made. While a decision is awaited on which category a medicine belongs to, or where shared care protocols are being drawn up, the clinical

responsibility and supply of the medicine will be retained by the prescriber who initiated the treatment.

In the case of patients whose medication is already being prescribed, the clinical responsibility and responsibility for the supply of the medicine to the patient will be retained by the current prescriber until the issues have been resolved.

3. Processes for managing medicines across the health community

a. Decision making

Budgetary and commissioning implications must be considered when assessing the cost-effective use of medicines across the Nottinghamshire ICS.

When considering classifying a medicine under the traffic light system, the committee will apply the criteria that define each of the traffic light classifications in order to obtain a classification as per the APC decision tree; *Appendix 6 Decision Tree Template*

The Committee will seek to decide by consensus and agreement of its membership. However on the occasions when the committee cannot reach a consensus, decisions will be made by a simple majority of those present. In the case of an equal number of votes, the Chair will have a casting vote.

b. The Nottinghamshire APC "Traffic Light" System

The Nottinghamshire Traffic Light system is in place to assist prescribers in making decisions about the medicines and preparations they prescribe. The system considers the clinical and cost effectiveness of the medicine as well as the suitability of the medicine to be prescribed in Secondary Care, Secondary Care and under "shared care" arrangements. The Nottinghamshire Traffic Light system is divided into six categories; RED, Amber 1, Amber 2, Amber 3, GREEN and GREY

Further detail on the definitions of the traffic light classifications can be found on the *Joint Formulary Website*

In the case of an AMBER 2 classification a specialist is defined by the APC as a clinician who has undertaken an appropriate formal qualification or recognised training programme within the area of practice described and has a working experience and knowledge within a speciality area of which they currently work. For example (but not limited to) a Diabetes Specialist Nurse or Midwife. It is the responsibility of the employing organisation which the specialist belongs to assess competence to practise in that specialist role.

It is not feasible for all medicines to be classified under the Nottinghamshire Traffic Light system. If a medicine is not listed in the Joint Formulary advice should be sought from the ICB Medicines Optimisation team and/or Trust pharmacy department. All formulations will be assessed for inclusion in the Joint Formulary separately.

c. Medicines with a positive NICE Technology Appraisal Guideline (TAG)

Where a medicine has received a positive NICE TAG the APC will review the medication within 90 days of publication to determine its significance to the Nottinghamshire ICS and where applicable develop guidance to assist the implementation. The APC will ensure that all NICE approved medicines appear on the Nottinghamshire Joint Formulary (including a

traffic light classification) from 90 days of publication or 30 days in the case of an Early Access to Medicines Scheme.
The ICB requires the full 90/30 days post publication of a TA to allow time for safe implementation including dissemination of information and amendments or production of necessary guidance. Therefore, a NICE TA medicine will not be added to the formulary for use until 90/30 days post publication.
The APC will provide advice on the local implementation of such guidelines within the health community.
Where a medication which is subject to a NICE TAG is confirmed as being suitable for hospital use only, the addition to the formulary with a RED traffic light classification, as well as the implementation will be delegated to the Trusts' Drugs and Therapeutics Committees.

d. Shared Care Protocols (SCP) and Prescribing Guidelines

Wherever possible the Regional Medicines Optimisation Committee (RMOC) standard templates should be used to develop local shared care documentation. An agreed standard version control header and footer should be used in all guidelines.

e. Nottinghamshire Joint Formulary

Appendix 2 Process for Formulary Submissions and Traffic Light Classifications outlines the process to be followed when a new medicine is requested to be included on the Nottinghamshire Joint Formulary.

The APCs responsibilities are

- to make evidence based, informed recommendations for the
    - inclusion of medicines, medical devices, wound care products and dietary products prescribed at the interface between Primary and Secondary Care.
    - classifications of these products within the Nottinghamshire Traffic Light System.
- to lead on the development, maintenance and review of the Nottinghamshire Joint Formulary

A formulary addition or amendment may be referred to the Nottinghamshire APC via:

- Trust Drugs and Therapeutics Committee (DTC)
- Local Medical Committee (LMC)
- ICB Medicines Optimisation Team
- Specialist Interface & Formulary Pharmacists
- Direct contact from a specialist

See *Appendix 3 Formulary Submission Requests form and Appendix 4 traffic light change request form* for further information.

f. Reconsideration of decisions

Decisions made by the Nottinghamshire APC can be referred back once by the submitting clinician to be reconsidered in the following circumstances:

- there has been a significant change in local/national guidance,
- the decision was based on incomplete or inaccurate information

- there is significant new evidence which was not available during the first review

The submission will be considered as outlined in *Appendix 2 Process for Formulary Submissions and Traffic Light Classifications.*

The submitting clinician or a representative will be strongly recommended to attend the meeting in person to discuss the reasons for reconsideration.

Appeals of decisions

The appeals process should generally be reserved for when the Nottinghamshire APC is judged not to have followed their published processes.

An appeals panel will be convened of Primary and Secondary Care prescribing representatives who were not involved in making the original decision. This may be an APC or similar formulary decision making group from a neighbouring area.

The appeals panel will consider whether;

- the process followed by the Nottinghamshire APC was consistent with that detailed in the 'Framework for Managing Medicines across the Nottinghamshire Health Community'
- the decision reached by the Nottinghamshire APC
    - was consistent with NHS commissioning principles
    - had taken into account and weighed all the relevant evidence
    - had not taken into account irrelevant factors
    - indicates that members of the APC acted in good faith
    - was a decision which a reasonable APC was entitled to reach.

