Non NICE Non Tariff (NNNT) Drugs Framework

Drugs not covered by NICE recommendations and not included in National tariff including grey drugs

NHS Leeds North Clinical Commissioning Group, NHS Leeds South and East Clinical Commissioning Group and NHS Leeds West Clinical Commissioning Group

Version:	2016-19
Ratified by:	NHS Leeds West CCG Assurance Committee on; 16 November 2016 NHS Leeds North CCG Governance on Performance and Risk Committee on; 17 November 2016 NHS Leeds South and East CCG Governance and Risk Committee on 13 November 2016
Name & Title of originator/author(s):	Dr Simon Stockill, Medical Director, NHS Leeds West CCG Dr Manjit Purewal, Medical Director NHS Leeds North CCG Dr David Mitchell, Medical Director NHS Leeds South and East CCG Dr Fiona Day, Consultant in Public Health Medicine, Leeds City Council
Name of responsible committee/individual:	NHS Leeds West CCG Assurance Committee NHS Leeds North CCG Governance, Performance and Risk Committee NHS Leeds South and East CCG Finance Activity and Performance Committee
Date issued:	December 2016
Review date:	December 2019
Target audience:	Primary and secondary care clinicians, individual funding request panels and the public
Document History:	Non NICE Non Tariff (NNNT) Drugs Framework issued 2014

On behalf of NHS Leeds North Clinical Commissioning Group, NHS Leeds South and East Clinical Commissioning Group and NHS Leeds West Clinical Commissioning Group

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1 Introduction

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. This is also the case for certain grey light drugs.

Prior approval for any non-NICE non Tariff (NNNT) medicine is required from the relevant Clinical Commissioning Groups (CCG) in Leeds, (NHS Leeds North Clinical Commissioning Group, NHS Leeds South and East Clinical Commissioning Group and NHS Leeds West Clinical Commissioning Group)

This is undertaken by the Leeds NNNT Drug Panel which has representation from all three Leeds CCGs.

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 Leeds Non Nice Non Tariff Drugs Panel regarding non-NICE, non-Tariff drug funding requests.

The panel will not support requests for drugs that have been classified as Black Light on the Leeds Traffic Light List, unless exceptionality can be demonstrated to the classification criteria. This is outlined in Appendix C which also covers use of drugs classified as Grey on the Leeds Traffic Light List.

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.

Policy development and review: consultation and engagement

The policy was developed to:

- ensure a clear and transparent approach is in place for exceptional/individual funding request decision making; and
- provide reassurance to patients and clinicians that decisions are made in a fair, open, equitable and consistent manner.

It was originally developed in line with NICE or equivalent guidance where this was available or based on a review of scientific literature. This included engagement with hospital clinicians,

general practice, CCG patient advisory groups, and the general public cascaded through a range, mechanisms.

The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing assurance. No concerns were raised with regard to the policy

4 Framework operation

4.1 A locally produced framework will be used to support decision making by the NNNT Drug 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 Final Appraisal Document (FAD) that supports use in the NHS. The CCGs will routinely commission drugs approved by the Scottish Medicines Consortium (SMC) where no NICE guidance exists. Where there is a conflict of advice between NICE and SMC, NICE guidance (including a final appraisal document) 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 final appraisal document that rejects use in the NHS.

Our commissioning position is the same as the guidance issued by NICE or SMC and is available at www.nice.org.uk or 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, or where no commissioning position statement exist for the patient.

The individual funding request 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."

Providers will not be paid for any activity covered by this framework which has not been approved in advance.

4.3.1 Endpoints

Following completion of the agreed treatment, a proportionate follow up process will lead to a final review appointment with the clinician where both patient and clinician agree that a satisfactory end point has been reached. This should be at the discretion of the individual clinician and based on agreeing reasonable and acceptable clinical and/ or cosmetic outcomes. This will usually have been outlined in the IFR request.

Once the satisfactory end point has been agreed and achieved, the patient will be discharged from the service.

Requests for treatment for unacceptable outcomes post treatment will only be considered through the Individual Funding Request route. Such requests will only be considered where a) the patient was satisfied with the outcome at the time of discharge and b) becomes dissatisfied at a later date. In these circumstances the patient is not automatically entitled to further treatment. Any further treatment will therefore be at the relevant Leeds Clinical Commissioning Group's discretion, and will be considered on an exceptional basis in accordance with the IFR policy.

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.

