University Hospitals of Leicester NHS
NHS Trust

POLICY FOR THE INTRODUCTION OF NEW MEDICINES INTO LEICESTER, LEICESTERSHIRE AND RUTLAND (LLR)

Approved By:	**UHL Policy & Guideline Committee**
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Trust Lead:	**Chair, LLR Therapeutics Advisory Service (TAS) Commitee**
Board Director Lead:	**Andrew Furlong, Medical Director**
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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

March 2024

Transferred over to current UHL policy template

LMSG nomenclature updated to LLR APC

Reference to CCGs removed and replaced with ICB

Traffic Light Section updated to change various amber classifications to yellow (specialist intiaition) and orange (requires shared care agreement)

Hyperlinks updated to the LLR APC website

Appendix re-ordered to match order in text

Appendix B updated to include new limits for LLR APC financial approval

KEY WORDS

New Medicines Policy

Therapeutic Advisory Service

Formulary

New Drugs

1 INTRODUCTION AND OVERVIEW

1.1 This policy describes the process through which new medicines are introduced into use within University Hospitals of Leicester (UHL) and the wider Leicestershire and Rutland (LLR) Health community. It does not cover the introduction of medical devices within UHL, which should be requested via NIPAG (New Interventions and Procedures Approvals Group).

2 POLICY SCOPE

2.1 This policy applies to all UHL staff involved in the prescribing or authorisation of medicines budgets

2.2 LLR TAS (Leicester, Leicestershire and Rutland Therapeutic Advisory Service) will not consider cancer chemotherapy. Chemotherapy reviewed within UHL by the local SACT (systemic anti cancer therapy) group.

2.3 TAS will not consider psychiatric medication. These will be reviewed by the Leicestershire Partnership Trust (LPT) medicines management group

3 DEFINITIONS AND ABBREVIATIONS

ICB = Integrated Care Board

LLR = Leicester, Leicestershire and Rutland

APC = Area Prescribing Committee

NIPAG= New Interventions and Procedures Approvals Group

SCA = Shared Care Agreement

TAS = Therapeutic Advisory Service

The Traffic Light" list defines the level and mechanisms of recommended use within the Leicestershire community

Red	Hospital prescribing only
Orange	Initiation in secondary care then continued prescribing in primary care. A shared care agreement is required and the GP is asked to take over prescribing through use of the SCA request form
Yellow	Initiation in secondary care then continued prescribing in primary care.
Green	Suitable for initiation in primary care
Black	Not recommended for prescribing within LLR

4 ROLES AND RESPONSIBILITIES

4.1 The executive director responsible for this policy is the Medical Director .

4.2 Clinical management group (CMG) pharmacists are responsible for ensuring that the process is adhered to and CMG Clincal Directors, finance leads and general managers are responsible for agreeing financial support for drugs with a cost impact of >£5k per annum within UHL.

4.3 The Therapeutic Advisory Committee (TAS) is responsible for making decisions on clinical effectiveness of new drugs and have delegated responsibility for agreeing funding for drugs with a cost impact of <£5k per annum within UHL. For the wider healthcare community Leicester, Leicestershire and Rutland Area prescribing committee (LLR APC) have responsibility for assessing cost impact across LLR before approving. The TAS secretary is responsible for managing the process and communicating decisions within the Trust.

4.4 UHL consultants (Includes non-medical consultants) are responsible for discussing applications with their Head of Service and then for following the process and making an online application

5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

All requests for new medicines to be introduced into LLR will follow the procedure described in section 5.1 of this policy document. In instances where it is not clear whether a new product is classed as a device or a medicine, the chair or professional secretary of TAS will discuss where the request would be most be appropriate to be reviewed with the chair of the New Interventions and Procedures Approval Group (NIPAG)

The purpose of LLR TAS is to act as an advisory body to individual Consultant staff, Clinical Management Group Clincal directors, Heads of Service within UHL and GP practice prescribing leads and to provide advice as required to external bodies such as Commissioners, on the management/ introduction of new pharmaceutical products and/or therapies within the Clinical Management Groups of UHL and the LLR community. The scope of responsibilities of TAS is reflected in the Terms of reference of that Group, which can be found here. An FAQ of frequently asked questions about TAS can be found in appendix A

