Warwickshire NHS
Primary Care Trust

Individual Cases Policy

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Approved By:	**Trust Board**
Replacing:	**N/A**
Date Approved:	**10.01.2007**
Date Issued:	**07.02.2007**
Review Date:	**07.02.2008**
Person Responsible:	**Tim Davies Director of Public Health**

NHS WARWICKSHIRE
INDIVIDUAL CASES POLICY

POLICY ON INDIVIDUAL ELECTIVE REFERRALS FOR CARE NOT ROUTINELY COMMISSIONED OR PROVIDED BY WARWICKSHIRE PCT

1. AIM OF COMMISSIONING

1.1 Within the resources available to us, NHS Warwickshire aim to commission and provide high quality clinical care 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.

1.2 The PCT will pursue this approach to commissioning in line with current government policy[1.] This will enable us 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.

1.3 NHS Warwickshire accepts that there may be individual cases where a patient's needs cannot be met through existing care pathways. The PCT have set up Individual Cases Panels 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 Commissioning Principles. (Appendix 1).

2 CURRENT PATIENT PATHWAYS

2.1 Acute Referrals

2.1.1 The PCT's preferred providers for acute care are detailed on the PCT's Choice Menu and can be accessed via the patients' General Practioners. In addition the PCT holds a portfolio of acute service level agreements with providers across the West Midlands for a full range of services, should an alternative provider or a 2nd opinion be required. Guidance on alternative referrals currently covered by SLAs can be obtained from the Commissioning Departments. 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

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

that the PCT will necessarily commissioning the treatment option recommended if this is outside of pathways of care that are normally commissioned by the PCT.

2.1.2 Patients requiring elective referral will be offered a choice of 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[2]. 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 if this is outside of the care pathways that are normally commissioned by the PCT.

2.2 Mental Health 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.

2.3 Referrals using these pathways can be made from primary care (or secondary care if appropriate) without the need to seek prior authorisation from the PCT. The PCT believes that these pathways will meet the vast majority of care needs for their populations in line with the PCT' Ethical Framework and Commissioning Principles.

3. POLICY GUIDANCE

3.1 In considering individual cases, the PCT will apply the Commissioning Principles and the following guidance which expands upon it.

3.2 Introduction of new drugs and technologies

3.2.1 The PCT does not expect to introduce new drugs/technologies in an ad hoc 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. There is also the risk that diversion of resources in this way will destabilise other areas of health care which have been identified as priorities by the PCT. The PCT expect consideration of new drugs/technologies to take place within the established planning frameworks of the NHS (i.e. the Local Delivery Plan process) after consideration by the appropriate committees (i.e. the PCT's Commissioning Advisory Group, and the Health Economy NICE Implementation Group). This will enable clear prioritisation

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[2] "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.

against other calls for funding and the development of implementation plans which will allow access for all patients with equal clinical need.

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 without delay but recognise 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 implement them in the way that applies to the technology assessments.

3.4 Treatments covered by PCT commissioning policies

3.4.1 Treatments not currently included in established pathways or identified for funding through the Local Delivery 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 or relative priority for funding. These include: aesthetic surgery, in vitro fertilisation and associated techniques, varicose vein surgery, bariatric surgery and vacuum-assisted wound closure.

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 Commissioning Advisory Group for local implementation.

3.4.3 A current full list of policy statements can be obtained from the Commissioning Department of the PCT.

3.4.4 Clinicians or patients uncertain about the status of a particular treatment should contact the PCT, Head of Commissioning or Director of Public Health, for advice.

3.5 Treatments covered by 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 are unlikely to 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 commissioning principles (1 to 8) in the Commissioning Principles 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 the danger of precedent setting for groups of patients. Such situations are should be considered by the Commissioning Advisory Group.

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 coming off drugs trials

3.6.1 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[3] and the Declaration of Helsinki[4], 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. 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 LDP process. Where the treatment is not prioritised through the LDP, 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. 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 personal circumstances may make such funding appropriate, the case will require consideration by the Individual Cases Panel.

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

3.8.1 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 usually only are considered after assessment by appropriate specialists within the existing pathway. Should a local 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 Cases Panel.

