Framework for Managing Medicines across the Nottinghamshire Health Community

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	5.0
Title	Framework for Managing Medicines across the Nottinghamshire Health Community
Author	Nicky Bird APC Manager, NHS Mansfield & Ashfield Clinical Commissioning Group, on behalf of the Nottinghamshire Health Community Updated by Laura Catt Prescribing Interface Advisor, NHS Mansfield & Ashfield Clinical Commissioning Group, on behalf of the Nottinghamshire Health Community
Approval Date	March 2019
Approving Committee	Nottinghamshire Area Prescribing Committee
Review Date	March 2021
Groups/Staff Consulted	NHS Mansfield & Ashfield CCG NHS Newark & Sherwood CCG NHS Rushcliffe CCG NHS Nottingham West CCG NHS Nottingham North & East CCG NHS Nottingham City CCG Sherwood Forest Hospitals NHS Foundation Trust Nottinghamshire Healthcare NHS Trust Nottingham University Hospitals NHS Trust Nottinghamshire Local Medical Committee Nottingham Treatment Centre Nottinghamshire Local Pharmaceutical Committee
Target Audience	All prescribers across primary and secondary care
Circulation List	NHS Mansfield & Ashfield CCG NHS Newark & Sherwood CCG NHS Rushcliffe CCG NHS Nottingham West CCG NHS Nottingham North & East CCG NHS Nottingham City CCG Sherwood Forest Hospitals NHS Foundation Trust Nottinghamshire Healthcare NHS Trust Nottingham University Hospitals NHS Trust NHS Bassetlaw CCG (in relation to mental health) Nottinghamshire Local Medical Committee
Superseded documents	Framework for Managing Medicines across the Nottinghamshire Health Community version 4

1. Introduction

This document is intended to define the process, which will apply within the Nottinghamshire Health Community 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 Health Community, 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 healthcare community.

For further information on the roles and responsibilities of the Nottinghamshire APC please see *Appendix 1 Nottinghamshire Area Prescribing Committee Terms of Reference*

2. Scope

This guideline is applicable to all healthcare professionals providing NHS services in the Nottinghamshire Health Community.

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 that is being treated elsewhere, but the reason for this action must be documented. The Nottinghamshire APC states; it would 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 in this area, advice will be sought from the Nottinghamshire APC in conjunction with the Nottinghamshire LMC (or other representative organisation). The Chair of the Nottinghamshire APC will write to 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. Whilst a decision is awaited as to which category a medicine belongs, or where shared care protocols are being drawn up, the clinical responsibility and supply of the medicine under issue to the patient will be retained by the prescriber who initiated the treatment.

In the case of patients who are already having their medication prescribed the clinical responsibility and responsibility for 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 Health Community.

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.

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 make decision by consensus and agreement of its membership. However on the occasions when the committee cannot reach consensus, decisions will be made by a simple majority of those present. In the case of equality 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 primary 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*

It is not feasible for all medicines to be classified under the Nottinghamshire Traffic Light system. Generally those medicines included the Nottinghamshire Joint Formulary will have a traffic light classification. If a medicine is not listed in the Joint Formulary then advice should be sought from the CCG Medicines Management 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 their significance to the Nottinghamshire health community 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) within 90 days of publication or 30 days in the case of an Early Access to Medicines Scheme.

The APC will provide advice on the local implementation of such policy within the health community

d. Shared Care Protocols and Prescribing Guidelines

Appendix 7 Nottinghamshire APC Shared Care Protocol Agreement template, appendix 8 Prescribing Information Sheet Template and *Appendix 9 Prescribing Guidelines to support Amber 2 and Amber 3 medicines* are the templates that must be used when developing a SCP or prescribing guideline.

e. Nottinghamshire Joint Formulary Group (NJFG)

The NJFG is a sub-group of the Nottinghamshire APC.

