Midlands and Lancashire Commissioning Support Unit

NHS Halton Clinical Commissioning Group
NHS Knowsley Clinical Commissioning Group
NHS Liverpool Clinical Commissioning Group
NHS St Helens Clinical Commissioning Group
NHS South Sefton Clinical Commissioning Group
NHS Southport and Formby Clinical Commissioning Group
NHS Warrington Clinical Commissioning Group

Collaborative Policy Development Project: Governing Body paper seeking sign off of all policies reviewed to date, ahead of implementation with Providers

Appendix 4

Revised Introduction to the PLCP policy

December 2017

Introduction

Purpose and scope

CCGs are legally obliged to have in place and publish arrangements for making decisions and adopting policies on how particular healthcare interventions are to be accessed. This document is intended to be a statement of such arrangements made by the CCGs and will act as a guidance document for patients, clinicians and other referrers in primary and secondary care. It sets out the eligibility criteria under which CCGs will commission the service.

The purpose of this policy is to describe the eligibility criteria under which the CCGs listed below will commission treatments or interventions classified as 'Criteria Based Clinical Treatments' (CBCT). The term Criteria Based Clinical Treatments, refers to procedures and treatments that are of value, but only in the right clinical circumstances. Previously, they were referred to as Procedures of Low Clinical Priority (PLCP).

In making these arrangements, the CCGs have given regard to relevant legislation and NHS guidance, including their duties under the National Health Service Act 2006, the Health and Social Care Act 2012, Equality legislation – duties discharged under the Public Sector Equality Duty 2011, the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, the Joint Strategic Needs Assessment, relevant guidance issued by NHS England and the NHS Constitution.

Context

CCGs have been established under the National Health Service Act 2006 as the statutory bodies charged with the function of commissioning healthcare for patients for whom they are statutorily responsible. CCGs receive a fixed resource allocation from NHS England to enable them to fulfil their duties and have to decide how and where to allocate resources to best meet the healthcare needs of their population.

It is evident that the need and demand for healthcare is greater than the resources available to a society to meet it. Therefore, it will not be possible for CCGs to commission all the healthcare needs of the population they serve. As a result, CCGs need to prioritise their commissioning intentions to ensure their limited resources are allocated effectively and based on the needs of the local population.

The CCGs intention is always to ensure access to NHS resources is equal and fair, whilst considering the needs of the overall population.

Using the CBCT policies as presented in this document, the CCGs can prioritise their resources using evidence based information that determines what is clinically effective and therefore cost effective and likely to provide the greatest proven health gain for the whole of the CCG's population.

The main objective for having CBCT policies is to ensure that:

- Patients receive appropriate health treatments in the right place and at the right time;
- Treatments with no or a very limited clinical evidence base are not routinely undertaken; and
- Treatments with minimal health gain are restricted.

This also means that certain procedures will not be commissioned by CCGs unless patients meet all the criteria set out in relation to a procedure or treatment; or exceptional clinical circumstances can be demonstrated.

CCGs recognise there may be exceptional clinical circumstances where it may be clinically effective to fund any of the procedures listed in this policy for individual patients. Either where:

- The clinical threshold criteria as specified by this policy is not met; or
- The procedure is not routinely commissioned;

In accordance with each CCG's Individual Funding Request (IFR) process, the patient's circumstances as clinically evidenced in an application made by the patient's clinician will be considered on a case-by-case basis. This position is supported by each CCG's Ethical Framework which can be found on the respective CCG website.

Background

The following CCGs have worked collaboratively to develop this harmonised core set of commissioning criteria:

- Halton CCG;
- Knowsley CCG;
- Liverpool CCG;
- St Helens CCG;
- South Sefton CCG;
- Southport and Formby CCG;
- Warrington CCG;

This policy aims to improve consistency by bringing together one common set of criteria for treatments and procedures across the Merseyside and Warrington CCG footprints. This will help to reduce variation of access to NHS services in different areas (which is sometimes called 'postcode lottery' in the media) and allow fair and equitable treatment for all local patients.

Principles

Commissioning decisions by CCG Commissioners are made in accordance with the commissioning principles set out as follows:

- CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
- CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
- The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
- CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
- CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community;
- CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
- Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered;

- Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

Core eligibility criteria

However, there are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed within this policy, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment;
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2 week rule;
  NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England;
- Reconstructive surgery post cancer or trauma including burns;
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures;
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis;
- For patients wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the *Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14*.