The appeals panel will not consider new information or receive oral representations. If there is significant new information, not previously considered by the Nottinghamshire APC, the request will be referred back for reconsideration.

The appeals panel will be able to reach one of two decisions;

- to uphold the decision reached by the Nottinghamshire APC, or
- to refer the request back to the Nottinghamshire APC with detailed points for reconsideration.

g. Request to fund medicines within Secondary Care

Appendix 7; Process for Funding Medicines within Secondary Care outlines the current funding routes available. Where funding of a treatment is not approved, prescribers should only refer patients into the Individual Funding Request (IFR) process if they are considered an individual or exceptional case where the patient would benefit significantly more than the rest of the patient population. Local IFR policies must be followed.

h. Tertiary Care Requests to Prescribe

If a patient is referred to a Tertiary Care centre, the above guidance remains applicable. As such, if a tertiary care centre recommends a RED traffic lighted medicine (according to the Nottinghamshire Joint Formulary), they should either:

a) Retain prescribing and monitoring responsibility for the medicine (and notify the ICB of the resource implications for the medicine costs), or
b) Request the referring Secondary Care specialist to take prescribing and monitoring responsibility on their behalf / in collaboration with them. If there are no specialists within the referring acute trust with suitable competence to prescribe and monitor, or if the medicine falls under a national policy of being Tertiary Care only, the prescribing and supply responsibility should remain with the Tertiary Care centre

As with all RED traffic lighted medicines, the Primary Care prescriber is not expected to take prescribing or monitoring responsibility.

I. Unlicensed and Off Label medicines

Each trust and the ICB have a policy for the prescribing and supply of unlicensed and off-label medicines which details their approach to the use of unlicensed medicinal products and medicinal products used outside the terms of their licence. The advice within these policies is consistent with all stakeholders agreeing a common approach.

When making decisions about medicines that are unlicensed or for an off-label use, the APC will take into account the policies and will not make decisions which may undermine the agreed approach.

For further information the policies are available on the individual stakeholders websites.

ICB Policy for the prescribing and supply of unlicensed and off-label medicines

NOTTINGHAMSHIRE AREA PRESCRIBING COMMITTEE
TERMS OF REFERENCE

Purpose of the Committee

- To accept delegated responsibility from the Integrated Care Board (ICB) and to represent the NHS and local health and care community in managing the entry of new medicines (including medical devices, wound care products and dietary products) into the NHS.

- To establish a collective strategic approach to prescribing and medicines management issues across the Nottinghamshire Integrated Care System (ICS), in relation to the safe, clinical and cost-effective use of medicines.

- To develop and approve policy on prescribing and medicines management issues at the interface between primary care, secondary care and accountable care organisations and identify associated resource implications for consideration by the commissioning organisations.

- To support and advise on robust governance arrangements for the effective delivery of medicine policy within a framework of the whole patient care pathway.

- To provide guidance on these issues for commissioners and providers within the ICS.

- To ensure all decisions are within agreed financial thresholds and support organisations to achieve savings/QIPP targets for prescribing.

Duties

- To approve and maintain prescribing policies, formularies, traffic light classifications, shared care agreements and prescribing guidelines for implementation across primary care, secondary care and accountable care organisations and to support and advise on a robust governance framework for the delivery of medicines policy.

- To ensure consideration is given to the impact of formulary and policy decisions on patients and carers.

- To utilise horizon scanning to provide advice and input into the planning process for the introduction of new medicines and priorities for funding. Establish a consensus, based on the available evidence, regarding the place in treatment for relevant new medicines / formulations, or for existing medicines with new indications, and ensure that such advice is disseminated to all stakeholder organisations.

- To consider and implement appropriately national guidance such as that produced by the Regional Medicines Optimisation Committees (RMOCs) or NICE.

- To actively review formulary choices to ensure cost-effective products are available, to feed back on decisions and financial implications to stakeholders and to make available policies and guidelines relating to prescribing and medicines management.

- Maintain strong links with NHS England specialised commissioning teams in order to assess local implications of high cost and/or excluded from tariff medicines.

- To support the safe withdrawal and discontinuation of decommissioned or discontinued medication.

- To establish and maintain a joint formulary between the ICB, organisations that provide NHS services and organisations that interface with the NHS. Examine the clinical and cost effectiveness of different preparations within particular clinical areas and agree on 'medicines of choice' to be applied consistently across both primary and secondary care.

- To make evidence based, informed decisions on the inclusion of medicines in the Nottinghamshire Joint Formulary and classification of these medicines within the Nottinghamshire Traffic Light System, by utilising independent reviews, or by carrying out independent reviews if these are not available

- To establish and maintain the mandate of the APC to agree prescribing policy for medicines management issues on behalf of the ICB, provider trusts and local authorities. Ensure that cost effectiveness is assessed and that all decisions are within agreed financial thresholds.

- To advise and assist the ICB in the formation, development and implementation of plans for the introduction of new pathways, treatments, local policies and national guidance with implications for prescribing.

- To provide advice and recommendations to the commissioning process in partner organisations on the resource implications of new prescribing policy, to ensure that prescribing and issues of medicines use are given due weight in wider healthcare planning and service delivery agreements locally.

- To make recommendations to assist in the resolution of problems relating to prescribing at the interface between primary, secondary, tertiary and social care.

- To develop effective communication channels with neighbouring APCs to enable sharing of proposed advice where this might impact significantly on another locality.

- To act as an independent body for appeals made against Derbyshire Area Prescribing Committee with regard to the process followed to reach a medicine related decision, with Derbyshire having a reciprocal agreement in place.

