

# INDIVIDUAL CASES POLICY

(INDIVIDUAL ELECTIVE REFERRALS FOR CARE NOT ROUTINELY  
COMMISSIONED OR PROVIDED)

<b>Author/s</b>	Director of Commissioning Assistant Director Scheduled Care
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## DOCUMENT CONTROL SUMMARY

<b>Title</b>	<b>INDIVIDUAL CASES POLICY  (INDIVIDUAL ELECTIVE REFERRALS FOR CARE NOT ROUTINELY COMMISSIONED OR PROVIDED)</b>
<b>Lead Director</b>	Director of Commissioning
<b>Purpose of document</b>	Buckinghamshire PCT (The PCT) recognises that there may be individual cases where a patient's needs cannot be met through existing commissioned care pathways. The PCT has set up an Individual Case Panel (ICP) to consider the circumstances of individuals for whom a referral outside existing pathways may be appropriate. In considering individual cases, the ICP will apply the Ethical and Commissioning Principles. This document sets out the policy framework within which the ICP operates.
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# INDIVIDUAL CASES POLICY

## (INDIVIDUAL ELECTIVE REFERRALS FOR CARE NOT ROUTINELY COMMISSIONED OR PROVIDED)

### Policy statement

1. Buckinghamshire PCT (The PCT) recognises that there may be individual cases where a patient's needs cannot be met through existing commissioned care pathways.
2. The PCT has set up an Individual Case Panel to consider the circumstances of individuals for whom a referral outside existing pathways may be appropriate. In considering individual cases, the Panel will apply the Ethical and Commissioning Principles.
3. The Individual Case Panel will not make commissioning policy on behalf of the PCT. Consideration by an Individual Case Panel will always start from the overall policy position (whether or not the intervention has been prioritised through the Commissioning Plan) and will seek to determine exceptionality on that basis.
4. The PCT aims to commission and provide high quality clinical care from the resources available to which access is available to all our population, equitably and consistently, based solely on clinical need. We believe that the best way to achieve this is by commissioning clear pathways of care which span the interfaces between primary and secondary care (and tertiary when required) and are supported by shared clinical protocols and arrangements for audit and outcome evaluation. The PCT pursues this approach to commissioning in line with current government policy<sup>1</sup> and aims to develop a comprehensive range of care pathways, linked to a variety of care providers, to which our population will have consistent and equitable access based on clinical need.
5. The mechanism through which investment and disinvestments decisions are taken is the Commissioning Plan process. The PCT will not expect to make decisions outside this process and in particular will not expect to commit new resources in year to the introduction of new healthcare technologies (including new drugs, surgical procedures, public health programmes) since to do so risks ad hoc decision making and can destabilise previously identified priorities.

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<sup>1</sup> Commissioning a Patient-Led NHS; available at:  
[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4116716&chk=%2Bb2QD](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4116716&chk=%2Bb2QD)

## **1 DETERMINATION OF 'EXCEPTIONALITY'**

There is no complete definition of the conditions which are likely to come within the definition of exceptionalism. However, in order for individual funding to be agreed there must be some unusual or unique clinical factor about the patient that suggests that they are:

- Significantly different to the general population of patients with the same condition in question
- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the same condition

**1.2** The fact that a treatment is likely to be efficacious for a patient is not, in itself, a basis for an exemption. If a patient's clinical condition matches the 'accepted indications' for a treatment that is not funded, their circumstances are not, by definition, exceptional. It is for the requesting clinician (can be accompanied by information from a patient) to make the case for exceptional status. Social value judgments are rarely relevant to the consideration of exceptional status.

**1.3** The Individual Case Panel will not usually make a decision to fund a patient where by so doing a precedent would be set that establishes new policy (because the patient is not, in fact, exceptional, but representative of a group of patients); however, if a drug is proposed before a policy decision has been reached by the PCT, this can be considered by the ICP pending a policy being agreed.

**1.4** In cases where the Individual Case Panel feels strong evidence has been provided in support of a particular health technology, it should make a recommendation to the PEC & Commissioning Board (PEC&CB) for further consideration by the Priorities Forum/Commissioning Plan process, but individual funding of the specific case must be refused.

## **2 PATIENT PATHWAYS**

### **2.1 Acute Referrals**

**2.1.1** The PCT's preferred providers for acute care are detailed on the PCT "Choose and Book" and can be accessed via the patients' General Practitioner. In addition the PCT holds a portfolio of acute service level agreements with providers across South Central and across the rest of the UK for a full range of services, should an alternative provider or a second opinion be required.

**2.1.2** Guidance on alternative referrals currently covered by SLAs can be obtained from the Commissioning Department. The provision of a referral for a second opinion is, as the term implies, for an opinion as to the appropriateness of future treatment options. It does not imply that the PCT will necessarily commission the treatment option recommended if this is outside of pathways of care that are normally commissioned by the PCT.

**2.1.3** Patients requiring elective referral will be offered a choice of commissioned provider in line with the Choose and Book requirements at the point of referral.

Where the referral required is of a specialist nature for which there are capacity issues or where the patient has particular needs it may be appropriate to offer a restricted choice<sup>2</sup>. The provision of choice is to allow patients the opportunity to choose the provider of the service that is to be provided. It does not entitle the patient to choose any form of treatment outside of the care pathways which are normally commissioned by the PCT.

## **2.2 Mental Health/ Continuing Care Referrals**

**2.2.1** These should be made in line with the service level agreements that exist for these services. A list of service level agreements can be obtained from the Commissioning department.

**2.2.2** Referrals using these pathways can be made from primary care or secondary care if appropriate. The PCT believes that these pathways will meet the vast majority of care needs for their populations in line with the PCT's Ethical and Commissioning Principles.

**2.2.3** Any proposed referrals outside these pathways will first need to be agreed for funding by Buckinghamshire PCT before the referral can be made.

## **3. GUIDANCE USED BY THE ICP**

**3.1** In considering individual cases, the ICP will apply the Ethical and Commissioning Principles and the following guidance expanding upon it. A flow chart demonstrating the process is attached to this policy (**Appendix 2**).