The purpose of the NJFG is;

- 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 medicine may be referred to the Nottinghamshire APC via:

- Trust Drugs and Therapeutics Committee (D&TC)
- Nottinghamshire Joint Formulary Group
- Local Medical Committee (LMC)
- CCG Medicines Management Team
- Specialist Interface & Formulary Pharmacists
- Email mailto:maccg.nottsapc@nhs.net

See *Appendix 2 Process for Formulary Submissions and Traffic Light Classifications, Appendix 3 Formulary Submission Requests form and Appendix 4 traffic light change request form* for further information.

f. Reconsideration of decisions

Decisions made by either the Nottinghamshire APC or the Joint Formulary Group 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 Joint Formulary Group or 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/JFG or similar formulary decision making group from a neighbouring area.

The appeals panel will consider whether;

- the process followed by the Nottinghamshire APC or JFG was consistent with that detailed in the 'Framework for Managing Medicines across the Nottinghamshire Health Community'
- the decision reached by the Nottinghamshire APC or JFG
    - 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 or JFG acted in good faith
    - was a decision which a reasonable APC or JFG 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 or JFG, 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 JFG
- to refer the request back to the Nottinghamshire APC or JFG with detailed points for reconsideration.

g. Request to CCGs to Fund Medicines within Secondary Care

Appendix 10 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 above the rest of the patient population. Local IFR policies must be followed, these are available on each CCG website.

NHS England is the statutory body for the consideration of IFRs for Prescribed Specialised Services (including services for Military and Offender Health and the Cancer Drugs Fund). Information on the Prescribed Specialised Services listed in the NHS England Manual is available at https://www.england.nhs.uk/commissioning/spec-services/key-docs/

IFRs for procedures or medicines not listed in the NHS England Manual for Prescribed Services should be discussed with the CCG IFR team.

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 patients CCG 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 remains with the tertiary care centre

As with all Red traffic lighted drugs, the primary care prescriber is not expected to take prescribing or monitoring responsibility.

I. Unlicensed and Off Label medicines

Each trust and CCG 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.

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

Appendix 1

NOTTINGHAMSHIRE AREA PRESCRIBING COMMITTEE
TERMS OF REFERENCE

Purpose of the Committee

- To accept delegated responsibility from all stakeholders 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 Health and care Community, 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 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 healthcare community.

- 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 appropriately implement national guidance such as that produced by the Regional Medicines Optimisation Committees (RMOCs)

- To actively review formulary choices to ensure cost-effective products are available and to feedback 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 establish and maintain a joint formulary between the Clinical Commissioning Groups (CCGs), 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 establish and maintain the mandate of the APC to agree prescribing policy for medicines management issues on behalf of the CCGs, provider trusts and local Authorities. Ensure that cost effectiveness is assessed and that all decisions are within agreed financial thresholds.

- To develop and review prescribing specifications that form part of the contracts for Acute and Community Providers and other organisations that provide NHS services.

- To advise and assist the CCGs and provider trusts 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 medicines use issues 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 regards 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. 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 principals 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

Mid Notts CCGs	• Senior medicines management pharmacist • GP prescribing lead
Greater Notts CCGs	• Senior medicines management pharmacist • GP prescribing lead x2
Public Health County or City	
NUH	• Senior pharmacist • Clinician
NHCT*	• Senior pharmacist • Non-medical prescriber
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	
Nottingham Treatment Centre representative	Chief pharmacist

*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 work outside the meeting where required
- Come to meetings prepared with all documents and ready to contribute to the debate.
- Declare any outside financial or personal conflicts of interest at the start of each meeting and annually.

Chair

The Chair and deputy chair will be democratically elected 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 decision by consensus and agreement of its membership. However on the occasions when the committee cannot reach consensus, decisions will be made by a simple majority of those present. In the case of equality of votes, the Chair will have a casting vote.

Quorum

The meeting will be deemed quorate where there is representation from each of the CCG partnerships (Mid Notts and Greater Notts) and Secondary Care Trusts (SFHT, NUH, NHCT).