- To respond in a timely manner to local, regional and national changes in NHS policy that will affect prescribing and medicines management locally e.g. NICE guidance, and provide advice on the local implementation of such policy within the health community.

- Review NICE Technology Appraisals to determine their significance to the Nottinghamshire health community and where applicable develop guidance to assist the implementation. Ensure that all NICE TA included medicines appear on the Nottinghamshire Joint Formulary (including a traffic light classification) within the necessary timescale following publication.

- To act as a focus for developing and refining local professional opinion on prescribable products and associated pharmaceutical issues, and to convey such opinions to all relevant organisations and bodies, including those not directly represented on the committee

- To review all key safety concerns relating to medicines and devices issued via NHS England, Medicines and Healthcare Products Regulatory Agency publications or other patient safety organisations.

- To advise on policy and procedures for the clinically appropriate use of medicines outside their marketing authorisation.

- To work within the principles of local policy on working with the Pharmaceutical Industry and register declarations of interest for committee members.

- To make recommendations for methods of implementing APC approved guidelines and receive feedback on the implementation of APC guidelines to current practice.

- To consider the impact of decisions on all protected characteristics covered by the Equality Act 2010 and to uphold the NHS constitution

Working Arrangements

Membership

Nottingham and Nottinghamshire ICB – primary care	• Senior medicines management pharmacist x2 • GP prescribing lead x3
Public Health County or City	Currently vacant
NUH	• Senior pharmacist • Clinician
NHCT*	• Senior pharmacist
SFHFT	• Senior pharmacist • Clinician
Community Services Provider representative	Non-Medical Prescriber, preferably of a profession other than pharmacy
Lay representative	
Nottinghamshire Local Medical Committee (LMC) representative	
Nottinghamshire Local Pharmaceutical Committee (LPC) representative	Currently vacant
PCN pharmacist representative	

*NHCT representation includes Community General Healthcare Services

Co-option

Additional members will be co-opted from clinical networks, specialist services/ organisations, working groups as required according to agenda items under discussion.

Member Responsibilities

Membership is drawn from senior positions within each organisation represented and must fulfil the following responsibilities:

- Represent the views of their constituent organisations and professional groups.
- Ensure adequate consultation has been undertaken within their organisation where appropriate
- Ensure that decisions taken by the committee are communicated and implemented by their organisation and professional groups.
- Commit to attend meetings regularly.
- Nominate a deputy if they cannot attend wherever possible.
- Contribute to agenda items.
- Commit to working outside the meeting where required
- Come to meetings prepared with all documents and be ready to contribute to the debate.
- Declare any outside financial or personal conflicts of interest at the start of each meeting and annually.
- To abide by the meeting code of conduct (Appendix ONE).

Lay members are expected to represent the views of patients and where necessary may be asked to seek such views via external patient groups. Lay members are also responsible for supporting the dissemination of key messages and outputs to external patient groups, being mindful of the confidentiality of papers and minutes until decisions are ratified.

Chair

The Chair and deputy chair will be elected democratically from within the membership of the committee.

The Chair and deputy Chair will serve for a period of 3 years, with an annual review of the appointment to take account of changes within year.

The Chair will ensure there is a written report on an annual basis.

Voting Structure

The Committee will seek to make decisions by consensus and agreement of its membership. However, on those occasions when the committee cannot reach a consensus, decisions will be made by a simple majority of those present. In the case of an equal number of votes, the Chair will have the casting vote.

Quorum

The meeting will be deemed quorate where there is representation from the ICB (primary care) and Secondary Care Trusts (SFHT, NUH, NHCT). At least two Doctors are required, one of whom should be a GP.

Document ratification

New and updated documents which are to be hosted on the APC website will, in most cases, be presented and ratified at a meeting. Where a document has reached its expiry, had a full review but received only minor changes, classed as:

- minor wording update
- update to links
- contact detail update
- NO change to medication or dosage
- NO change to monitoring requirements

the document may be circulated to members for virtual ratification outside the meeting with a fixed time for response of 2 weeks. Members are expected to review the changes and either approve or reject these to the author. Approval must be returned by members required for quoracy before the virtual ratification is complete.

Relationships and Accountability

Each organisation will need to agree accountability arrangements for the Committee.

The Committee will need to determine links with primary care prescribing/ commissioning subcommittees, Trust Drugs and Therapeutics Committees and other neighbouring Area Prescribing Committees.

The Committee will need to ensure clear links/accountability with Commissioning, Finance groups and Governance Groups.

Administration

- Meetings will take place monthly, with the focus on guidelines one month and formulary the next.
- The administrative services to the Committee will be provided by the medicines optimisation interface team, employed by the ICB.
- Meeting agenda and papers will be circulated to members one week prior to each meeting.
- Minutes of the meeting will be circulated to members within two weeks of each meeting.
- A summary bulletin will be produced and circulated every other month.
- The venue chosen for the meeting will be accessible for the whole health community, to ensure attendance by all members of the Committee. Virtual meetings hosted by Microsoft Teams will also be utilised to ensure maximum attendance.
- The Committee will have the ability to establish time-limited task groups as and when required, to undertake specific tasks.
- In the event of urgent decisions being required between scheduled meetings, e-mail communication will be used. Where this fails, an emergency meeting may be called.

Appendix ONE

Meeting Code of Conduct

To ensure the meetings are productive with consensus decisions and equitable opportunity for contribution from all members, members are asked to note and respect the following.

The points listed are as determined by committee members during the February 2023 APC development session.

