

Statement of Principles

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1 Introduction

- 1.1 This document sets out the principles underlying the commissioning decisions and policies of this Integrated Care Board (referred to hereinafter as "ICB").
- 1.2 This document and each commissioning policy is a separate public document in its own right.
- 1.3 The purpose of the suite of policies is to assist the ICB to address its highest priorities within a balanced budget, and to reduce the risk of harming its patients and its population through excessive healthcare.
- 1.4 In preparing its policies and in defining the principles on which those policies are based, the ICB is mindful of the NHS Constitution, of relevant legislation, and of court decisions, especially as quoted in Appendix 1.

2 Principles

- 2.1 In developing local commissioning policies, the ICB will commission only treatments or services which accord with all of the following principles:
 - Appropriateness
 - Effectiveness
 - Cost-effectiveness
 - Ethics
 - Affordability

3 Appropriateness

- 3.1 The principle of appropriateness refers to the questions of:
 - a. whether the commissioning of the service falls within the remit of the ICB
 - b. whether the purpose of the service is to maintain or improve an essential component of health status
 - c. whether the service will use the best means of achieving its purpose.
- 3.2 The ICB will commission a treatment or service only where it is satisfied that it meets the criteria, including the criteria for appropriateness, set out in this Statement of Principles.
- 3.3 To accord with the principle of appropriateness, a treatment or service must meet one or more of the following criteria:
 - a. It has the intended outcome of preventing, diagnosing or treating a medical condition (See definitions in appendix 2)
 - b. It enhances dignity at the time of death

- c. It has the intended outcome of preventing unwanted pregnancy
 - d. It provides part of such services or facilitates for the care of pregnant women, women who are breastfeeding and young children as may be reasonably required
 - e. It is considered by the ICB to be necessary in order to meet a legal requirement.
- 3.4 Even if one or more of the criteria in section 3.3 is met, the ICB may decide that a treatment or service is not appropriate for it to commission for one or more of the following reasons:
- a. The ICB is aware that there are different ways of managing a particular condition, and after giving the matter due consideration and taking relevant advice in the course of setting a policy it has decided that one particular way of managing that particular condition is normally more appropriate than others. The ICB's position will depend on the condition in question. In some circumstances it may take a view that it prefers to commission services that address the underlying problem rather than simply the symptoms (or vice versa). In other circumstances it may prefer to commission services that adopt a palliative approach. In other circumstances it may prefer to commission services that preserve certain other bodily functions.
 - b. The timing of a particular treatment is clinically unfavourable e.g. in relation to development, reproduction, weight loss etc..
 - c. For investigations and diagnostic services, the information being sought would not substantially affect the clinical management of the patient.
 - d. The particular service provider is not within the range of choices offered by the ICB for the service in question or the rights to extended choice set out in the NHS constitution.
 - e. The service falls within the defined remit of another public sector commissioner.
 - f. The ICB considers that other services competing for the same ICB resource more clearly have a purpose of preserving life or of preventing grave health consequences. "Services likely to prevent grave health consequences" are defined in Appendix 2.
 - g. The ICB considers that the use of health care for the problem in question would amount to excessive medicalisation, which would be detrimental either at the level of the individual patient or at the level of the population. "Excessive medicalisation" is defined and explained in Appendix 2.
 - h. The treatment is new and has not yet been considered or prioritised for inclusion in the ICB's service agreement portfolio.

3.5 If the ICB considers a treatment or service to be appropriate, then it may commission it, provided that it also accords with the principles of effectiveness, cost-effectiveness and ethics.

4. Effectiveness

4.1. The ICB defines an effective treatment or service as one which is capable of achieving its intended outcome, and of doing so with the benefits exceeding any harm done.

4.2. The ICB will commission a treatment or service only where it is satisfied that it meets the criteria, including the criteria for effectiveness, set out in this Statement of Principles.

4.3. The ICB may satisfy itself that a treatment meets the criteria for effectiveness by considering the content and quality of the available evidence, including evidence of plausibility (i.e. a rational basis for expecting the treatment to work) and evidence obtained from research.

