

General Policy for Individual Funding Request Decision Making

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Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of health and healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to policies in that suite
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1. Introduction

- 1.1. Each policy in that framework is a separate public document in its own right but may be applied with reference to other policies in that suite.
- 1.2. At Appendix 1, this document incorporates some references and explanatory notes. Those references and notes are illustrative only and Appendix 1 does not form part of this General Policy for Individual Funding Request Decision Making. Superscripts of the style ^{Ref: xx} in the main text refer to entries in that appendix.
- 1.3. Under the Health and Social Care Act 2012, 'A ICB must arrange for the provision of [certain health services] to such extent as it considers necessary to meet the reasonable requirements of the persons for whom it has responsibility'. ^{Ref: 1}
- 1.4. The ICB is responsible for arranging the provision of certain healthcare services for the population residing within its area. ^{Ref: 2} This policy applies to any patient for whom the ICB is the responsible commissioner, as defined by NHS England's guidance, "Who Pays? Determining responsibility for payments to providers" (2013). ^{Ref: 3}
- 1.5. In delivering its commissioning function, the ICB has a duty to achieve financial balance. ^{Ref: 4}
- 1.6. In exercising its commissioning functions, the ICB will adhere to the NHS Constitution. In so doing, the ICB is 'committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources'. ^{Ref: 5}
- 1.7. In accordance with the NHS Constitution, the ICB also commits to making decisions in a clear and transparent way'. ^{Ref: 6}
- 1.8. The ICB seeks to make best use of its available resources to meet the healthcare needs of its population, through the consistent application of its Statement of Principles for healthcare commissioning. ^{Ref: 7}
- 1.9. The ICB recognises that there are a number of general circumstances when it is appropriate to consider funding at the level of the individual.
- 1.10. This document sets out the ICB's policy for decision making in relation to the following circumstances:
 - 1.10.1 requests for interventions for which no local commissioning policy exists
 - 1.10.2 requests for interventions for which there is NICE guidance (Technology Appraisals, Clinical Guidelines, Interventional Procedures Guidance)
 - 1.10.3 requests to fund treatment as part of clinical research
 - 1.10.4 requests to provide funding for continuation of treatment commenced as part of clinical research
 - 1.10.5 requests to provide funding for continuation of treatment commenced in the private sector
 - 1.10.6 requests for retrospective funding

- 1.10.7 requests for treatments commenced as a "trial of treatment" which have not been sanctioned by the ICB
- 1.10.8 requests for treatments commenced on the NHS by another responsible commissioner
- 1.10.9 requests for parallel/co-funding (NHS and private care)
- 1.10.10 requests for access to care/treatment from a provider not listed on the national Free Choice Network.

2. IFR Definition

- 2.1 The NHS Confederation defines an individual funding request is a request to fund treatment that does not have services already agreed through existing commissioning arrangements and is within the commissioning responsibility of ICB. ^{Ref: 8} However for the purposes of this document and suite of policies, a wider definition is used, i.e. An individual funding request is a request to fund treatment that is within the commissioning responsibility of the ICB and which either does not have services already agreed through existing commissioning arrangements or requires prior approval on an individual patient basis.
- 2.2 Reasons for not having a commissioned service include:
 - 2.2.1 the medical condition in question is rare
 - 2.2.2 the treatment is new or unproven in effectiveness
 - 2.2.3 the treatment is a high-cost intervention
 - 2.2.4 the treatment is of value and clinical benefit, but funding is not available from the prioritisation process.
- 2.3 An individual funding request is not a request to fund a service development, to fund an existing commissioned service where the ICB has not commissioned the whole pathway of care or to fund treatment from a provider of the individual's choosing where that is not the usual provider of that service for the ICB.
- 2.4 A service development is a change to the ICB's portfolio of service agreements such that a particular new healthcare intervention shall be routinely commissioned for a defined group of patients. Service developments are likely to result from a prioritisation process. Some requests for healthcare may more appropriately be considered as service developments than as individual funding requests. This is particularly likely when a significant number of similar requests is anticipated.

3. Policy statement: Requests for interventions for which no local commissioning policy exists

- 3.1 If a request is received for individual patient funding (as defined above) for a service or treatment for which the ICB has no policy, then the default position is that the ICB will not offer that funding. However, the ICB may decide to move away from that default position and in doing so it may consider:
 - 3.1.1 whether a policy for this service or treatment, based on the principles of

appropriateness, effectiveness, cost effectiveness, ethics and affordability would be likely to permit funding to be offered

3.1.2 whether there is a usual pathway for the management of similar patients within service agreements, and if so whether there are good reasons why this patient should be managed differently to those similar patients

3.1.3 whether there is authoritative guidance that, while not having policy status, may be relevant and helpful. The use of such guidance is at the discretion of the ICB.