Subgroups

The Nottinghamshire Joint Formulary Group is a subgroup of the Nottinghamshire Area Prescribing Committee.

Relationships and Accountability

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

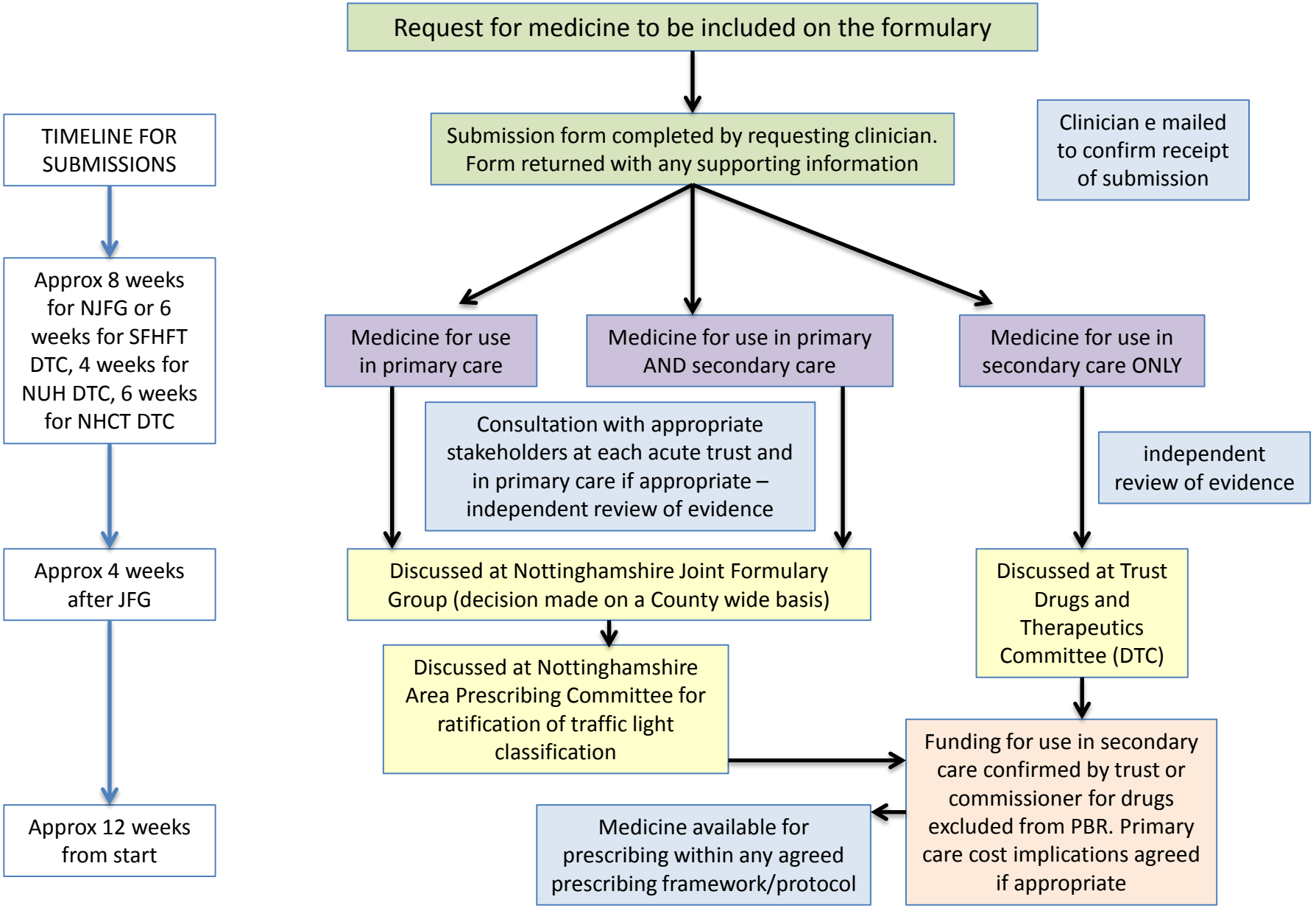
The Committee will need to determine links with primary care prescribing/ commissioning subcommittees, Trust Drugs and Therapeutics Committees and other neighbouring Area Prescribing Committees.

