

BLACK Drugs Policy

The purpose of this brief is to provide GPs with an overview of how to deal with requests to prescribe a BLACK drug and dealing with patients already on treatment.

The [Derbyshire Joint Area Prescribing Committee](#) (JAPC) manages the entry of medicines and prescribable medical devices into the Derbyshire NHS geography, develops prescribing guidelines and approves locally agreed formularies. JAPC defines BLACK drugs according to the following criteria:

Criteria for classification

- 1) Are classified by the BNF as 'less suitable for prescribing', and includes anti-malarials (where a private prescription may be provided)
- 2) Have a lack of data on effectiveness compared with standard therapy
- 3) Have a lack of data on safety compared with standard therapy
- 4) Have known increase in risk of adverse events compared with standard therapy
- 5) Have a lack of data on cost-effectiveness compared with standard therapy
- 6) Less cost-effective than current standard therapy
- 7) Have NICE guidance that recommends they should not be used
- 8) Those that are deemed by national publications (e.g. by NHSE/NHS Clinical Commissioners) of limited value, unless agreed by local agreement.

Key Messages

- **New patients** requesting or being considered for a BLACK drug
 - Clinicians should submit an individual funding request (IFR) and await a positive outcome before initiating a BLACK drug.
- **Existing patients** already on a BLACK drug
 - Treatment should not be withdrawn abruptly from patients, but should be continued until the next clinical review where their NHS clinician will decide whether it is appropriate to either switch or stop treatment. Please contact Medicines Management Team for advice. If the clinician feels the patient is exceptional and wishes to continue the BLACK drug, then an IFR should be made.
- What is meant by '**exceptional clinical circumstances**'?
 - Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition AND likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition.
- How to make an **Individual Funding Request (IFR)**?
 - All requests must be made on a standard treatment request form which can be obtained electronically from DerbyshireCCG.IFRfundingrequest@nhs.net

New patients requesting or being considered for a BLACK drug

Clinicians should submit an IFR (see below for details), and await a positive outcome, before initiation of treatment for a BLACK medicine/treatment/medical device for NHS prescribing. Before considering an IFR clinicians should speak to the medicines management team for advice

Existing patients already on a BLACK drug

For patients that are already on the medicine/treatment/medical device prior to the BLACK classification, this should not be withdrawn abruptly from patients, but should be continued until the next clinical review where their NHS clinician will decide whether it is appropriate to switch or stop treatment.

The medicines management team can advise you why this decision was made and the process it followed. You should contact your practice facing pharmacist/ technician. They may also be able to advise you on recommending suitable formulary alternatives.

The IFR process

The IFR process is used to consider individual requests for funding where a service, intervention or treatment falls outside existing local service agreements. The IFR process will ensure that each request for individual funding is considered in a fair and transparent way. The IFR panel will conclude whether the patient has 'exceptional' clinical circumstances or not. Further information is available in the [IFR policy](#).

What is meant by 'exceptional clinical circumstances'?

The CCG cannot fund requests that should be fairly applied to other patients who have similar clinical circumstances and who should rightly also be offered the treatment if the patient was to be approved. This would require the CCG to agree a new commissioning policy (or amend an existing one) setting out that the treatment is now available for a new group of patients and how this group had been identified. Therefore, to meet the definition of 'exceptional clinical circumstances' you must demonstrate that your patient is both:

- Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition e.g. metastatic bowel cancer not just bowel cancer

AND

- Likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition

In other words, you must show that your patient is very different from others in a group of patients with the same condition/stage of the disease and have clinical features that mean that they will derive much more benefit from the treatment you are requesting.

What to consider before submitting an IFR

If you think that a patient is 'exceptional' and it is clinically appropriate for them to continue treatment indefinitely then you should submit a request to the IFR panel. The Q & A in appendix 1 will help support you understand the principles of what defines exceptionality and the criteria the IFR team will use in its decision making process.

Very few patients have clinical circumstances which are genuinely exceptional. To justify funding for treatment, the consideration is whether it is fair to fund this patient's treatment when the treatment is not available to others.

How do I make an Individual Funding Request (IFR)?

All requests must be made on a standard treatment request form which can be obtained electronically from DerbyshireCCG.IFRfundingrequest@nhs.net. It is the responsibility of the referring clinician to ensure that the form is completed accurately by seeking specialist information from other clinicians as required. The form aims to ensure that all the necessary information is obtained so it is important that it is completed comprehensively and accurately, along with any relevant research papers, by the referring clinician to avoid delays in reaching a decision. All forms must be typed and any handwritten forms will be returned.

The form can either be returned electronically to the email address above or by post to:

Toll Bar House, 2 Derby Road, Ilkeston, Derbyshire, DE7 5FH

How can I get advice on what to include when completing a treatment request form?

You can phone Helen Moss 015 931 6127 or e-mail the IFR Team for advice on whether to submit a treatment request form and what to include.

How will I be informed of the decision?

You will receive a letter informing you of the decision of the screening of your request within 20 working days of receipt of your treatment request form. If your request is being taken to the IFR Panel, you will be informed of the date of the panel, usually within a further 20 working days, and will receive a letter outlining the decision of the panel within 5 working days after the panel meeting.

Appendix 1

What can I do if my patient has failed to respond to all treatment options due to co-morbidity or cannot tolerate the side effects?

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.

My patient has a more severe form of the condition. Is this exceptional?

Many conditions are progressive and thus inevitably there will be a more severe form of the condition. Severity of a patient's condition does not in itself usually indicate exceptionality.

My patient has failed on previous conventional treatment. What can I do?

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.

Does the IFR process consider non-clinical factors?

The IFR process only considers clinical information. Although 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. 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 many of the patients who cannot routinely access the care requested.

Does the IFR process consider social factors?

Non-clinical and social factors have to be disregarded for this purpose in order for the IFR screening groups and then IFR Panel, to be confident of dealing in a fair manner in comparable cases.

What can I do if my patient cannot be given the usual treatment due to a pre-existing co-morbidity which is unrelated to the condition?

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.

My patient was having private treatment but is now reverting to NHS funded treatment. What can I do?

Requests to Continue Funding of Care Commenced privately e.g. reverting to NHS care patients who are having private treatment have a right to revert to NHS funded treatment at any point during their care. However, if they wish to exercise this right, the Derbyshire CCGs will expect their care to be transferred to local pathways.

What can I do if my patient has moved in the area and is currently undergoing treatment that has been previously approved by another CCG?

Occasionally patients move into the area and become the responsibility of a local CCG when a package of care or treatment option has already been approved by the CCG that was previously responsible for the patient's care. The Derbyshire CCGs policy states that continued prescribing of the black drug will be assessed at the next clinical review and either stopped or switched as appropriate.

What can I do if I think a proposed intervention will benefit a group of patients?

If the proposed intervention is thought to offer a benefit to a specific group of patients (i.e. those with more severe disease or those with common co-morbidities), this change is not an IFR. Clinicians may submit a query, or request a review of the traffic light status of the drug, to the Derbyshire Joint Area Prescribing Committee at sderccg.derbyshiremedicinesmanagement@nhs.net.

Further information is available in the IFR policy.

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