3.2 On the basis of that consideration, the ICB shall decide how to respond to that request.

4. Policy statement: Requests for services or treatments for which there is NICE guidance (Technology Appraisals, Clinical Guidelines, Interventional Procedures Guidance) or equivalent.

4.1 The ICB shall comply with the requirements of any of the following in relation to its residents requesting a health care intervention that falls within the ICB commissioning remit:

4.1.1 an Act of Parliament or other statute

4.1.2 a direction from a court of England and Wales

4.1.3 guidance issued by the National Institute for Health and Care Excellence (NICE) in its technology appraisal category

4.1.4 other guidance that ICBs are required to regard as mandatory.

4.2 Non-mandatory guidance shall not be regarded as ICB policy unless or until the ICB formally adopts it as policy through its due governance process. The ICB shall have regard to relevant non-mandatory guidance issued by NICE and NHS England. In instances where the ICB determines not to follow such non-mandatory guidance, it will provide an explanation for this decision. In addition, the ICB may at its discretion take into account guidance from other sources. Factors to be taken into account when considering such guidance include, without limitation:

4.2.1 the evidence base cited in support of such guidance

4.2.2 whether the guidance is applicable to the commissioning of health care interventions by the NHS in England.

5. Policy statement: Requests to fund treatment as part of clinical research

5.1 The ICB recognises that treatments which are being studied via clinical research have, by their very nature, potential risks and benefits which are as yet unquantified. The ICB does not wish to stifle innovation and may support the undertaking of high-quality research in line with its priorities. However, the IFR route is not appropriate for consideration of applications to fund clinical research for groups of patients.

5.2 Consideration of requests to the ICB to support treatment costs either during or after a clinical trial (which may be a trial sponsor's precondition for allowing a patient to enter a clinical trial) has been delegated to those responsible for IFR decision-making because

it is a decision to fund a treatment which is not normally funded at the patient level and it will commit additional, often substantial, resource from the ICB. This decision therefore has to be subject to normal priority setting processes at the level of the individual.

- 5.3 Clinicians may, on behalf of their patients, make an individual funding request to the ICB for treatment that is not normally commissioned by the ICB, in circumstances where an individual patient is suitable to enter a clinical trial which is dependent on ICB funding for the treatment costs of the trial. The ICB's default position is not to fund treatment for an individual as part of clinical research. However, the ICB reserves the discretion, via the IFR decision-making process, to authorise or not to authorise funding in each individual case.
- 5.4 Clinicians may, on behalf of their patients, make an individual funding request to the ICB for approval prior to the patient entering a clinical trial to fund continuation of funding of treatment after the trial has been completed. The ICB will not generally fund continuation of treatment without this prior approval.
- 5.5 The ICB observes the usual arrangement, in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki adopted by the World Medical Assembly, that at the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits. The ICB expects research ethics committees or equivalent local committees to require that no clinical trial is approved unless funding is identified by those conducting the trial and explicitly approved by the proposed funder to ensure that any patients in a trial who benefit from the treatment in the trial are able to continue the treatment. To satisfy this requirement the ICB may, at its discretion and if other aspects of this policy are satisfied, make a provisional offer of funding before research ethics committee authorisation is confirmed, but that funding will be conditional on research ethics committee authorisation being confirmed before the treatment commences.

6. Policy statement: Requests to pick up funding for continuation of treatment commenced as part of clinical research

- 6.1 IFR requests may be submitted for funding continuation of treatments previously commenced in the following circumstances:
 - 6.1.1 where the trial in question has been funded, wholly or in part, by the ICB; or
 - 6.1.2 where the trial in question has been funded by the manufacturer of the intervention, or where the intervention has been provided by the manufacturer on a "compassionate use" basis outside of a formal clinical trial ^{Ref: 9}; or
 - 6.1.3 where the trial in question has been a non-commercially funded clinical trial, covered by Department of Health Guidance HSG (97) 32.
- 6.2 The ICB's position is that the continued provision of a treatment after the end of a clinical trial is the responsibility of those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment, and that this position remains until the trial results are available. Subject to the terms of this policy, the ICB may fund access to the treatment which was the subject of the clinical trial after the completion of a clinical trial funded as described in section 6.1 when:
 - 6.2.1 the treatment which was the subject of the clinical trial has been demonstrated to deliver clinical benefit to the patient; and