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

Administration

- Meetings will take place bi-monthly.
- The administrative services to the Committee will be provided by NHS Mansfield & Ashfield CCG hosted Shared Medicines Management team.
- Meeting agenda and papers will be circulated to members one week prior to each meeting.
- Minutes of the meeting and bulletin will be circulated to members within two weeks of each meeting.
- The venue for the meeting will be chosen which is accessible for the whole health community to ensure attendance by all members of the Committee.
- 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 in between scheduled meetings, e-mail communication will be used. Where this fails, an emergency meeting may be called.

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 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 Nottinghamshire Joint Formulary Group. 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 (eg presentation to local groups, directorate, cross-town groups)

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

1. Name of drug (include strengths and forms).
2. 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) ……
3. Is this submission: (Delete as appropriate)
a) to add a drug to the formulary? **Yes / No** b) to replace a drug currently on the formulary (please specify drug) **Yes / No** ..... c) a modification of usage to a drug already listed within the formulary (i.e. new indication for use)? **Yes / No**
4. Indication(s) covered by this submission. Is this in line with the licensed indication?
5. Please provide a summary of the condition(s) for which the drug 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.
6. How will the requested product be used to treat this / these condition(s)? Please include dosage, length of treatment, place in therapy, monitoring requirements etc. **Please attach guidelines for the use of the drug for this condition if relevant. In some cases, guidelines may be required before final approval. Individual trusts may have guidance on guideline production.**
7. What is currently used to treat this / these condition(s)? Please include drug(s), doses, length of treatment, monitoring etc.
8a. What are the advantages of the new drug over existing practice? **e.g. enhanced efficacy, route, side effect profile, compliance, reduced hospitalisation, avoidance of**

surgery, reduced need for community support.

8b. What are the disadvantages of the new drug over existing practice? Please be as expansive as possible.
e.g. It's relatively new so therefore may have uncertain side effect profile, nurses, other doctors and GPs will be unfamiliar with it, costs more, requires extra monitoring, evidence base is poor for the intended use, etc

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

If possible, please include original references with this submission. If not, please provide complete references so that the original papers can be obtained.

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

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

12. How many patients are likely to be initiated on this drug (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 in practise uptake is significantly different to 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			

13a. How much will this treatment cost per patient (please state if per course / month / annum)?
Note that drugs prescribed in hospital incur VAT which isn't included in BNF prices. Individual trusts may have guidance on free of charge treatments eg. post clinical trials. Pharmacy can assist with this section if needed.

13b. 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.	
14. What is the anticipated traffic light classification of this drug?	**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 by the relevant secondary care trust Drugs and Therapeutics Committee(s) (D&TC) 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 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 guideline.** The supporting prescribing guideline must have been agreed 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.	
15. Should the submission be approved, a review of use will take place at 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.	

Section 2- Signatures (completed forms should be printed and signed)
Sections marked with * must be completed.
Each clinican 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 drug for any purpose? If yes, please give details. This form should be completed and sent with the submission. If no, please state 'no'.

***Submitting Clinician / GP**				
Name (in BLOCK LETTERS):				
Position:			Trust:	
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	

***Submission Approval**				
For Secondary Care submissions **Submission approved by Head of Service:*				
Name of Head of Service (in BLOCK LETTERS):				
Trust:				
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	
For Nottingham Treatment submissions **Submission approved by Chair of the TC Medicines Management Committee:*				
Name of Chairman: (in BLOCK LETTERS):				
Email address:				
Declaration of Interest: (see above)	***Yes / No***	Details:		
Signature:			Date:	
For Primary Care submissions * Submission approved by CCG GP Prescribing Lead:				
CCG GP Prescribing Lead: (in BLOCK LETTERS):				
CCG 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 drug for any purpose? If yes, please give details. [This form] should be completed and sent with the submission. If no, please state 'no'.

