

# TREATMENT WE NEED



How to Apply for  
NHS Exceptional Funding for Treatment

by Peter Telford



Peter Telford

## About the author.

Peter is a barrister who has worked on Pro Bono medical appeals since 2006. He is also a member of the National Alliance for Rare Disease.

Other titles he has written include: "Your Patients Right to Treatment" © P. Telford 2008 a booklet for Consultants.

He is currently working on the European Recommendation on Improving Patient Access in Rarer Disease due to be presented to the European Parliament March 2009.

Whilst every effort has been made to ensure that the statements of law are correct at the time of going to press, no responsibility can be taken for misstatements. No two cases are the same and any reader who wants to know how the law applies to his or her particular case should take advice from a lawyer.

With many thanks to Nick Carter Solicitor and Survivor and John Halford, Solicitor for their comments and suggestions. Humbling at times but useful.

The author has asserted his moral right to be identified as the author of this work.

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*“My daughter is only 42. She has two young children. Now the doctor has said she will die without this treatment but the NHS won’t pay. We have no money for the drug. Her children won’t see their mother as they grow up.”*

*“The PCT have written to my consultant and told him they won’t pay for the drug I need. I did not even know about the application. How can I challenge the PCT?”*

*“I’ve paid taxes all my life but the NHS won’t pay for me when I need the treatment people get in the next County. This is wrong.”*

## The Problem.

For a number of medical conditions there are treatments that are not normally prescribed and funded by the Primary Care Trust (PCT) in your area. These include treatments for rarer diseases and rarer cancers.

When a condition, disease or cancer is rare, the diagnosis and treatment may have been delayed, the information on the clinical efficacy of the treatment might be difficult to obtain and the usual sources of guidance for a PCT might not be available. There may be no evidence on cost effectiveness of the treatment because no one has studied that. The cost of the treatment in absolute terms might be relatively high.

Some of these treatments can be helpful in putting the disease or cancer into remission or

making your quality of life better. Your consultant might recommend the treatment but unless it is funded by your PCT, the treatment will not be prescribed on the NHS. Unless you pay privately you will not get the recommended treatment.

For a number of reasons, the PCT may refuse to fund your treatment. These treatments may be described by the PCT who manages your NHS locally as “lacking evidence of clinical effectiveness” or “high cost” or “not cost effective” or “lacking guidance from NICE”.

You may be confused by this. The NHS was set up to provide you with treatment for illness which has been diagnosed. The treatment is designed to improve your health. The NHS is managed in your area by the PCT. Your

consultant is employed by a Hospital Trust. The Hospital Trust contracts his/her services to your PCT to treat you in order to improve your health. You may wonder how a PCT can refuse to provide treatment for a condition including a rarer cancer that can respond to treatment which the NHS consultant they use wants to prescribe. It is as if the PCT does not trust the judgement of their consultant.

The real problem lies in the fact that the PCT takes funding decisions, not your consultant.

- ◆ The PCT has a Committee to make the funding decision which is sometimes unqualified to decide complex matters.
- ◆ The PCT Committee often does not have your consultant present when they make

## The Answer.

If your PCT does not routinely fund the treatment you need, you will almost certainly have to show your case is exceptional.

PCTs have to apply a fair and lawful process in coming to their decision. The PCT can lawfully say “yes” to one person and still say “no” to another with the same condition. There might be different circumstances for each of those two patients. The PCT has to follow the same procedure in each case.

This booklet is written to show you how to make your case for exceptional funding for treatment.

their decision and does not contact the consultant to clarify issues.

- ◆ Many PCT Committees fail to have a suitable expert in your condition, disease or cancer to advise them.

This procedure results in some decisions by PCTs being made wrongly in ignorance of all the facts. It often results in heartache and stress for patients and families.

It is a problem compounded by having 152 different PCTs all doing their own thing in regard to how to make their decision.

This process of refusal can appear even odder when patients in a neighbouring PCT would automatically get that treatment.

