End of Trial Treatment Final Draft

Decision support framework for ongoing access to treatment requests following an industry sponsored trial or sponsorship, privately funded treatment, an N of 1 trial of treatment, treatment initiated/approved by another CCG (or PCT) or a not for profit trial funded by a national recognised body eg Medical Research Council

Leeds North CCG, Leeds South and East CCG and Leeds West CCG

Version:	Final draft
Ratified by:	Leeds West CCG Assurance Committee on (date) Leeds North CCG Governance, Performance and Risk Committee on (date) Leeds South and East CCG Governance and Risk Committee on (date)
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Name of responsible committee/individual:	Leeds West CCG Assurance Committee Leeds North CCG Governance, Performance and Risk Committee Leeds South and East CCG Governance and Risk Committee
Date issued:	
Review date:	April 2015
Target audience:	Primary and secondary care clinicians, individual funding request panels and the public
Document History:	nil

Produced on behalf of NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG

Background

This framework supports Leeds Clinical Commissioning Groups (CCGs), Leeds North CCG, Leeds South & East CCG and Leeds West CCG when deciding to continue funding on going access to treatment request following an intervention not routinely commissioned by the CCGs.

In the absence of a positive NICE appraisal and subsequent direction by the Secretary of State, there is no general legal requirement to continue funding a licensed treatment which has been provided to participants as part of an industry sponsored clinical trial, either when the trial ends, or when the individual exits a trial. Unless an express arrangement is entered into between the trial sponsor and the NHS organisation, there is no automatic presumption that funding for continuation of treatment will be met by any NHS commissioner.

Leeds CCGs have developed this framework to assist in arriving at a reasoned and equitable decision in each case where it is asked to pick up treatment costs following a trial of treatment.

Purpose

The purpose of the ongoing access to treatment framework is to enable officers of Leeds CCGs to exercise their responsibilities and to provide advice for General Practitioners, Clinicians and members of the public. The implementation of the framework will ensure that commissioning decisions are not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements.

The CCGs IFR policy outlines the process for decision making with regard to ongoing access to treatment and seeks to improve consistency in this decision making process.

This framework covers all interventions where there is a request to pick up an intervention.

This document is intended as an aid to decision making. It should be used in conjunction with Leeds CCG policies on Individual Funding Requests and associated decision making frameworks.

Scope

The ongoing access to treatment framework is supported by criteria for decision making (appendix A).

Leeds CCGs have already established a process to consider and manage requests against the following:

- Procedures requiring prior approval as identified in Leeds CCGs Commissioning Policies
- Requests for approval for exception to the Leeds CCGs Cosmetic Exclusions and Exceptions Policy)
- Procedures approved by the National Institute of Clinical Excellence outside normal commissioning timeframes and commissioning intentions.
- Procedures not normally funded through existing Service Agreements e.g. alternative therapies.
- New treatments and drugs not widely available from the National Health Service

This framework supports decisions for treatment pick up including following an industry sponsored trial or sponsorship, privately funded treatment, an N of 1 trial of treatment, treatment initiated/approved by another CCG (or PCT) or a not for profit trial funded by a national recognised body eg MRC.

As part of informed consent for a non-routinely commissioned intervention or clinical/treatment trial patients should be advised that there can be no assumption that treatment with an experimental drug or intervention will continue after leaving or finishing the trial.

Responsibility for providing on-going access to a treatment lies with those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment.

Commissioning position

Source of pick up request	CCGs commissioning statement
Privately funded treatment	See NHS vs Private Treatment framework.
Trial of treatment (industry or N of 1)	Not routinely commissioned and not funded unless there is prior approval on an IFR basis
Treatment initiated by predecessor PCT/CCG	Routinely commissioned where the treatment has been demonstrated to deliver clinical benefit to the patient.
Trial of treatment funded by predecessor	Routinely commissioned where the clinical trial has

PCT/CCG	been funded (wholly or in part) by PCT or CCG and where the treatment which was the subject of the clinical trial has been demonstrated to deliver clinical benefit to the patient.
Not for profit trial	Not routinely commissioned and not funded unless the clinical trial was wholly funded by non-commercial bodies, and the trial was sanctioned by the National Institute for Health Research (NIHR) database (http://public.ukcrn.org.uk/search/Portfolio.aspx), and it has been demonstrated that the patient has benefitted clinically from the treatment provided as part of the clinical trial, and the CCGs determine that, given other demands upon their resources, the expenditure to support the on-going treatment can be justified and the CCGs can afford that expenditure.
Industry sponsored trial or funding	Not routinely commissioned and not funded unless there is prior written agreement between the CCGs and the sponsoring organisation concerned. The CCGs will not pick up the funding of a patient's treatment when company sponsored funding (eg compassionate funding priory to licence) is withdrawn without the prior agreement of the CCGs.