1. Strive to attend all meetings, sending apologies to the chair for unavoidable absences.
2. Prepare for the meeting by reading the agenda, papers and any emails before the meeting.
3. Talk to the chair before the meeting if you need to clarify anything.
4. Arrive on time. Stay to the end.
5. Participate fully in the meeting;
    1. Listen to what others have to say and keep an open mind.
    2. Contribute positively to the discussions.
    3. Try to be concise and avoid monologues.
    4. Do not interrupt others
6. Help others concentrate on the meeting. Avoid side conversations, background noise or other distractions.
7. Have the best interests of the organisation and the local health community in mind at all times.
8. Draw attention to any potential conflicts of interest that may arise in the meeting.
9. Fulfil any responsibilities assigned to you at the meeting and be prepared to report back on your progress at the next meeting.

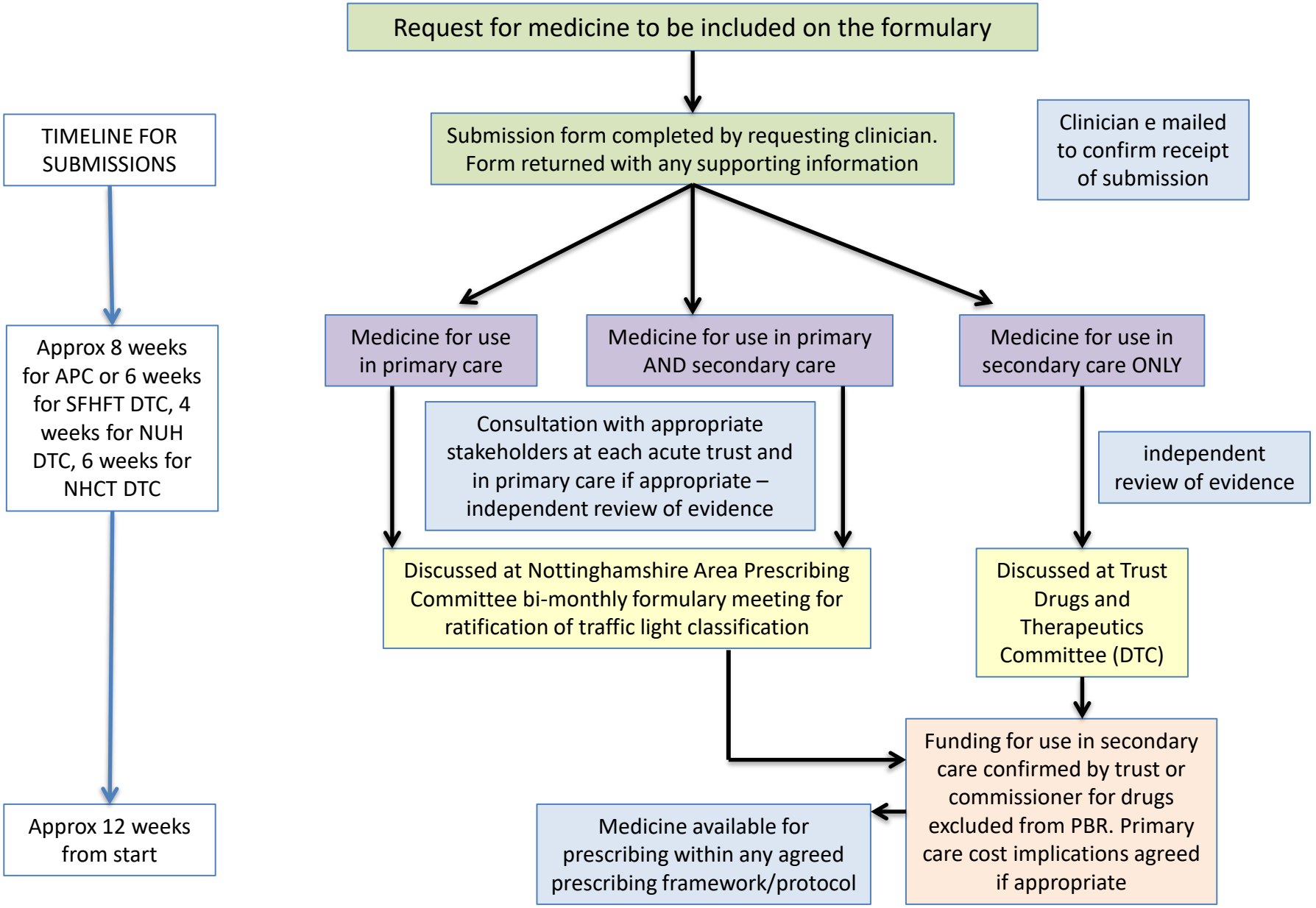
To achieve these points the chair, with assistance from the committee will aim to:

- Ensure a timely decision is made
- Enable and encourage everyone to contribute
- Encourage questioning and debate which is not aimed personally
- Ensure items are presented clearly with defined outcomes highlighted
- Maintain focus and keep to time
- Clarify actions and summarise at the end of each item.

On Line meeting etiquette

- Arrive on time
- Keep your camera on
- Remain muted when not speaking
- Use the hand raising and chat functions to contribute
- Avoid background distraction.
- Ensure your space is private to maintain confidentiality, using headphones in shared offices and other rooms.

Appendix 2 Process for Formulary Submissions and Traffic Light Classifications



Appendix 3 Formulary Submission Form

Electronic completion – click in the box below the question and type. The box will expand to accommodate the text. Please keep your submission comprehensive and indicate which, if any, information has been supplied by a pharmaceutical company.