5.1 Procedure for new medicine introduction

5.1.1 The process for introduction of new medicines is summarised in appendix B.

5.1.2 The Funding Section of the application form must be completed in conjunction with the Clinical Management Group Lead Pharmacist, Finance lead and General Manager. This scopes the clinical and cost impact of introducing the new medicine

5.1.3 The forecasted annual cost of the medicine must be calculated and consideration needs to be given to where funding for the medicine would be obtained (viz. Within Tariff / Excluded to Tariff). In instances where the medicine is excluded from tariff, the request must go to TAS for review before it goes to the responsible Commissioner for Leicestershire patients. Table 1 describes the route for financial approval

Table 1: Summary of Approval routes required for New Drug Funding applications

Drug status	Approval required from
Medicines Included in Tariff ≤ £100k per annum	CMG Board Commissioning Collaborative Board (if >30k per annum impact across the wider healthcare community)
Medicines Included in Tariff cost impact > £100k per annum	UHL Commercial Executive Commissioning Collaborative Board (if >30k per annum impact across the wider healthcare community)
Medicines excluded from tariff: Specialist	NHS England (Midlands Area)
Medicines excluded from tariff: Non specialist	LLR ICB*

* In year investment not usually available, needs to be considered as part of annual bidding round

5.1.4 Applications to TAS must be completed on line at the TAS Section of the LLR APC website. Before applying, the requestor must confirm that TAS has not already reviewed the product/indication by visiting the website. Requestors must ensure that:

- As much information is supplied with the request including any clinical references and proposed policies/procedures
- Where existing therapies are available a hierarchy is provided that outlines where the new medicine will be placed
- Declare any actual or potential conflicts of interest

5.1.5 The responsibility for the above in respect of introducing a new product/indication thus rests with the individual Consultant concerned. Failure to comply will result in a delay in the request being reviewed by TAS.

5.1.6 Applications for new antimicrobials and antimicrobial vaccines should also be made via the TAS website. These will be reviewed by the Antimicrobial Working Party (AWP) then endorsed by TAS.

5.1.7 Following receipt of a new medicine request by TAS, an acknowledgement will be sent to the requestor within two weeks. Then the evidence base supporting the use of the new medicine will be independently reviewed by the Medicines Information Service and submitted for consideration at the next available TAS/AWP meeting. The strength of evidence will be assessed and rated and there must be evidence of meaningful clinical benefit in order for a medicine to be supported. Evidence using surrogate end points will be considered providing these are biologically plausible. The implications for the use of this medicine in primary care will also be considered as part of the committee's deliberations.

5.1.8 Following consideration of the evidence at TAS, if the request is not supported, the Chair of TAS will inform the requestor within two weeks of the meeting outlining the reasons for this.

5.1.9 If the request is supported, the secretary of TAS will inform the requestor and the relevant Clinical Management Group Clinical Director, Manager and Lead Pharmacist within two weeks of the meeting and advise them of the TAS recommendation.

5.1.10 Procurement of approved medicines within UHL will commence when both components of the process are complete (TAS committee support and financial support from the Clinical Management Group or commissioner). As part of this process, a risk assessment will take place to ensure that consideration is given to any patient/ staff safety implications associated with the introduction of the new medicine

5.1.11 Shared Care Agreements (SCAs) are required if the LLR Area Prescribing Commitee (LLR APC) allocates anorange status to a product i.e. a product which requires specialist prescribing initially but which can be taken on by a GP at an appropriate (agreed) time. NB: Products that receive orange status will remain classified as red (Secondary Care only) until a fully ratified SCA is available.

5.1.12 Requestors can appeal against the decision made by TAS and may be invited to, or may request to, attend a future TAS meeting to present a case for the medicine requested or any new evidence that may not have been considered previously

5.1.13 Products not supported by TAS and LLR APC are given a black status on the Leicestershire Traffic Light List. These products are not available for prescribing in either secondary or primary care. UHL prescribers should not ask GPs to prescribe these drugs.

6 EDUCATION AND TRAINING REQUIREMENTS

The TAS secretary will provide requestors with a user guide to the process on request. Awareness of the process is highlighted by clinical pharmacists to prescribers.