Policy Categories

Each procedure/treatment is categorised as either 'not routinely funded' or 'restricted' and these are defined as follows:

- **Not routinely funded (NRF)** – This means the CCG does not routinely commission the treatment and will only commission this treatment for an individual patient where an IFR application in line with the CCG's IFR process, demonstrates clinical exceptionality;

- **Restricted –** This means the CCG will commission the treatment where the patient meets the specific criteria as set out within this Commissioning Policy. Where a patient does not meet the specific criteria specified the CCG will only commission this treatment for an individual patient where an IFR application in line with the CCG's IFR process, demonstrates clinical exceptionality;

Diagnostic Procedures

Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should **not** be carried out unless the eligibility criteria are met or approval has been given by the CCG or GP (as set out in the approval process of the patients responsible CCG) or as agreed by the IFR Panel as a clinically exceptional case.

Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

Psychological factors

Psychological distress alone will not be accepted as a reason to fund surgery. Only very rarely is surgical intervention likely to be the most appropriate and effective means of alleviating disproportionate psychological distress. In these cases ideally an NHS psychologist with expertise in body image or an NHS Mental Health Professional (depending on locally available services) should detail all treatment(s) previously used to alleviate/improve the patient's psychological wellbeing, their duration and impact. The clinician should also provide evidence to assure the IFR Panel that a patient who has focused their psychological distress on some particular aspect of their appearance is at minimal risk of having their coping mechanism removed by inappropriate surgical intervention.

Psychological assessment and intervention may be appropriate for patients with severe psychological distress in respect of their body image but it should not be regarded as a route into aesthetic surgery. Any application citing psychological distress will need to be considered as an IFR .

Lifestyle and surgery

Lifestyle factors can have an impact on the functional results of some elective surgery. In particular, smoking is well known to affect the outcomes of some foot and ankle procedures. In addition, many studies have shown that the rates of postoperative complications and length of stay are higher in patients who are overweight or who smoke. Therefore, to ensure optimal outcomes, all patients who smoke or have a body mass index of 35 or greater and are being considered for referral to secondary care, should be able to access CCG and Local Authority Public Health commissioned smoking cessation and weight reduction management services prior to surgery.

Patient engagement with these "preventive services" may influence the immediate outcome of surgery. While failure to quit smoking or lose weight will not be a contraindication for surgery, GPs and Surgeons should ensure patients are fully informed of the risks associated with the procedure in the context of their lifestyle.

CBCT Referral/Treatment Listing Processes

Primary Care

Referrals for treatment should **not** be made unless the patient clearly meets the criteria as this can raise unrealistic expectations for the patient and lead to disappointment. If a General Practitioner/Optometrist/Dentist considers a patient might reasonably fulfil the eligibility criteria for a restricted procedure, as detailed in this document (i.e. they meet the specific criteria listed for each treatment) the General Practitioner/Optometrist/Dentist should follow the process for referral. NB. This may be via a referral management or prior approval team.

If in doubt over the local process, the referring clinician should contact the relevant CCG, IFR Team or Referral Management Team for guidance. Failure to comply with the local process may delay a decision being made.

Any referral letter should include specific information regarding the patient's potential eligibility. If the referral letter does not clearly outline how the patient meets the criteria, then the letter should be returned to the referrer for more information.

In cases where there may be an element of doubt the General Practitioner/Optometrist/Dentist should discuss the case with the IFR Team in the first instance.

Secondary Care

The secondary care consultant will also determine whether the procedure is clinically appropriate for a patient and whether the eligibility criteria for the procedure are fulfilled or not. The consultant may also request additional information before seeing the patient.

If a secondary care consultant considers a patient might reasonably fulfil the eligibility criteria for a restricted procedure, as detailed in this document (i.e. they meet the specific criteria listed for each treatment) the consultant should follow the listing process for treatment. NB. For some CCGs this will involve following a process of prior approval. If in doubt over the CCG requirements, the consultant should contact the relevant CCG or the IFR Team for guidance. Failure to comply with the CCGs' processes may delay a patient's treatment and/or release of funding resources.

Patients who fulfil the criteria may then be placed on a waiting list according to their clinical need. The patient's notes should clearly reflect exactly how the criteria were fulfilled including prior approval authorisation where relevant. This will allow for case note audit to support contract management.

Should the patient not meet the eligibility criteria this should be recorded in the patient's notes and the consultant should return the referral back to the General Practitioner/Optometrist/Dentist, explaining why the patient is not eligible for treatment.

IFR Applications/Clinical Exceptionality

Exceptionality is where a patient does not meet all of the criteria outlined for a specific procedure or treatment or, the procedure or treatment is not routinely commissioned.

In this scenario, should a patient not fulfil the clinical criteria but the referring clinician is willing to support the application as clinically exceptional, the case can be referred to the IFR Panel for consideration. The person who fills in the IFR can be a consultant or a GP.

In dealing with clinically exceptional requests for an intervention that is considered to be a poor use of NHS resources, the Merseyside CCGs have endorsed through the CCG Alliance the following description of exceptionality contained in a paper by the NW Medicines and Treatment Group:

- The patient has a clinical picture that is significantly different to the general population of patients with that condition; **and** as a result of that difference; the patient is likely to derive greater benefit from the intervention than might normally be expected for patients with that condition.

