

Appendix 4: Definitions and Examples of Clinical Exceptionality

Note: these definitions and examples are taken from the NHS England *Commissioning Policy: Individual Funding Requests*. They have been adopted within the Gloucestershire policy for consistency with the NHS England definitions to help clinicians, service users, and ICB team members to understand the concept of clinical exceptionality.

There can be no exhaustive description of the situations which are likely to come within the definition of exceptional clinical circumstances and the onus is on the requesting clinician to make a compelling case to the ICB. The following examples and definitions are provided for guidance only.

1. Clinical exceptionality: failure to respond to standard care

- 1.1. The fact that a patient has failed to respond to, or is unable to be provided with, all treatment options available for a particular condition (either because of a co-morbidity or because the patient cannot tolerate the side effects of the usual treatment) is unlikely, on its own, to be sufficient to demonstrate exceptional clinical circumstances. There are common comorbidities for many conditions. These considerations are likely to have been taken into account in formulating the general policy.
- 1.2. Many conditions are progressive and thus inevitably there will be a more severe form of the condition – the severity of a patient's condition does not in itself usually indicate exceptionality. Many treatments have side effects or contraindications, and thus intolerance or contraindication of treatment does not in itself, usually indicate exceptionality.
- 1.3. So, to support an IFR based on failure to respond to standard care, the IFR Panel would normally need to be satisfied that the patient's inability to respond to or be provided with, the usual treatment was a genuinely exceptional circumstance, which lies outside the natural history of the condition and is not characteristic of the relevant group of patients with the condition. For example:
 - If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients within the group for whom it is already known that the usual treatment is not available or is not clinically effective. The fact that this particular patient falls into that group is unlikely to be a proper ground on which to base a claim that they are exceptional as an individual.
 - As regards side effects, as an example, all patients who are treated with long-term high-dose steroids will develop side effects (typical and well-recognised) and thus develop these side effects and wish to be treated with something else does not make the patient exceptional.

- If the usual treatment cannot be given because of a pre-existing co-morbidity which is unrelated to the condition for which the treatment is being sought under the IFR or is not unusual in the relevant patient group or generally, the fact that the co-morbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional. As an illustration, some comorbidities are common in the general population, for example, diabetes which affects around 7% of adults, or asthma which affects at least 10% of the population. Diabetes and its treatments affect many other conditions; for example, steroids make glucose control more difficult. With any condition, there will be a recognised proportion who also have comorbidity which is common in the general population, and thus a patient cannot be exceptional by virtue of also having comorbidity which is common in the general population.

1.4. If the proposed intervention is thought to offer a benefit to patients in these groups generally (i.e. those with more severe disease or those with common co-morbidities), the question is whether there is sufficient justification, including consideration of factors such as clinical effectiveness of the treatment in question, likely value for money, priority and affordability, for making a change to the policy that covers the patient pathway. In this way, an improvement can be made to that policy to benefit the whole subgroup of patients of which the requesting patient is potentially just one such person. This change needs to be considered as service development and not as an IFR.

2. Clinical exceptionality: severity

2.1. Should severity be cited by the requesting clinician as part of the argument for exceptionality, the application should make clear:

- Whether there is evidence that the patient's presentation lies outside the normal spectrum for that condition. Preferably, a recognised scoring or classification system should be used to describe the patient's condition.
- Whether there is evidence that the patient has progressed to a very severe form of the condition much more rapidly than the range of progression that is documented and usually observed within the natural history of the condition.
- How the patient is expected to benefit from the treatment sought and in what quantifiable way.
- That there is evidence that the impact of the condition on this patient's health is significantly greater than its impact on the rest of the patient group, e.g. the condition is usually a mild disease but the presenting case is an extremely severe presentation; and
- That there is a plausible argument that the severity of the condition is prognostic of a good response to treatment.

3. Clinical exceptionality: genotypes

- 3.1. When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile), the IFR Panel will require evidence of the prevalence of the genotype in the patient group. The applicant will need to show how the specific genotype would make the patient a) different from others in terms of clinical management and b) able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.

4. Clinical exceptionality: multiple grounds

- 4.1. There may be cases where clinicians seek to rely on multiple factors to show that their patient's case is clinically exceptional. In such cases, each factor will be looked at individually to determine (a) whether the factor is capable, potentially, of making the case exceptional and (b) whether it does make the patient's case exceptional. One factor may be incapable of supporting a case of exceptionality (and should therefore be ignored), but it might be relevant to another factor. That is a judgment within the discretion of the IFR Panel.
- 4.2. If it is determined that none of the individual factors means that the patient's clinical circumstances are considered exceptional, the combined effect of those factors as a whole will be considered. In this way a decision can be reached on whether the patient's clinical circumstances are exceptional, bearing in mind the difference between the range of factors that can always be found between individuals and the definitions used here of exceptional clinical circumstances.

5. Clinical Exceptionality: non-clinical and social factors

- 5.1. The IFR process only considers clinical information. Although initially, it may seem reasonable to fund treatment based on reasons grounded in a moral or compassionate view of the case or because of the individual's situation, background, ambition in life, occupation or family circumstances, these reasons bring into play a judgement of 'worthiness' for treatment. As a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. Consideration of these nonclinical factors would introduce this concept of 'worth' into clinical decision-making. It is a core value that NHS care is available - or unavailable - equally to all. Whilst everyone's individual circumstances are, by definition, unique and, on compassionate grounds, reasons can always be advanced to support a case for funding, it is likely that the same or similar arguments could be made for all or any of the patients who cannot routinely access the care requested.
- 5.2. Non-clinical and social factors have to be disregarded for this purpose for the triage panel and then IFR Panel, to be confident of dealing fairly in comparable cases. If these factors were to be included in the decision-making process, the ICB would not know whether it is being fair to other patients who cannot access

such treatment and whose non-clinical and social factors would be the same or similar.

5.3. Consideration of social factors would also be contrary to ICB's policy of non-discrimination in the provision of medical treatment. If, for example, treatment were to be provided on the grounds that this would enable an individual to stay in paid work, this would potentially discriminate in favour of those working compared to those not working. These are value judgements that the triage panel and IFR Panel should not make.

5.4. Clinicians are asked to bear this Policy in mind and not to refer to social or non-clinical factors to seek to support the application for Exceptional Funding.