



Commissioning Policy for the Funding of PbR Excluded Medicines

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Target audience:	<p>Stoke-on-Trent CCG\ North Staffordshire CCG</p> <ul style="list-style-type: none"> • Medicines Optimisation Team • Commissioning Team • IFR manager • Finance • Clinicians <p>UHNM/ SSOTP/NSCH</p> <ul style="list-style-type: none"> • Pharmacy • Finance • Clinicians

CONSULTATION AND RATIFICATION SCHEDULE

Name and Title of Individual	Date Consulted
Manir Hussain	
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Name of Committee	Date of Committee
CCG Joint Medicines Optimisation Committee	12 th August 2015
CCG Joint Planning Committee	10 th May 2016
Governing Board Meeting	6 July 2016

VERSION CONTROL

Policy Name:			
Version	Valid from	Valid to	Document/Path
1	April 2012	January 2013	
2	August 2013	October 2014	
3	May 2014	August 2015	
4	July 2016	July 2018	

1. Purpose

The purpose of this policy is to provide clarity on the commissioning arrangements of North Staffordshire CCG and Stoke-on-Trent CCG with regards to drugs that are PbR-excluded. It supersedes the medicines management section of the Excluded and Restricted Procedures UHNS, version 4, April 2011.

2. Introduction

North Staffordshire CCG and Stoke-on-Trent CCG have authority to commission health services for their resident population and make decisions within the context of statutes, statutory instruments, regulations and guidance.

CCGs have a responsibility to seek the greatest health advantage possible for local populations using the resources allocated to them. They are required to commission comprehensive, effective, accessible services which are free to users at the point of entry (except where there are defined charges) within a finite resource. It is, therefore, necessary to make decisions regarding the investment of resources in interventions which achieve the greatest health gain for the population.

This Policy is designed to offer clarity to providers of health services on which PbR-excluded drugs are commissioned by North Staffordshire CCG and Stoke-on-Trent CCG for their patient populations.

3. Scope

The scope of this policy applies to services commissioned by the CCGs from:

- University Hospitals of North Midlands NHS Trust,
- North Staffordshire Combined Health Care NHS Trust,
- Staffordshire and Stoke-on-Trent Partnership NHS Trust

This policy only covers PbR-Excluded drugs as defined by the Department of Health (DH).

4. PbR-Excluded Drugs list

The PbR-Excluded drugs that are routinely commissioned by North Staffordshire CCG and Stoke-on-Trent CCG are categorised as follows:

- I. **Category 1** – These are drugs that have been recommended by NICE as part of a Technology Appraisal Guidance (NICE HTA) and approved by the Health Economy NICE Implementation Group (HENIG) for implementation.

Drugs listed in this category must only be used as per NICE criteria and will require completion of a continual assurance request (CAR) or a Blueteq entry (phased introduction of Blueteq as defined in the SDIP)

- II. **Category 2** – Drugs that are not covered by a NICE HTA, but are funded by a commissioning agreement with the CCGs.

Drugs that do not appear in Category 1 or 2 will not be routinely funded by the CCGs and prior approval must be sought from the CCGs via the Individual Funding Request (IFR) or service development processes.

Where drug therapy has been initiated prior to the 1st April 2012 and does not appear in Category 1 or Category 2, CCG funding will be continued (with the exception of NHS England-funded drugs) until a formal review is undertaken and the CCGs decide to decommission.

5. Specialised Commissioning

Many PbR-excluded drugs, including some recommended in a NICE HTA are now commissioned and funded by NHS England rather than the CCGs. The current NHS Commissioning Board (NHS England) manual for prescribed specialised services should be consulted for details of drugs commissioned by NHS England. See <http://www.england.nhs.uk/>

6. Individual Funding Requests (IFR)

Prior approval (via the IFR process or other relevant commissioning process) from the relevant CCG will be required to initiate any PbR-excluded drug that does not appear in either Category 1 or Category 2 lists. This may include for example, requests to use a drug outside the recommendations of a NICE HTA or use of drug therapy outside its licensed indication.

Requests for individual funding will be considered under the procedures laid out in the IFR policy.

7. Commissioning New Drugs

The process for commissioning new drugs within the North Staffordshire and Stoke-on-Trent health economy will be as follows:

1. Any new drugs that are not commissioned by NHS England, are approved by a NICE HTA (Health Technology Appraisal) and approved by the HENIG for use in line with stated NICE criteria will be included in the Category 1 drug list.
2. The CCG will not normally fund NICE HTA drugs prior to HENIG approval and any costs incurred by providers prior to HENIG approval will be met by the provider if they initiate therapy without prior approval. In urgent cases, where a patient's treatment cannot be delayed, the CCG will consider funding before HENIG approval, by way of a virtual panel with GP and hospital representation.
3. Funding of drugs approved by the HENIG will be done within the timescales mandated by the Department of Health (3 months).
4. From 1st April 2012, all NICE HTA drugs approved by HENIG will require the completion of continual assurance requests once therapy is started (Example Appendix 3). These should be sent to the named person within the medicines optimisation team as stated on the form

(or completed online using an electronic PbRE monitoring system). The function of the continual assurance request is to provide assurance to the commissioners that the drug is being used in line with NICE criteria.

