East Midlands Specialised Commissioning Group

Supplemental to *Defining the boundaries between NHS and Private Healthcare* (P005V2)

An explanation of the East Midlands Specialised Commissioning Groups approach to continuing funding treatment which was commenced on a private basis

1. Definitions

Private patients are patients who receive private healthcare.

Private healthcare means medical treatments or medical services which are not commissioned and funded by the NHS.

***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 ongoing treatment or complete the course of treatment.

NHS commissioned care is healthcare which is routinely funded by the patient's responsible primary care trust. The PCT will have policies which define the elements of healthcare which the PCT is and is not prepared to commission.

An exception is a patient that does not conform to a rule or generalisation. The grounds for being considered an exception will be different in different situations.

Exceptional clinical circumstances means the patient has a clinical picture that is significantly different to the general population of patients with that medical condition and, as a result of that difference, the patient is likely to derive greater benefit from the proposed treatment than might normally be expected for patients with that condition.

Cost effectiveness analysis is a method for measuring the benefits and effectiveness of a particular expenditure. Cost effectiveness analysis provides an examination of expenditure to determine whether the money spent could have been used more effectively and will include analysis of whether the resulting benefits could have been attained through less financial outlay.

An outlier is a clinical observation of the progress of a patient that lies outside the normal clinical picture for the patient subgroup of interest. The "normal" is usually defined to mean greater than two standard deviations from the average or mean outcome. 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. The fact that a patient is an outlier may be an indication of exceptionality.

2. Description

In deciding whether or not to fund a treatment the PCT 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 – known as the target group.

A cancer drug X is used as an illustration. Clinical trials suggest that on average Drug X extends life by 4 months although amongst the target group there will be a range of responses. The evidence suggests that out of every 100 patients treated most will not get any benefit at all from Drug X and some will get only a very small benefit. However there will be a minority that will get a few weeks and notably 3 patients can be expected to get one year's extension to life at a reasonable quality. It should be noted that in this example, the range of responses from patients from no response at all to one year's extension to life at a reasonable quality are all anticipated and can be considered to be within the range of normal reactions to the drug.

Having assessed the treatment, the PCT reaches the decision that Drug X does not provide cost-effective treatment and does not deliver value for money when used in the target group.

However, when assessing cost-effectiveness for the 3 patients getting much better outcomes (i.e. one year's extension to life at a reasonable quality), the treatment does present good value for money. A key question in this situation is whether these 3 patients can be identified in advance of treatment? If they can, then the option to treat the 3 patients would be prioritised against other competing needs and on this basis the treatment might well be funded.

All too often however it is not possible to identify the subgroup in advance. Under these circumstances, for the three patients to benefit all 100 patients would need to

be treated. If new evidence came to light which enables clinicians to identify those most likely to benefit the PCT would then seek to review the policy for this treatment with a view to considering whether there are grounds for changing its existing policy.

An option open to any PCT would be to fund all patients to a point where the 3 can be clearly identified. However this approach could only be justified if it delivered value for money. Whether it was value for money would be influenced by the cost of the treatment, the speed with which patients could be identified and the availability of a valid measure which reliably links response to the outcome.

A particular problem relating to outcome is the fact that proxy measures are frequently used in clinical trials and 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.

The effect of privately funded treatment.

When PCTs decide not to fund treatments, patients may choose to seek treatment in the private sector. Having then responded to treatment, it is not uncommon for the patient to stop funding themselves and seek funding from the NHS, on the basis that they are likely to be in the top end of responders (i.e. one of the 3 patients in the example above). The application is made on the basis that the treatment is of proved cost effectiveness for that individual patient.

What are the policy issues for the PCT to consider?

In order to approach this difficult issue, PCTs would usually ask themselves 3 questions:

1. Is this treatment routinely funded for patients in this individual patient's clinical situation?

2. If not, should the PCT adopt a policy variation to change its policy with regard to patients in this individual patient's clinical situation?

3. If the PCT's policy is not to be varied, should the patient be funded as an individual case?

Issue 1: The PCT has already considered issue 1. On the assumed basis that it cannot identify patients in advance who are likely to benefit from the treatment (i.e. the clinicians cannot identify the characteristics of the about 3 patients out of 100 who are likely to secure one year's extension to life at a reasonable quality), there is unlikely to be a case for the PCT to revisit the decision about the routine funding of the drug.

Issue 2: The patient is likely to argue that funding should be provided because the drug has proved to be clinically effective in his or her particular case. At first glance PCT may be tempted to vary its policy on providing drug X to allow it to be funded by the NHS where it has been proved to be clinically effective for an individual.

However, save where funding is provided for the initial stages by another NHS body (in which case see the PCT's separate policy on this issue), this approach would mean only allowing NHS funding to be made available to patients who can afford to

fund the early stages of the treatment themselves. It would thus involve making the NHS's willingness to provide treatment contingent on a prior private investment by the individual patient.

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

PCTs would therefore be acting entirely rationally (and thus lawfully) if they refuse to make a policy variation to provide drug X in either of the above circumstances.

Issue 3: If the PCT agreed that its policy was not to be varied, the case may come before an IFR panel. This panel will need to ask whether the patient should be funded as an individual case.

The policy of most PCTs is that, outside treatments that are routinely commissioned, individual treatments will only be approved in exceptional cases.

The IFR panel will therefore have to decide whether the facts of this case constitute "exceptional circumstances".

Whether a case, on its facts, does or does not represent exceptional circumstances depends on the precise individual facts of the case. However:

- On the assumed facts set out above, the response of one year's extension to life at a reasonable quality would appear to be well within the range of normal reactions to the drug and therefore it would be straining the meaning of the words to describe the clinical circumstances as exceptional.

- Properly analysed, the IFR committee ought to consider that the patient was a representative of the group of patients for whom drug X provided one year's extension to life at a reasonable quality. If the PCT made a decision not to change its policy to fund that group of patients, the IFR committee should consider themselves bound by that policy decision.

- Patients often make a case that funding should be provided based on their personal or social circumstances, taken in combination with their individual clinical circumstances. PCT IFR policies often provide that decisions should be made on clinical circumstances alone and that personal or social circumstances should not be taken into account in making IFR decisions. Thus unusual or even unique personal circumstances should not change the IFR decision.

What could amount to exceptional clinical circumstances: In order to be considered an exception in the above circumstances, a patient may have to demonstrate that his clinical circumstances meant he/she was properly considered to be an "outlier".

An *outlier* is a clinical observation 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 range of responses demonstrated by rest of the group. Alternatively their initial clinical presentation and/or natural history might be very different to the rest of the group, with a consequent difference in outcome. In order for an outlier to be identified it is necessary to characterize the patient subgroup of interest.

In this particular instance the issue of interest is whether or not the patient was an outlier in response to treatment. In order for this to be the case the patient's response would have to depart considerably from the upper range of 1 year's extension to life.

Even if the patient has demonstrated this the PCT will still need to prioritise the need against competing needs within the available resources.

3. References

- J Bowater, L Bridge and R Lilford The relationship between progression-free and post-progression survival in treating four types of metastatic cancer 2008 Cancer Letters , Vol. 262, No. 1, pp. 48-53.

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