



## **Commissioning Policy (EMSCG P007V2)**

### **Orphan Drugs**

*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 Nottingham North & East Clinical Commissioning Group have adopted this policy, in its existing form, at a meeting of its Governing Body on 20 August 2013.*

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

# Commissioning Policy (EMSCG P007V2)

## Orphan Drugs

---

---

### 1. Background Note

---

The European Union legislation defines an orphan drug as one that could treat a disease with a prevalence of less than five per 10,000 of the population. Orphan drugs can be designated by the European Medicines Evaluation Authority (EMA) and in due course may be given marketing authorisation by the EMA. This then allows the drug to be marketed across the EU countries but this does not mean that it has to be funded by healthcare organisations.

The fact that a drug has been licensed by the EMA does not impose any obligation on the PCT to fund the drug for the target patient group. The PCT has carefully considered the ethical issues around the funding of high cost drugs and other treatments for small numbers of patients but is satisfied that it would not be right to depart from its established procedures for the assessment and prioritisation of treatments.

### 2. The policy

---

This document should be read in conjunction with documents listed in section 4.

- 2.1 This policy applies to any patient for whom the PCT is the Responsible Commissioner.
- 2.2 The PCT will, in the absence of Direction made by the Secretary of State, commission both existing and new orphan drugs using the same decision making principles and processes as are applied to the commissioning of other treatments.

### 3. Key principle supporting this policy

---

- 4.1 Primary care trusts have legal responsibility for NHS healthcare budgets and their primary duty is to live within the budget allocated to them.
- 4.2 PCT commissioners have a responsibility to make rational decisions in determining the way in which they allocate resources and to act fairly between patients.

- 4.3 New treatments should be assessed for funding according to the basic principles of clinical effectiveness, safety and cost effectiveness and then prioritised within an ethical framework that supports consistent and affordable decision making.

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

East Midlands Specialised Commissioning Group supporting documents  
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

East Midlands Specialised Commissioning Group Commissioning policy: Use of cost-effectiveness, value for money and cost-effectiveness threshold, EMSCGP026V1, July 2009

#### **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](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](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](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>  
The West Midlands Specialised Services Agency Enzyme Replacement Therapy Series

The National Institute for Health and Clinical Excellence, Guide to the Methods of Technology Appraisal

<http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf>

The National Institute for Health and Clinical Excellence, Appraising life-extending, end of life treatments,

<http://www.nice.org.uk/media/88A/F2/SupplementaryAdviceTACEoL.pdf>

|                                |  |
|--------------------------------|--|
| Regional leads for this policy | Dr Tim Daniel<br>Consultant in Public Health<br>East Midlands Specialised Commissioning Team   |
|                                | Malcolm Qualie<br>Head of Public Health Policy<br>East Midlands Specialised Commissioning Team<br>E mail: <a href="mailto:Malcolm.Qualie@emscg.nhs.uk">Malcolm.Qualie@emscg.nhs.uk</a><br>Tel: 0116 295 0862 |
| Version                        | 2  |
| Policy effective from          | 2009   |
| Date of next review            | 01/01/2014   |
| 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: EMSCGP007V2 Orphan Drugs.....**

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: EMSCGP007V2 Orphan Drugs.....**

**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 ... EMSCGP007V2 Orphan Drugs

#### 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).

This specific policy deals with the commissioning of orphan drugs using the same decision making principles and processes as are applied to the commissioning of other treatments. This aids in ensuring equity through parity with other treatments, and through consistency of process based upon basic principles of clinical effectiveness, safety and cost effectiveness as well as within an ethical framework that supports consistent decision making.

**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 Public Health Policy

Directorate/Service area: East Midlands Specialised Commissioning Group

Date: 06/06/09



**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](mailto: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.