- 6.2.2 the ICB has been enabled to consider all available evidence relating to the benefits and harms of the trial treatment on the trial population, responsibility for the continuation of funding remaining with the drug company until they make their results clearly available.
- 6.3 The provision of funding to continue a treatment to a patient who leaves a clinical trial where the treatment costs have been funded as described in section 6.1 does not represent a policy decision by the ICB to fund that treatment for other patients who were not part of the clinical trial. Any application for a service development to support funding for the treatment in question will be assessed and prioritised under the ICB's service development policy in the normal way.
- 6.4 Where funding has been provided to a patient under section 6.1.1 of this policy, the ICB reserves the right to seek a formal clinical review of the patient's present and future healthcare needs and to consider whether the decision to provide the patient with on-going funding for the treatment which was the subject of the clinical trial, or any other treatment provided to the patient, is equitable and appropriate. The ICB shall have regard to its other commissioning policies and its Statement of Principles for healthcare commissioning ^{Ref: 7} when conducting any such review.
- 6.5 The policy of the ICB is that it will not provide funding for a patient's treatment at the end of a clinical trial that has been funded as described in section 6.1.2, unless the Board has given its prior written agreement or, where commissioning responsibility for a patient has transferred from another NHS body to the ICB, written agreement has been provided by the NHS commissioning organisation which was the responsible commissioner for the patient when the trial was commenced. Service providers seeking such funding from the ICB will need to provide clear evidence of any such agreement.
- 6.6 The ICB may, at its discretion, consider providing funding for on-going access to treatment after the end of trials as described in section 6.1.3 only if:
- 6.6.1 the clinical trial was wholly funded by non-commercial bodies; and
 - 6.6.2 the trial was sanctioned by the National Institute for Health Research database (<http://public.ukcrn.org.uk/search/Portfolio.aspx>); and
 - 6.6.3 it has been demonstrated that the patient has benefited clinically from the treatment provided as part of the clinical trial; and
 - 6.6.4 the ICB determines that, given other demands upon its resources, the expenditure to support the on-going treatment can be justified and the ICB can afford that expenditure.
- 6.7 It is the responsibility of the organisation conducting the trial, usually a service provider organisation, and the patient's clinician to ensure that patients are fully informed, before entering trials of the type described in section 6.1.2, that NHS funding for the continuation of treatment delivered as part of a clinical trial that has been sponsored by a pharmaceutical or medical devices company, or provided on a "compassionate use" basis, may not be provided unless it has previously been agreed in writing by the patient's responsible NHS commissioner at the outset of the trial. Patients should also be informed about the circumstances in which "compassionate use" funding is being provided, how long this funding will be provided and what will happen when it is withdrawn. All such arrangements must be explicitly approved by the relevant service provider governance body (for example the Drugs and Therapeutics Committee). The patient should agree to

their management plan on discontinuation of treatment. This process of obtaining informed consent includes making patients aware of this commissioning policy. The patient's consent should be documented.

7. Policy statement: Requests to pick up funding for continuation of treatment commenced in the private sector

7.1 The ICB will not pick up funding for continuation of treatment commenced in the private sector either in the UK or abroad unless the treatment would normally be provided within standard NHS treatment pathways and unless the patient satisfies the eligibility criteria in any relevant ICB policy.

8. Policy statement: Requests for retrospective funding

8.1 Requests for funding must be submitted before treatment is initiated. Retrospective approval for individually funded requests will not normally be approved. However, any request will be considered on its merits and in accordance with any separate policy in force at the time.

9. Policy statement: Requests for treatments commenced as a "trial of treatment" which have not been sanctioned by the ICB

9.1 The policy of the ICB is that it will not agree the funding of a patient's treatment at the end of a 'trial of treatment' for treatments which are not routinely commissioned by the ICB. ^{Ref: 10}

9.2 Funding will only be provided when the ICB has given its prior written agreement. This is also a requirement where a patient has transferred from another NHS body that the trial of treatment was commenced. Provider trusts seeking funding will need to provide evidence of any such agreement

10. Policy statement: Requests for treatments commenced on the NHS by another responsible commissioner ^{Ref: 11}

10.1 This policy applies to any patient for whom the ICB is the responsible commissioner.

10.2 Where responsibility for providing NHS services to a particular patient has been transferred to the ICB, the ICB will, subject to the terms of this policy, honour existing funding commitments made by the patient's previous commissioner.