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[3] http://www.legislation.hmso.gov.uk/si/si2004/20041031.htm
[4] http://www.wma.net/e/policy/b3.htm

3.9 Decisions inherited from other primary care trusts

3.9.1 Occasionally patients move in to the area and become the responsibility of the PCT when a package of care or treatment option has already been approved by the PCT that was previously responsible for the patient's care. The PCT will normally honour such decisions providing the care pathway has been initiated (for example an appropriate referral has already been made and approved).

4. CONSIDERATION OF INDIVIDUAL CASES

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

4.2 Initial Discussion with PCT Commissioning Manager.
The Commissioning Manager 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 Manager may be able to suggest an alternative that will meet the patient's clinical needs. The Commissioning Manager is unable to authorise referrals outside existing pathways and is not able to take an individual's personal circumstances into account.

4.3 If the Commissioning Manager 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 a Senior Commissioning Manager and a Public Health Specialist together. The pair will be able to consider three options; agree the request without reference to the Individual Cases Panel, refuse the request without reference to the Individual Cases Panel, or refer to the Individual Cases Panel.

4.4 Agreeing the request at this level will only be an option where there is very compelling clinical evidence or indication, where the expected clinical benefit is significant and where a delay caused by waiting for the panel to meet would be potentially detrimental to the patient. Refusing the request is an option where there is 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 Cases Panel. All decisions made by the Commissioning Manager / Public Health Specialist pair will be recorded and reported to the Commissioning Advisory Group.
Health Specialist pair can approve individual episodes or packages of care up to the value of £10,000 in line with the criteria laid out in paragraph 4.4 above.

4.6 The Individual Cases Panel will consider all cases referred to it by the Commissioning Manager / Public Health Specialist screening tier. In reaching a decision on individual funding, the Panel will apply the PCT' Commissioning Principles (Appendix 1). The Panel will set out their decision and the reasons for it in writing to both the referring doctor and the patient.

4.7 If the doctor or patient is unhappy with the Panel decision they have two options open to them.

a) If the doctor or patient feels that they have further relevant information available which has not been considered by the Individual Cases Panel, they may ask the Panel to reconsider the case specifically in the light of this further information.

b) If the doctor or patient feels that all the relevant information was available to the Panel when the decision was made, but they remain unhappy with the decision, they may ask for it to be reviewed by the PCT' Appeal Panels. The Appeal Panel will review the process followed by the Individual Cases Panel. The Appeal Panel will set out their decision and the reasons for it in writing to both the referring doctor and the patient.

4.8 Should the doctor or patient remain unhappy with the Appeal 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 CASES PANEL

5.1 NHS Warwickshire will have an Individual Cases Panel and Appeals Panel.

5.2 Requests to consider an individual case will usually come from the clinician involved in the patient's care who wishes to initiate a referral outside local pathways. Less commonly, it may be the patient themselves (or the parent/guardian in the case of a minor) who makes the request. 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 administrator will write to the individual seeking consideration of the case confirming that the request has been received and seeking further information in cases where items i-v above have not been fully covered. 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 administrator will write to the patient to inform them of the individual cases process and to give them the opportunity to provide information to the Panel. The patient will be invited to provide written evidence that they would like the Panel to take into consideration. This might include: information on how their condition affects their quality of life; their understanding of the evidence base and how this might apply to them; information from friends or family; information from clinicians or patient support groups, etc.

5.5 The individual complex case administrator 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.

5.6 The individual case administrator will write to the patient informing them of the date set for consideration by the Panel and listing the items of information that will be presented to the Panel.

5.7 The commissioning directorate, 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 CASES PANEL

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

6.2 Membership:

Public Health Specialist
Director of Commissioning
2 Clinical Members of Professional Executive Committee
Non-executive Director

The panel members will determine who is to chair the panel.

6.3 The Group will meet monthly, quorum being attendance by four members. 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. 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).

6.4 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. The clinician seeking the referral (usually the GP) may attend to provide clarification of the reasons for seeking referral as set out in points a - e of para.5.2 above. Clinicians attending for this purpose will be excluded from the subsequent Panel discussion of the case. Patients will not be invited to attend the Panel meeting.

6.5 The Chair of the Panel will write, within five working days, to the patient (where appropriate) and to the referring clinician setting out the Panel's decision and the reasons for it.