Appendix A

Criteria for decision making

As part of informed consent for a non-routinely commissioned intervention or clinical/treatment trial patients should be advised that there can be no assumption that treatment with an experimental drug or intervention will continue after leaving or finishing the trial.

Responsibility for providing on-going access to a treatment lies with those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment.

The following are the factors to be taken into account when deciding to continue or stop funding treatment:-

a. All of the following:

   (i) If the treatment is licensed for the indication; and

   (ii) If good governance arrangements have been applied to patient's inclusion in a clinical or treatment trial; and

   (iii) If the patient demonstrates significant benefit; and

   (iv) If the specialist clinician responsible for the patient's care for this condition, and the patient, believe that the continuance of the treatment is justified on the basis of monitoring clinical benefit.

b. Plus one of the following:

   (i) If the cost of the treatment is equivalent to the current standard treatment for the condition; or

   (ii) If ceasing the treatment would be likely to have a significant impact on the outcome for the patient, which outweighs the need for more detailed clinical effectiveness data to be available. The decision to continue treatment would be subject to review if new data becomes available.

In the event that all factors (i) to (iv) and one of factors (v) or (vi) indicate a positive funding decision, the CCGs will also have regard to the number of patients likely to request funding in the current financial year and the overall financial position of the CCG.

Requests for pick-up funding, based on the assumption that the NHS should take responsibility for funding treatment once it is licensed.

Commonly the timing of requests for funding for patients who have been in clinical trials is around the time that a license for the drug/indication is granted. There is an assumption by some clinicians conducting clinical trials that once the drug is licensed then the NHS should assume responsibility for funding the drug. This is incorrect. The NHS has a responsibility to consider and prioritise new treatments being made available, but this in no way places any obligation on the commissioner to fund patients already on treatment funded by Industry by whatever route. Requests for the routine pick-up of funding should therefore be rejected. The appropriate time for a commissioner to assume responsibility for on-going funding is if, and when, a decision has been made to fund the service development, and access to the treatment is opened to all patients meeting treatment criteria under the commissioning policy.

Requests for pick-up funding made on the basis that a patient's response to the treatment should be considered as exceptional and should be considered under the CCGs Individual Funding Request (IFR) policy.

Although this type of request is more typical when patients have funded themselves privately, they can occur following industry funding e.g. compassionate use. Critical to assessing these cases is an understanding of some key aspects of priority setting and commissioning policy development.
A hypothetical cancer drug X will be used to illustrate key principles.

In deciding whether or not to fund drug X the commissioner will aim to consider the range of clinical presentations, natural histories and responses to treatment that might be exhibited by the patient group of interest (the "target group").

Clinical trials suggest that, on average, drug X extends life by 2 - 3 months, although there is naturally a range of responses amongst the target group. The evidence from trials suggests that, out of every 100 patients that receive treatment, most will not get any benefit from drug X. Some will get a few weeks' benefit and 3 patients are observed to live 12 months longer than expected and with a reasonable quality of life.

In this instance, the normal range of response of the target group is from no benefit, to one year's extension of life, to life at a reasonable quality.

The commissioner must take a policy decision on the basis of this evidence. Having assessed the cost-effectiveness of treating all patients in the target group, the commissioner reaches the decision that drug X is not cost-effective and should not be funded. However, the commissioner does a sub-group analysis on the three patients who get the most benefit and decides that for this group the treatment is cost-effective and does present good value for money and therefore ideally should be considered for funding during the annual commissioning round.

The final commissioning position will depend on whether or not this sub-group of 3 out of 100 patients can be identified in advance of treatment. If it is possible to clinically distinguish this subgroup before starting treatment, the treatment is likely to be funded. If the patients in this subgroup cannot be identified in advance, then it would be necessary to treat 100 patients for 3 people to derive benefit. This would not represent good value for money and so drug X would not be funded for any patient.
This position could be reviewed if new evidence came to light.

An alternative option which may be open to the commissioner is to fund all patients to a point where the 3 can be clearly identified. However this option could only be considered for interventions which involved a series of treatments (e.g. a course of chemotherapy) or ongoing treatment. Furthermore, this approach could only be justified if it delivered value for money. Whether it was value for money would be influenced by:

- the cost of each dose or course of treatment.
- the speed with which responders could be identified.
- the availability of a valid measure which reliably linked response to outcome.

