



## NON NICE NON TARIFF (NNNT) DRUGS FRAMEWORK

Drugs not covered by NICE recommendations and not included in National tariff

Leeds North CCG, Leeds South and East CCG and Leeds West CCG

Version:	final Draft
Ratified by:	Leeds West CCG Assurance Committee on (date) Leeds North CCG Governance, Performance and Risk Committee on (date) Leeds South and East CCG Governance and Risk Committee on (date)
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Name of responsible committee/individual:	Leeds West CCG Assurance Committee Leeds North CCG Governance, Performance and Risk Committee Leeds South and East CCG Governance and Risk Committee
Date issued:	
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Target audience:	Primary and secondary care clinicians, individual funding request panels and the public
Document History:	nil

Produced on behalf of NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG

## 1 Introduction

Prior approval for any non-NICE non-Tariff (NNNT) medicine is required from the relevant Clinical Commissioning Groups (CCG) in Leeds (Leeds West CCG, Leeds North CCG, Leeds South and East CCG). This is undertaken by the Leeds NNNT Panel which has representation from all three Leeds CCGs.

NHS England has responsibility for the commissioning of a number of drugs used in specialist services such as cancer treatments.

However, there are a number of high cost non-specialist drugs which fall into the non-NICE non-Tariff category which the Leeds CCGs will only fund if they are supported by adequate evidence of safety and effectiveness in the peer-reviewed published medical literature and represent good value for money.

## 2 Purpose

This Framework provides the supporting framework for decision making by the Leeds Non-NICE Non-Tariff Drugs Panel as described in the Individual Funding Requests Policy.

## 3 Scope

This Framework provides the supporting framework for decision making by the Non-NICE Non-Tariff Drugs Panel of NHS Leeds regarding non-NICE, non-Tariff drug funding requests.

This document is intended as an aid to decision making. It should be used in conjunction with Leeds CCG policies on Individual Funding Requests and associated decision making frameworks.

## 4 Framework operation

4.1 A locally produced framework will be used to support decision making by the NNNT Panel (Appendix A).

4.2 Appendix B shows the process of commissioning high cost drugs in the city.

### 4.3 CCG commissioning of drugs statement

*“The CCGs routinely commission drugs approved by the National Institute for Health and Clinical Excellence (NICE) or where NICE has produced a consultation appraisal that supports use in the NHS. The CCGs will routinely commission drugs approved by the Scottish Medicines Consortium (SMC). Where there is a conflict of advice between NICE and SMC, NICE guidance (including consultation appraisal) takes precedent.*

*The CCGs will not routinely commission drugs where NICE or SMC have rejected their use or where NICE has produced a consultation appraisal that rejects use in the NHS.*

*Our commissioning statements are the same as the guidance issued by NICE or SMC and are available at [www.nice.org.uk](http://www.nice.org.uk) or [www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)*

*The CCGs may develop commissioning statements for drugs not covered by NICE/SMC/tariff.*

*An individual funding request (IFR) may be submitted for a patient who is felt to be an exception to a commissioning statement of the Leeds CCGs.*

*An individual funding request for non NICE/ non SMC/ non tariff use of a drug must demonstrate:*

- that the patient is significantly different to the general population of patients with the condition in question; and*
- that the patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition.*

*We accept there are clinical situations that are unique (five or fewer patients) where an IFR is appropriate and exceptionality may be difficult to demonstrate.*

*Unless approved by NICE/SMC, in year introduction of a drug (where a drug trial is completed or licence granted) does not mean we will commission the use of this drug. An individual funding request is not an appropriate mechanism to introduce a new treatment for a group or cohort of patients. Where treatment is for a cohort larger than five patients, a proposal to develop the service, that is the introduction of a new drug, should go through the usual business planning process.”*

#### **4.4 Referral Process**

Refer to Leeds Individual Funding Requests Policy.

#### **4.5 Appeals**

Refer to Leeds Individual Funding Requests Policy.