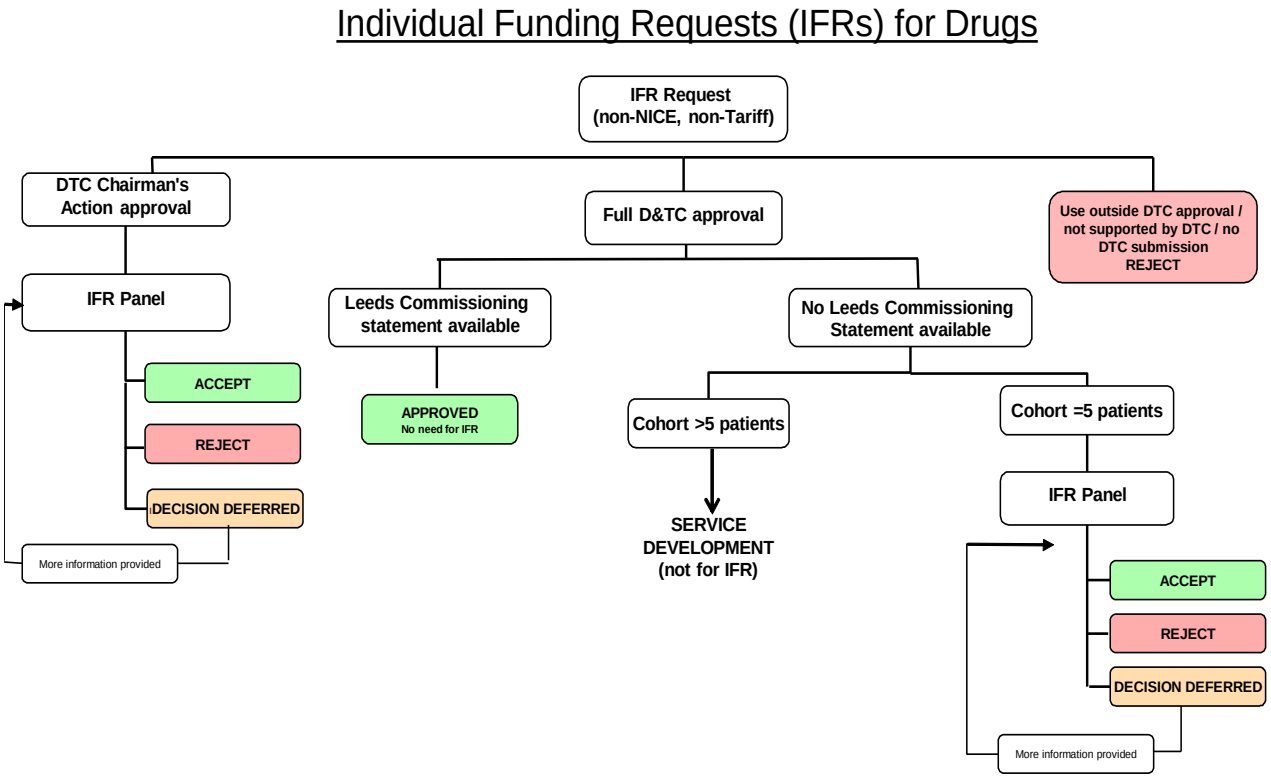
5 Responsibility for Document Development

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

Appendix A: Decision Making Framework



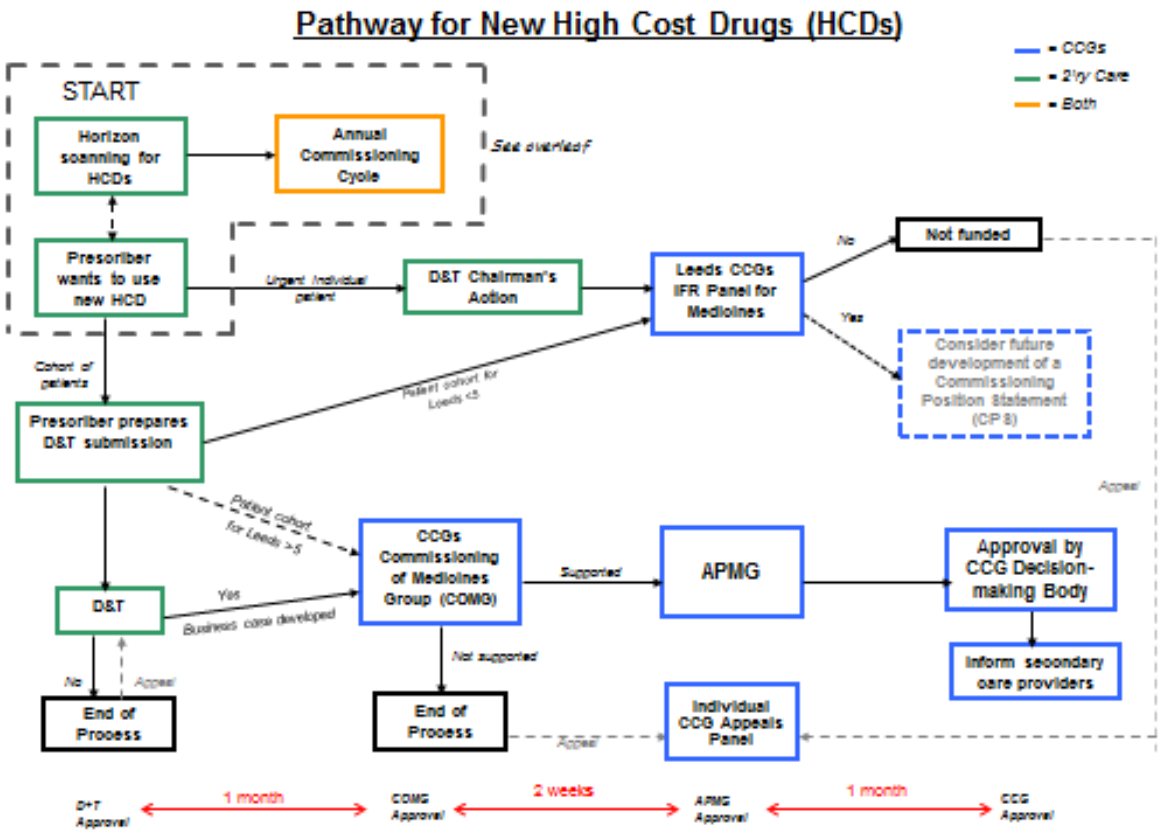
Exceptionality means:

