Commissioning Policy (EMSCG P004V2)

Ongoing access to treatment following the ending of industry sponsored clinical trials or funding

Although Primary Care Trusts (PCTs) and East Midlands Specialised Commissioning Group (EMSCG) were abolished at the end of March 2013 with the formation of 5 Nottinghamshire County wide clinical Commissioning Groups (CCGs) policies that were in place prior to 1 April 2013 remain in place to ensure a consistent approach.

The NHS Mansfield and Ashfield Clinical Commissioning Group have adopted this policy, in its existing form, at a meeting of its Governing Body on 23 March 2013.

This policy sets the overall parameters within which care will be delivered.

East Midlands Specialised Commissioning Group

Commissioning Policy (EMSCG P004V2)

Ongoing access to treatment following the ending of industry sponsored clinical trials or funding

1. Definition

A clinical trial means any study or evaluation of a treatment as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials.

NHS pick-up of trial funding refers to the situation where an NHS patient has been entered into a third party-sponsored clinical trial and where funding is being sought to provide continued treatment after the trial has finished.

This policy is designed to be read in conjunction with the *Guidance note: Access to NHS funding following third party funded treatment*

2. The policy

2.1 This policy applies to any patient for whom the PCT is the Responsible Commissioner.

2.2 The PCT will not pick up funding of treatments at the end of clinical trials or when company sponsored funding is withdrawn without prior agreement of an NHS commissioning organisation (past or present). Providers trusts will need to provide evidence of any such prior funding.

2.3 When a treatment is considered a low priority and is not generally funded, the SCG's view is that it is the moral responsibility of those initiating and sponsoring treatment to ensure ongoing access to treatment, when this is required.

2.4 It is the clinician's responsibility to ensure that patients are fully informed of and agree to their management plan at the end of the trial. This includes making patients aware of this commissioning policy and, where relevant, any unsuccessful request for post-trial funding. Their consent should be documented.

2.5 Requests to pick up company sponsored funding (commonly called compassionate funding) will not be considered. Patients offered company sponsored treatment should also be adequately consented about their management plan following withdrawal of sponsorship.

2.6 Continued funding by the PCT of former trial patients in this context does not represent a policy decision in relation to that treatment and, as such, sets no precedent for the funding of other patients.

2.7 The treatment in question will be assessed and prioritised in the normal way following the completion of the trial or at such other time as the PCT considers appropriate. The treatment will only be considered for routine funding thereafter in accordance with the PCT's service development policy.

2.8 Nothing in this policy commits the PCT to funding patients who are involved in any other type of clinical trial.

3. Key principles supporting this policy

3.1 Primary care trusts have legal responsibility for NHS healthcare budgets and their primary duty is to live within the budget allocated to them.

3.2 The NHS should only invest in treatments which are of proven effectiveness unless it does so in the context of well designed, sufficiently powered and properly conducted clinical trials.

3.3 PCT commissioners have a responsibility to make rational decisions in determining the way in which they allocate resources and to act fairly between patients.

3.4 All NHS commissioned care should be provided as a result of a specific policy or decision to support the proposed treatment. A third party has no mandate to pre-commit resources from PCT budgets unless directed by the Secretary of State.

3.5 The priority for an individual patient or group of patients for funding for NHS commissioned healthcare to meet the healthcare needs of that individual or group of patients must always be assessed against other competing demands and within the resources available.

3.6 PCTs should strive to provide equal treatment in the same clinical circumstance, A PCT should therefore not offer to one patient a treatment which cannot be afforded for all patients in the same clinical circumstance.

3.7 At the conclusion of any clinical trial, patients entered into the trial should be entitled to be informed about the outcome of the trial and to share any benefits that result from it. This duty, which falls on the party conducting the trial, will include, for example, ensuring access to treatment identified as beneficial in the trial or to other appropriate care or benefits.

4. Local documents which have a direct bearing on this policy

EMSCG Definitions (EMSCGN001V1), 2009

East Midlands Specialised Commissioning Group supporting documents
EMSCG Key Principles (EMSCGN003V1), 2009

Please refer to your PCTs documentation relating to:

Priority setting processes within the organisation
Individual Funding Procedures within the organisation
The principles guiding prioritisation

The National Specialised Commissioning Group: Funding of treatments for patients leaving clinical trials (March 2008).
The Medicines for Human Use (Clinical Trials) Regulations 2004. (Statutory Instrument 2004 Number 1031. *The regulations for clinical trials are set out in the Medicines for Human Use (Clinical Trials) Regulations 2004. The regulations, as originally passed, have been subsequently amended by the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and may be further amended. PCTs are advised to seek advice to ensure that they are consulting the current version of the Regulations.*
http://www.statutelaw.gov.uk/SearchResults.aspx?TYPE=QS&Title=medicines+for+human+use+%28clinical+trials%29+regulations+2004&Year=&Number=&LegType=All+Legislation.