### **3.2 Introduction of new drugs and technologies**

**3.2.1** The PCT does not expect to introduce new drugs/technologies in an adhoc basis through the mechanism of individual case funding. To do so risks inequity, since the treatment will not be offered openly and equally to all with equal clinical need. The PCT expects consideration of new drugs/technologies to take place within the established planning frameworks of the NHS (i.e. the Commissioning Plan process) after consideration by the appropriate committees i.e., PEC Commissioning Board, the Buckinghamshire Area Prescribing Committee and the Buckinghamshire and Milton Keynes Priorities Forum. This will enable clear prioritisation against other calls for funding and the development of implementation plans which will allow access for all patients with equal clinical need.

**3.2.2** There are high cost interventions which the PCT is required to consider from time to time. The PCT will broadly follow the QALY/ICER system recommended by NICE for valuing the clinical and cost effectiveness of interventions but, in adopting commissioning policies for particular interventions. It reserves the right to deviate from the NICE strict financial limits where there are compelling reasons to do so. However the PCT does not

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<sup>2</sup> "Choose & Book" – Patients' Choice of Hospital and Booked Appointments. Policy Framework for Choice and Booking at Point of Referral. DH, London, August 2004.  
[www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance).

accept that additional NHS investment is necessarily justified solely because a medical condition is rare.

### **3.3 NICE New Technology Appraisals**

- 3.3.1** Drugs and technologies that are approved as the result of a NICE technology appraisal need to be implemented within 3 months of the appraisal being published. The PCT will seek to ensure implementation of NICE technology appraisals only, without delay but recognises that delays may be inevitable where significant service change and/or development are required as part of the implementation. NICE also produces clinical guidelines, which are a valuable source of good practice, but the health service is not required to statutorily implement them in the same manner as applies to the technology appraisal guidance. Neither is the PCT statutorily required to fund NICE Interventional Procedure Guidance (IPG)

### **3.4 Treatments covered by PCT commissioning policies**

- 3.4.1** Treatments not currently included in established pathways or identified for funding through the Commissioning Plan process are not routinely funded. For a number of these interventions the PCT has published specific policy statements setting out restrictions on access based on evidence of effectiveness, cost effectiveness or relative priority for funding.

For cases coming through the Prior Approval Process, details can be accessed on the PCT website at:

<http://www.miltonkeynes.nhs.uk/default.asp?ContentID=548>

or by contacting the ICRP secretary. A flow chart demonstrating the process is attached to the this policy (**Appendix 3**)

- 3.4.2** Policy development is an ongoing process and future policy on further treatments, in response to NICE Guidance/Guidelines, health technology assessments, etc. will be produced by the PEC & Commissioning Board for local implementation. Decisions taken by the Buckinghamshire and Milton Keynes Priorities Forum and the Buckinghamshire Area Prescribing Committee will actively feed into the decision-making process of the PCB.

- 3.4.3** Clinicians uncertain about the status of a particular treatment should contact the PCT Commissioning Department for advice.

### **3.5 Treatments not covered by the PCT commissioning policies**

- 3.5.1** Patients with rare conditions and/or patients for whom first or second line treatments are inappropriate for some reason may not have potential treatment options that are covered by NICE or by local commissioning policies. In such circumstances the case that is being made by the treating clinician should be judged against the Ethical and Commissioning Principles in the Ethical Framework document.

- 3.5.2** It is important that decisions on individual cases are not used as a means of “creeping implementation” for new technologies, Consideration therefore needs

to be given as to the likelihood of other patients having the same clinical need and this would create a precedent for groups of patients. Such situations should be considered by the PEC Commissioning Board.

**3.5.3** Patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon.

### **3.6 Requests to continue funding for patients entering into or coming off drugs trials**

**3.6.1** The PCT does not expect to fund patients entering clinical trials unless prior approval for funding individual patients in such trials has been obtained from the PCT. In approving the funding of individual patients for clinical trials, the PCT will also make it absolutely clear what particular elements of the trial that it will be willing to fund.

**3.6.2** The PCT does not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines Act 2004<sup>3</sup> and the Declaration of Helsinki<sup>4</sup>, the responsibility for ensuring a clear exit strategy from a trial AND ensuring that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. The initiators of the trial (provider trusts and drug companies) have a moral obligation to continue funding patients benefiting from treatment until such time as the PCT agrees to fund through the Commissioning Plan process. Where the treatment is not prioritised through the Commissioning Plan, the responsibility remains with the trial initiators indefinitely.

### **3.7 Requests to continue funding of care commenced privately**

**3.7.1** Patients have a right to revert to NHS funding at any point during their care for conditions that would normally be funded under the NHS. However, if they wish to exercise this right, the PCT will expect their care to be transferred to local pathways. Funding for the individual to continue care in a private facility, or to transfer to an NHS provider with which a clinician consulted privately has a link, will not routinely be authorised. Where exceptional circumstances may make such funding appropriate, the case will require consideration by the Individual Case Panel.

### **3.8 Request to pay for additional private care**

Patient may pay for additional private healthcare while continuing to receive care from the NHS. The PCT cannot subsidise private care with public money. This would be a breach of core NHS principles. A patient cannot pay for additional private care if the NHS element of care and the private element of care cannot be delivered separately. Guidance can be found at

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_096428](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_096428)

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<sup>3</sup> <http://www.legislation.hmso.gov.uk/si/si2004/20041031.htm>

<sup>4</sup> <http://www.wma.net/e/policy/b3.htm>

### **3.9 Requests for referral to a specialist provider (tertiary, regional or supra-regional centre or specialist private provider)**

**3.9.1** The majority of referrals to specialist centres are made by secondary care consultants. The PCT expects consultants to refer patients for tertiary/specialist care using established pathways covered by Service Level Agreements. Accordingly, requests for referrals to specialist providers outside existing pathways will need to be considered first by the PCT after assessment by appropriate specialists within the existing pathway.

