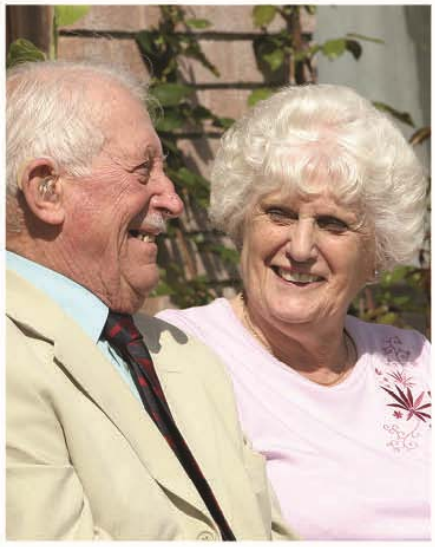
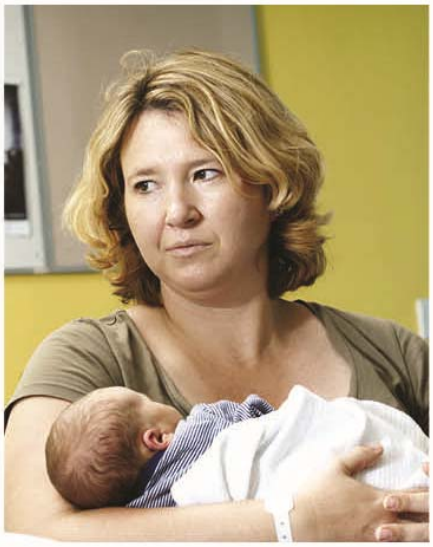
NHS Commissioning Board

Commissioning Policy: Defining the boundaries between NHS and Private Healthcare

April 2013

Reference : NHSCB/CP/12





THE NHS CONSTITUTION
the NHS belongs to us all

NHS Commissioning Board

Commissioning Policy: Defining the Boundaries between NHS and Private Healthcare

First published: April 2013

Prepared by the Medical Directorate, NHS Commissioning Board, working with Public

First published April 2013

Published by the NHS Commissioning Board, in electronic format only.

Contents

Policy Statement

This policy applies to any patient in circumstances where the NHS Commissioning Board (NHS CB) is the responsible commissioner for their NHS care. It equally applies to any patient needing medical treatment where the Secretary of State has prescribed that the NHS CB is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

This policy defines the boundaries between privately funded treatment and entitlement to NHS funding, under a range of circumstances.

Equality Statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

Guidance note

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 receiving 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 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 NHS CB's Individual Funding Request (IFR) policy.

Although this type of request is more typical when patients have funded themselves privately, they can also 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 make 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 on-going treatment. Furthermore, this approach could only be justified if this approach 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 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 receive requests to fund patients who have either received third party funding or who have funded themselves privately for treatments not usually commissioned by the NHS 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(4) of the NHS Act 2006 (as amended) 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.

Reference

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*, Volume 262, Issue 1, Pages 48-53

The Policy

1. This policy applies to any patient in circumstances where the NHS CB is the responsible commissioner for their NHS care. It equally applies to any patient needing medical treatment where the Secretary of State has prescribed that the NHS CB is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