The CCGs are of the opinion that exceptionality should be defined solely in clinical terms. To consider social and other non-clinical factors automatically introduces inequality, implying that some patients have a higher intrinsic social worth than others with the same condition. It runs contrary to a basic tenet of the NHS, namely that people with equal need should be treated equally. Therefore, non-clinical factors will not be considered except where this policy explicitly provides otherwise.

The CCG must justify the grounds upon which it is choosing to fund treatment for a particular patient when the treatment is unavailable to others with the condition.

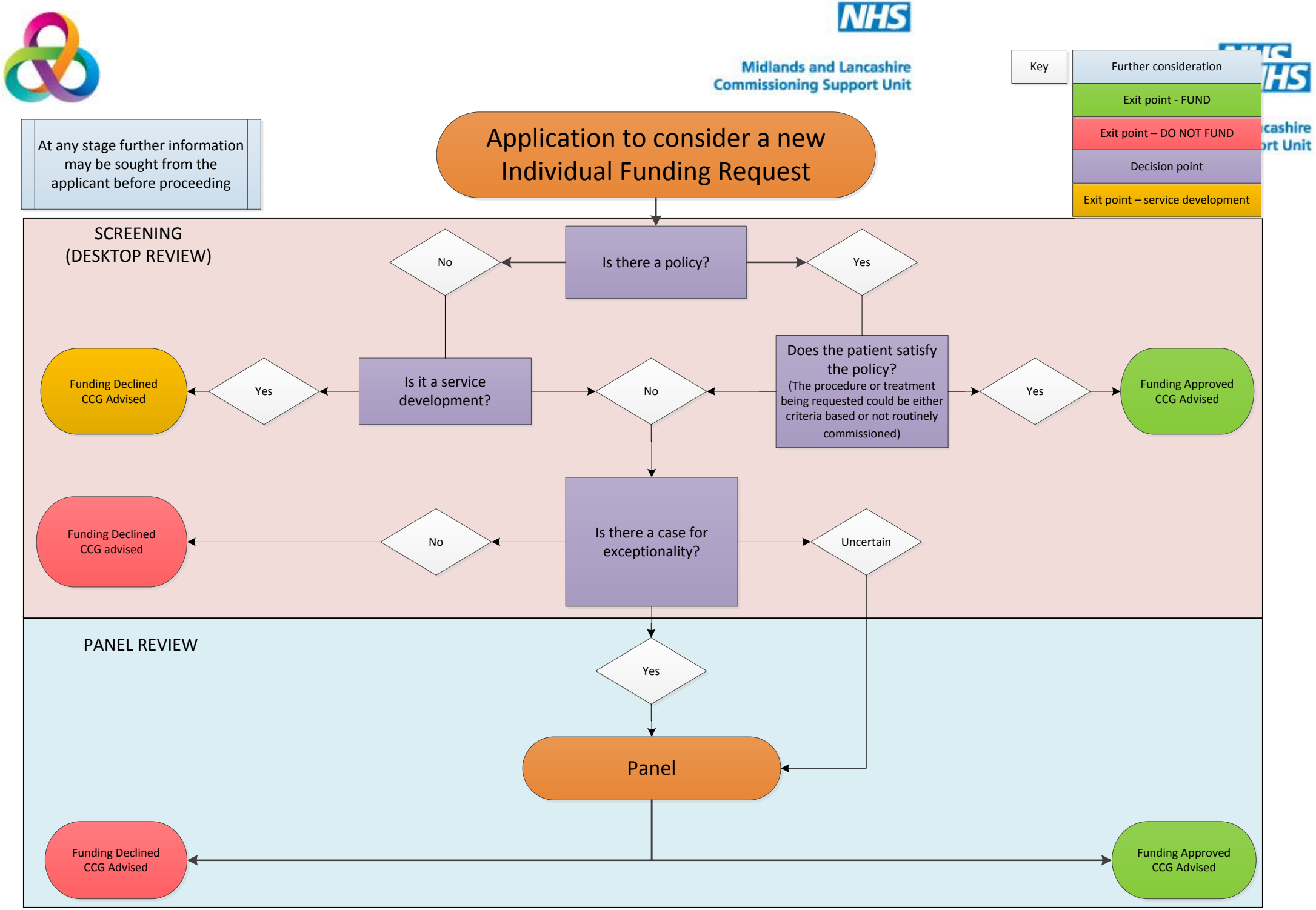
Individual Funding Requests should only be sent to the respective NHS.net accounts as below. Guidance regarding IFRs and an application form, can be found on the CCGs websites.

IFR contact information follows, however please refer to the CCG IFR policy for more information:

Individual Funding Request Case Manager
Midlands and Lancashire Commissioning Support Unit (MLCSU)
1829 Building
Countess of Chester Health Park
Liverpool Road
Chester
CH2 1HJ
Telephone: 01244 650 305

Email addresses for Individual Funding Request teams at CCGs:

CCG	Email Address
Halton CCG	IFR.manager@nhs.net
Knowsley CCG	
Liverpool CCG	
South Sefton CCG	
Southport & Formby CCG	
St Helens CCG	
Warrington CCG	Warringtonccg.IFR@nhs.net


Midlands and Lancashire Commissioning Support Unit
Key
Further consideration
Exit point - FUND
Exit point – DO NOT FUND
Decision point
Exit point – service development
At any stage further information may be sought from the applicant before proceeding
Application to consider a new Individual Funding Request
SCREENING (DESKTOP REVIEW)
Is there a policy?
No
Yes
Is it a service development?
Yes
Funding Declined CCG Advised
No
Does the patient satisfy the policy?
(The procedure or treatment being requested could be either criteria based or not routinely commissioned)
Yes
Funding Approved CCG Advised
Is there a case for exceptionality?
No
Funding Declined CCG advised
Uncertain
PANEL REVIEW
Yes
Panel
Funding Declined CCG Advised
Funding Approved CCG Advised

Medicines

Prior approval for treatment should always be sought from the responsible Medicine Management Team when using medicines as follows:

- Any new PbR excluded drug where the drug has not yet been approved/prioritised for use in agreement with the local CCG;
- Any existing PbR excluded drugs to be used outside of previously agreed clinical pathways/indication;
- Any PbR excluded drugs that are being used out with the parameters set by NICE both in terms of disease scores or drug use. It must not be assumed that a new drug in the same class as one already approved by NICE can be used, this must be subject to the process in Point 1;
- Any drug used out with NICE Guidance (where guidance is in existence);
- Any proposed new drug/new use of an existing drug (whether covered by NICE or PBR excluded or not) should first be approved by the relevant Area Medicines Management Committee, and funding (where needed) agreed in advance of its use by the relevant CCG;
- Any medicines that are classed by the CCG as being of limited clinical value;
- Any medicines that will be supplied via a homecare company agreement;

Clinical Trials

The CCGs do not expect to provide funding for patients to continue treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

Photographic evidence

Photographic evidence may be required in cases which are being considered for clinical exceptionality in line with the IFR processes. However, photographic evidence will not be accepted for consideration unless it is impossible to make the case in any other way.

The decision to submit photographic evidence remains with the patient and responsible clinician and must meet the CCGs criteria for submission as outlined by the CCGs IFR Policy.

If photographs are accepted for consideration in accordance with the CCGs criteria, they will be examined by clinical members of the IFR team. In the course of the work for the case the applicant should be aware that other members of the IFR Panel, IFR Process Reviews Panel or IFR team who prepare the papers may need to handle or see the photographs.

Personal data

In making referrals to the IFR Team, clinicians and other referrers in primary and secondary care should bear in mind their obligations under the Data Protection Act 1998 and their duty of confidence to patients. Where information about patients (including photographs) is sent to the IFR Team and is lost or inadvertently disclosed to a third party before it is safely received by the IFR Team, the referrer will be legally responsible for any breach of the Data Protection Act 1998 or the law of confidence.

Therefore, please consider taking the following precautions when using the Royal Mail to forward any information about patients including photographic evidence:

Clearly label the envelope to a named individual i.e. first name & surname, and job title.

Where your contact details are not on the items sent, include a compliment slip indicating the sender and their contact details in the event of damage to the envelope or package.

Use the Royal Mail Signed for 1st Class service, rather than the ordinary mail, to reduce the risk of the post going to the wrong place or getting lost.

Costs incurred will be the responsibility of the referrer, this includes photographic evidence.

OPCS Codes

OPCS codes have been recorded against procedures and treatments where possible, however these lists are not exhaustive and providers will have to satisfy themselves that procedures are coded correctly.

Copies of this policy

Electronic copies of this policy can be found on the websites of the respective CCGs. Alternatively; you may contact the CCG and ask for a copy of the Criteria Based Clinical Treatments 2017-18 policy document.

Monitoring and review

This policy will be subject to continued monitoring using a mix of the following approaches:

- Prior approval process;
- Post activity monitoring through routine data;
- Post activity monitoring through case note audits;

This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding clinical and cost effectiveness.

From time to time, CCGs may need to make commissioning decisions that may suspend some treatments/criteria currently specified within this policy.

Evidence

At the time of publication the evidence presented per procedure/treatment was the most current available. Where reference is made to older publications these still represents the most up to date view.