- ◆ It shows how to make an Application to your PCT and if the application is refused how to make an Appeal.

- ◆ It shows what has worked in previous applications and gives examples of Appeals.

- ◆ It shows how to take your case further if your Appeal is refused.

The booklet points you to sources of support in your fight for treatment. It mainly refers to the situation as it affects cancer patients. This booklet is also useful for those with rare conditions and diseases.



# Understanding the Jargon.

The PCTs and NHS use a lot of technical words and phrases.

Do not be afraid of them. These include:

**Appeal Panel** – the PCT committee who decide if the process for making the funding decision was fair. See Panel.

**“Application”** – usually when the consultant applies within the PCT for permission to prescribe your treatment. Often you may know nothing about this until it is refused. In law this is your application for funding. The application may have missed out vital information.

**“Appeal”** – when the application is refused but the patient asks the PCT to review the decision. Almost all PCTs operate an appeal procedure.

**“AWMSG”** - All Wales Medicines Strategy Group provides guidance in Wales. NICE guidance on same subject matter takes precedence.

**Cancer Network** – usually a local group of PCTs and experts who have put together up to date information on some treatments.

**“Clinical effectiveness”** – how well the treatment works on average.

**“Cohort of patients”** – the people who were diagnosed with your level of condition at the same time as you were diagnosed.

**“Consultant”** – the key to your successful application. Without this support you will not succeed.

**“Co Payment”** – Sometimes referred to as Top Up. Only relevant if you have enough money to pay for a treatment and all additional costs associated with your additional treatment. Private treatment in a private setting at near enough the same time as NHS treatment. Historically not allowed in all PCTs. The full draft guidance on how it is supposed to work is at [www.dh.gov.uk](http://www.dh.gov.uk). All PCTs should allow Co Payment subject to certain restrictions. DH state that before you can do this, you should have been refused an Application and Appeal. This draft guidance does not state what is to happen if the situation is urgent. This area is under constant review by the DH.

**“Cost effectiveness”** – not just the price of the treatment but the benefit per £.

**DPA 1998** - Data Protection Act 1998 – You can use this to access your information stored on computers by the PCT.

**“DH”** – Department of Health. The PCT has to take this guidance into account and often is bound to follow it.

**Documents** – these can include medical records, letters, scans, written notes and e-mails.

**“FOI 2000”** - Freedom of Information Act 2000. Requests can be made under the FOI 2000 which allows you to get documents held by the PCT relating to their decisions about you as well as your medical records for minimal cost.

**“Health benefit”** – different meanings in different conditions.

**Healthcare Commission** – a government body involved in a strategic view of general delivery of healthcare services.

**“ICER”** – Incremental Cost Effectiveness Ratio. Measurement of clinical effectiveness vs cost by comparison of treatment. A concept for economists.