A particular problem relating to outcome is the fact that proxy measures are frequently used in clinical trials and also in clinical practice. In the case of cancer treatments, disease-free progression is frequently used as a marker of long-term survival, but the correlation between these two measures has been seriously questioned by Bowater, Bridge and Lilford.

Commissioners frequently get requests to fund patients who have either received third party funding or who have funded themselves privately for treatments not normally commissioned by the commissioners on the basis that they have responded exceptionally well to the treatment.

Let us say that a patient seeks funding for drug X because the drug has proved to be clinically effective in his or her particular case, and that they are likely to be one of the 3 patients who benefit the most. At first glance, the decision maker may be tempted to vary its policy to permit drug X to be funded in those instances where response has been demonstrated. However, except in those circumstances where funding is provided for the initial stages by another NHS body, such a policy would mean only allowing NHS funding to be made available to patients who can either afford to fund the early stages of the treatment themselves or are fortunate enough to access drug-company supported initial treatment. It would thus involve making the NHS's willingness to provide treatment contingent on a prior private investment by the individual patient or a commercial investment by an interested party.

Section 1(3) of the NHS Act 2006 provides that all NHS treatment should be provided free of charge unless Regulations have been made to permit charging. The policy stance set out above would not involve direct charging, but may be considered by a decision maker to offend against the spirit of the NHS, in that a policy variation of this nature would make treatment dependent on an individual's ability to fund (a prior) part of their own care or have that care funded by a party that was hoping to use the investment to persuade the NHS to fund further treatment.

A commissioning body would therefore be acting entirely rationally (and thus lawfully) in refusing to make either a policy variation to provide drug X to patients who had, by virtue of funding treatment outside of the NHS, been identified as the 3 patients who benefit more from treatment or to fund them as an individual patient on grounds of exceptionality.

References

J Bowater, L Bridge and R Lilford: The relationship between progression-free and post-progression survival in treating four types of metastatic cancer, Elsevier, Cancer Letters;262(1):48-53.

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.

World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects. Latest revision: 59th WMA General Assembly, Seoul, October 2008. http://www.wma.net/en/30publications/10policies/b3/ accessed August 2013

The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009, http://www.npc.nhs.uk/local_decision_making/constitution_handbook.php accessed August 2013

Appendix B: Version Control Sheet

Version	Date	Author	Status	Comment
1.0	10.8.13	Jon Fear	Draft v 1	Draft for CCGs
2.0	9.9.13	Fiona Day	Draft v2	Addition of cover page
3.0	10.9.13	Fiona Day	Draft v3	Addition of Cross reference NHS/private policy

Appendix C: Plan for Dissemination of Framework Documents

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

Acknowledgement: University Hospitals of Leicester NHS Trust.

Title of Framework:	Complementary and Alternative Therapies Framework		
Date finalised:		**Dissemination lead: Print name and contact details**	CCG Medical Director
Previous framework already being used?	**No**		
If yes, in what format and where?	n/a		
Proposed action to retrieve out-of-date copies of the document:	n/a		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Paper or Electronic**	**Comments**
Clinicians		Electronic	
Clinicians		Electronic/ Paper	
Panel Members		Electronic and	

Dissemination Record - to be used once framework is approved.

Date put on register / library of framework documents		**Date due to be reviewed**	

Disseminated to: (either directly or via meetings, etc)	**Format (i.e. paper or electronic)**	**Date Disseminated**	**No. of Copies Sent**	**Contact Details / Comments**

Appendix D: Equality Impact Assessment

To ensure the Individual Funding Requests Policy for the Clinical Commissioning Groups in Leeds reflects due process for identifying the effect, or likely effect, of the policy on people with Equality Act protected characteristics – age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, sexual orientation - and that the policy demonstrates due regard to reducing health inequalities, addressing discrimination and maximising opportunities to promote equality the following steps have been taken.

The update to the policy results from the iterative refresh process, and the requirement to make changes to care as indicated by an evolving evidence-base. This means that access is broadened as more treatments and interventions become available without the need for an IFR. There is no change to the underlying principles of the policy. In order for an IFR to be approved according to the core principles for managing Individual Funding Requests, it must be demonstrated that the patient's case is exceptional.

The following consultation and engagement activities have been undertaken. The evidence-based policy has been circulated to all GPs and secondary care consultants for comment, and has been made available on the internet to the public, along with Plain English patient information leaflets. The core principles for managing Individual Funding Requests in Leeds have been made available online for twelve weeks and disseminated through Patient Advisory Groups and Patient Reference Groups along with a cascade through the Community and Voluntary Service network. Feedback from all these sources has been collected by the Clinical Commissioning Groups. There is also an open and transparent approach to the processes of the decision making panel with an established mechanism for appeals.