Entitlement to NHS Care

2. NHS care is made available to patients in accordance with the policies of the NHS CB. However, individual patients are entitled to choose not to access NHS care and/or to pay for their own healthcare through a private arrangement with doctors and other healthcare professionals. Save as set out in this policy, a patient's entitlement to access NHS healthcare should not be affected by a decision by a patient to fund part or all of their healthcare needs privately.
3. An individual who has commenced treatment that would have been routinely commissioned by the NHS CB (NHS-commissioned care) on a private basis can, at any stage, request to transfer to complete the treatment within the NHS. In this event, the patient will, as far as possible, be provided with the same treatment as the patient would have received if the patient had had NHS treatment throughout. However, the NHS CB will not reimburse the patient for any treatment received as a private patient before a request is made to move back into the NHS.
4. Patients are entitled to seek part of their overall treatment for a condition through a private healthcare arrangement and part of the treatment as NHS-commissioned healthcare. However, the NHS-commissioned treatment provided to a patient is always subject to the clinical supervision of the NHS treating clinician. There may be times when an NHS clinician declines to provide NHS-commissioned treatment if he or she considers that any other treatment given, whether as a result of privately funded treatment or for any other reason, makes the proposed NHS treatment clinically inappropriate.
5. An individual who has chosen to pay privately for an element of their care, such as a diagnostic test, is entitled to access other elements of care as NHS-commissioned treatment, provided the patient meets NHS CB commissioning criteria for that treatment. However, at the point that the patient seeks to transfer back to NHS care:
    - the NHS CB is at liberty to request the patient be reassessed by an NHS clinician
    - the patient will not be given any preferential treatment by virtue of having accessed part of their care privately, AND
    - the patient will be subject to standard NHS waiting times
6. A patient whose private consultant has recommended treatment with a medication normally available as part of NHS- commissioned care can ask his

or her NHS clinician to prescribe the treatment as long as:

- the clinician considers it to be medically appropriate in the exercise of his or her clinical discretion
- the drug is normally funded by the NHS CB, AND
- the clinician is willing to accept clinical responsibility for prescribing the medication

7. There may be cases where a patient's private consultant has recommended treatment with a medication which is specialised in nature and the patient's GP is not prepared to accept clinical responsibility for the prescribing decision recommended by another doctor. If the GP does not feel able to accept clinical responsibility for the medication, the GP should consider whether to offer a referral to an NHS consultant who can consider whether to prescribe the medication for the patient as part of NHS funded treatment. In all cases there should be proper communication between the consultant and the GP about the diagnosis or other reason for the proposed plan of management, including any proposed medication.
8. Medication recommended by private consultants may be more expensive than the medication options prescribed for the same clinical situation as part of NHS treatment. In such circumstances, prescribing advice from the either the NHS CB or the Clinical Commissioning Group should be followed by the NHS GP without being affected by the privately recommended medication. This advice should be explained to the patient who will retain the option of purchasing the more expensive drug via the private consultant.
9. The NHS CB will not make any contribution to the privately funded care to cover the cost of treatment that the patient could have accessed via the NHS.

Parallel provision of NHS and privately funded care

10. NHS care is free of charge to patients unless regulations have been brought into effect to provide for a contribution towards the cost of care being met by the patient. Such charges include prescription charges and some clinical activity undertaken by opticians and dentists. These charges are not "co-funding" but constitute a rarely permitted form of "co-payment". The specific charges are set by Regulations. These charges have always been part of the NHS.
11. Patients are entitled to contract with NHS acute trusts to provide privately funded patient care as part of their overall treatment. It is a matter for NHS trusts as to whether and how they agree to provide such privately funded care. However, NHS trusts must ensure that private and NHS care are kept as clearly separate as possible. Any privately funded care must be provided by an NHS trust at a different time and place from NHS commissioned care.

    In particular:

    - Private and NHS funded care cannot be provided to a patient in a single episode of care at a NHS hospital
    - If a patient is an in-patient at a NHS hospital, any privately funded care must

be delivered to the patient in a separate building or separate part of the hospital, with a clear division between the privately funded and NHS funded elements of the care, unless separation would pose overriding concerns regarding patient safety

- A patient is not entitled to "pick and mix" elements of NHS and private care within NHS funded treatment provided as part of the same episode of care. (e.g. a patient undergoing a cataract operation as an NHS patient cannot choose to pay an additional private fee to have a multi-focal lens inserted during his or her NHS surgery instead of the standard single focus lens inserted as part of NHS commissioned surgery)

12. Private prescriptions may not be issued during any part of NHS commissioned care.

13. When a patient wishes to pay privately for additional treatment not usually funded by the NHS CB, the patient will be required to pay all costs associated with the privately funded episode of care. The costs of all medical interventions and care associated with the treatment include the costs of assessments, inpatient and outpatient attendances, tests and rehabilitation. This also includes complications of treatment where these are solely a consequence of the privately funded treatment, except where the patient is admitted under emergency care.