4.4. If the ICB is satisfied by evidence in relation to a particular treatment or service that the probable effect on a population of patients is that the benefits of the treatment or service will substantially outweigh the harm done by the treatment or service, then the ICB regard the treatment or service as effective.

4.5. If the ICB is satisfied by evidence in relation to a particular treatment or service that the probable effect on a population of patients is that the harm done by the treatment or service will substantially outweigh the benefits of the treatment or service, then the ICB will regard that treatment or service as not being effective.

4.6. If the ICB is satisfied by evidence in relation to a particular treatment or service that the probable effect on a population of patients is that the harm done by the treatment or service and the benefits of the treatment or service are balanced with neither substantially outweighing the other, then the ICB will not regard that treatment or service as according with the Principle of Effectiveness.

4.7. If the ICB does not have sufficient evidence to decide whether that the probable effect on a population of patients is that the benefits of the treatment or service substantially outweigh or are substantially outweighed by the harm done by the treatment or service, then the ICB will not regard that treatment or service as according with the Principle of Effectiveness. However:

a. The ICB shall consider any evidence offered by the patient or their clinical advisors.

b. If the ICB concludes that there is a deficit in the evidence available for a particular treatment or service then it may move to a position of being uncertain whether the treatment or service is effective. In such a circumstance it may commission a treatment or service only in accordance with the General Policy for Individual Funding Request Decision Making, which considers funding services in a research context.

5. Cost-Effectiveness

- 5.1. The ICB defines a treatment or service that is cost-effective as one which achieves a greater health gain than alternative uses of the same money by the ICB.
- 5.2. The ICB will consider the cost-effectiveness of a treatment or service only if it has judged that the treatment or service is effective, in accordance with section 4.
- 5.3. In circumstances when a treatment or service is regarded as appropriate and effective, the ICB may commission that treatment or service only if it is also satisfied that the cost is reasonable in relation to the expected benefits and adverse effects and may refer to the NICE threshold for cost per quality adjusted life year that may be in force at the time.
- 5.4. The ICB may consider a treatment or service not to be cost-effective if it fails to meet any national or local value for money or cost-effectiveness criterion that may be in force at the time.
- 5.5. The ICB recognises that the costs, expected clinical benefits and expected clinical dis-benefits of a particular treatment may vary from patient to patient and therefore the ICB may adopt a policy to commission a service only for those patients for whom the balance between costs and net expected benefits is the most favourable.
- 5.6. In comparing two possible treatment options the ICB may consider the relative and marginal costs and benefits and will decide which service to commission accordingly. (See detail in appendix 2)
- 5.7. The ICB may consider cost-effectiveness at the population level as well as at the individual level in order to ensure equity of health outcomes.

6. Affordability

- 6.1. The ICB aspires to use the Principle of Cost-Effectiveness to assist it to make commissioning decisions that make best use of resources. However, the ICB reserves the right to consider affordability above cost-effectiveness given the need for the ICB to prioritise the use of resources in accordance with the other principles set out in this policy.

7. Ethics

- 7.1 The ICB defines ethical healthcare as that which is provided justly and fairly according to need, and in accordance with systems of accepted beliefs and of relevant professional bodies such that the health of the population is maximised within the resources available. A healthy population is one in which health and wellbeing are prevalent in a fair and sustainable fashion.

- 7.2 The ICB's default position is that the treatment or service can be delivered ethically.
- 7.3 The ICB will commission treatments or services based on the health and healthcare needs of their resident population, as assessed by the ICB. In doing so, they will seek to reduce health inequalities within the population.
- 7.4 The ICB's commissioning policies, in line with the Equality Act 2010 will not discriminate on the basis of age, disability, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation. The ICB will also not discriminate on social disadvantage, lifestyle, occupation, offending background, trade union membership, financial status or family status (including responsibility for dependents).
- 7.5 The ICB will also apply the human rights principles of Freedom, Respect, Equality, Dignity and Autonomy when developing and applying commissioning policies ensuring that they respect people's human rights in line with the Human Rights Act 1998 and the NHS Constitution.
- 7.6 All commissioning policies will be subject to equality impact assessment and the ICB may take the results of that assessment into account.
- 7.7 The ICB will not commission a service that does not follow the usual pathway, if the sole purpose of commissioning it would be to enable a patient to bypass a policy criterion that other patients are expected to follow.
- 7.8 The ICB will not commission a service if the sole reason for commissioning it would be because that service is commissioned by another Commissioning Organisation or Commissioning Organisations.