**“Judicial Review” (“JR”)** – where a High Court judge decides if the PCT has been acting unlawfully.

**“Licensed treatment”** – accepted as a proven safe and clinically effective treatment for use in the UK.

**Local Cancer Network** – an advice body which should have up to date clinical data on treatments.

**“Marketing authorisation”** – the new phrase for licensing a treatment.

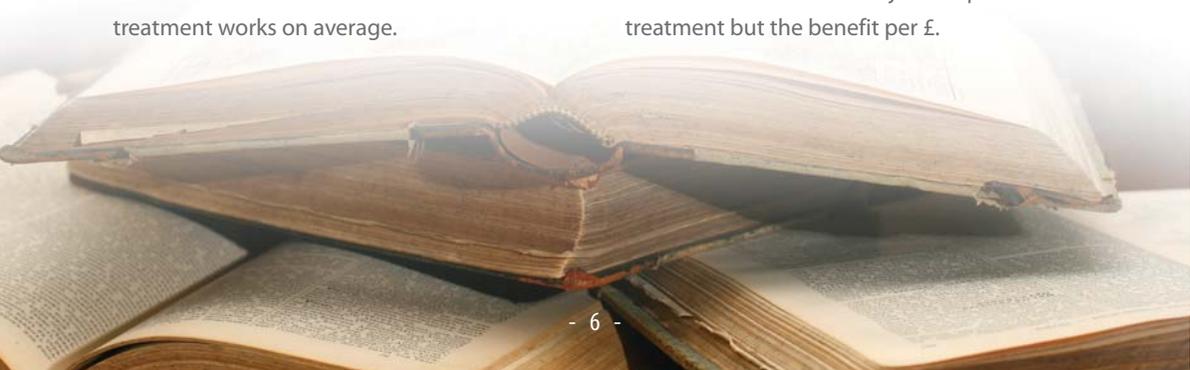
**“Minutes”** – Notes taken by the PCT panel who decide your Application or Appeal. Should show what **Documents** they had and their **Reasons** for any decisions.

**NHS** – National Health Service. NHS Act 2006 states that there should be a comprehensive health service designed to secure improvement in the physical and mental health of people and in the prevention diagnosis and treatment of illness in England. Similar provisions apply in Scotland, Wales and Northern Ireland.

**NHS Confederation** – NHS body giving advice to PCTs.

**NICE** – National Institute for Health and Clinical Excellence. A government body which decides if the treatment is cost effective. NICE does not usually provide guidance on Orphan conditions unless the government asks them to. NICE does not provide guidance on Ultra Orphan conditions.

**NICE “negative” guidance** – where NICE decide a treatment has not been shown to them to be cost effective. Must be taken into account by a PCT but need not always be followed.



**NICE positive guidance** – where a treatment has been shown to be cost effective and NICE say so. Must be followed by a PCT.

**Ombudsman** – an independent official appointed by the Government whose job is to represent patients interests when they complain about poor management in the NHS.

**Orphan condition** - A condition that affects less than 5 in 10000 of population.

**Panel** – the PCT committee making the funding decision. See also **Appeal Panel**. **Panel** and **Appeal Panel** should have properly qualified, expert and experienced panel members. You can find this out by asking under the DPA 1998 and the **FOI 2000**. If they are not competent members, this may make the decision unlawful.

**PCT** – Primary Care Trust. In England, it manages the NHS locally in your area. The same principles of Application and Appeal apply to Scotland, Wales and Northern Ireland Health Boards.

**“QALY”** - Quality Adjusted Life Year - a measure of how NICE decide cost effectiveness for the average patient.

**“Reasons for refusal”** – The written letter setting out why the PCT refused.

**“Risk share”** – when the manufacturer of the treatment- usually a Pharmaceutical company - offer to share the cost of treatment with the PCT. Individual schemes with different details.

**Secretary of State for Health** – the Cabinet Minister whose responsibility it is to ensure the **NHS** is doing its job.

**SHA** – Strategic Health Authority. The **NHS** body above the PCT which oversees a number of PCTs in its geographical area management procedures.

**IMPORTANT: DH** guidance states that **SHA** should coordinate PCTs in making better policies on which treatments should be funded.

**“Significant benefit”** – unknown what this means unless put in context. Clinical benefit? Cost benefit? Statistical significance? Significant to whom?

**SMC** - Scottish Medicines Consortium. Provides mainly clinical efficacy guidance in Scotland. Must follow NICE guidance unless it has assessed a single treatment and gives different guidance.

**Timeliness** – PCTs should make a decision within a reasonable period of time.

**“Top up”** – See Co Payment.

**Transparency** – the duty on PCTs to show how they make their decision.

**Ultra Orphan condition** - Like **Orphan condition**. Rarer still. Not universally defined but NICE use less than 1 in 50000 as a guide. USA and Department of Health might use the absolute number of patients in the population.