Supporting Clinicians / GPs				
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 drug you want to request in future. Somebody else may already be submitting the same drug 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 hard copies of completed forms should be sent to:

Formulary / DTC Pharmacist at either:

Pharmacy Department
King's Mill Hospital
Mansfield Rd
Sutton in Ashfield
Nottinghamshire
NG17 4JL
Tel 01623 672213

Pharmacy Department
Nottingham University Hospitals NHS Trust
Queen's Medical Centre Campus
Derby Road
Nottingham
NG7 2UH
Tel 01159 249924 ext 64185

Pharmacy Department
Pharmaxo
Nottingham NHS Treatment Centre
Lister Road
Nottingham
NG7 2FT

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 NottsAPC@nottspct.nhs.uk

Appendix 5

NOTTINGHAMSHIRE AREA PRESCRIBING COMMITTEE

Front Sheet for Joint Formulary Requests

Date of JFG Meeting:	**Agenda Item / Number:**
Title of Paper:	**Person Presenting Paper:**
Sponsoring Organisation:	**Patient and Public Involvement (PPI)**
Are there any Equality and Diversity implications?	
Declarations of Interest (If Applicable):	
Summary (including reference to previous decisions)**:**	
Recommendation to the JFG:	
How will the formulary change be communicated and who will implement the change?	
Are there any service implications which need to be highlighted to either commissioners or providers?	
Assessment of the evidence – does the medicine offer advantages over existing therapy? • Clinical effectiveness • Safety • Cost effectiveness • NICE approved • Affordability for Nottinghamshire Healthcare Community • Offer significant benefits to patients	
Who is the commissioner?	
Is the request linked to any pathway redesign?	
Who is supporting the submission?	
Summary of recommendations by National bodies:	

Local recommendations	
Implications for Secondary Care:	**Implications for Primary Care:**
Governance Implications	
Implications for Patients:	**Governance Implications:**
Financial Implications	
Cost per patient and predicted cost per annum (NB if > £80k impact to primary care, submission will need to be referred for funding decision). *Give an indication of current spend and whether this will increase*	**Predicted patient numbers per annum.**
Is the medicine outside PBR or on the high cost drug exclusion list (if yes CCG funding will be needed)?	**Is the drug likely to prevent hospital admissions / outpatient appointments (please use NNT where available)?**
Comparison with other drugs / does it replace any other treatment?	**Other costs involved eg training, consumables etc**
How will usage of the medicine be audited in secondary care and by who? *e.g internal audit,*	**How will usage of the medicine be audited in primary care and by who?** Eg EPACT or prescribing team audit

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

"Reviewed and Rejected" OR "No Formal submission" if identified via horizon scanning

YES

Does the medicine or condition being treated meet one or more of the following criteria:
- 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 the medicine or condition being treated meet one or more of the following criteria:
- 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 Nottinghamshire APC Shared Care Protocol Agreement

NOTTINGHAMSHIRE AREA PRESCRIBING COMMITTEE SHARED CARE PROTOCOL AGREEMENT

(*insert medicine(s) and specialty*)

OBJECTIVES

- *Include brief bullet points of the objectives of the Shared Care Protocol*

REFERRAL CRITERIA

- Prescribing responsibility will only be transferred when it is agreed by the specialist and the patient's primary care prescriber that **the** patient **is stabilised on their regimen without adverse effect and with benefit demonstrated**

PROCESS FOR TRANSFERRING PRESCRIBING TO PRIMARY CARE

- The request for shared care should include individual patient information, outlining all relevant aspects of the patients care and which includes direction to the specific information sheets at www.nottsapc.nhs.uk.