#### **4.6 Panel Terms of Reference**

Refer to Leeds Individual Funding Requests Policy.

## 5 Responsibility for Document Development

Leeds CCGs' Medical Directors have overall responsibility for document development.

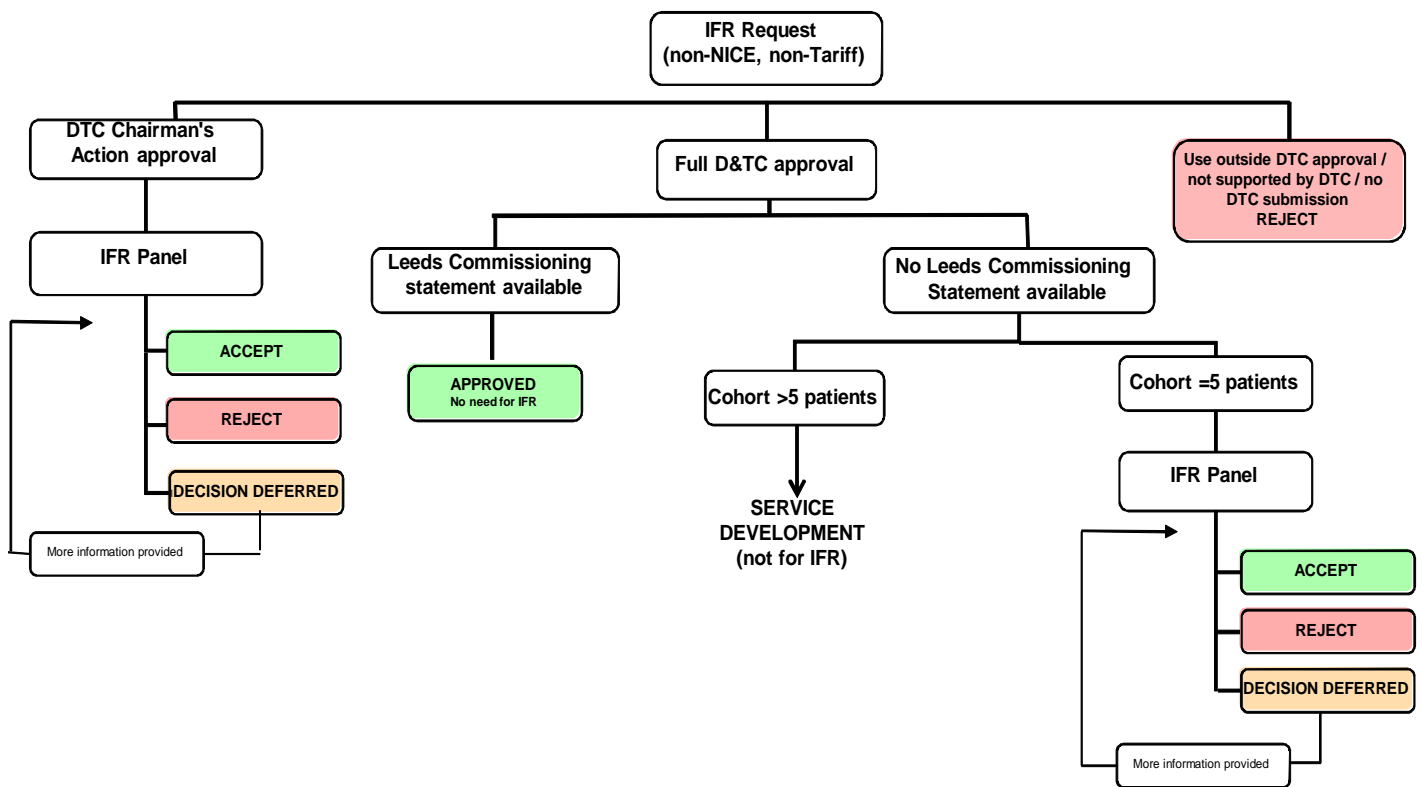
## 6 References

<http://www.nice.org.uk/>

[http://www.scottishmedicines.org.uk/smc/CCC\\_FirstPage.jsp](http://www.scottishmedicines.org.uk/smc/CCC_FirstPage.jsp)