This application should reflect a consensus agreement from your directorate/speciality. Medicines which are to be prescribed only in secondary care will be considered by the trust's Drugs and Therapeutics Committee. Medicines expected to be prescribed in primary care will be considered by the Area Prescribing Committee. These medicines are considered on a County-wide basis. Therefore, consultation should also be sought amongst relevant clinicians from other Nottinghamshire acute trusts if appropriate. Please indicate below what process you have been through to achieve this (e.g., presentation to local groups, directorate, cross-town groups).

Section 1 – Completed by Consultant / GP (not for completion by medical representatives)

1. Name of medicine (include route, strengths and forms).

2. Declaration of Interest of submitting clinician.
Have you, a close family member, your colleagues, department or practice ever received any payment or goods, directly or in kind, from the makers of this medicine for any purpose?
If yes, please give details. This Guidance should be used when answering this question.
If no, please state 'no'.

3. Specify organisations to which this application applies. (Delete as appropriate)

Nottingham University Hospitals NHS Trust **Yes / No**
Sherwood Forest Hospitals NHS Foundation Trust **Yes / No**
Nottingham NHS Treatment Centre **Yes / No**
Nottinghamshire Healthcare NHS Trust **Yes / No**
Primary Care **Yes / No**
Other (please specify) _____

4a. Is this submission: (Delete as appropriate)

a) to add a medicine to the formulary? **Yes / No**
b) to replace a medicine currently on the formulary **Yes / No**
(if yes, please specify the medicine) _____.
c) a modification of usage to a medicine already listed within the formulary (i.e., a new indication for use)? **Yes / No**

4b. If the medication is an injectable

a) Will it likely be administered by a district nurse? **Yes / No**

If yes, please contact NHCT pharmacy for a risk assessment

b) Can it be administered as an Infusion? **Yes / No**

Consideration required for Medusa IV Guide availability, Drug Error Reduction Software (DERS)

c) Is any addition equipment required? **Yes / No**

E.g. filters, pumps, dedicated giving sets

5. Indication(s) covered by this submission. Is this in line with the licensed indication?

6. Please provide a summary of the condition(s) for which the medicine will be used. Include any relevant morbidity, mortality and quality of life data related to the condition that may be beneficial in support of this application.

7. How will the requested product be used to treat this / these condition(s)? Please include dosage, length of treatment, place in therapy, monitoring and deprescribing requirements, etc.

Please attach guidelines for the use of the medicine for this condition if relevant. In some cases, guidelines may be required before final approval. Individual trusts may have guidance on guideline production.

8. What is currently used to treat this / these condition(s)? Please include medicine(s), doses, length of treatment, monitoring and how it will be affected if this submission is approved.

9a. What are the advantages of the new medicine over the existing practice?
e.g., enhanced efficacy, route, side effect profile, compliance, reduced hospitalisation, avoidance of surgery, and reduced need for community support.

9b. What are the disadvantages of the new medicine over the existing practice? Please be as expansive as possible.
e.g., It's relatively new, so therefore, it may have an uncertain side effect profile, nurses, other doctors and GPs will be unfamiliar with it, it costs more, requires extra monitoring, the evidence base is poor for the intended use, etc.

10. Please provide published literature (e.g., efficacy, safety) that provides a balanced view of the medicine. Comparative studies with current "gold standard treatments" and systematic reviews of all the literature, such as Cochrane reviews, are of particular interest. A list of references is insufficient, include details such as study type, number of patients and a summary of the findings. Relative Risk Reductions are not regarded as meaningful results, and please describe the Number Needed to Treat (NNT) data where appropriate.

If possible, please include original references with this submission. If not, please provide complete references to obtain the original papers.

11. Are there any published pharmacoeconomic evaluations to support your request? If so, please provide details.

12. Is the use of this medicine in accordance with local or national plans (e.g., Trust business plan, NSF, NICE etc.)? Please provide details if appropriate.

13. How many patients will likely be initiated on this medicine (by all clinicians)?
If precise numbers are unknown, indicate a range, i.e., <5, 5-10, 10-20, 20-50, 50-100, 100-500.
If practise uptake is significantly different from that predicted, use will be audited.

		Expected patient numbers	
		First-year	**Subsequent years**
At NUH	Inpatients		
	Outpatients		
At SFHFT	Inpatients		
	Outpatients		

At Nottingham NHS Treatment Centre	Inpatients		
	Outpatients		
At Nottinghamshire Healthcare Trust	Inpatients		
	Outpatients		
Primary Care			

14. FUNDING

14a. How is this medicine funded for this indication?

a. *Excluded from tariff (NHS England funded)
b. *Excluded from tariff (Cancer Drugs Fund)
c. *Excluded from tariff (ICB funded)
d. *Reimbursed through National tariff (i.e., in tariff medicine)
*Other (please specify)

14b. How much will this treatment cost per patient (please state if per course/month/annum)?
Note that medicines prescribed in the hospital incur VAT which isn't included in BNF prices. Individual trusts may have guidance on free-of-charge treatments, e.g., post-clinical trials. Pharmacy can assist with this section if needed.

14c. How does this cost compare to current treatments?
(Please include associated costs such as administration costs, hospital activity costs etc.). Pharmacy can assist with this section if needed. Some price comparison graphs are available here.

14d. What are the non-medication costs associated with this treatment?
(e.g., additional clinic appointments/blood tests/scans / other service costs)
(NB: For medications supplied free of charge through compassionate access schemes, the commissioners will only routinely fund associated activity costs if there is a formally agreed commissioning position).