- If the GP does not agree to share care for the patient then he/she will inform the Specialist of his/her decision in writing within 14 days, outlining the reason for decline. Agreement can be assumed if the GP does not provide written decline.

- In cases where shared care arrangements are not in place, or where problems have arisen within the agreement and patient care may be affected, the responsibility for the patients management including prescribing reverts back to the specialist.

CONDITION TO BE TREATED

Max 1/2 side of A4. Include information on;

- *The disease*
- *Diagnostic criteria and investigations*
- *General treatment and management*
- *Patient selection for drug treatment*

NATIONAL/ LOCAL GUIDANCE

Including a summary of any national guidance or changes in practice, for example NICE guidance (include web links if relevant)

CLINCAL INFORMATION

List information sheets relevant to the SCP

AREAS OF RESPONSIBILITY

Part of the Shared Care Protocol for xxx
REVIEW DATE (USUALLY 3 YEARS):
DATE APPROVED BY THE NOTTINGHAMSHIRE APC:

(include any other medicine specific responsibilities)

Specialist's Roles and Responsibilities

1. The specialist will confirm the working diagnosis.
2. The specialist will recommend and initiate the treatment.
3. The specialist will ensure that the patient has an adequate supply of medication (usually 28 days) until shared care arrangements are in place. Further prescriptions will be issued if, for unseen reasons, arrangements for shared care are not in place at the end of 28 days. Patients should not be put in a position where they are unsure where to obtain supplies of their medication.
4. If shared care is considered appropriate for the patient, and the patient's treatment regimen is confirmed and benefit from treatment is demonstrated, the specialist will contact the GP.
5. The specialist will provide the patient's GP with the following information:
   - diagnosis of the patient's condition with the relevant clinical details.
   - details of the patient's treatment to date
   - details of treatments to be undertaken by GP*
   - details of other treatments being received by the patient that are not included in shared care
   - details of monitoring arrangements

   *Including reasons for choice of treatment, medicine or medicine combination, frequency of treatment, number of months of treatment to be given before review by the consultant.
6. Whenever the specialist sees the patient, he/she will
   - send a written summary within 14 days to the patient's GP.
   - record test results on the patient-held monitoring booklet if applicable
   - communicate any dosage changes made to the patient
7. The specialist team will be able to provide training for primary care prescribers if necessary to support the shared care agreement.
8. Contact details for during working and non working hours will be made available
9. Details for fast track referral back to secondary care will be supplied.
10. The specialist will provide the patient with details of their treatment, follow up appointments, monitoring requirements and nurse specialist contact details.
11. The specialist will highlight the importance of monitoring to the patient and explain the potential withdrawel of treatment if monitoring appointments are not attended

Primary Care Prescriber's Roles and Responsibilities

If the primary care prescriber does not agree to shared care for the patient then he/ she will inform the Specialist of his/her decision in writing within 14 days.

The Primary Care Prescriber will be responsible for:

1. Ensuring that he/she has the information and knowledge to understand the therapeutic issues relating to the patients clinical condition.
2. Undergoing any additional training necessary in order to carry out the prescribing and monitoring necessary
3. Agreeing that in his / her opinion the patient should receive shared care for the diagnosed condition unless good reasons exist for the management to remain within secondary care.
4. Prescribing the maintenance therapy in accordance with the written instructions contained within the information sheets, and communicating any changes of dosage

made in primary care to the patient. It is the responsibility of the prescriber that makes a dose change to communicate this to the patient.