### Appendix A: Decision Making Framework

## Individual Funding Requests (IFRs) for Drugs



#### Exceptionality means:

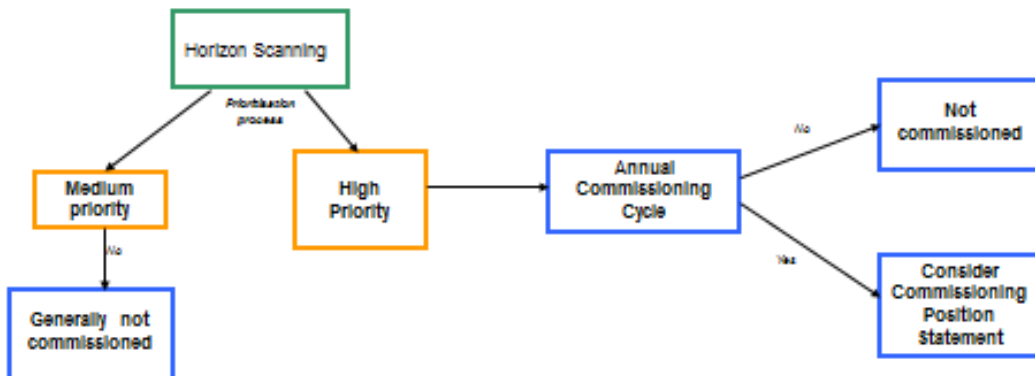
•the patient is significantly different to the general population of patients with the condition in question;

and

•the patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition.