5. New drugs that are not commissioned by NHS England and are not covered by NICE HTAs will be subject to local negotiations between the lead commissioning manager and the provider. If approved these will be listed in the Category 2 list.

8. Validation of Invoices

The CCGs are utilising mechanisms to validate and report on high cost drugs invoices and data. To aid this process, from 1 July 2013 the providers will be required to supply a minimum dataset for high cost drugs supplied.

Data (on invoices) should include (but not be limited to): hospital number, drug, strength, form, volume, cost, therapeutic class and speciality or clinical indication. Drugs will be required to be categorised into NICE, non-NICE and IFR-approved.

Invoices for drugs not appearing in category 1, category 2 or without CCG prior approval will not be paid.

9. Additional costs associated with clinical trials

The funding by the CCG of additional costs associated with clinical trials will be in accordance with the following regional policies:

- WM10 Ongoing access to treatment following completion of non-commercially funded trials.
- WM11 Ongoing access to treatment following completion of NHS commissioner-funded trials.

Further details can be found on the following links:

http://www.wmsc.nhs.uk/uploaded_media/WM10%20Policy%20-%20Ongoing%20funding%20non-commercial%20trials.pdf

http://www.wmsc.nhs.uk/uploaded_media/WM11%20Policy%20-%20Ongoing%20access%20following%20completion%20of%20NHS%20funded%20trials.pdf

10. Maintaining the PbR-Excluded Drugs List

These lists will be regularly updated in line with the annual DH published list of PbR-excluded drugs and the in-year NICE/HENIG and commissioning decisions influencing the list.

The process for maintaining the drugs list will be the responsibility of the CCG Medicines Optimisation Team.

11. Distribution of the Policy and Drugs List

The policy and the drugs list will be distributed to the following stakeholders in both North Staffordshire CCG and Stoke-on-Trent CCG:

- Medicines Optimisation Team
- IFR team
- Finance Director
- Medical Director
- Clinical Director – planned care.
- Clinical Director – unplanned care
- UHNM Clinical Director of Pharmacy

Equality Impact Assessment

Name of Policy	Commissioning Policy on the funding of PbR-excluded drugs
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Aims of policy	<p>The purpose of this policy is to provide clarity on the commissioning intentions of North Staffordshire CCG and Stoke-on-Trent CCG in respect to the funding of PbR-excluded drugs.</p> <p>This Policy is designed to help North Staffordshire CCG and Stoke-on-Trent CCG to meet this obligation in providing equitable access to health care.</p>
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Does or could the policy have any impact on any of the equality strands in relation to:	Yes	No
<ul style="list-style-type: none"> • Promoting and achieving equality • Eliminating discrimination 		
Ethnicity		N
Religion or belief		N
Disability		N
Gender		N
Sexual orientation		N
Age		N

Give details of how the policy targets or excludes particular equality groups	
Equality area	Reason
Ethnicity	Not applicable
Religion or belief	Not applicable
Disability	Not applicable
Age	Not applicable
Gender	Not applicable
Sexual orientation	Not applicable
Does the policy affect any of the equality groups disproportionately?	No
Are there barriers which could inhibit access to the benefits of the	No

<p>policy? E.g.</p> <ul style="list-style-type: none"> • Communication/ information • Physical access • Location • Sensitivity 	
<p>Does the policy give different groups the same choices as everyone else?</p>	Yes

Indicate what evidence has been used to inform the policy?	
Demographic data and other statistics	N
Recent research findings	N
Results of recent consultations and surveys	N
Results of ethnic monitoring data and any equalities data from local authority /joint services	N
Information from groups /agencies	Y
Comparisons between similar functions and strategies	N
PALs complaints and public enquires information	Y
Audit reports and reviews	N
Give details of evidence used to inform the policy	
<p>The evidence used to inform this policy consists of:</p> <ul style="list-style-type: none"> • Advice and guidance from DH • Current relevant regional policies and guidance • NHS England commissioning policies 	
How will the impact of the policy and the impact on different equality groups be monitored?	
<p>Through surveys post service implementation Through complaints and PALs</p>	

Summary of overall assessment
In summary, any negative impact on equality is unlikely and the policy is concordant with current advice and guidance from NICE, DH and NHS England..