World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects. Latest revision : 59th WMA General Assembly, Seoul, October 2008. www.wma.net/e/policy/b3.htm

5. Documents which have informed this policy

The National Health Service Act 2006, The National Health Service (Wales) Act 2006 and The National Health Service (Consequential Provisions) Act 2006 : Department of Health - Publications

Department of Health, World Class Commissioning Competencies, December 2007, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080958

Department of Health, The NHS Constitution for England, July 2009, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093419

The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009, http://www.npc.co.uk/policy/resources/handbook_complete.pdf

NHS Confederation Priority Setting Series, 2008, http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx

Letter from the National Patient Safety Agency, National Research Ethics Service to all UK NHS Research Ethics Committees March 2008.

Regional leads for this policy	Dr Tim Daniel Consultant in Public Health East Midlands Specialised Commissioning Team
	Malcolm Qualie Head of Public Health Policy East Midlands Specialised Commissioning Team E mail: Malcolm.Qualie@emscg.nhs.uk Tel: 0116 295 0862
Version	First
Policy effective from	1st July 2009
Date of next review	As required – minimum 3 yearly
Acknowledgements	West Midlands SCG

Appendix 1

East Midlands Specialised Commissioning Group

Equality Impact Assessment Test for Relevance

Race, Religion/Belief, Disability, Gender, Age and Sexual Orientation

Name of the Service/Policy/Function: …EMSCGP004V2 Ongoing access to treatment following the ending of industry sponsored clinical trials or funding……..

1. What you are trying to achieve in this service/policy/function
   (Write short notes to explain the policy/service)

This policy forms part of a comprehensive framework of East Midlands commissioning policies that are a pro active response to the changing legal environment within which the NHS now operates, and will inform local decisions upon treatments. They will aim to do this by complying with the national overarching policies and principles which provide guidance to local decision makers. These are namely the core principles of the NHS, World Class Commissioning competences, the Next Stage Review and the NHS Constitution.

This policy and the associated policies are based upon recommendations for Primary Care Trusts (PCT's) outlined in the Department of Health's report (DH in conjunction with the National Prescribing Centre) called 'Defining Guiding Principles for Processes supporting Local Decision Making about Medicines'. This is because this report aims to ensure compliance with all of the national overarching policies and principles outlined above.

2. Which population groups the service/policy/function is intended to benefit and how?

This framework of policies has been directed and guided by the recommendations of the DH report as previously mentioned, in order to ensure compliance with the various developments in the NHS outlined above, which aim to address issues of equality, accountability, transparency and the 'postcode lottery'. Therefore, this policy and its related policies are intended to benefit the whole of the East Midlands population by helping to ensure greater equality, accountability, transparency and by reducing the 'postcode lottery' throughout the East Midlands region.

3. Related policy areas that may be affected by changes in this service/policy/function

As this policy forms part of a framework of policies, the following are interrelated and should work together:

P004V2 ‘Ongoing access to treatment following the ending of industry sponsored clinical trials or funding’.
P005V2 ‘Defining the boundaries between NHS and private treatments’.
P007V2 ‘Orphan Drugs’.
P017V1 ‘Experimental and Unproven treatments’.
P018V1 ‘In year service developments and the PCT approach to treatments not yet assessed and prioritised’.
P019V1 ‘Ongoing access to treatment following completion of NHS Commissioner funded trials’.
P020V1 ‘Patients seeking NHS funded hospital treatment in the European Union, European Economic Area or Switzerland’.
P021V1 ‘Choice’.
P022V1 ‘Ongoing access to treatment following a ‘trial of treatment’ which has not been sanctioned by the responsible primary care trust for a treatment not routinely funded or which has not been formally assessed and prioritised’.
P023V1 ‘Patients changing responsible commissioner’.
P024V1 ‘Ongoing access to treatment following completion of non commercially funded trials’.
P025V1 ‘Prior Approval’.
P026V1 ‘Use of cost effectiveness, value for money and cost effectiveness thresholds’.
P027V1 ‘Commissioning policy for guidance produced by the National Institute of Clinical Excellence’.

East Midlands Specialised Commissioning Group

Equality Impact Assessment Test for Relevance

Race, Religion/Belief, Disability, Gender, Age and Sexual Orientation

Name of the Service/Policy/Function: EMSCGP004V2 Ongoing access to treatment following the ending of industry sponsored clinical trials or funding……..
Question 1 - Screening

For each of the six equality categories, ask the questions in the table below:
Please answer Yes or No to the following questions

Question	Age	Disability	Race	Religion and Belief	Gender	Sexual Orientation
Do different groups have different needs, experiences, issues and priorities in relation to the proposed policy service?	NO	NO	NO	NO	NO	NO
Is there potential for or evidence that the proposed policy service will not promote good relations between different groups?	NO	NO	NO	NO	NO	NO
Is there potential for or evidence that the proposed policy service will affect different population groups differently (including possibly discriminating against certain groups)?	NO	NO	NO	NO	NO	NO
Is there public concern (including media, academic, voluntary or sector specific interest) in the policy area about actual, perceived or potential discrimination against a particular population group or groups?	NO	NO	NO	NO	NO	NO

If the answer to any of the above is "yes" you will need to carry out an equality assessment in the relevant equality area(s).