## Appendix B: Commissioning Cycle and Pathway for High Cost Drugs

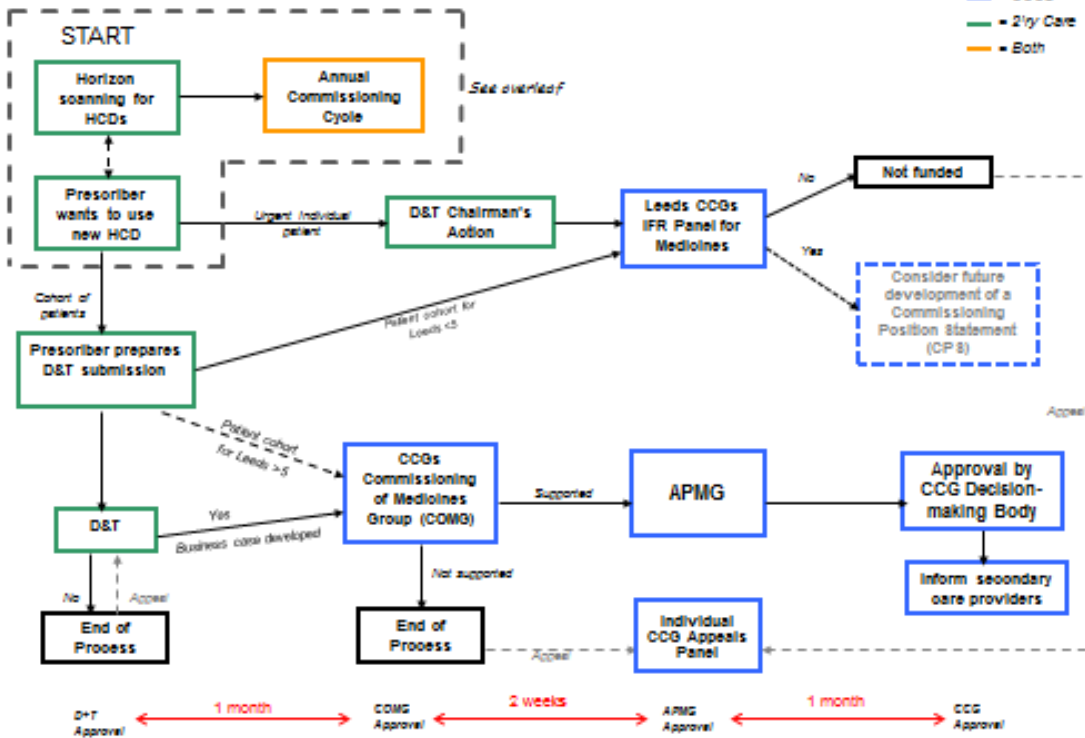
### Commissioning Cycle for HCDs



#### Notes for discussion:

- Horizon scanning process – sort in to High and Medium Priority (with CCG clinical input) – define process for prioritising
- For prioritised medicines, the drug / service to go through the Annual Commissioning Cycle (ACC); some may be rejected here
- Where funding agreed through ACC, Commissioning Position Statement could be written at this time.

## Pathway for New High Cost Drugs (HCDs)



### Appendix C: Version Control Sheet

Version	Date	Author	Status	Comment
1.1	8.7.8	F Day	Draft	Addition of LMC as consultee
1.2	3.9.8	F Day	Draft	Updating of appendix A to current version.
1.3	20.4.10	J Fear	Draft	Updating of appendix A to current version. Updating of PEC to Clinical Commissioning Executive.
1.4	02.09.13	J Aldred and F Day	Draft	Updating parent organisations. Updating Appendix A
1.5	9.9.13	F Day	Draft	Addition of cover sheet
1.6	10.9.13	F Day	Draft	Addition of flowchart on high cost drugs commissioning at 4.2
1.7	11.9.13	F Day	Draft	Addition of commissioning policy statement from CCG website in 4.3



**Appendix D: Plan for Dissemination of Framework Documents**

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Acknowledgement: University Hospitals of Leicester NHS Trust.

<b>Previous framework</b>	<b>No</b>	<b>Dissemination lead: Print name and contact</b>	CCG Medical
<b>If yes, in what format</b>	n/a		
<b>Proposed action to retrieve out-of-date copies of the</b>	n/a		
<b>To be disseminated to:</b>	<b>How will it be</b>	<b>Paper</b>	<b>Comments</b>
Clinicians		Electronic	
Clinicians		Electronic/	
Panel Members		Electronic	

**Dissemination Record - to be used once framework is approved.**

<b>Date put on register / library of framework</b>		<b>Date due to be reviewed</b>	
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<b>Disseminated to: (either directly or via</b>	<b>Format (i.e. paper or</b>	<b>Date</b>	<b>No. of Copies</b>	<b>Contact Details / Comments</b>



## **Appendix E: Equality Impact Assessment**

To ensure the Individual Funding Requests Policy for the Clinical Commissioning Groups in Leeds reflects due process for identifying the effect, or likely effect, of the policy on people with Equality Act protected characteristics – age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, sexual orientation - and that the policy demonstrates due regard to reducing health inequalities, addressing discrimination and maximising opportunities to promote equality the following steps have been taken.

The update to the policy results from the iterative refresh process, and the requirement to make changes to care as indicated by an evolving evidence-base. This means that access is broadened as more treatments and interventions become available without the need for an IFR. There is no change to the underlying principles of the policy. In order for an IFR to be approved according to the core principles for managing Individual Funding Requests, it must be demonstrated that the patient's case is exceptional.

The following consultation and engagement activities have been undertaken. The evidence-based policy has been circulated to all GPs and secondary care consultants for comment, and has been made available on the internet to the public, along with Plain English patient information leaflets. The core principles for managing Individual Funding Requests in Leeds have been made available online for twelve weeks and disseminated through Patient Advisory Groups and Patient Reference Groups along with a cascade through the Community and Voluntary Service network. Feedback from all these sources has been collected by the Clinical Commissioning Groups. There is also an open and transparent approach to the processes of the decision making panel with an established mechanism for appeals.