15. Should the submission be approved, a review of use will take place in approximately six months. Please give reasons if this is not felt to be appropriate, i.e., if a longer period is required to assess efficacy. Please provide audit criteria – you will be required to provide the audit data.

16. What is the anticipated traffic light classification of this medicine?	**Please tick**
RED – Medicines which should normally be prescribed by specialists only.	
AMBER 1 – Medicines that should be initiated by a specialist and prescribed by primary care prescribers only under a **shared care** protocol once the patient has been stabilised. Prior agreement must be obtained by the specialist from the primary care provider before prescribing responsibility is transferred. The shared care protocol must have been agreed upon by the relevant secondary care trust Drugs and Therapeutics Committee(s) (DTC) and approved by the Nottinghamshire APC.	
AMBER 2 – Medicines suitable to be prescribed in primary care after Specialist* recommendation or initiation. A supporting prescribing guideline may be requested, which must have been agreed upon by the relevant secondary care trust D&TC(s) and approved by the Nottinghamshire APC.	

**Specialist is defined by the APC as a clinician who has undertaken an appropriate formal qualification or recognised training programme within the described area of practice.*	
AMBER 3 – Primary care/non-specialist may initiate as per APC guidelines. The supporting prescribing guideline must have been agreed upon by the relevant secondary care trust D&TC(s) and approved by the Nottinghamshire APC.	
GREEN – Medicines suitable for routine use and can be prescribed within primary care within their licensed indication, in accordance with nationally recognised formularies, for example, the BNF, BNF for Children, Medicines for Children or Palliative Care Formulary. Primary care prescribers take full responsibility for prescribing.	

EPMA (Electronic Prescribing & Medicines Administration)
Medication Request Submission Form

This form should be used to request specific 'dose sentences' (pre-built prescriptions) which are to be created for use in Nervecentre EPMA.
Refer to examples below on how to populate the columns. This form should be completed by the submitting clinician.
Please note this EPMA section does not apply to parenteral SACT (Systemic Anti-Cancer Therapies) – these remain on Chemocare. Oral SACT therapies should be included here.
If you have any queries regarding the EPMA section of this form, please contact the team directly at: For NUH ***epma@nuh.nhs.uk.***
Accountability for this EPMA section will be with the EPMA Pharmacy team, not the DTC.

1) Medication Requests - Non-Injectables

Medication Name (& Form – only if necessary)	Route	Dose Details / Dose Range (e.g. mg, mmol)	Frequency	Minimum Interval +/- Maximum Dose in 24 Hours (if applicable)	Indication (if desired)	Duration (if desired)	Associated Observations / Bloods Results	Administration Instructions / Prescriber Information	Additional Comments / Documents to Link
e.g. Zomorph® MR 10mg Capsules	Oral	20mg	BD	Every 12 hours – 8am & 8pm	Pain relief	3 days (6 doses)	eGFR	If age <70 years, and eGFR >50ml/min/1.73 m^2	Consider co-prescribing PRN opioid. Consider co-prescribing laxatives and anti-emetics. Add a link to the "NUH Adult Acute Pain (Including Opioid) Guidelines"

2) Medication Requests – Injectables

Medication Name	Route (inc. central or peripheral, if necessary)	Dose Details / Dose Range (e.g. mg, mmol)	Diluent (as necessary)	Volume (as a range, if necessary)	Duration / Rate / Maximum Concentration (as applicable)	Frequency	Indication (if desired)	Associated Observations / Bloods Results	Administration Instructions / Prescriber Information	Additional Comments / Documents to Link
e.g. Piperacillin/ Tazobactam	IV Infusion	4.5 grams	Sodium Chloride 0.9% or Glucose 5%	50ml-150ml	30 minutes	Every 6 hours OR Every 8 hours	Infection X	eGFR		Link to the Antibiotic Website.

Section 2- Signatures (completed forms should be printed and signed)
Sections marked with * must be completed.
Each clinician must make a declaration of interest:
Have you, a close family member, your colleagues, department or practice ever received any payment or goods, directly or in kind, from the makers of this medicine for any purpose? If yes, please give details. This Guidance should be used when answering this question. If no, please state 'no'.

***Submitting Clinician / GP**				
Name (in BLOCK LETTERS):				
Position:			Trust:	
Email address:				
Declaration of Interest: (see above)	***See Q2***	Details:		
Signature:			Date:	

***Submission Approval**				
For Secondary Care submissions **Submission approved by Head of Service (confirming both clinical and financial approval in place)*				
Name of Head of Service (in BLOCK LETTERS):				
Trust:				
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	
For Primary Care submissions * Submission approved by ICB GP Prescribing Lead:				
ICB GP Prescribing Lead: (in BLOCK LETTERS):				
ICB Name:				
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	

Each clinician must make a declaration of interest:
Have you, a close family member, your colleagues, department or practice ever received any payment or goods, directly or in kind, from the makers of this medicine for any purpose? If yes, please give details. This Guidance should be used when answering this question. If no, please state 'no'.

Supporting Clinicians / GPs / Pharmacists				
Name (in BLOCK LETTERS):				
Position:			Trust:	
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	
Name (in BLOCK LETTERS):				
Position:			Trust:	
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	
Name (in BLOCK LETTERS):				
Position:			Trust:	
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	
Name (in BLOCK LETTERS):				
Position:			Trust:	
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	
Name (in BLOCK LETTERS):				
Position:			Trust:	
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	

Please request a new form for any medicine you want to request in future. Somebody else may already be submitting the same medicine, and we can send you unbiased supporting information and prices with the most up-to-date form. Blank forms and further information is available from the Formulary/ DTC Pharmacist (contact details below).