Should a consultant feel that a referral outside existing pathways is a priority for a particular patient, the consultant should ask for the case to be considered by the Individual Case Panel. The consultant should not refer the patient to another provider without first getting the approval of the PCT.

The PCT will decline to fund any patient referred to another provider outside existing pathway without first getting the funding approval from the PCT.

### **3.10 Decisions inherited from other Primary Care Trusts**

**3.10.1** Occasionally patients move in to the area and become the responsibility of Buckinghamshire PCT when a package of care or treatment option has already been started by another PCT that was previously responsible for the patient's care. Buckinghamshire PCT will normally honour such decisions providing the care pathway has already been initiated and the PCT is satisfied that the treatment is appropriate and is in the best interest of the patient. Where policies exist, the PCT is expected to fund in line with criteria.

### **3.11 Request for funding for treatment abroad**

Buckinghamshire PCT will not routinely fund treatment outside the UK, in recognition that:

- It is more difficult to ensure equivalent clinical standards, patient safety and performance requirements in treatment facilities falling outside of direct UK Government jurisdiction
- It is more difficult to ensure effective patient care and follow on care with treatment facilities with whom the PCT does not have an established contractual or clinical relationship
- There may be additional treatment or patient/carer travel costs which might fall to the PCT, and which would generally be better used to fund direct patient care for the wider group of patients for whom the PCT has funding responsibility
- There may be additional transactional costs associated with putting in place small scale contractual arrangements with non-UK based treatment facilities, and these costs would generally be better used to fund direct

patient care for the wider group of patients for whom the PCT has funding responsibility

Applications for funding for treatment within an EEA country (or Switzerland) may be considered by the PCT in accordance with current Department of Health's Guidance (see [www.dh.gov.uk](http://www.dh.gov.uk) for more details) where:

- A particular treatment is clinically justified, cost effective and would otherwise be routinely funded by Buckinghamshire PCT but where treatment in the UK could not be provided without an "undue delay".

In determining whether there might be an undue delay, the PCT will have regard to the patient's estimated treatment time within the NHS, an objective assessment of the patient's clinical circumstances and treatment needs (and if appropriate other, non-clinical circumstances), the probable course of the patient's illness, the history of the patient's illness and, if appropriate, the level of pain or disability the patient is experiencing.

and/or

- Where a particular treatment is clinically justified, cost effective and would otherwise be routinely funded by the PCT, and there is clinical consensus (usually from local NHS consultants) that due to the patient's specific clinical circumstances, sufficient clinical expertise to provide the intervention concerned would only be available outside the UK.

Buckinghamshire PCT will not normally provide funding other than where prior approval has been sought, and confirmed, by the PCT and, where relevant, the Department of Health ahead of treatment commencing. The PCT strongly recommends that treatment is not undertaken without written funding approval on the assumption that retrospective NHS funding might be available.

#### **4. CONSIDERATION OF INDIVIDUAL CASES**

- 4.1** Where a doctor wishes to make a referral/request for funding for an intervention not routinely funded within current pathways the following process should be followed.

**[Please note:** This will include any consultant/clinician in a primary, secondary or tertiary centre who wishes to make a referral to another consultant either within or outside his/her own Trust hospital]

Referral forms which are required to be used within the process are attached to this policy. However from time to time forms may change and providers will be alerted as and when this occurs.

**[Please note:** For general practitioners, a detailed letter would usually be sufficient, however it needs to include the following:

1. Patient Initials
2. NHS Number

3. Date of Birth
4. RTT (Referral to Treatment) Date
5. Full documentation accompanying the case i.e. all correspondence.
6. Clearly demonstrate compliance with the principles outlined within the Ethical and Commissioning Framework (**Appendix 1**)
7. Grounds for exceptionality which is stated in section 1.8]

#### **4.2 Initial Discussion with PCT Commissioning Team**

The Commissioning Team/relevant commissioning clinician will be able to advise whether the proposed referral would be covered by our existing portfolio of SLAs or current individual case commissioning policies.

If not, the Commissioning Team may be able to suggest an alternative that will meet the patient's clinical needs. The Commissioning Team is unable to prioritise referrals outside existing pathways and is not able to take an individual's personal circumstances into account.

- 4.3** If the Commissioning Team has reason to consider that simple application of SLAs and/or commissioning policies would be inappropriate for a case then the case should be considered by the Case Review Panel which will meet no less frequently than once per month.

Membership:

- Senior Commissioning Manager
- Public Health Specialist
- Pharmaceutical Advisor
- Commissioning Clinician
- Nurse
- Individual Case Secretary
- Additional expert as required

The group will be able to consider three options:

- agree the request without reference to the Individual Case Panel;
- refuse the request without reference to the Individual Case Panel;
- or refer to the Individual Case Panel

- 4.4** Refusing the request is an option where there is a clear policy concerning the situation and where there is no evidence that the individual would constitute an exception. Where there is uncertainty, the case should be referred to the Individual Case Panel. All decisions made by the Case Review Panel will be recorded and will go to the Individual Case Panel for ratification which will be reported to the PEC Commissioning Board.

The Case Review Panel can approve individual episodes or packages of care up to the *per request value* of £25,000 in line with the criteria laid out in paragraph 4.4 above. If the *per request value* exceeds £25,000, the case will be automatically referred up to the Individual Case Panel, together with the details of the recommendation for funding.

- 4.5** The clinician can appeal against the initial refusal of the PCT to refer the case to the Individual Case Panel. He/she will have to fill in completely the application form for consideration of individual case funding, and only when the full information is received and reviewed by the Commissioning Manager and verified as to its completeness and validity, will the case be referred up to the Individual Case Panel. Incomplete forms will be rejected by the Commissioning Team and will not be forwarded to the Individual Case Panel for consideration of funding.
- 4.6** The Individual Case Panel will consider all cases referred to it by the Case Review Panel. In reaching a decision on individual funding, the Panel will consider each case in line with the PCT's Ethical and Commissioning Principles. The Panel will set out its decision and the reasons for it in writing to the referring doctor.
- 4.7** If the referring doctor feels that he or she has further relevant information available which has not been considered by the Case Review Panel he/she may ask for it to be reviewed by the PCT's Individual Case Panel. The Individual Case Panel will set out its decision and the reasons for it in writing to the referring doctor.
- 4.8** Should the referring doctor remain unhappy with the (*process*) adopted in reaching Individual Case Panel's decision, they may ask for it to be reviewed by the Individual Case (Process) Appeals Panel.
- 4.9** Should the referring doctor or patient remain unhappy with the Appeals Panel decision, it is open to them to pursue the matter through the NHS Complaints Procedure. Information on how to do this is available from the PCT's Complaints Managers.

## **5. PREPARING A CASE FOR THE INDIVIDUAL CASE PANEL**

- 5.1** The PCT will have an Individual Case Panel and an Appeal Panel.
- 5.2** Requests to consider an individual case will come from the clinician involved in the patient's care and who wishes to initiate a referral outside local pathways. It is the responsibility of the individual seeking Individual Case consideration to ensure that all relevant information is forwarded to the PCT. This should include:
- a) An outline of the patient's problem and the circumstances of the case, including any previous treatment
  - b) A clear statement of the referral/treatment plan proposed for the patient, including at what point the patient would return to local pathways
  - c) Consideration of whether the patient's needs could be met within existing pathways
  - d) If the care could be provided within existing pathways, a statement of why an alternative referral, which would not be offered to others with similar clinical need, is a priority in this case

e) If the care is not routinely funded by the PCT, evidence to show that the patient is significantly different to the population of patients with similar clinical needs who would also not be offered the treatment. This should include evidence that the patient is likely to gain significantly more benefit from the treatment than would be expected for other patients not currently offered it.

**5.3** The PCT's individual case secretary will write to the individual seeking consideration of the case confirming that the request has been received and seeking further information in cases where information is incomplete. If information is required from third parties, written consent shall be obtained from the patient prior to seeking such information.

**5.4** The Individual Case Secretary may also write to other health professionals with clinical involvement in the patient's care (for example consultant, therapist etc) for clarification of the patient's needs, evidence base etc, if appropriate.

**5.5** The Individual Case Secretary, with support from public health and medicines management where appropriate, will produce a summary of the case for the information of the Panel. This will act as the front sheet to the attached documentation received from the referring clinician, patient, etc.

## **6 INDIVIDUAL CASE PANEL**

**6.1** The Individual Case Panel is a sub-committee of the PEC Commissioning Board. It has delegated authority from the PCT Board to make decisions in respect of funding for individual cases.

**6.2** Membership:

- Public Health Consultant /Deputy
- Director of Commissioning/ Assistant Director of Commissioning
- 2 Clinical Members of Professional Executive Committee or their nominated clinical representatives
- Non-Executive Director
- Pharmaceutical Advisor
- Nurse
- Individual Case Secretary

The Non-Executive Director will be chair of the Panel.

The PCT reserves the right to amend the membership of the Panel, after due consultation with the PCB.

The pharmaceutical advisor/public health specialist/mental health commissioner/commissioner for adult health partnerships/continuing care commissioner may be requested to attend the Panel meeting as and when necessary, in order to clarify funding issues around difficult and complex cases.

**6.3** The Group will meet monthly, quorum being attendance by at least four members, one of which must be the Commissioning Clinician or representative.

The decision of the Individual Case Panel will be carried on a majority vote. In the case of a tie in the voting, the Chair will have a casting vote.

Cases will be considered at the next available Panel meeting. If further information is required to prepare the case for consideration, this may delay presentation to the Panel until the next or subsequent month. All required information from the Trust/clinician must be sent to the PCT at least five (5) working days before the scheduled date of the next meeting of the Panel.

- 6.4** In cases where urgent consideration can be justified, an “extraordinary” Panel meeting may be convened or another method of rapid discussion (e.g. via e-mail) will be considered. Rapid discussion via e-mail may also be used, subject to agreement of Panel members, on other occasions to expedite rapid decision making for example, where it is difficult to achieve quorum for a scheduled meeting or where there is only one case to discuss.

In the rare but very extreme complex cases, where the patient’s life is in imminent danger, the relevant Commissioning Manager can take an immediate funding decision on the patient without recourse to the Panel after urgent discussion with the Lead Clinician and Public Health Consultant but the case must be reviewed at the subsequent Panel meeting by the full Panel.

- 6.5** Cases will be anonymised before consideration by the Panel. Panel members having clinical involvement with a particular case will be excluded from the discussion of that case. Clinicians and patients will not be invited to attend the Panel meeting.
- 6.6** The Chair of the Panel will write, within ten working days, to the referring clinician setting out the Panel’s decision and the reasons for it.
- 6.7** If the referring clinician is unhappy with a Panel’s decision he/she may ask for further consideration or appeal as set out in paragraph 4.7 above.
- 6.8** The Panel will provide a summary of its decisions to the PEC & Commissioning Board and will flag up to the PCB any individual decisions which may have implications for wider PCT policy
- 6.9** The Panel will have devolved responsibility to be able to approve individual episodes or packages of care up to the value of £25,000. For values greater than this additional approval will be required from the Chief Executive.

## **7 INDIVIDUAL CASES APPEALS PANEL**

### **7.1 Membership:**

- PCT PEC Chair or Deputy
- PCT Professional Executive Committee Chair or Vice-Chair
- PCT Director of Public Health/ Public Health Consultant
- Non-Executive Director
- Appropriate Lead to present case – by invitation
- Individual Case Secretary (minutes)

*[Please note: the panel member at the Individual Case Panel cannot be a member of the Appeals Panel for the same patient]*

The Non-Executive Director will chair the Appeals Panel.

The PCT may from time to time amend the membership of the Panel, after due consultation with the PCB.

**7.2** The Appeals Panel will be convened within 20 working days to consider appeals against Individual Case Panel decisions, the quorum being attendance by at least three members including the PCT PEC Chair.

**7.3** The doctor wishing to appeal against an Individual Case Panel decision must notify the Individual Case Secretary at the PCT of their intention in writing, within 40 working days of the date of the Panel's decision.

**7.4** The Appeals Panel will consider whether the original decision of the Individual Case Panel was valid in terms of process, factors considered and criteria applied<sup>5</sup>. In deciding an appeal, the Appeals Panel will consider whether:

- a) the decision was consistent with the principles of Buckinghamshire PCT, as set out in the Ethical and Commissioning Principles
- b) the decision was consistent with the Individual Cases Policy
- c) the decision was consistent with previous similar decisions
- d) in reaching the decision the Panel had:
  - i) taken into account and weighed the relevant evidence;
  - ii) given proper consideration to the claims of the patient (or group of patients) under discussion and accorded proper weight to their claims against those of other groups competing for scarce resources;
  - iii) taken into account only material factors
  - iv) acted in utmost good faith
  - v) taken a decision that is in every sense reasonable

**7.5** It is important to note that the Appeals Panel will not consider new information in support of a case. If new information becomes available, the Individual Case Panel should be asked to reconsider the case in the light of this.

**7.6** The decision of the Appeals Panel will be carried on a majority vote. In the case of a tie in the voting, the Chair will have a casting vote.

The Appeals Panel Chair will write to the referring clinician within ten working days with the Panel decision.

**7.7** The Appeals Panel will not be able to refer a decision back to the Individual Cases for further consideration. If the Appeals Panel finds that there was a failing in the process, as defined in paragraph 7.4, they will also have the

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<sup>5</sup> McCloskey, B. Judicial Review, A Good Practice Guide for Health Authorities. (1999) Association of Directors of Public Health with Dearden Management, Bristol.

responsibility of making the definitive decision on whether the PCT should approve the treatment being requested. A failure in the process of handling an individual case request does not necessarily mean that the decision that was made was incorrect.

- 7.8** Patients who remain unhappy with the Appeal Panel decision may pursue the matter through the NHS Complaints Procedure. Information on this can be obtained from the PCT Complaints Manager.

## **8 EVALUATION AND AUDIT**

- 8.1** On-going evaluation will take place through regular reporting to the PCB. In addition process audits of, for example, time taken to consider cases, consistency of decisions, etc, will be undertaken.

- 8.2** A report will be given to the PEC Commissioning Board on a quarterly basis

## **9 TRAINING AND SUPPORT**

- 9.1** Opportunities for training for Individual Case Panel and Appeals Panel members in evaluation of evidence and health care ethics will be established and provided on a rolling basis.

## **10 MONITORING AND COMPLIANCE**

- 10.1** The PCT will monitor compliance with this policy on an ongoing basis, and annually within contract review, through the forum of contract commissioning meetings.

## **11 POLICY REVIEW**

- 11.1** This policy will be reviewed in September 2011 by the PEC & Commissioning board and the Governance and Risk Committee before submission to the Board for approval (or earlier if necessary).

## **BUCKINGHAMSHIRE PCT ETHICAL and COMMISSIONING PRINCIPLES**

Buckinghamshire PCT receives a fixed budget from central government with which to commission all the health care required by their populations. Buckinghamshire PCT has insufficient resources to fund all types of health care that might be requested for their populations. It is inevitable that Buckinghamshire PCT has to make choices about which types of healthcare to commission. This document sets out the principles Buckinghamshire PCT will use to make these decisions in order to make the process consistent, transparent and fair.

Our commissioning decisions will be based on the following principles:

### **1 HEALTH OUTCOME**

The aim of commissioning is to achieve the greatest possible improvement in health outcome for our population, within the resources that we have available. In deciding which interventions to commission, Buckinghamshire PCT will prioritise those which produce the greatest benefits for patients in terms of both clinical improvement and improvement in quality of life.

### **2 CLINICAL EFFECTIVENESS**

We will ensure that the care we commission is based on sound evidence of effectiveness. We will usually expect this to come from sources such as the National Institute for Public Health and Clinical Effectiveness, well designed systematic reviews and meta-analyses or randomised controlled trials.

The key success factors in evaluating clinical effectiveness are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of prioritisation and commissioning. Choice of appropriate clinically and patient-defined outcome needs to be given careful consideration, and where possible quality of life measures and cost utility analysis should be considered. We will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment that is shown to be ineffective. Issues such as safety and drug licensing will also be carefully considered. When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients' health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other sources and this will also be considered. Patients' evidence of significant clinical benefit is relevant.

### **3 COST EFFECTIVENESS**

We will take into account cost-effectiveness analyses of healthcare interventions (where available) to assess which yield the greatest benefits relative to the cost of providing them. We will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. We will consider technical cost-benefit calculations (e.g. quality adjusted life years), but these will not by themselves be decisive.

#### **4 EQUITY**

We consider each individual within our populations to be of equal value. We will commission and provide health care services based solely on clinical need, within the resources available to us. We will not discriminate between individuals or groups on the basis of age, gender, gender identity, sexual orientation, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intelligence, disability, physical or cognitive functioning. However, where treatments have a differential impact as a result of age, sex or other characteristics of the patient, it is legitimate to take such factors into account.

Buckinghamshire PCT has a responsibility to address health inequalities across our population. We acknowledge the proven links between social inequalities and inequalities in health, access to health care and health needs. Higher priority may be allocated to interventions addressing health needs in sub-groups of our population who currently have poorer than average health experience (e.g. higher morbidity or poorer rates of access to healthcare).

#### **5 ACCESS**

Buckinghamshire PCT will ensure that the care we commission is delivered as close to where patients live as possible. Some services cannot be provided in local settings and we may need to commission some services from distant providers in order to ensure quality, safety and value for money. Buckinghamshire PCT will also ensure that it commissions safe services for its population.

#### **6 PATIENT CHOICE**

Buckinghamshire PCT respects the right of individuals to determine the course of their own lives, including the right to be fully involved in decisions concerning their health care. However, this has to be balanced against Buckinghamshire PCTs' responsibility to ensure equitable and consistent access to appropriate quality healthcare for all the population. In commissioning healthcare, Buckinghamshire PCT will:

- i) ensure that in assessing the effectiveness of health care, we take account of outcomes that are important to patients and the patient's experience of the care.
- ii) ensure, wherever possible, that within the care commissioned or provided there are a range of alternative options available, and that patients are given the necessary support to make an informed choice.
- iii) recognise that evidence of effectiveness usually relates to groups rather than individuals. We have set up an "individual case" mechanism to allow individuals to be considered as an exception to commissioning policy where evidence is available to suggest that an intervention not routinely funded may be of particular benefit to them in relation to other patients who might not be funded.
- iv) as a general rule, decline to provide individual funding for care that is not routinely commissioned or provided solely on the basis that an individual, or a clinician involved in their care, desires it. This is in line with our responsibility to ensure consistent and equitable access to care for all our population. It reflects our concern not to fund for one individual care which could not be openly offered to everyone in our population with equal clinical need.

v) decline to provide a treatment of little benefit simply because it is the only treatment available

vi) consider treatments which effectively treat 'life time' or long-term chronic conditions equally to urgent and life-prolonging treatments

## **7 AFFORDABILITY**

Buckinghamshire PCT may not be able to afford all interventions supported by evidence of clinical and cost-effectiveness within their available budgets. Where this is the case further prioritisation will be undertaken based on criteria including national and local policies and strategies, local assessment of the health needs of the population, to ensure that we do not exceed our available resources.

Buckinghamshire PCT is duty-bound not to exceed its budget, and the cost of treatment must be considered. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other uses. This is known as opportunity costs and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way. The concept derives from the notion of scarcity of resources. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high.

## **8 NEEDS OF THE COMMUNITY**

Public health is an important concern of Buckinghamshire PCT, and Buckinghamshire PCT will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE and National Service Frameworks). Others are produced locally. Buckinghamshire PCT also supports effective policies to promote preventive medicine which help stop people becoming ill in the first place.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient's condition, or to stop, or slow the progression of disease. Where it has been decided that a treatment has a low priority and cannot generally be supported, a patient's doctor may still seek to persuade Buckinghamshire PCT that there are exceptional circumstances which mean that the patient should receive the treatment.

## **9 QUALITY**

Buckinghamshire PCT will aim to commission high quality services as evidenced against national and international best practice. The quality of services will be measured where possible not only in terms of quality of outcomes and clinical effectiveness but also in terms of process and organisational efficiency; reducing dependency on health care; the quality of patient care; and the quality of the patient experience.

## **10 POLICY DRIVERS**

The Department of Health issues guidance and directions to NHS organisations which may give priority to some categories of patient, or require treatment to be made available within a given period. These may affect the way in which health service

resources are allocated by individual PCTs. Buckinghamshire PCT operates with these factors in mind and recognise that their discretion may be affected by National Service Frameworks, NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

**11 EXCEPTIONAL NEED**

There will be no blanket bans on treatment since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Each case of this sort will be considered on its own merits in light of the clinical evidence. Buckinghamshire PCT has procedures in place to consider such exceptional cases on their merits and this will be done through the Individual Case Policy of Buckinghamshire PCT

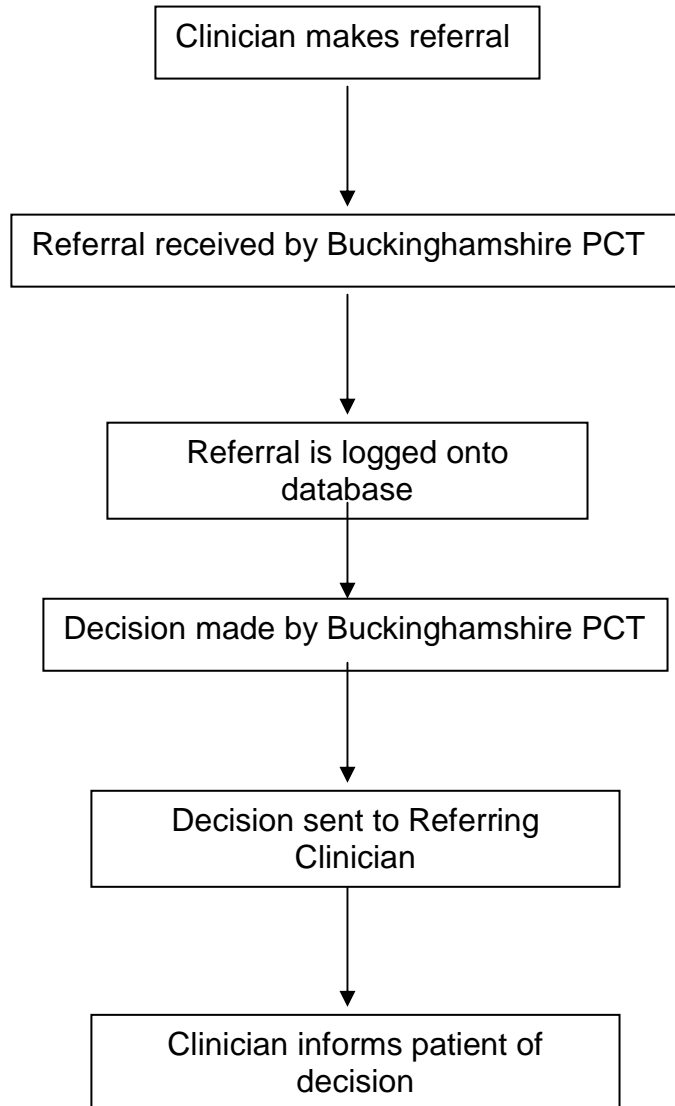
**12 DISINVESTMENT**

As well as commissioning new services on the basis of the criteria above, Buckinghamshire PCT will keep existing services under review to ensure that they continue to deliver clinical- and cost-effective services at affordable cost. Where possible we will seek to divert resources from less effective services to more effective ones.

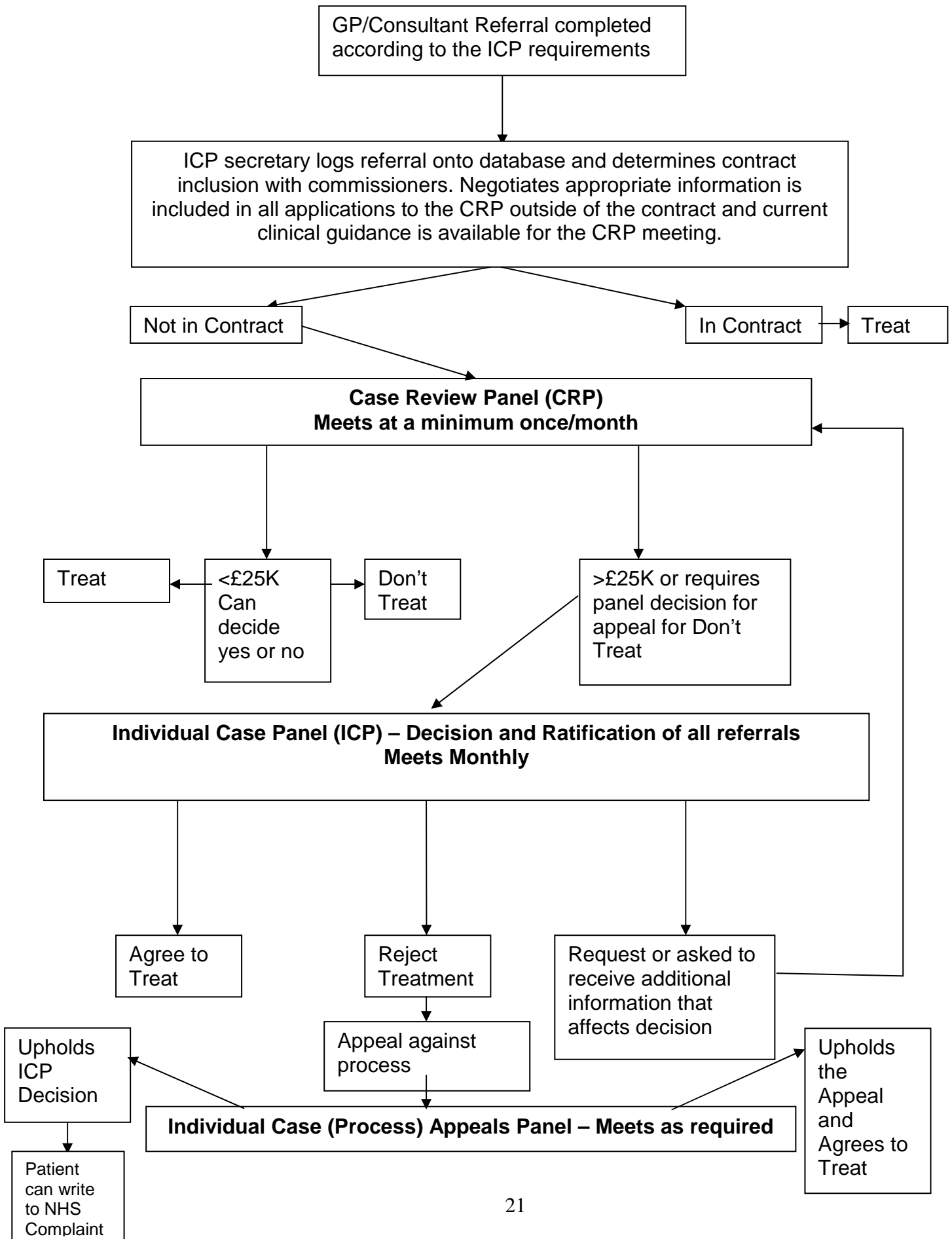
# APPENDICES

## APPENDIX 1

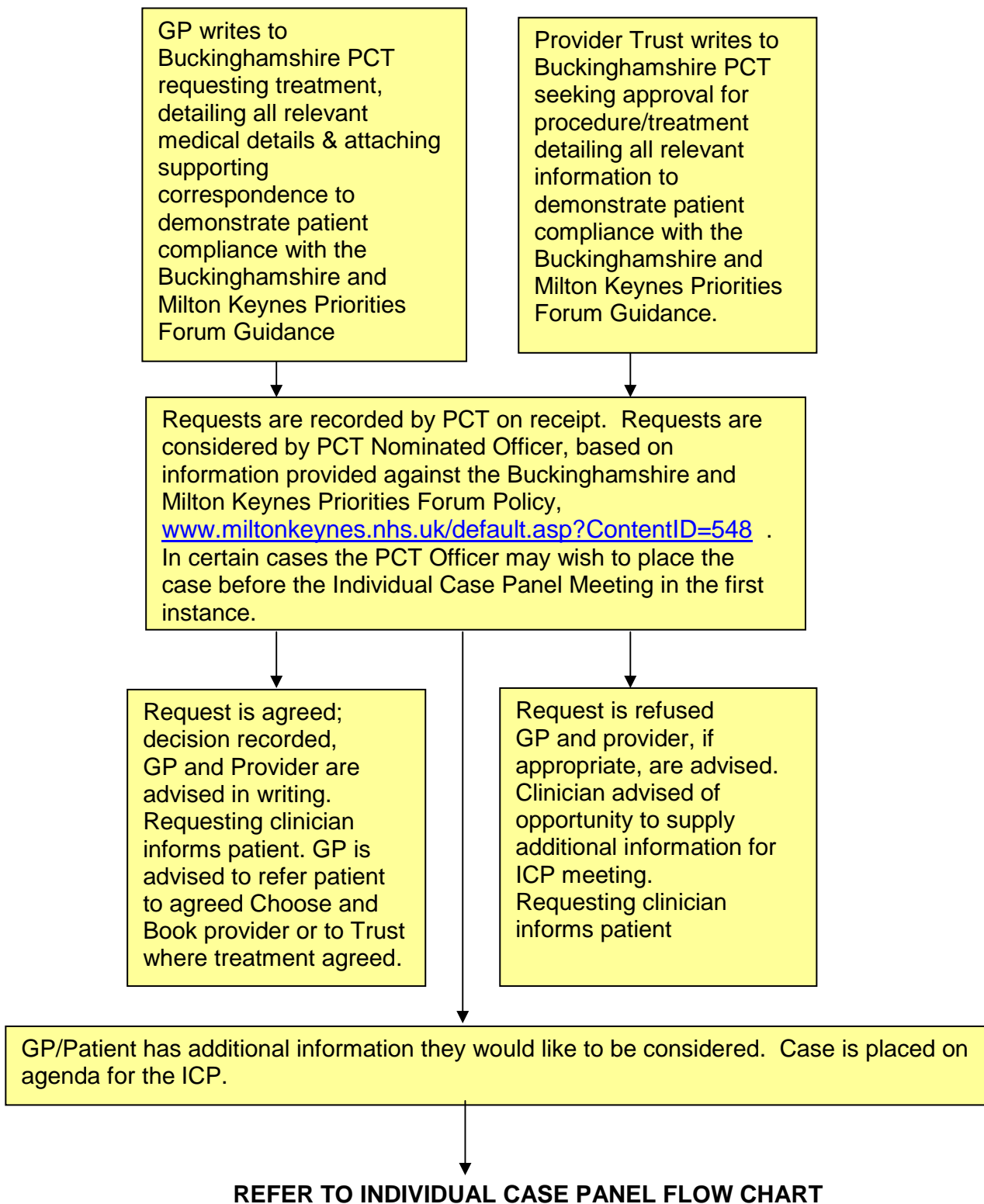
### DECISION PATHWAY FOR CLINICIANS



INDIVIDUAL CASE PANEL FLOW CHART



**LOW PRIORITIES TREATMENT APPROVAL PROCESS**



## INDIVIDUAL CASE PANEL (ICP) – TERMS OF REFERENCE

### **Purpose**

1. The purpose of the Individual Case Panel (ICP) is to make decisions of behalf of Buckinghamshire PCT for referrals from clinicians where a patient's needs cannot be met through existing care pathways commissioned through Buckinghamshire PCT.
2. The ICP will only hear cases referred through the mechanism of the screening tier – 'Case Review Panel' (CRP), who will have ensured the information required for consideration by the ICP is available for either ratification or decision.
3. In considering these cases, the CRP and subsequently the ICP will apply the Ethical and Commissioning Principles adopted by Buckinghamshire PCT.
4. Following an analysis of referrals that have been agreed by panel, the commissioner responsible for this will convey to the Prioritisation Panel any cases which fall into the area of potential new investment as a result of their frequency of appearance before the ICP

### **Process**

This is described in the Individual 'Case Policy for Buckinghamshire PCT' which also contains membership of the CRP. Decisions are made on a majority vote basis.

### **Membership of the full Individual Case Panel**

- Non-Executive Director is the Chair of the ICP
- Director of Commissioning/Assistant Director of Commissioning
- Public Health Consultant/Deputy
- Two Clinical Members of the Professional Executive Committee or their nominated clinical representatives.
- Pharmaceutical Advisor
- Nurse
- ICP Secretary

The panel will usually have Specialist Advisers who will sit on the panel to represent their particular field of activity and will be drawn from the following specialists:

- Public Health
- Mental Health Commissioning
- Partnership Commissioning

### **Quorum**

At least 4 members one of which should be the Commissioning Clinician or representative.

### **Meetings**

Meetings will normally be held monthly, or with greater frequency should an 'extraordinary' meeting be required to be convened. Extraordinary meetings may be undertaken as 'virtual' meetings i.e. by conference call or e-mail to facilitate a rapid decision or where the establishment of a quorum would be difficult.

## **INDIVIDUAL CASE (PROCESS) APPEALS PANEL (ICAP) – TERMS OF REFERENCE**

### **Purpose**

The purpose of the Individual Case Appeals Panel (ICAP) is to consider appeals made by clinicians about the decision/s reached by the Individual Case Panel (ICP).

The ICAP will review the process followed by the ICP and will set out its decision with supporting reasons the referring clinician.

### **Process**

The panel will only consider whether the original decision of the ICP was valid in terms of process, factors considered and criteria applied.

The ICAP will not consider new information in support of a case. In such an event, the ICP should be asked to reconsider the case in the light of this.

In deciding an appeal, the ICAP will consider the following:

- The decision was consistent with the principles of Buckinghamshire PCT as set out in the PCTs Ethical and Commissioning Principles (Appendix 1)
- The decision was consistent with the Individual Cases Policy (Appendix 2)
- The decision was consistent with previous similar decisions
- In reaching the decision the ICP had :
  - a) Taken into account and weighed all the relevant evidence
  - b) Given proper consideration to the claims of the patient (or groups of patients) under discussion and accorded proper weight to their claims against those of other groups competing for scarce resources
  - c) Taken into account only material factors
  - d) Acted in utmost good faith
  - e) Taken a decision that is in every sense reasonable

The ICAP will not refer a decision back to the ICP for further consideration. If it finds that there was a failing in the process, it has the responsibility of making a definitive decision as to whether Buckinghamshire PCT should approve the treatment as requested.

The decision of the ICAP will be carried by a majority vote and conveyed to the referring clinician.

### **Membership of the ICAP**

- PCT Chair or Deputy
- PCT Professional Executive Committee Chair or Vice Chair
- PCT Director of Public Health/Public Health Consultant
- Non-Executive Director (Acting as Chair for the ICAP)
- Appropriate Lead involved with the case to present the case by invitation

### **Quorum**

At least three members to include the PCT Chair of the Panel Committee

**Meetings** - The Panel will be convened as necessary to consider appeals and may be undertaken by conference call or e-mail to facilitate a rapid decision or where the establishment of a quorum would be difficult.