14. Any privately funded arrangement which is agreed between a patient and a healthcare provider (whether a NHS trust or otherwise) is a commercial matter between those parties. Except for in those circumstances as set out above, the NHS CB is not a party to those arrangements and cannot take any responsibility for the terms of the agreement, its performance or the consequences for the patient of the treatment.

Co-funding

15. Co-funding and forms of co-payment, other than those limited forms permitted by Regulations, are currently contrary to NHS policy. The NHS CB will not usually consider any funding requests of this nature.

16. If a patient is advised to be treated with a combination of drugs, some of which are not routinely available as part of NHS commissioned treatment, the patient is entitled to access the NHS funded drugs and can consult a clinician privately for those drugs which are not commissioned by the NHS.

17. If a combination of drugs or other treatments is to be administered simultaneously, some of which are not funded by the NHS, and there are *no* patient safety issues, the patient must fund all of the drugs provided and the other costs associated with the proposed treatment. Patients in such circumstances can seek exemption by applying to the NHS CB for funding for the whole treatment on the grounds that the patient has exceptional circumstances. These will be considered under the individual funding request process. The fact that a patient has been prepared to fund part of their own treatment is not an appropriate reason to support a claim for exceptional circumstances.

18. If a combination of drugs or other treatments is to be administered simultaneously, some of which are not funded by the NHS, but where there are concerns about patient safety, the provider trust must apply to the NHS CB in the form of an individual funding request setting out the reasons why, in this case, the clinician feels that the patient would be put at risk in separating private and NHS care.

    The NHS CB is entitled to seek expert opinion concerning issues of patient safety in this context.

    Patients should provide written consent to receive private care which should include an explanation of the costs associated with the private care (including any associated costs), the likely outcome of the treatment and the proposed exit strategy should the patient be unable to fund on-going private treatment. Ideally a standard document should be used for this purpose.

NHS continuation of funding of care commenced on a private basis

19. NHS CB policies define which treatment the NHS CB will and thus, by implication, will not fund. Accordingly, if a patient commences a course of treatment that the NHS CB would not usually fund, the NHS CB will not pick up the costs of the patient either completing the course of treatment or receiving on-going treatment.

20. A patient is entitled to apply for funding by means of an individual funding request. However, where the NHS CB has decided not to fund a treatment routinely, the fact that the patient has demonstrated a benefit from the treatment to date (in the absence of any evidence of exceptionality) would not be a proper basis for the NHS CB to agree to support the application. To adopt any other stance would result in the NHS CB approving funding differentially for persons who could afford to fund part of their own treatment.

    If funding is granted, the NHS CB will not reimburse the patient for any treatment received as a private patient before the exceptional request was successful.

Other

21. Individual patients who have been recommended treatment by an NHS consultant that is not routinely commissioned by the NHS CB under its existing policies are entitled to ask their GP for referral for a second opinion, from a different NHS consultant, on their treatment options. The NHS CB's Area Team is available to offer advice about other providers in such circumstances. However, a second opinion supporting treatment which is not routinely commissioned by the NHS CB does not create any entitlement to NHS funding for that treatment. The fact that two NHS consultants have recommended a treatment would not usually amount to exceptional circumstances.

Monitoring requirements

22. A provider does not need to seek prior approval for private treatment *which is*

provided separately from NHS care.

The NHS CB expects providers to keep records of NHS patients who have also received parallel private treatment.

The NHS CB will expect routine reporting detailing the number of patients who sought additional private care alongside NHS care, the indications and how the trust put separate facilities in place. This is to ensure there was no NHS subsidy of the private care.