East Midlands Specialised Commissioning Group

Equality Impact Assessment Test for Relevance

Race, Religion/Belief, Disability, Gender, Age and Sexual Orientation

Name of the Service/Policy/Function: … EMSCGP004V2 Ongoing access to treatment following the ending of industry sponsored clinical trials or funding……

Question 2 - Why have you come to these conclusions?

(Write short notes to explain why you have drawn your conclusions including any evidence (of whatever type) that you have to support your assessment).

This policy does not discriminate in any of the ways outlined in Question 1 – screening, because the overall aim of the policy and, indeed, the entire framework of policies is to provide equity of treatment for all patients within the East Midlands. Specific examples of this, are that it is compliant with the NHS Constitution, (which is a declaration of rights that are underpinned by law), which aims to address variations in the availability of medicines and treatments resulting from inconsistency in local decision making processes by ensuring a robust and consistent way of dealing with the commissioning of treatments and medicines for the whole of the East Midlands. This framework of policies also helps to deliver the Constitution's statement to "expect rational local decisions on funding of new drugs and treatments" to take place, as the framework of policies shows an equitable and transparent process. It is also compliant with the Next Stage Review (which lays out the future direction of the NHS), which advises that patients should have access to the most clinically and cost effective medicines and treatments, as the framework of policies as a whole outlines how medicines and treatments are prioritised.

The generic framework of policies themselves aims to ensure equity throughout, as their development and issue is supported by the 'Key Principles for the development of commissioning policies by the PCT'. This explicitly outlines that PCT's should provide equal treatment (point 7).

Specifically within this policy, it explicitly advises that the NHS will not pick up the costs following the ending of industry sponsored treatment, and this applies to any patient throughout the East Midlands. As this policy has been guided by the principle 3.3 that PCT commissioners have a responsibility to make rational decisions…and to act fairly between patients – this ensures fairness for all patients throughout the East Midlands region through consistency and ensuring there are no exceptions to funding which could in fact be discriminatory against those for whom funding has been declined. Similarly, it has also been guided by principle 3.6 that PCT's should strive to provide equal treatment in the same clinical circumstance; a PCT should therefore, not offer to one patient a treatment which cannot be afforded for all patients in the same clinical circumstances. This re enforces the previous point that this policy has been designed to improve equity through equality of treatment of patients regardless of circumstance.

Based on the information set out above, I have decided that an equality impact assessment is not necessary.

Signed: Malcolm Qualie

Job title: Head of Health Policy

Directorate/Service area: East Midlands Specialised Commissioning Group

Date 06/06/2009

Copy of the completed form should be sent to:

1) Director of Specialised Commissioning

2) Corporate Services Manager
Specialised Commissioning
4 Smith Way, Grove Park
Leicester
LE19 1SS
Email: serina.korol@lcrpct.nhs.uk

Appendix H - Human Rights Assessment Tool

East Midlands Specialised Commissioning Group

Human Rights Assessment Tool

The Human Rights Act, which came into force in October 2000, incorporates into domestic law the European Convention on Human Rights to which the UK has been committed since 1951. Section 6 of the Human Rights Act makes it unlawful for a public authority to act in a way, which is incompatible with a Convention right. The underlying intention of the Act is to create a Human Rights culture in public services.

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

		Yes/No	Comments
1.	Will it affect a person's right to life?	NO	Any approach to service developments/drugs and treatments are made within an ethical framework, taking into consideration clinical and cost effectiveness, and are outlined in the 'key principles' document supporting these policies. Thus, any decisions made are made ethically and equitably. Similarly "although the right to life is fundamental, there is no corresponding right to medical treatment in all circumstances" (DH, Human Rights in Healthcare – A framework for local action p 36).
2.	Will someone be deprived of their liberty or have their security threatened?	NO	
3.	Could this result in a person being treated in a degrading or inhuman manner?	NO	
4.	Is there a possibility that a person will be prevented from exercising their beliefs?	NO	
5.	Will anyone's private and family life be interfered with?	NO	

If the answer is "yes" to any of the questions on the proforma can the policy be amended to avoid impacting upon Human Rights? If not, please refer it to the Director of Corporate Affairs to enable legal advice to be sought before proceeding.