5. Where applicable keep the patient-held monitoring booklet up to date with the results of investigations changes in dose and alterations in management and take any actions necessary. It is the responsibility of the clinician actioning the results from monitoring, in accordance with this shared care guideline, and thereby prescribing for the patient to complete the patients record with the necessary information.
6. Reporting any adverse effect in the treatment of the patient to the specialist team.
7. The Primary Care Prescriber will ensure that the patient is monitored as outlined in the information sheet(s) and will take the advice of the referring specialist if there are any amendments to the suggested monitoring schedule.
8. The Primary Care Prescriber will ensure that the patient is given the appropriate appointments for follow up and monitoring, and that defaulters from follow up are contacted to arrange alternative appointments. It is the Primary Care Prescribers responsibility to decide whether to continue treatment in a patient who does not attend appointments required for follow up and monitoring

Community Pharmacist Roles and Responsibilities

1. Professionally check prescriptions to ensure they are safe for the patient and contact the GP if necessary to clarify their intentions.
2. Fulfil legal prescriptions for medication for the patient unless they are considered unsafe.
3. Counsel the patient on the proper use of their medication.
4. Advise patients suspected of experiencing an adverse reaction to their medicines to contact their GP.

Patient's Roles and Responsibilities

1. Take their medication as agreed, unless otherwise instructed by an appropriate healthcare professional.
2. Attend all follow-up appointments with GP and specialist. If they are unable to attend any appointments they should inform the relevant practitioner as soon as possible and arrange an alternative appointment.
3. Inform all healthcare professionals of their current medication prior to receiving any new prescribed or over-the-counter medication.
4. Report all suspected adverse reactions to medicines to their GP.
5. Store their medication securely away from children.
6. Read the information supplied by their GP, specialist and pharmacist and contact the relevant practitioner if they do not understand any of the information given

REFERENCES

Any relevant references should be stated

AUTHORS

Include name of authors and their base

IN CONSULTATION WITH

Include name of consultees and their base

Specialist CONTACT DETAILS (In Hours and Out of Hours)

Appendix 8

Medicine

Traffic light classification- Amber 1
Information sheet for Primary Care Prescribers

Licensed Indications

Prescribing outside of licensed indication
If yes please specify

Any exclusions

Therapeutic Summary

Medicines Initiation
Include authority of specialist to initiate treatment

Products available
Include brand and generic

Dosages and route of administration

Reconstitution and storage (if applicable)

Duration of treatment

Monitoring Requirements and Responsibilities

Explicit criteria for review and discontinuation of the medicine

Contraindications

Precautions

Clinically relevant medicine interactions and their management

Information given to patient

Community Pharmacist's Role (if applicable)

Patient's Role (if applicable)