For Primary Care and Secondary Care submissions, electronic and/or hard copies of completed forms should be sent to:

Formulary / DTC Pharmacist
Pharmacy Department
Sherwood Forest Hospitals NHS Foundation Trust
Mansfield Rd
Sutton in Ashfield
Nottinghamshire
NG17 4JL
Tel 01623 672213

Formulary / DTC Pharmacist
Pharmacy Department
Nottingham University Hospitals NHS Trust
Queen's Medical Centre Campus
Derby Road
Nottingham
NG7 2UH
Tel 0115 9709200

NottsAPC: please contact via nnicb-nn.nottsapc@nhs.net

APPENDIX 4 Requests for Traffic Light Classification/Reclassification

To be completed by person making request

Name of medicine *(include strength and form)*	
Indications	
Current traffic light classification *(NB – if currently grey will require a full submission and review of evidence)*	
Requested traffic light classification	
Reason for request *(e.g. linked to pathway/service redesign)*	
Will any local guidelines require amendment if the TL change is agreed?	
Have you been asked to prescribe this already? *If yes please state by whom*	
Have you any declaration of interest for this request *If yes, please give details; if no, please state "no"*	
Name and profession & organisation	
Further information	

Signature: …… **Date:** ……

All submissions should be typed. An electronic or hard copy of the completed form should be returned to the Chair of the Nottinghamshire Joint Formulary.

The completed form should be returned to nnicb-nn.nottsapc@nhs.net

NOTTINGHAMSHIRE AREA PRESCRIBING COMMITTEE

Front Sheet for Formulary Requests

Date of APC Meeting:	
Title of Paper:	**Person Presenting Paper:**
What are the Equality and Diversity or health inequality considerations?	
Declarations of Interest (If Applicable):	
Summary (including reference to previous decisions)**:**	
Assessment of the evidence – does the medicine offer advantages over existing therapy?	

• Clinical effectiveness	
• Safety	
• Cost effectiveness	
• NICE approved	
• Offer significant benefits to patients	
• Affordability for Nottinghamshire Healthcare Community	

•

Summary of recommendations by National bodies:	
Local recommendations **Derbyshire-** **Leicestershire-** **Lincolnshire-** **Northampton-** **Doncaster-** **Sheffield-**	

Implications for Secondary Care: *This section should include factors such;* - *Will there be any effect on activity, resource (including staff and costs) and access to the medicine?* - *Will it bring about a change in current practice? If yes what will be needed? Any training needs?* - *Have relevant clinicians been involved in the submission?*	**Implications for Primary Care:** *This section should include factors such;* - *Will there be any effect on activity, resource (including staff and costs) and access to the medicine?* - *Will it bring about a change in current practice? If yes what will be needed? Any training needs* - *Can supplies be obtained easily within the community?*
Implications for Patients: *What are the implications of the proposed decision for the patient group? Consider efficacy and safety of medication.* *What are the alternative options for the patients?* *What patient impacts need to be considered? Eg. Patient information, access to treatment if approved.*	**Governance Implications:** *This section should include factors such;* - *Will there be any patient monitoring?* - *What assurances will there be in regard to quality and assessment of risk?* - *Any training requirements for HC staff? How will these be delivered and quality maintained?*
Financial Implications	
Predicted patient numbers per annum. *What are likely patient numbers?* *Is there likely to be any growth in numbers?*	**Predicted cost impact per annum (NB if > £80k PA impact to primary care, submission will need to be referred for funding decision).** *Give an indication of current spend and whether this will increase* *Comparison with other drugs / does it replace any other treatment?* *Any relevant patent expiries?*
How will usage of the medicine be audited? *e.g internal audit, EPACT2 data*	**Other costs involved eg training, consumables etc**
Commissioning implications	

Are there any service implications which need to be highlighted to either commissioners or providers? *Who is the commissioner?* *Is the request linked to any pathway redesign?* *Are there any monitoring requirements that may need highlighting to commissioners?*	**Is the drug likely to prevent hospital admissions / outpatient appointments (please use NNT where available)?**

If the medicine does NOT offer advantages over existing therapy below? Clinical effectiveness Safety Cost effectiveness NICE approved Affordability for Nottinghamshire Healthcare Community Other significant benefits to patients	**Grey**
Does or is the medicine or condition being treated: • Require specialist assessment to enable patient selection, initiation & ongoing treatment? • Designated 'hospital only' by it's Marketing Authorisation, NICE or MHRA? • An unlicensed or 'off-label' medicine & not upheld in a nationally recognised • formulary or guideline? • Not available or prescribable in primary care? • Requires long-term ongoing monitoring of complicated treatments & • investigations and a specialist needs to monitor efficacy and/or progress? • Requires long-term ongoing monitoring of toxicity by a specialist? • Require preparation by a hospital pharmacy? • Being investigated as part of a clinical trial in secondary care? • Formulated or administered in such a way that makes it unsuitable for primary care? *Also consider a red classification if the medicine or condition is* • Significantly more cost effective for it to be obtained by secondary care? • New drug or indication with limited local experience either in primary or • secondary care? • Been requested by the specialist that prescribing remains within secondary care • · Uncommon so that a GP is unlikely to be familiar with it.	**Red**
Does or is the medicine or condition being treated: • Require specialist involvement to enable patient selection and initiation of treatment • Require short or medium term specialist monitoring and/or assessment until the patient is stable? • Require specific long term monitoring for toxicity which a GP is able to carry out? • Specifically recommended as suitable for shared care by the DH or NICE? • Have limited experience in primary care but the GP is likely to see enough patients to maintain competency in prescribing?	**Amber 1 (Shared Care)**