# The PCT Management Process.

## Who decides who is exceptional?

The PCT usually sets up a panel to decide. They are usually health directors and GP and executives of the PCT. These panels each have their own PCT name. They might not be called a “panel” in your PCT; they might be a “High Cost Drugs (“HCD”) Committee” or a “Special Case Group (“SCG”)” or a Patient Individual Needs (“PIN”) panel”. In this booklet we simply refer to the people on the PCT who decide as “the panel” and what you have to show is “exceptional circumstances”.

## How do these panels decide?

The PCT will have usually set out its own procedure for what to consider in an application.

There are 152 PCTs. Each has its own policies and procedures. You can find out about your PCT at [http://www.rarercancers.org.uk/information/trust\\_us](http://www.rarercancers.org.uk/information/trust_us)

**IMPORTANT:** You should telephone or write to the PCT and ask them for their policy and procedure documents for Applications and Appeals. You are entitled to see these under the FOI 2000.

Somewhere in your PCT Application procedure document will be the idea of your case being somehow “exceptional”. The PCT might not use the words “exceptional circumstances”. They might use “Special Commissioning” or “Patient Individual Needs (PIN)” to describe their procedure.

The PCT should decide on the basis of the evidence in your case. That evidence comes from different sources. The main source of evidence is your consultant.



## What do I have to prove to the PCT?

- ◆ Clinical effectiveness – consultant should do this
- ◆ Cost effectiveness – consultant should do this
- ◆ Exceptional circumstances – you must do this in collaboration with your consultant

You have to show your case is exceptional. Exceptional means different things in different circumstances. Those circumstances are a mixture of your condition and recommended treatment within the context of your PCT policy. Just because a PCT does not usually fund treatment for your condition does not mean they will never fund the treatment. If you are outside the “usual” circumstances for your PCT, then your PCT may still pay for it.

**IMPORTANT:** Working with your consultant is vital to the chances of success. The consultant will know about factors in your clinical condition which make you exceptional. The consultant will be able to guide you so that you can improve your cost effectiveness. Without consultant support you stand little chance of success.

## What factors the PCT looks at.

The PCT have to take into account a number of different factors. These include: -

- 1 your medical condition,
- 2 your application letter,
- 3 your consultant’s clinical opinion,
- 4 clinical effectiveness,
- 5 cost effectiveness (not the absolute cost of treatment).
- 6 the impact of the PCT decision on your family members as well as upon you (to comply with human rights legislation).