7 PROCESS FOR MONITORING COMPLIANCE

7.1 Audit

Data on outcomes and safety must be collected for any new medicine being used to provide evidence on safety and efficacy. This also helps to inform decisions made on new formulary recommended choices. The Leicestershire community needs to demonstrate to patients and carers that we can introduce new products in a safe and effective way, and closing the loop through audit is one aspect of delivering that responsibility. TAS will ask the original requestor for a report on

- Usage
- Efficacy
- Outcomes
- Audits and key performance indicators, 12 months after the original application. In UHL this audit will be supported by the clinical audit team.

7.2 The processes described in this policy will be reviewed every 3 years to ensure that it facilitates the most efficient (staff resource and finance) method of introducing new medicines into the organisations.

POLICY MONITORING TABLE

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Decisions of the committee	TAS secretary	Report of decisions	Annual	MEDOC – recorded in minutes CMG leads
Medicine related NICE TAs reviewed before implemtation period. This is usually 90 days but may be sooner	TAS Secretary	NICE TA monitoring spread sheet	Annual report	LLR APC, MEDOC
Audit of drugs supported completed after 12-18 months	TAS secretary and CASE team will record Requestor responsible for completion	CASE monitoring spread sheet	Annual report	TAS committee LLR APC

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

LLR APC appliance/device or product ratification/approval process. 2019. Available at: https://www.areaprescribingcommitteeleicesterleicestershirerutland.nhs.uk/wp-content/uploads/2019/05/New-product-pathway-process.pdf

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

The updated version of the Policy will be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system.

Appendix A – Frequently Asked Questions about new medicine introduction

UHL: Do I need to get CMG approval to endorse the New Drug Funding application form?

Yes, for two reasons:

You need to establish that you have the support of your peers with respect to the application for a new product and that would include your Head of Service and CMG Medical Lead.

There are also often funding implications, and whilst TAS cannot consider funding issues, endorsement by your HoS and CMG Medical Lead will ensure this implication has been appropriately considered.

I have used this product elsewhere. Why do I have to seek approval from TAS?

Whilst you may have used the product in other Trusts, all Secondary Care Trusts/Health communities tend to have their own formularies and specific choices of agent within a class UHL/Leicestershire are no different in this respect. To confirm whether the product you wish to prescribe is available in UHL please refer to either the Leicestershire Medicines Formulary or the LLR APC website

The product has been reviewed by NICE and is recommended as a treatment of choice as part of a NICE Guidance. Do I still need to apply for access via TAS?

Yes. As a teaching hospital trust, UHL are very keen to support new treatment modalities. All NICE approvals that are available in UHL will go to TAS as standard but will require information from the clinical team regards place in therapy and likely impact. While approval from a clinical perspective is likely to be a formality if NICE approved remember that your CMG /APC or commisioner (whichever is appropriate) will also need to support its use.

This may not be granted immediately depending on the financial impact of the new therapy.

How will TAS decide whether to support my request for a new product?

TAS will make the decision on whether to support your request from available clinical evidence. The UHL Medicines Information Service supplies this information independently. Emphasis will be placed on the novel nature of the product vs existing therapies available for the indication cited. Where the prodcut you are requesting is an addition to a class of drugs you may be asked what products (if any) you expect the new product to replace. You may be also asked to produce a hierarchy to explain how the new product fits into the existing therapeutic management of a given condition.

The potential finacial impact will be considered if the cost implications are likely to be borne primarily in the community. It will also make a recommendation to the LLR APC as to the appropriate traffice light status. LLR APC will however, make the final decision on traffic light status.

TAS does not make the final decision on whether a product will be available to prescribe. It will, however, make a recommendation to your CMG on whether your request has been supported from a clinical point of view.

Your CMG will make the final decision on affordability of the product within UHL

What if my request is not supported?

You will receive a letter from the Chair of TAS explaining why your request has not been supported. This is usually because there is little clinical evidence to endorse its use. TAS may also consider the product provides no additional benefit over and above currently available thereapies.

You can appeal against the decision and may be invited to attend a future TAS meeting to present your case for the product request.