References

APPENDIX 9 Prescribing Guidelines to support Amber 2 and Amber 3 medicines

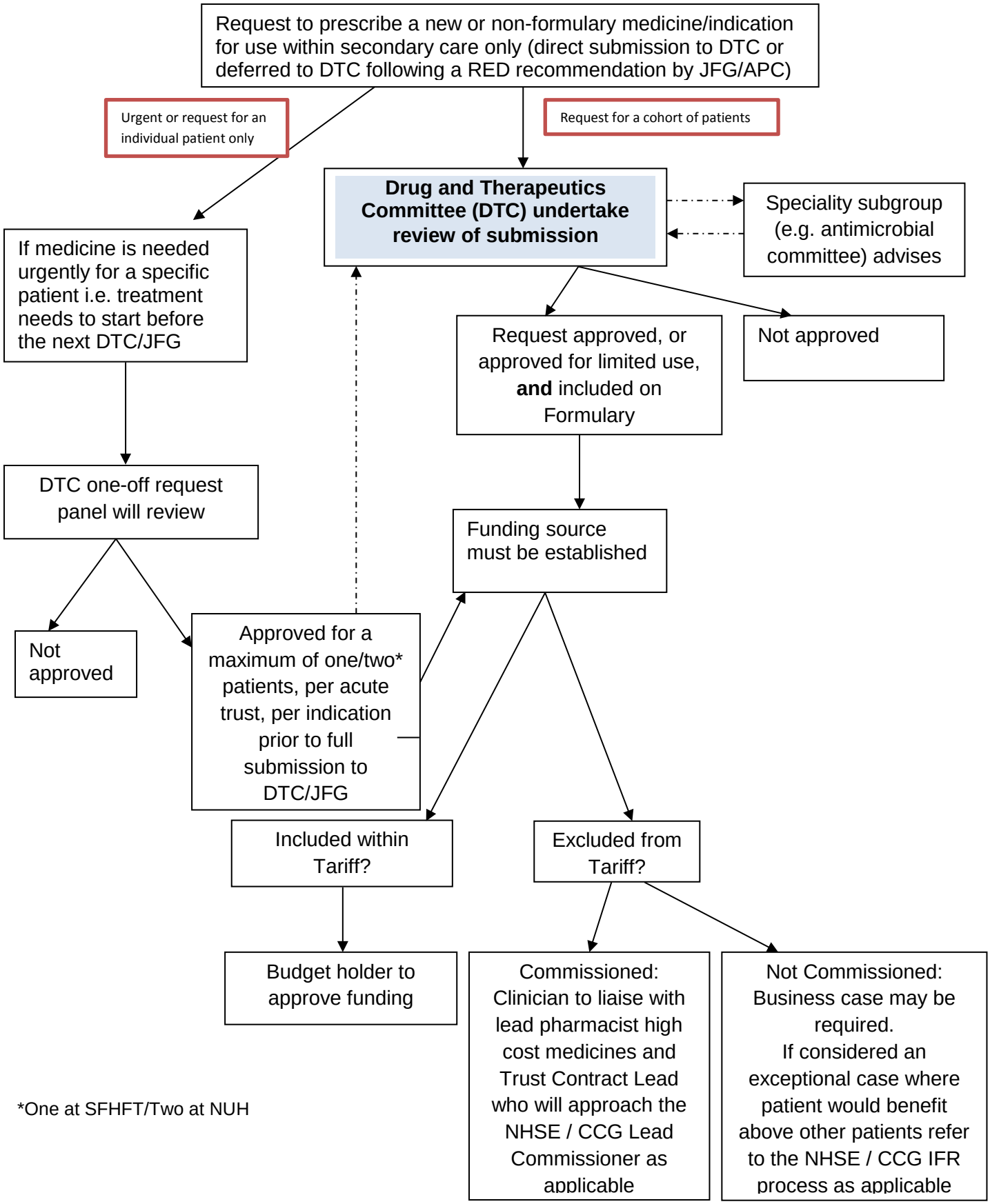
The list below indicates the type of information that should be included in an Amber 2 or Amber 3 guideline.

- Any treatment algorithm should be simple and easy to follow, highlighting when a medicine should be started, changed or stopped. It should place the medicine in line with the original formulary submission.
- The guideline should clearly state whether it is aimed at primary care clinicians, secondary care clinicians or both.
- There should be explicit criteria for review and discontinuation of the medicine and this should also be an emphasis to communicate this to the patient.
- If any of the medicines within the algorithm are being used outside their marketing authorisation this should be clearly stated.
- Important adverse effects - including incidence, identification, importance and management should be listed.
- A reference to the appropriate resource should be made for further information i.e. BNF and SPC

Additional Information

- All Trusts within the Nottinghamshire health community will need to work collaboratively when developing a prescribing guideline
- Clinical effectiveness, cost effectiveness and safety should be considered when producing the algorithm
- Consultation with primary care prescribers must be sought when developing or reviewing the guideline, including CCG prescribing leads and prescribing teams.
- A prescribing guideline will usually be approved for three years after which time an up-dated version should be re-submitted. Any major changes in national guidance should prompt a review of the guideline at an earlier date.
- Requests for the APC to develop new guidelines will be considered by the interface team and prioritised according to the perceived benefit to the whole health community.

APPENDIX 10 Example Process for Funding of Medicines within Secondary Care



*One at SFHFT/Two at NUH