Does the medicine or condition being treated: • Require specialist initiation?	**Amber 2 (Specialist initiation or recommendation)**
Is the medication or condition being treated: • Suitable to be initiated in primary care by a clinician following a guideline?	**Amber 3 (Primary care prescriber initiation)**
Is the medication or condition being treated: • Suitable to be prescribed and the ongoing monitoring of safety, efficacy and progress to be carried out within primary care with no special restrictions?	**Green**

Nottinghamshire Area Prescribing Committee — Decision Tree

Assessment of Evidence—Does the medicine offer advantages over existing therapy?
- Clinical effectiveness
- Safety
- Cost effectiveness
- NICE approved
- Affordability for Nottinghamshire Healthcare Community
- Other significant benefits to patients

NO → GREY

(Awaiting assessment if part of horizon scanning and a full review has not been carried out)

YES

Does or is the medicine or condition being treated:
- Require specialist assessment to enable patient selection, initiation & ongoing treatment?
- Designated 'hospital only' by it's Marketing Authorisation, NICE or MHRA?
- An unlicensed or 'off-label' medicine & not upheld in a nationally recognised formulary or guideline?
- Not available or prescribable in primary care?
- Requires long-term ongoing monitoring of complicated treatments & investigations and a specialist needs to monitor efficacy and/or progress?
- Requires long-term ongoing monitoring of toxicity by a specialist?
- Require preparation by a hospital pharmacy?
- Being investigated as part of a clinical trial in secondary care?
- Formulated or administered in such a way that makes it unsuitable for primary care?

Also consider a red classification if the medicine or condition is
- Significantly more cost effective for it to be obtained by secondary care?
- New drug or indication with limited local experience either in primary or secondary care?
- Been requested by the specialist that prescribing remains within secondary care
- Uncommon so that a GP is unlikely to be familiar with it (incidence less than 1 in 10,000)

YES → RED

Hospital prescribing only

NO

Does or is the medicine or condition being treated:
- Require specialist involvement to enable patient selection and initiation of treatment
- Require short or medium term specialist monitoring and/or assessment until the patient is stable?
- Require specific long term monitoring for toxicity which a GP is able to carry out?
- Specifically recommended as suitable for shared care by the DH or NICE?
- Have limited experience in primary care but the GP is likely to see enough patients to maintain competency in prescribing?

YES → AMBER 1

Shared Care Protocol Required

NO

Does the medicine or condition being treated:
- Require specialist initiation?

YES → AMBER 2

Specialist Initiation

NO

Is the medication or condition being treated:
- Suitable to be initiated in primary care but requiring recommendation by a specialist?

YES → AMBER 2

Specialist recommendation

NO

Is the medication or condition being treated:
- Suitable to be initiated in primary care following an APC approved guideline

YES → AMBER 3

Primary Care Initiation following an APC guideline

NO

Is the medication or condition being treated:
- Suitable to be prescribed and the ongoing monitoring of safety, efficacy and progress to be carried out within primary care with no special restrictions?

YES → GREEN

(Guideline *may* be required)

APPENDIX 7 Example Process for Funding of Medicines within Secondary Care

Request to prescribe a non-formulary medicine or indication for use within secondary care only (if requesting primary care prescribing, apply to APC)

Contact specialist pharmacist to discuss the request and ascertain cost and ensure alternative formulary medicine is not suitable (e.g. allergy, intolerance, ineffective etc)

Request is for an specific patient only?

Yes (individual patient)
Follow the Trust's one-off request process. This will require:

1) MDT or colleague support if medicine is unlicensed, or being used outside license / established practice / national reference source
2) Clinical approval from head of service
3) Financial approval for the duration of treatment from the budget holder unless submitting an Individual Funding Request (IFR) to the commissioner (the patient's ICB or NHS England)

IF DTC one-off request panel approval obtained continue as per the below

One-off patient with DTC and budget holder support:
Specialty funds within secondary care Trust for individual patient. If cohort or similar patients require for same indication, cohort application process to be followed

IFR to NHSE
Complete online process via the Apollo portal – application will require support from Chief Pharmacist and Medical Director in addition to DTC

IFR to ICB
Complete appropriate application form as directed by DTC. Application will require support from Chief Pharmacist and Medical Director in addition to DTC

If IFR is approved, high cost pharmacist to pass-through to correct commissioner as part of month end process. If IFR declined, Trust budget holder to approve / decline funding within secondary care Trust

No (i.e. cohort request) –includes applications to DTC/APC classified as RED.
Follow the Trust's formulary submission process. This will require:

1) MDT or colleague support, especially if medicine is unlicensed, or being used outside license / established practice / national reference source
2) Clinical approval from head of service

Is the medicine / indication excluded from Tariff (PbR excluded)?

No (In-tariff medicine)
Financial approval should be sought for the duration of treatment for all patients from the budget holder. If the specialty is unable to fund – consider internal business case

Yes (excluded from tariff)

Lead Pharmacist High Cost Medicines and/or Trust Contracting Lead will confirm the medicine/indication is commissioned and therefore suitable for "pass-through".

If not commissioned / not "pass through" , discuss with Lead Pharmacist High Cost Medicines who can advise on business case to ICB or Clinical Commissioning Policy Proposal to NHSE depending on responsible commissioner.

If funding route unavailable, DTC decline the application on funding grounds