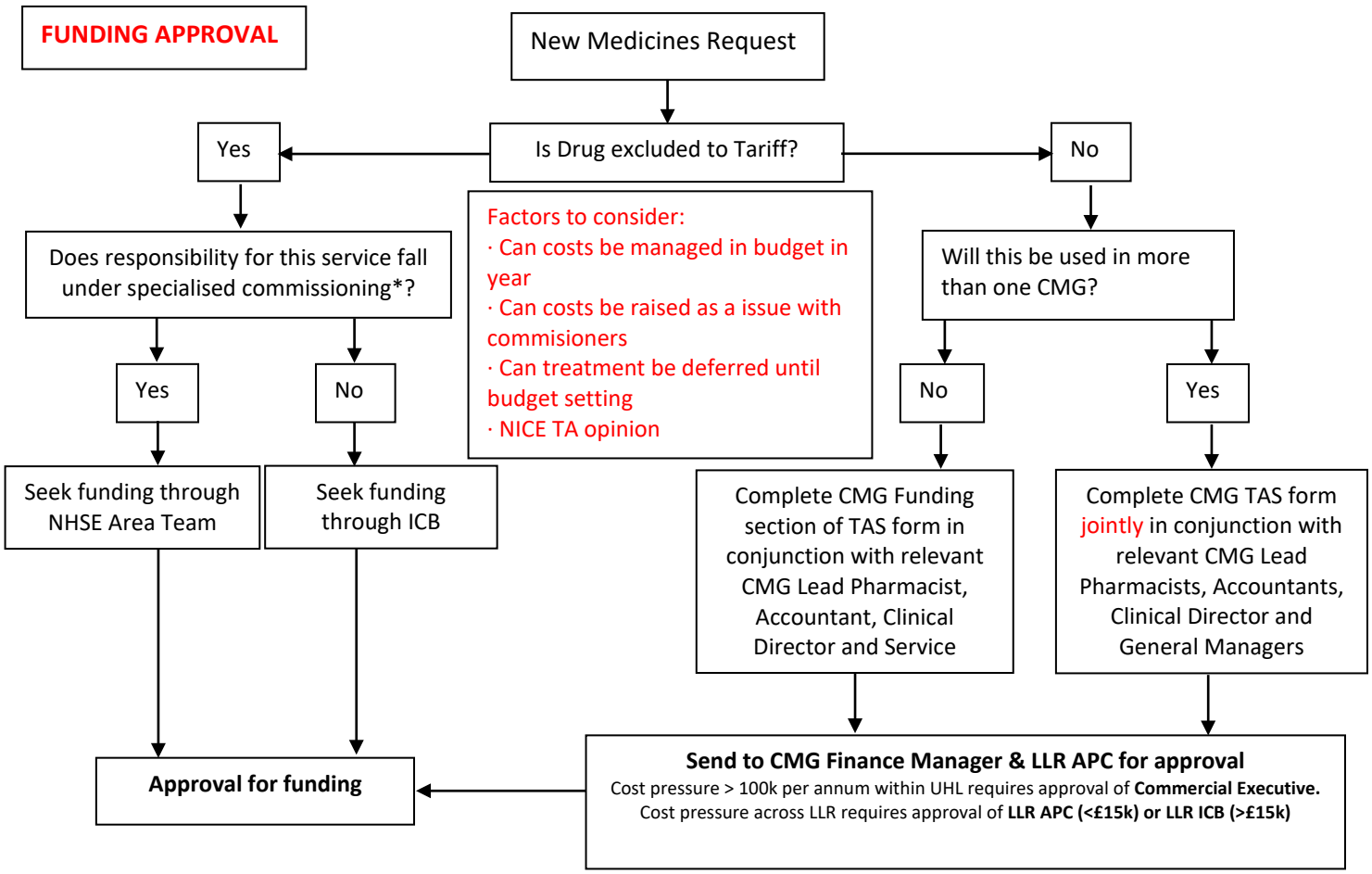
Why does TAS ask for audit data from me on this new product?

