Midlands and Lancashire
Commissioning Support Unit

NHS Birmingham Cross City Clinical Commissioning Group
NHS Birmingham South Central Clinical Commissioning Group
NHS Solihull Clinical Commissioning Group
NHS Dudley Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group
NHS Walsall Clinical Commissioning Group
NHS Wolverhampton Clinical Commissioning Group

Collaborative Commissioning Policy

On-going access to treatment following a 'trial of treatment' which has not been sanctioned by the Clinical Commissioning Group for a treatment which is not routinely funded or has not been formally assessed and prioritised

Version 1.2 – October 2014

1. The policy

1.1 This policy applies to any patient for whom the Clinical Commissioning Group is the responsible commissioner.

1.2 In this policy a reference to "treatment" is a reference to any healthcare intervention provided or proposed to be provided by a clinician of any nature whatsoever.

1.3 The policy of the Clinical Commissioning Group is that it will not pick up the funding of a patient's treatment at the end of a 'trial of treatment' for treatments which are not routinely commissioned by the Clinical Commissioning Group unless the Group has given its prior written agreement or, where commissioning responsibility for a patient has transferred from another NHS body to the Clinical Commissioning Group, written agreement has been provided by the NHS commissioning organisation which was the responsible commissioner for the patient at the date that the trial of treatment was commenced. Provider trusts seeking funding will need to provide evidence of any such agreement.

1.4 It is the responsibility of the Provider and the patient's clinicians to ensure that patients are fully informed and consented before they agree to a trial of treatment. As part of that process patients must be informed in the event that no written agreement has been secured from the Clinical Commissioning Group to provide for future funding for the treatment. In these situations the patient should be made aware of this policy and the Clinical Commissioning Group's policy on experimental and not proven treatments.

1.5 In the event that funding is not sanctioned, responsibility for providing on-going access to a treatment is the responsibility of the provider trust in which treatment was initiated.

1.6 In the event that the Clinical Commissioning Group makes an exception to the policy by providing funding to continue a treatment to a patient which has been commenced on a trial basis, this decision does not represent a policy decision by the Clinical Commissioning Group to fund that treatment for other patients who are in the same or similar clinical circumstances. Any application for a service development to support funding for the treatment in question will be assessed and prioritised under the Clinical Commissioning Group's service development policy in the normal way.

2. Documents which have informed this policy

- The Clinical Commissioning Group's Commissioning Policy: Ethical Framework to underpin priority setting and resource allocation

- Department of Health, The National Health Service Act 2006, The National Health Service (Wales) Act 2006. http://www.legislation.gov.uk/ukpga/2006/41/contents

- Department of Health, The NHS Constitution for England, 2012, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_132961

- 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

  Priority setting: an overview
  Priority setting: legal consideration
  Priority setting: strategic planning
  Priority setting: managing new treatments
  Priority setting: managing individual funding requests

Glossary

TERM	DEFINITION
Experimental and unproven treatments	*Experimental and unproven treatments* are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. The reasons may include the following: • The treatment is still undergoing clinical trials for the indication in question. • The evidence is not available for public scrutiny. • The treatment does not have approval from the relevant government body. • The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field. • The treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body. • The treatment is rarely used, novel, or unknown and there is a lack of evidence of safety and efficacy. • There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.
NHS pick-up of trial of treatment	*NHS pick-up of trial of treatment* refers to the responsible commissioner funding on-going treatment for either experimental, not normally commissioned or awaiting assessment and prioritisation and where the clinician has initiated a trial of treatment without sanction regardless of how the treatment has been funded.
Priority setting	*Priority setting* is the task of determining the priority to be assigned to a service, a service development, a policy variation or an individual patient at a given point in time. Prioritisation is needed because the need and demands for healthcare are greater than the resources available.
Service Development	A *Service Development* is an application to the Clinical Commissioning Group to amend the commissioning policy of the Clinical Commissioning Group to provide that a particular healthcare intervention should be routinely funded by the Group for a defined group of patients. The term refers to all new developments including new services, new treatments (including medicines), changes to treatment thresholds, and quality improvements. It also encompasses other types of investment that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms. Equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. However, where investment is made outside of the annual commissioning round, such investment is referred to as an *in-year service development*.
Treatment	*Treatment* means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.
Trial of treatment	A t*rial of treatment* refers to a situation where a clinician has exposed a patient to a treatment for the purpose of assessing whether or not the patient is likely to benefit from longer term treatment.

Guidance note

Where a provider of healthcare has started a patient on a treatment which is either not routinely commissioned or which is experimental, without the knowledge and consent of the Clinical Commissioning Group, the Provider can neither commit nor require the Clinical Commissioning Group to fund on-going treatment of that patient.

This is the case whether or not the Provider has a contract for the provision of health care with the Clinical Commissioning Group.

To pick-up funding in this situation would not only put the Clinical Commissioning Group at considerable financial risk, it would also leave the Clinical Commissioning Group vulnerable to having its funding priorities, identified by reference to the needs of its population in accordance with its statutory duties, destabilised by a third party.

In considering any individual funding request for pick up following a trial of treatment, the Clinical Commissioning Group would obviously need to have regard to the individual circumstances of the particular case. However, even where a patient has been shown to have benefited from the trial of treatment, the Clinical Commissioning Group must weigh this against the principle adopted in its *Commissioning Policy: Ethical framework to support priority setting and resource allocation* that third parties cannot determine its funding priorities and bear in mind the wider and longer term risks associated with picking up funding from a third party.