10.3 The ICB will also, subject to the terms of this policy, honour existing funding commitments made by publicly funded healthcare services in Wales, Scotland, Northern Ireland, the Isle of Man or the Channel Islands where responsibility for providing NHS services to a particular patient has transferred to the ICB from health bodies in those countries.

10.4 Where sections 10.2 or 10.3 apply, the ICB reserves the right to seek a formal clinical review of the patient's future healthcare needs and to consider whether the decision to provide the patient with any further courses of treatment of the type previously provided, and of any other nature, is equitable and appropriate. The ICB shall have regard to its other commissioning policies and its ethical framework for priority setting and resource allocation when conducting any such review.

10.5 The rights under sections 10.2 and 10.3 above shall not apply if the patient would not, for any reason, have continued to have had the treatment in question commissioned for

the patient by the patient's previous responsible commissioning organisation.

- 10.6 This policy should be read in conjunction with the Department of Health's responsible commissioner guidance, currently: "Who Pays? Establishing the Responsible Commissioner" ^{Ref: 11}

11. Policy statement: Requests for co-funding (NHS and private care)

- 11.1 The ICB defines "co-funding" as any arrangement under which the cost of an episode of care within the NHS is part-funded by an NHS commissioner and part-funded by the patient. Co-funding is not permitted within the NHS, apart from the limited forms of co-payment which exist under current legislation ^{Ref:12}. The ICB will not enter into any agreement which is not permitted.

12. Policy statement: Requests for parallel funding (NHS and private care)

- 12.1 The ICB defines "parallel funding" as any arrangement under which a patient pays for additional private healthcare while continuing to receive care from the NHS.

- 12.2 If a request is received for a patient to self-fund part of their care which would otherwise not be funded by the ICB, the ICB's default position will be to commission as follows, in accordance with national guidance in force at that time. ^{Ref: 13}

- 12.3 In keeping with current guidance, the ICB will only enter into a commissioning arrangement of parallel funding if:

12.3.1 the provision of private and NHS funded care is not within the same episode of care

12.3.2 the provision of private and NHS funded care is kept separate in relation to time and place, except in circumstances where to do so would pose overriding concerns of patient safety.

- 12.4 The ICB 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.

- 12.5 When a patient wishes to pay privately for additional treatment which is not commissioned by the ICB, the patient will be required to pay all costs associated with the privately funded episode of care (including assessments, inpatient and outpatient attendances, diagnostic tests, medication, appliances or equipment 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.

- 12.6 If a patient wishes to receive a combination of treatments (e.g. medicines, procedures, appliances, equipment, services. etc.), some of which are not routinely commissioned by the NHS, the patient is entitled to access the NHS- funded elements of care and can consult a clinician privately for those elements which are not commissioned by the NHS. If the NHS element of care cannot be delivered separately (in relation to time and place) to the private element of care, the ICB may consider a joint funding arrangement provided that there would be a clinical disadvantage to the patient in separating the treatment, the patient clearly satisfies all necessary policy criteria for the NHS funded element, the cost to the ICB is no greater than it would have been if the NHS component was funded separately, and the funding arrangement accords with any statutory or mandatory guidance in force at the time. Otherwise, parallel funding cannot be supported, and the

patient will be required to fund all costs associated with the proposed treatment.

12.7 For further examples please see Appendix 2. ^{Ref: 14}

13. Policy statement: Requests for access to treatment by a provider not listed on the national Free Choice Network

13.1 The ICB expects that clinicians will refer patients appropriately for secondary and tertiary care using established pathways covered by local contractual arrangements. The ICB considers this to be the default position.

13.2 The ICB acknowledges that there may be circumstances where a patient wishes to have their treatment provided by an alternative provider. ^{Ref: 15}

13.3 Under the 'Free Choice' policy (2008), patients can choose from any clinically appropriate and "accredited provider" in England. An "accredited provider" includes NHS Foundation Trusts and independent sector hospitals which meet the quality and cost criteria specified by the Department of Health. ^{Ref: 16} All "accredited providers" are listed on the 'Free Choice Network' which is accessible to all GPs via the Choose and Book System.