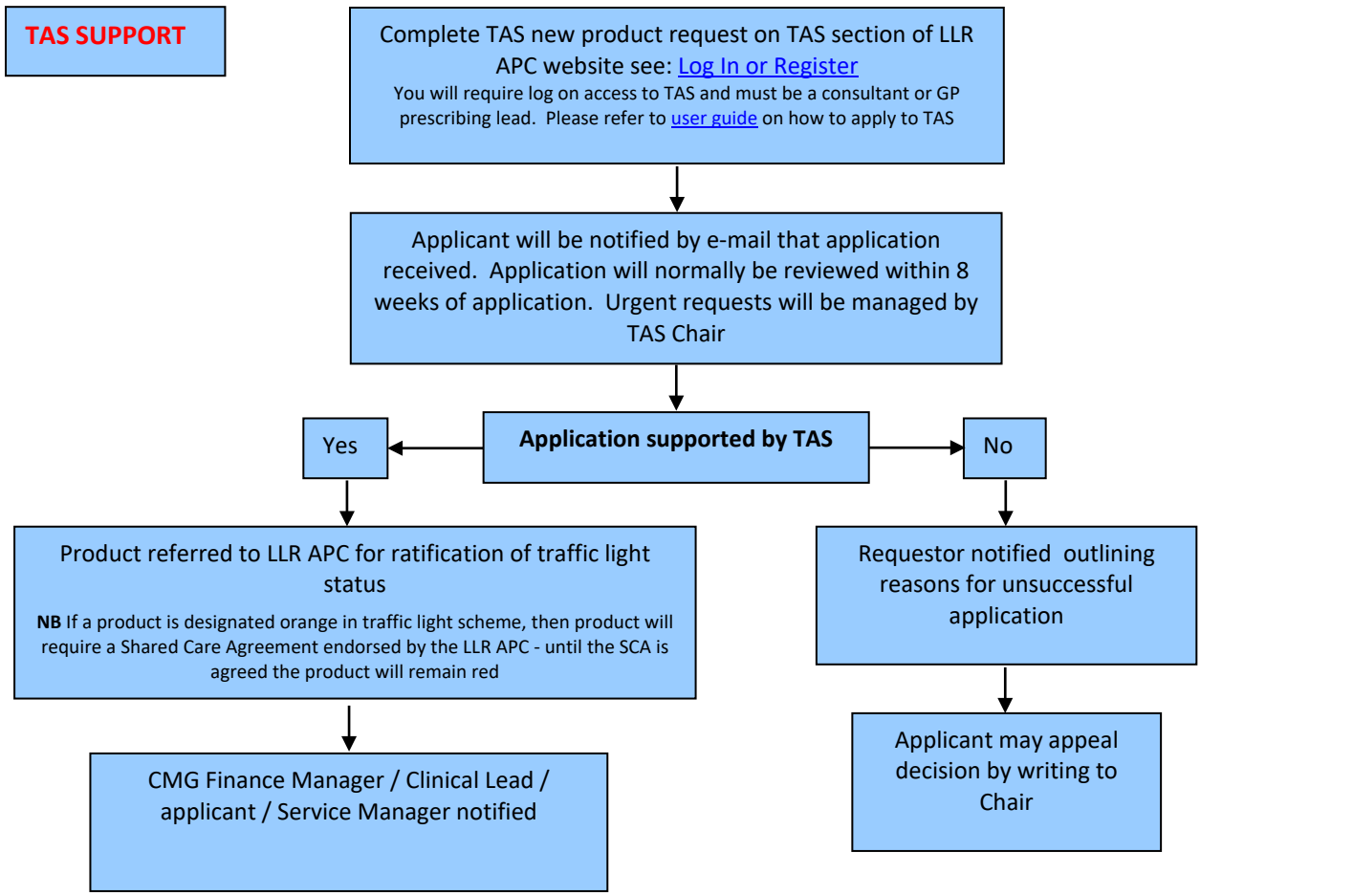
It is obviously important to collect data on outcomes and safety on any new product being used to evidence safety and efficacy. This also helps to inform decisions made on new formulary inclusions.

Lastly, the Trust / Leicestershire community needs to demonstrate to our patients and carers that we can introduce new products in a safe and effective way, and closing the loop through audit is of course one aspect of delivering that responsibiltiy.

APPENDIX B: SUMMARY OF PROCESS FOR REQUESTING NEW, NON-CANCER PRODUCTS IN LLR

Funding approval and TAS application support both need to be in place before a product can be **ordered**





*For further advice contact medicines.info@uhl-tr.nhs.uk