8. Application, Monitoring and Review

- 8.1 When adopted, these principles will be in force with immediate effect for the development of new policies. However existing policies based on previous sets of principles will remain in force until their review date, or until superseded by new policies. The sets of principles on which they were based shall remain on the record and shall continue to give validity to those policies.
- 8.2 The policy and procedure will be reviewed every three years. Where review is necessary due to legislative change, this will happen immediately.

Appendix 1 – Statutes and equivalent:

The NHS Constitution commits the ICB:

- *to provide best value for taxpayers' money and the most-effective, fair and sustainable use of finite resources.*
- *to make decisions in a clear and transparent way*

The Health and Social Care Act 2012 requires the ICB:

- *to 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'*
- *to arrange the provision of certain healthcare services for the population residing within its area.*

The Court of Appeal (e.g. R v North West Lancashire Health Authority ex parte A, D & G, July 29th, 1999) recognises that:

- *it is an unhappy but unavoidable feature of state funded health care that [ICBs] have to establish certain priorities in funding different treatments from their finite resources. It is natural that each [ICB], in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each [ICB], keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose -- indeed, it might well be irrational not to have one.*

Appendix 2 – Definitions:

The ICB defines a **medical condition** as any illness, injury or impairment in which there is an abnormality in the structure or function of the body or mind.

The ICB defines **treating** as providing a healthcare service with the intention of curing a medical condition, halting or delaying its progress, reducing its impact, relieving symptoms, or delivering alternatives to impaired biological functions.

The ICB defines an **abnormality** in the structure or function of the body or mind as a situation where either:

- a. a part of the body or mind is substantially impaired in the delivery of one or more of its functions, or
- b. a part of the body or mind is substantially impairing another part in the delivery of one or more of its functions, or
- c. there is a threat that (a) or (b) will happen imminently.

(This definition does not apply to an abnormality of appearance which may be defined separately in policies for cosmetic services.)

The ICB defines **services likely to prevent grave health consequences** as those which:

- prevent or relieve major pain, disability or physical discomfort; (See definitions below) or
- directly treat a diagnosed mental health condition; or
- maintain dignity at the time of death; or
- deliver healthcare which is reasonably requires for pregnant and newly delivered women, women who are breastfeeding and young children; or
- overcome an impairment which is preventing the patient from living a healthy lifestyle; or
- satisfy equivalent definitions or criteria within specific policies, especially those policies relating to assisted conception and cosmetic procedures.

The ICB defines **major pain, disability or physical discomfort**; in the context of appropriateness, as a situation where that pain, disability or physical discomfort:

- Is the dominant feature of the condition, and
- Is of a level of severity that would lead most people to seek healthcare for that feature of the condition alone, and
- Is preventing usual activities, or is significantly disrupting the sleep pattern, and
- Is present for all or most of the time, and
- Is not primarily related to certain activities which could be avoided without detriment to health, and
- Has a plausible basis, and
- (for surgical treatments or services) either is likely to be permanent, or if short term is not relieved by medication, and
- Is recognised by the clinicians providing treatment as the main feature that will be addressed by any treatment or service.

On rare occasions an extreme odour that prevents social contact may be regarded as a disability in this context.

Treatment that is likely to support the patient to be employable (or to benefit from education) is likely to accord with the principle of appropriateness, as the ICB recognises education and employment as important determinants of health. It is unlikely that such a treatment or service will have employability as its only treatment purpose. However, a treatment intention of enabling the patient to have a *particular* employment will not normally be sufficient to accord with the principle of appropriateness, and a policy that did regard such a treatment or service as appropriate may discriminate against people without that particular career aspiration. The ICB will also disregard an individual's circumstances and intentions in relation to whether or not they could engage in employment or education or would wish to do so when deciding to fund a treatment or service that is likely to support their employability or ability to engage in education.

The ICB aspires:

- to deliver healthcare when that health-care is essential
- to contribute to the prevention of ill health

- to promote wellbeing; and
- to influence the values and attitudes of society when those values and attitudes define a health state as being abnormal.

In addressing the latter, the ICB regards it as often beneficial to society to extend the range that is perceived as normal, and to avoid situations where disease is defined sociologically rather than pathologically.

The ICB therefore defines excessive medicalisation as a situation in which:

- An offer of healthcare may create or perpetuate a perception in society that a condition is an illness
- An offer of healthcare may reduce or restrict the range of variation which society considers to be normal
- An offer of healthcare for a particular presentation may distract from the more appropriate strategy of enabling and empowering the patient to cope with and manage the condition themselves
- An offer of state funded healthcare may promote the misunderstanding that the NHS should fund every possible biological intervention, whereas some biological interventions should be regarded as a good which the individual should prioritise themselves against other calls on their personal budgets.

It is likely to be beyond the scope and capacity of the ICB to carry out a detailed economic appraisal of every service that it is asked to fund, especially if that service is rarely used. The inclusion of the principle of cost effectiveness does not require the ICB to do so, but it does enable the ICB to consider economic appraisals that have been carried out, e.g. by NICE, or to consider and take account of the value for money of the service in general terms or in the particular circumstances of an individual patient.

The ICB regards cost-effectiveness as a relative concept. Therefore, if two equally effective treatment options for the same condition would satisfy the cost-effectiveness principle compared with doing nothing, then this principle would determine that the less costly option would be commissioned. Similarly, if a slightly more effective treatment was very much more costly than the alternative, then the ICB would consider the marginal costs and marginal benefits in determining which one it would commission. This is shown in the examples below.

In all of these examples assume that the cost-effectiveness criterion (threshold) that is in force is that one unit of benefit shall cost not more than £100

Example 1	Treatment A	Treatment B	Difference
Expected average benefit	10	15	5
Cost	£1,100	£1,800	£700
Cost per unit of benefit	£110	£120	£140

In Example 1, neither option would be commissioned as they both cost more than £100 for each unit of benefit

Example 2	Treatment A	Treatment B	Difference
Expected average benefit	10	15	5
Cost	£1,200	£1,600	£400
Cost per unit of benefit	£120	£107	£80

In Example 2, neither option would be commissioned as they both cost more than £100 for each unit of benefit. As both treatments cost more than this threshold, then the difference (marginal analysis) is not relevant.

Example 3	Treatment A	Treatment B	Difference
Expected average benefit	10	12	2
Cost	£900	£1,500	£600
Cost per unit of benefit	£90	£125	£300

In Example 3, Treatment A may be commissioned as it costs less than £100 for each unit of benefit, but treatment B would not be commissioned as it costs more than £100 for each unit.

Example 4	Treatment A	Treatment B	Difference
Expected average benefit	10	12	2
Cost	£600	£1,000	£400
Cost per unit of benefit	£60	£83	£200

In Example 4, although both options come below the £100 threshold in absolute terms, the additional benefit from treatment B is above the threshold, and therefore the difference would not be considered cost-effective and only option A would be commissioned.

Example 5	Treatment A	Treatment B	Difference
Expected average benefit	10	15	5
Cost	£800	£1,250	£450
Cost per unit of benefit	£80	£83	£90

In Example 5, both options come below the £100 threshold in absolute terms, and the additional benefit from treatment B is also comes below the threshold. Therefore, the ICB may commission that additional benefit, and may commission treatment B.

Although in absolute terms treatment A is more cost-effective, treatment B and the difference between A and B are both below the cost-effectiveness threshold and therefore may be commissioned.

Please note, that if the cost-effectiveness criterion (threshold) was raised to £115, then in example 1 Treatment A would be commissioned, and in Example, 2 Treatment B would be commissioned.