13.4 In accordance with the current guidelines set out in the NHS Choice Framework 2014-15, ^{Ref: 16} and the rights to extended choice set out in the NHS Constitution, the ICB may allow patients to choose to be referred to any "accredited provider" who can offer the appropriate level of care in the following situations:

13.4.1 if a patient is being referred for their first appointment as an outpatient with physical or mental health problems

13.4.2 if a patient is being referred by their GP for a diagnostic test

13.4.3 if a patient is being referred to maternity services.

13.5 The ICB will not commission the referral unless the patient meets the intervention-specific commissioning policy criteria or, in the absence of a commissioning policy, the request is in accordance with the ICB's principles for commissioning health care. ^{Ref: 7}

13.6 This policy does not apply to patients undergoing urgent or emergency treatment.

13.7 In the situation where a patient request's funding abroad, the ICB will consider funding in accordance with national guidance. ^{Ref: 16}

Appendix 1 – References and explanatory notes

This Appendix describes the basis for the policy but does not form part of the policy.

Reference Number	Called from paragraph	Details
1	1.4	NHS Act 2006, Pt 1 s3 (1), as amended by Health and Social Care Act 2012, Pt 1 s13(2)(a)
2	1.5	NHS Act 2006, Pt 1 s3 (1A), as amended by Health and Social Care Act 2012, Pt1 s13 (3)
3	1.5	NHS England 'Who Pays? Determining responsibility for payments to providers' 2013 Available at: https://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf
4	1.6	NHS Act 2006, Pt 11, Ch6, 223H, as amended by Health and Social Care Act 2012 Pt 1 s27
5	1.7	The NHS Constitution 2013, p4. Available at: http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx (accessed 9/2/15)
6	1.8	The NHS Constitution 2013, p6. Available at: http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx (accessed 9/2/15)
7	1.9; 6.4; 13.5	Statement of Principles, <i>revised 2015</i>
8	2.1	From NHS Confederation: http://www.nhsconfed.org/~/_media/Confederation/Files/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf
9	6.1.2	Pharmaceutical companies frequently provide free treatment to patients in hospital in the period between the end of a clinical trial and licensing. This has been called 'compassionate funding'.

Reference Number	Called from paragraph	Details
10	9.1; (para 3.6)	Good research into the effectiveness of healthcare interventions usually involves large numbers of patients, using a controlled and ideally randomised study design, with a long period of follow up. The experiences of individual patients may simply involve a placebo effect, may not be sustained into the future, and may not include an objective assessment of the balance between costs and benefits. If the patient has received private sector treatment to try out a generally unproven intervention, then to accept the results of that trial as exceptionality would be inequitable to patients who could not afford private treatment and would fail to satisfy the commissioning principle of ethical delivery. If the patient had received the trial from an NHS funded provider, then that provider may have been acting out with the contract specification and the matter of continuation would be a matter between the patient and that provider. Therefore, evidence that the patient has a claim that a patient has tried out a treatment with claims of success does not amount to a case of exceptionality against a policy based on the principle of effectiveness or value for money.
11	10	Who Pays? Guidance from NHS England: https://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf
12	11.1	NHS Act 2006, Part 9
13	12.2	Department of Health, 'Guidance on NHS Patients who wish to Pay for Additional Private Care', 2009. Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_096576.pdf (accessed 9/2/2015) - but see also http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-12.pdf is a NHS England commissioning policy and not guidance to the NHS.
14	12.7	Examples of parallel funding might include a patient privately funding a drug which is not normally commissioned by the ICB whilst receiving NHS medical care on a specialist bone marrow transplant unit; a patient privately funding a cancer drug which is not commissioned by the NHS in addition to receiving chemotherapy treatment on the NHS; a patient choosing to fund physiotherapy from a private provider following NHS funded hip replacement surgery.
15	13.2	Such situations may arise when the patient has clinical need for a service which is not available within the locally commissioned service pathway; the patient wishes to have a second opinion; the patient is a medical practitioner wishing to be treated outside of the locally commissioned service for reasons of confidentiality; the patient requires regular healthcare to continue during a temporary period away from home; the patient wishes to have their treatment in a provider closer to their place of work; a patient has recently moved to the area and wishes to continue their existing arrangements in relation to their treatment provider.
16	13.3; 13.4; 13.7	Department of Health, 'NHS Choices Framework', 2014. Available at: https://www.gov.uk/government/publications/the-nhs-choice-framework (accessed 9/2/2015)