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**Appendix 1**

**Experimental and Unproven Treatments Policy**

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| **1** | **The policy** |
| 1.1 | This policy applies to any patient for whom the CCG is the Responsible Commissioner, except as set out below:* treatments which are judged experimental or not to be of proven effectiveness will not routinely be funded; and
* funding for individual patients or groups of patients within poorly designed trials will not be supported.
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| 1.2 | The CCG will strive to fulfil the requirements placed upon CCGs as set out in the Department of Health letter to the NHS (9 July 2009) (Gateway number 12153), provided that the CCG is satisfied as to affordability and has taken account of competing demands upon its budget.  |
| 1.3 | The CCG will be prepared to consider funding a clinical trial or to sponsor a patient into an existing trial but funding cannot be guaranteed. The ability of the CCG to support R&D is influenced by:* Financial constraints. Any trial has to be prioritised against competing needs.
* The research priorities of the clinical community. However desirable a trial, clinical or R&D support, there can be no guarantee that a given evaluation is a research priority for the clinical and R&D community, on whom commissioners are dependent on delivering a trial.
* Capacity constraints within the CCG’s team for those trials that have to be fully commissioned by the CCG.
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| 1.4 | The CCG will give consideration, within its level of commissioning responsibility ie not for specialised and rare conditions that should be considered the remit of NHS England Specialised Commissioning, to supporting experimental treatment or off label use for rare clinical situations for which good quality clinical trials are considered impossible. These will be considered under the individual funding request category: *individual requests* (see Commissioning Policy 09: Individual Funding Requests) These will be identified on the basis of:* the incidence of the clinical condition / circumstance;
* the nature of the intervention;
* the nature of the clinical research community.
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| 1.5 | When a case has been identified under paragraph 1.4 the CCG will consider the following: * the potential benefit and risks of the treatment;
* the biological plausibility of benefit based on other evidence;
* an assessment of value for money;
* the priority of the patient’s needs vis-à-vis other competing demands.
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| 1.6 | The clinician will be expected to provide as much information as possible about the treatment, relevant research upon which the claim for biological plausibility of the treatment is based, and costs, as well as clinically relevant information on the patient. In addition, the clinician will identify the clinical markers and clinical outcomes that will be monitored to assess treatment response. |
| 1.7 | When a case has been identified under paragraph 1.4 the funding options which the CCG will consider are: * Not to fund.
* Fund on the condition that the patient enters a properly conducted *‘n of 1’* trial. This option is currently not open to NHS commissioners.
* Fund a trial of treatment but make ongoing treatment subject to the demonstration of clinical benefit for the individual patient using criteria agreed in advance with the clinical team.
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| 1.8 | In all instances, contribution to any relevant clinical database or population registry which is operating will be an additional condition of approval of funding for the treatment. |
| 1.9 | The CCG is not a research organisation but will be prepared to consider requests to sponsor an individual patient to enter a clinical trial. When such an application is made, the CCG will give consideration to:* The potential strategic importance of the treatment. This requires a judgment to be made on whether the trial will address CCG priorities for the programme area.
* The quality of the trial and whether or not it is going to generate the sort of information needed to enable the CCG to reach a view on the clinical effectiveness and cost effectiveness of the treatment. Specialist advice may need to be sought on the methodology to be adopted within any trial.
* Ownership of the data. Trials which do not guarantee that the data will be made available in the public domain will not be considered for funding.
* Affordability.
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| 1.10 | Where an application is made under paragraph 0, the clinician will be expected to provide as much information about the patient, the treatment and the trial as possible. A copy of the trial protocol should also be included with the application. |
| 1.11 | If pick-up funding may be required following a trial, details of this potential should be indicated in any application for funding. If the patient is sponsored, a record of acceptance should be kept in the patient notes to ensure pick-up is carried out. Discussion on and tracking of any future commitments will also be carried out. This is of particular importance given the frequent reorganisation of the commissioning arm of the NHS. |
| 1.12 | The CCG may either consider initiating a national trial or be asked to consider funding a trial of treatments considered of importance to commissioners. Such trials are a major undertaking and usually require collaboration with other CCGs. As such they will be infrequent events.  |
| **2** | **Documents which have informed this policy** |
| 2.1 | Delivering Excellence for Swindon 2010 - 2015 |
| 2.2 | Individual Funding Requests: NHS Swindon commissioning policy no9 |
| 2.3 | West Midlands Strategic Commissioning Group, Commissioning Policy 1: Ethical Framework to underpin priority setting and resource allocation within collaborative commissioning arrangements, November 2009  |
| 2.4 | West Midlands Strategic Commissioning Group, Commissioning Policy 9: Individual Funding Requests, November 2009  |
| 2.5 | West Midlands Strategic Commissioning Group, Guidance Note 2: The role of commissioners in the evaluation of individual treatments and the funding of clinical research. November 2009 |
| 2.6 | Department of Health letter, Requirements to support research in the NHS, Gateway number 12153, July 2009. <http://www.dh.gov.uk/en/Publicationsandstatistics/>Lettersandcirculars/Dearcolleagueletters/DH\_102101 |
| 2.7 | Department of Health: HSG(97)32:Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS. <http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/DH_4016456> |
| 2.8 | Department of Health, The National Health Service Act 2006, The National Health Service (Wales) Act 2006 and The National Health Service (Consequential Provisions) Act 2006.<http://www.dh.gov.uk/en/Publicationsandstatistics/>Legislation/Actsandbills/DH\_064103 |
| 2.9 | Department of Health, World Class Commissioning Competencies, December 2007, <http://www.dh.gov.uk/en/Publicationsandstatistics/>Publications/PublicationsPolicyAndGuidance/DH\_080958 |
| 2.10 | Department of Health, The NHS Constitution for England, July 2009, <http://www.dh.gov.uk/en/Publicationsandstatistics/>Publications/PublicationsPolicyAndGuidance/DH\_093419 |
| 2.11 | 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 |
| 2.12 | NHS Confederation Priority Setting Series, 2008, http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx |