Policies for the Commissioning of Healthcare

Policy for considering applications for exceptionality to commissioning polices

Lancashire Clinical Commissioning Groups

1. Introduction

1.1 This document is part of a suite of policies that the CCG 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 polices in that suite.

1.2 This policy is based on the Statement of Principles.

1.3 This policy relates to the consideration of applications for exceptionality to the CCGs' commissioning polices.

1.4 In terms of individual funding requests, exceptionality is defined as a circumstance in which there is a policy or equivalent which does not normally provide for a particular service to be commissioned but in which a particular patient has a feature which leads to a decision that the policy will not be applied and the service will be commissioned for that particular patient. All of the CCGs' commissioning policies include provision to consider exceptionality and this policy describes how that consideration will take place.

1.5 The CCG aspires to have policies that address a wide range of possible circumstances. Exceptionality considers circumstances that are not addressed in the policy. Therefore the more circumstances that are addressed in the policy itself, the fewer will be the number of circumstances in which exceptionality needs to be granted. A good and comprehensive policy is likely to mean that the need to consider exceptions is limited, although the CCG will nevertheless consider every case for exceptionality on its merits.

2. Policy Remit

2.1 This policy applies in circumstances when an individual funding request (IFR) has been received, where there is a policy or equivalent that does not normally provide for the CCG to commission the service and where

the patient (or a clinician acting on behalf of the patient) has made a case that the patient should be regarded as an exception to the policy.

2.2 A policy or equivalent could be:

- A formally adopted policy of the CCG;
- A NICE Health Technology Appraisal that has been in force for more than three months and therefore has mandatory status;
- Non-mandatory guidance that the CCG has adopted as a policy;
- A service specification;

2.3 This policy should not be used by patients who already meet criteria for funding of their treatment under any other CCG policy.

3. Policy

3.1 An application seeking to establish that a patient should be treated as an exception to an established CCG commissioning policy or equivalent ("the Standard Policy") will normally explain:

- why the patient in question is materially different to the usual population of patients to whom the Standard Policy applies in terms of the principle or principles on which the Standard Policy is based; and
- why that material difference means the Standard Policy should not apply. (Please see Annex 1 below for further explanation.)

3.2 The following arguments, if fully and satisfactorily explained, validated and substantiated, will normally be accepted as demonstrations of exceptionality:

- That, for consideration against a policy based on appropriateness, the purpose of the requested intervention in this patient is different to the purpose in the usual population of patients to whom the policy applies, such that for this patient the CCG considers the service to be appropriate within the context of the Statement of Principles. (but see Annex 2 below).
- That, for consideration against a policy based on effectiveness, this patient is different to the usual population of patients in that the evidence of effectiveness on which the policy relies is not relevant to this patient, and that there is alternative, high quality and positive research evidence that is relevant to the intervention in this patient.
- That, for consideration against a policy based on cost-effectiveness, the cost-effectiveness of the requested intervention in this patient is different to the cost-effectiveness in the usual population of patients to whom the policy applies, such that for this patient the expected cost per QALY is clearly below the current NICE threshold.
- That, for consideration against a policy based on ethics, the circumstances of this patient are different to the purpose in the usual population of patients to whom the policy applies, such that the

concern about ethics is not relevant to this patient.

- That, for consideration against a policy based on affordability, the need, urgency or cost is different to that in the usual population of patients to whom the policy applies, such that for this patient the requested service is affordable. In considering such requests the CCG may nevertheless consider whether there is a mechanism to deliver the funding without disadvantage to other patients.

3.3 The following arguments may be considered as a case or part of a case for exceptionality, but will be interpreted with caution (please see the annexes below for further explanation):

- The policy being applied does not regard the intervention as according with the principle of appropriateness, but the purpose of the treatment in this patient is to address pain, or some other feature that would place the intervention within the definition of appropriateness. (Annex 2)
- This patient is a particularly severe case. (Annex 3)
- A criterion in the policy is not suitable for application to this particular patient. (Annex 4)

3.4 The following arguments will not normally provide a basis for a determination of exceptionality (please see the annexes below for further explanation):

- The policy is flawed. (Annex 5)
- The wrong policy has been applied. (Annex 6)
- One or more previous cases has been decided in a certain way and the CCG is obliged to apply that 'precedent' in the present case. The CCG will instead judge each case on its merits, having due regard to whether there have been previous cases. (Annex 7)
- This patient is clinically suitable for treatment. (Annex 8)
- This patient only narrowly fails to meet the criteria in the policy.
- The patient has already tried the treatment and it has worked. [Ref: 10] (Annex 9)
- The patient healthcare intervention sought should be funded simply on the basis that the patient is suffering problems with psychological wellbeing as a result of the condition or of the unavailability of funding. (Annex 10)
- NICE guidance (or other non-mandatory guidance) says that it should be funded. (Annex 11)
- The patient's circumstances are unusual. (Annex 12)
- The end of a commissioned pathway has been reached.

3.5 The CCG defines exceptionality solely in clinical terms. Personal or social circumstances will not be taken into consideration. In essence it is a question of equity. To consider personal, social or other non-clinical factors could introduce inequity by implying that some patients have a higher intrinsic social worth than others with the same condition.

3.6 The CCG considers that, in general, clinicians will be best placed to advance arguments as to exceptionality such as those set out above on behalf of patients. The CCG therefore encourages patients to seek support from a clinician when making an application under this policy. However, the CCG will accept applications made by patients without clinical support and will not reject such an application simply because it has been made by a patient.

4. Exceptions

4.1 It is not possible to foresee all the reasons why a person's application should be dealt with as an exception to the CCG's standard commissioning policies. The CCG is entitled to determine what constitutes exceptionality in each particular case. However, the assessment of exceptionality should be undertaken with due regard to provisions of this policy and its appendices.

Annexes

to the Policy for considering applications for exceptionality to commissioning polices

(The Policy for considering applications for exceptionality to commissioning polices, including these annexes, forms part of the General Policy for Individual Funding Request Decision Making)

Annex 1

The policies adopted by the CCG are based explicitly on one or more of the five principles of appropriateness, effectiveness, cost-effectiveness, ethics and affordability.

If a policy does not normally provide for the CCG to commission a service because it has a purpose which the CCG does not aspire to deliver (the principle of appropriateness) then a successful case would need to demonstrate that the purpose in the patient in question is different to the purpose of that treatment in the usual population of patients to whom the policy applies.

If a policy does not normally enable the CCG to commission an intervention because research evidence shows that it is does not achieve its purpose (the principle of effectiveness) then a successful case would need to demonstrate that the research evidence is not applicable to the patient in question as that patient is fundamentally different to the research population.

If a policy does not normally enable the CCG to commission an intervention because it is not considered to be cost effective, then a successful case would need to demonstrate that it would be cost effective for the patient in question, when compared with the alternative management of that patient if the service was not commissioned.

If a policy does not normally enable the CCG to commission an intervention because it is not considered to be ethical, then a successful case would need to demonstrate that it would be ethical to be commissioned for the patient in question. That case may need to consider the impact on the whole population and not just on the patient in question.

Annex 2

A demonstration that the purpose of the treatment in this patient would place the intervention within the definition of appropriateness in the context of the Statement of Principles, is indeed a valid case for exceptionality to a policy based on the Principle of Appropriateness. However the CCG may require a clear and detailed explanation before accepting exceptionality. A simple

statement that the problem is causing pain, or discomfort or is limiting activities is insufficient. The case must clearly show, with explanation:

- that the definition of major pain, disability or physical discomfort, in Appendix 2 of the Statement of Principles is met, and
- that there is a plausible reason why the problem is causing those symptoms, and
- that there is good reason to expect that the intervention will substantially improve those symptoms.

Annex 3

Severity cannot normally be regarded as part of a case for exceptionality if the policy being applied is based on appropriateness, effectiveness or ethics.

In the case of a policy based on cost-effectiveness or affordability, the spectrum of severity is likely to have been considered at the time when the policy (often originating as NICE Guidance) was drafted. However it is possible that there could be cases of extreme severity beyond what could have been expected at the time of drafting the policy. If in such a case there is also an expectation that the intervention would result in a greater benefit (e.g. from a worse level of health than other patients at baseline to the same level of health as other patients at outcome) at the same cost, then the NICE cost-effectiveness threshold could be met for these patients but not for the usual patient population. Such may be the format of a valid case for exceptionality. However it would need to be demonstrated:

- that the severity in this patient is beyond what had been envisaged when the policy was drafted, and
- that for this patient the cost per QALY would be below the NICE threshold.

Annex 4

The default position is that all policy criteria will be applied as written. However there are circumstances in which the CCG may decide, on the basis of a case from the applicant or the applicant's advisors, that a particular policy criterion can either be set aside or interpreted differently for a particular patient. There are two categories in which this may happen:

- When the circumstances of the particular patient make a criterion irrelevant. By way of example, if a fertility services policy set a minimum age for egg harvesting, which was intended for application for women who had unsuccessfully attempted to conceive, but a 15 year old women (i.e. younger than the age set in the policy needed to have cancer treatment which would damage her ovaries and was requesting egg harvesting and storage before that treatment, then it may be considered that the age limit was irrelevant for that patient - NB this example is illustrative only and does not refer to this CCG's actual

policy for that circumstance).

- When the patient has not been tested against a particular criterion, but has been tested against an alternative standard. If the CCG is convinced by the applicant that the alternative standard is equivalent (i.e. it covers the same clinical ground and is at least as stringent as the policy criterion), and the patient does meet that alternative standard, and there are good reasons why the alternative test was used, then the CCG may decide that it is excessively pedantic to require the patient to be re-tested against the policy criterion.

Annex 5

The process of exceptionality is designed to consider individual cases and not to change policy. There are separate processes for changing policy, which include a three year review and an interim review if there are any issues raised or national changes that impact on the policy. If as part of considering individual cases, concerns about the policy are identified, then the policy may be reviewed before its review date, and the patient may be reconsidered against the new policy. Research evidence is continually produced and the need to take account of new research is a major reason why policies are reviewed periodically. However a policy system can be robust only if policies remain in force until they are formally reviewed. Therefore research evidence published before the date on which a policy was adopted can be used as a case for exceptionality against that policy. However research evidence published subsequent to that date can be used as a suggestion that the CCG should expedite a review of the policy but not as part of a case for exceptionality.

Notwithstanding the paragraph above, the CCG may apply discretion in accordance with paragraph 4.1 of this policy, and cases of great severity and urgency may be subject to that discretion when new and overwhelming evidence of effectiveness is published, and when the CCG's director of finance has confirmed that funding can be made available for this and other similar cases that may arise.

Annex 6

A case that the wrong policy has been applied, or that there had been other irregularities in the process of considering the patient's request, is a matter for appeal and not for exceptionality.

Annex 7

In considering arguments based on previous decisions, the CCG may take into account the facts that:

- no two cases are identical,
- reference to other cases may breach the confidentiality of the patients involved in those other cases,
- the CCG retains the right to apply discretion in relation to any case for exceptionality.

Annex 8

A statement that the patient is clinically suitable for treatment places the patient within the usual population of patients to whom the policy applies, and not as an exception to it.

Annex 9

This policy statement derives from section 9 of the General Policy for Individual Funding Request Decision Making. Notwithstanding that section, there may be some interventions with a robust evidence base of success in selected patients, where policy is that the patient would need to have undergone a trial of the proposed treatment before a commitment is made to using it on a longer term. In such circumstances that trial of the treatment would be within the contract and considering its outcome would be a valid part of applying that policy.

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 ethics. 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 cost-effectiveness.

Annex 10

Interventions for which the intended outcome is to address directly the distress or disability associated with a diagnosed mental health condition, may be regarded as according with the principle of appropriateness. That

gives the CCG the freedom to commission psychiatric and psychological interventions for patients with a mental illness.
Potentially a person wishing to have an intervention that is not normally commissioned on grounds of appropriateness could claim that they are distressed / depressed / suffering problems with psychological wellbeing as a result of the condition or of the unavailability of funding. Therefore they would suggest that they were an exception to the policy in that the purpose of their intervention was to address the distress or disability associated with a diagnosed mental health condition.

Such claims could be interpreted in two ways, and each interpretation may be valid for some patients. However neither interpretation would support a claim of exceptionality. Those interpretations are:

- The patient has a mental illness (which may be the illness of depression, or may be some other mental illness). A mental illness is an abnormality of the mind. That abnormality may involve a structural problem or a chemical imbalance in the brain, or simply an anomaly in the way in which the mind is operating at that time. However, it is an illness in its own right, and is best managed by using psychiatric and psychological interventions to address the root of the problem. It is not usually best managed by addressing other features of the patient's life which may be the focus of the illness, but are not the primary cause of the mental illness. If such features are addressed, then the illness will remain and the focus of the mental illness may simply shift to another focus. For this reason, a mental illness is not usually regarded as a matter of exceptionality for a request for a non-mental health intervention.

- The patient's psychological symptoms are reactive to the physical problem or to the lack of funding availability. In that circumstance there is no mental illness. Such a reaction, even if referred to as depression, is simply a normal and indeed expected reaction to an undesired circumstance. It is therefore not a matter of exceptionality.

In any individual case, the CCG will consider a case for exceptionality based on expert clinical psychiatric advice that the provisions of this paragraph do not apply in the case of that particular patient.

Annex 11

Mandatory NICE guidance (Health Technology Assessment Appraisals) automatically becomes CCG policy and should be applied. Therefore no case for exceptionality should be based on the patient satisfying the criteria for treatment under mandatory NICE guidance.

Other NICE guidance, and other non-mandatory guidance are not CCG policy (unless explicitly adopted as such) and it remains a matter of discretion for the CCG to decide whether to adopt such guidance as policy. If such guidance is not adopted it has no force within the CCG and a case for exceptionality based on the patient satisfying such guidance is not valid.

Annex 12

Rarity does not itself form a case or part of a case for exceptionality. However circumstances leading to the granting of exceptionality may (or may not) be rare.