6.6 Patients or clinicians unhappy with a Panel decision may ask for further consideration or appeal as set out in paragraph 4.7 above.

6.7 The Panel will provide a summary of its decisions to the Commissioning Advisory Group (CAG) and will flag up to the CAG any individual decisions which may have implications for wider PCT policy

6.8 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 and one other member of the Board.

7. INDIVIDUAL CASES APPEALS PANEL

7.1 Membership:

PCT Chief Executive or deputy

PCT Chair or other Non Executive Director
PCT Professional Executive Committee Chair or vice Chair
PCT Director of Public Health

7.2 The Appeals Panel will be convened when necessary to consider appeals against Individual Cases Panel decisions.

7.3 Individuals wishing to appeal against an Individual Cases Panel decision must notify the PCT Chief Executive of their intention, in writing, within three months of the date of the Panel meeting. All appellants will be directed to the Patient Advice Liaison Service (PALS) for additional support.

7.4 The Appeals Panel will consider whether the original decision of the Individual Cases Panel was valid in terms of process, factors considered and criteria applied[5]. In deciding an appeal, the Appeals Panel will consider whether:

a) the decision was consistent with the principles of the PCT, as set out in the 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 all 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 The individual requesting the appeal and the referring clinician will be invited to attend the Appeal Panel meeting to observe the process and provide clarification on their written submission if required.

7.6 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 Cases Panel should be asked to reconsider the case in the light of this.

7.7 The Appeal Panel chair will write to the appellant and referring clinician within two working days with the Panel decision.

7.8 The Appeal Panel will not be able to refer a decision back to the Individual Cases for further consideration. If the Appeals Panel finds

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

that there was a failing in the process, as defined in paragraph 7.4, they will also have the responsibility of making the definitive decision on whether they 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.

7.9 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 CAG. In addition process audits of, for example, time taken to consider cases, consistency of decisions, etc, will be undertaken.

9. TRAINING AND SUPPORT

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

10. POLICY REVIEW

10.1 This policy will be reviewed bi-annually by the Professional Executive Committee and Board.

NHS WARWICKSHIRE
COMMISSIONING PRINCIPLES

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

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, the 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 Health and Clinical Effectiveness, well designed systematic reviews and meta-analyses or randomised controlled trials.

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.

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, sex, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intellectual/cognitive functioning or physical functioning.

The 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.** The PCT will ensure that the care we commission is delivered as close to where patients live as possible. For example, we will look at opportunities to move care from hospitals to primary care where this is likely to improve access and maintain quality. Some specialist services cannot be provided in local settings and we may need to commission some services from distant providers in order to ensure quality.

6). **Patient Choice**. The PCT respect 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 the PCTs' responsibility to ensure equitable and consistent access to appropriate quality healthcare for all the population. In commissioning healthcare, the 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.

iv) the PCT will not 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.

7). **Affordability**. The 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.

8). **Disinvestment**. As well as commissioning new services on the basis of the criteria above, the PCT will keep existing services under constant 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.

9) **Quality**
The PCT will aim to commission high quality services as evidenced against national & 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.

PROCESS

1). The mechanism through which investment and disinvestments decisions are taken is the Local Delivery 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.

2). To support the LDP process, the PCT will use a Commissioning Advisory Group (CAG) to advise them on the clinical and cost-effectiveness of new healthcare interventions and also on opportunities for disinvestments from less effective services. The CAG will do this through an ongoing programme of work throughout the year.

3). Since the Commissioning Advisory Group assesses individual interventions on their own terms it may be that not all interventions supported by the Group will be affordable from available budgets. The LDP process will be the final determiner of those interventions prioritised for investment in the coming year.

4). The PCT will use an Individual Case Panel to consider individuals who might have circumstances that make them an exception to the policies above. It is not the role of the Individual Case Panel to 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 LDP) and will seek to determine exceptionality on that basis.

5). Determination of ‘exceptionality’:

- In order for 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 condition in question
    - Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition
- 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 (or patient) to make the case for exceptional status.
- Social value judgements are rarely relevant to the consideration of exceptional status

6). The Individual Case Panel can **NOT** 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). In cases where the Individual Case Panel feels strong evidence has been provided in support of a particular health technology they should make a recommendation for further consideration by the Priorities Forum/LDP process, but individual funding of the specific case must be refused.