Documents which have informed this policy

- The NHS CB's Generic Commissioning Policy (reference): Ethical Framework to underpin priority setting and resource allocation
- Department of Health's 2004 Code of Conduct for Private Practice http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085197
- Department of Health, Guidance on NHS patients who wish to pay for additional private care, Guidance on NHS patients who wish to pay for additional private care, march 2009 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_096428
- Department of Health, The National Health Service Act 2006 (amended by NHS Health and Social Care Act 2012), 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
- 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

Patients and clinicians should ensure that they have checked any relevant treatment specific policy on the NHS CB's website as the treatment required may not be routinely commissioned by the NHS CB.

Glossary

TERM	DEFINITION
Co-funding of NHS care	*Co-funding of NHS care* is any arrangement under which the cost of an episode of care within the NHS (for example an out-patient visit, an operation, etc) is part funded by an NHS commissioner and part funded privately by the patient. Co-funding is not permitted within the NHS apart from the limited forms of co-payment permitted under regulations.
Co-payment	*Co-payment* is where the Government has passed Regulations which require patients to make a contribution to the overall cost of NHS commissioned care.
Cost effectiveness	*Cost effectiveness* is an assessment as to whether a healthcare intervention provides value for money.
Effectiveness - general	*Effectiveness* means the degree to which pre-defined objectives are achieved and the extent to which targeted problems are resolved.
Effectiveness - clinical	C*linical effectiveness* is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
Efficacious	A treatment is *efficacious* where it has been shown to have an effect in a carefully controlled and optimal environment. However, it is not always possible to have confidence that data from trials which suggest that treatments will be efficacious will translate into clinically meaningful health gain and more specifically the health gain of interest. This is the difference between disease oriented outcomes and patient oriented outcomes. For example a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy but this relationship might not be borne out in reality.
Exceptional	*Exceptional* means out of the ordinary, unusual or special.
Exceptional clinical circumstances	*Exceptional clinical circumstances* are clinical circumstances pertaining to a particular patient which can properly be described as out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the

	case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.
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.
Healthcare intervention	A *healthcare intervention* means any form of healthcare treatment which is applied to meet a healthcare need.
Healthcare need	*Healthcare need* is a health problem which can be addressed by a known clinically effective intervention. Not all health problems can be addressed.
In-year service development	An *in-year service development* is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the commissioner agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances

	because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.
NHS commissioned care	*NHS commissioned care* is healthcare which is routinely funded by the patient's responsible NHS Commissioner. Commissioners have policies which define the elements of healthcare which they are, or are not, not prepared to commission for defined groups of patients.
NHS Directions	*NHS Directions* are instructions issued by the Secretary of State who has powers under NHS primary legislation to give directions to all NHS bodies (other than NHS Foundation Trusts) including the NHS CB which place a legal requirement on NHS bodies to act in accordance with the Direction.
NHS pick-up of private patients	*NHS pick-up of private patients* refers to situations where a patient has chosen to access a treatment not normally available on the NHS, by self funding private care and who then seeks NHS funding to provide on-going treatment or complete the course of treatment.
Outlier	*An outlier* is a clinical observation of a patient or group of patients that lies outside the normal clinical picture. The outlier may be different from the patient group of interest in one of two ways. Their response to treatment may be very different to the rest of the group or their clinical presentation / natural history might be very different to the rest of the group. In order for an outlier to be identified it is necessary to characterize the patient subgroup of interest.
Private healthcare	*Private healthcare* means medical treatments or medical services which are not funded by the NHS, whether provided as a private service by an NHS body or by the independent sector. A patient may choose to seek treatment on a private basis even where that treatment is available from an NHS provider.
Private patients	*Private patients* are patients who receive private healthcare, funded on a pay-as-you-go basis or via a medical insurance policy.
Service Development	A s*ervice development* is an application to the NHS CB to amend the commissioning policy of the NHS CB to provide that a particular healthcare intervention should be routinely funded by the NHS CB 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*.
Similar patient(s)	*A similar patient* refers to the existence of a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of one or more similar patients indicates that a policy position may required of the commissioner.
Value for money	*Value for money* in general terms is the utility derived from every purchase or every sum spent.