•*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



Appendix C: Commissioning Statements for 'Black Light' and 'Grey drugs

Black Light Drugs are not recommended for use within the Leeds health economy.

Grey drugs are locally agreed medicines which are recommended for specific indications but not others.

Occasionally, drugs classified by the Leeds Area Prescribing Committee as either Black Light or Grey in the Leeds Traffic Light List may require a commissioning position statement.

This will be decided by the Leeds Commissioning of Medicines Group. All commissioning statements will go to Clinical Directors for approval and then to each individual CCG for final agreement.

Any complaints regarding the Black Light classification of a medicine will be considered by the Leeds Area Prescribing Committee, the group responsible for Traffic Light classifications.

An individual patient's response to Black Light treatment will ***not*** be considered as a reason for exceptionality.

Appendix D Equality Impact Assessment

Title of policy	Non NICE Non Tariff Drugs Framework	
Names and roles of people completing the assessment	Fiona Day Consultant in Public Health Medicine, Helen Lewis, Head of Acute Provider Commissioning	
Date assessment started/completed	26.6.16	25.7.16

1. Outline	
Give a brief summary of the policy	The purpose of the commissioning policy is to enable officers of the Leeds CCGs to exercise their responsibilities properly and transparently in relation to commissioned treatments including individual funding requests, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCGs. This policy relates to requests for Non NICE non tariff drugs.
What outcomes do you want to achieve	We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness.

2. Evidence, data or research	
Give details of evidence, data or research used to inform the analysis of impact	See list of references

3. Consultation, engagement	
Give details of all consultation and engagement activities used to inform the analysis of impact	Discussion with clinicians and patient representatives on the principles of decision making. Discussion with patient leaders relating to changes in the content of the policy and advice on proportionate engagement. The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing assurance. No concerns were raised with regard to the policy. Local clinical commissioning and clinical providers have had the opportunity to comment on the draft policies.

4. Analysis of impact			
This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to; eliminate unlawful discrimination; advance equality of opportunity; foster good relations			
	Are there any likely impacts? **Are any groups going to be affected differently?** **Please describe.**	**Are these negative or positive?**	**What action will be taken to address any negative impacts or enhance positive ones?**
Age	No		
Carers	No		
Disability	No		
Sex	No		

Race	No		
Religion or belief	No		
Sexual orientation	No		
Gender reassignment	No		
Pregnancy and maternity	No		
Marriage and civil partnership	No		
Other relevant group	no		

If any negative/positive impacts were identified are they valid, legal and/or justifiable? **Please detail.**	

5. Monitoring, Review and Publication			
How will you review/monitor the impact and effectiveness of your actions	Annual report of IFR activity reported through relevant committees to Governing Bodies of the 3 CCGs. A limited equity audit is undertaken as part of this. Complaints and appeals monitoring.		
Lead Officer	Simon Stockill	**Review date:**	Dec 2019

6.Sign off			
Lead Officer			
Director on behalf of the 3 Leeds CCG Medical Directors	Dr Simon Stockill, Medical Director, Leeds West CCG	**Date approved:**	24.8.16

Appendix E Policy Consultation Process:

Title of document	Non NICE Non Tariff (NNNT) Drugs Framework
Author	J Alldred, Leeds CCGs medicines lead
New / Revised document	Revised
Lists of persons involved in developing the policy	F Day Consultant in Public Health Medicine, Leeds City Council J Alldred
List of persons involved in the consultation process:	See appendix A

Appendix F 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 Alldred 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
1.8	18.11.13	F Day	Draft	Addition of endpoints statement, change of review date to april 2016
1.9	29.11.	F Day	Draft	Addition of Providers will not be

	13			paid for any activity with regards this framework which has not been approved in advance.; addition of dissemination plan
2.0	7.7.15	F Day; J Alldred	Final amended	Addition of appendix C on grey drugs; amendments to sections 1 and 3 to reference the inclusion of grey drugs.
3.0	14/7/16	J Alldred	Refreshed	Updating of references