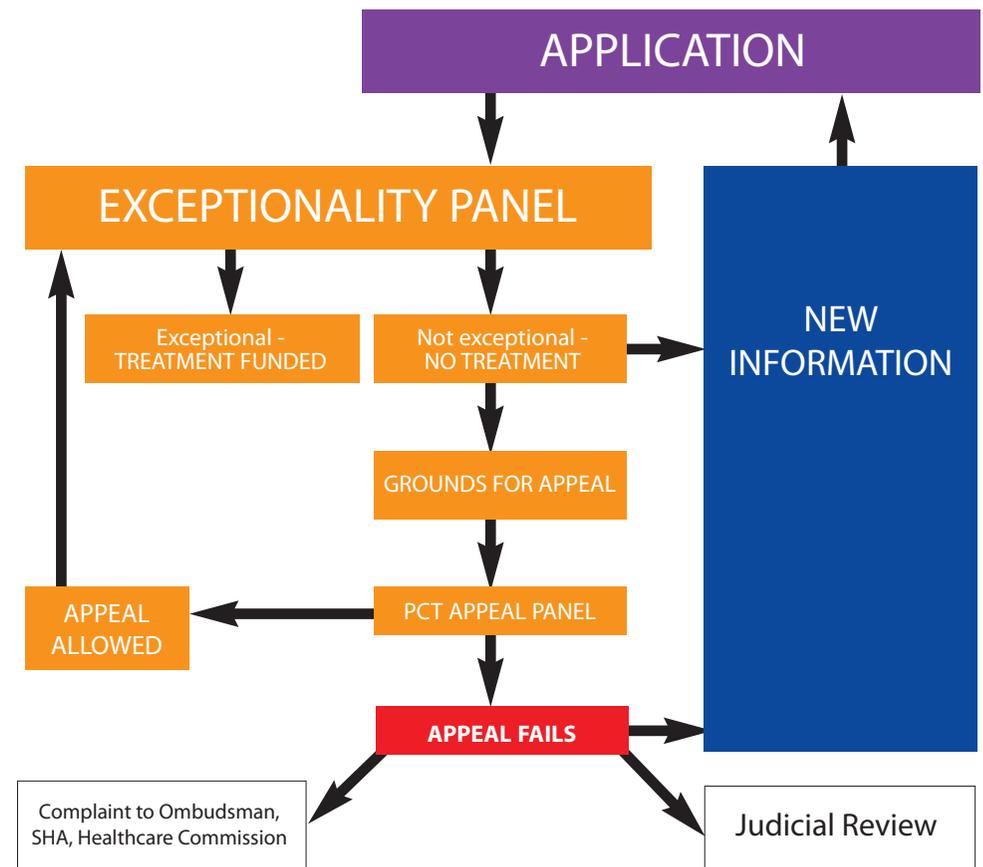
The information they base their decision on has to be relevant to the issue they have to decide. They cannot act solely on their own prejudices. Some PCTs ignore guidance. Some PCTs treat guidance as if there were no exceptions. Some PCTs make the mistake of thinking that if NICE guidance does not provide exceptions, there are none to be found. That is wrong. Guidance should not be followed slavishly, otherwise mistakes can be made. It would be like a vehicle driver following Satellite Navigation without engaging their brain.

## Guidance.

The **PCT** looks at guidance from **NICE, SMC, AWSMG**, their Local Cancer Network, NHS Confederation documents. They should also take account of published clinical data.

**IMPORTANT:** All **NICE** guidance stresses that their guidance does not override the professional clinical advice of your consultant.

There is an ongoing debate about what this means. One interpretation of the law is that when a consultant has carefully considered NICE negative guidance on a particular treatment and yet decided to recommend that their patient is treated notwithstanding what NICE guidance says, the PCT should accept this. There is yet to be a legal test case on this point. It may all depend on how well your consultant justifies his argument.



## The Application.

You should make an application long before you need the treatment. Then you will know what the PCT decision is. You will be faced with extra delay if you decide to Appeal or seek judicial review.

Before you apply, write down a full history of your case from day one. Include your family history. Write down the names and contact details of all the people who are dealing with your case. If you have family, friend or a lawyer who is acting on your behalf you must give notice to the PCT of your written consent to them seeing your information.

You can apply more than once as long as there has been "a material change in circumstances". For example, the clinical evidence might change from the time when the PCT made their first decision to refuse.

Usually the panel will decide on Documents only. It is vital that you put in as good a written case as possible.

As well as the letter from your consultant to your PCT you need to send to the PCT:

A letter from you about you and all your family circumstances.

- ◆ Your GP support
- ◆ Any family or MP support
- ◆ You can find a good example of a consultant's letter in the booklet "Your Patient's Right to Treatment". It is on the website ([www.southernlaw.co.uk](http://www.southernlaw.co.uk))

## What should I put in my letter?

Miss nothing out. You know your own case. Tell the PCT. You should use the factors (1) to (6) in "What factors the PCT looks at" to form the basis of your letter. Citizens Advice Bureau ("CAB"), local lawyers and your Charities will be able to help.



## Can you attend the PCT panel meeting?

It is unusual but it is up to your PCT. Some PCTs allow you to bring family, friend or a lawyer. Others refuse.

You should ask if your PCT will allow you or your friend or lawyer to attend the exceptional panel meeting. The PCT may be interested to know more about your case. You are best placed to answer their questions.



## The Panels Decision.

This will involve looking at the following subjects.



## Exceptional circumstances.

What exceptional means in law in the context of the NHS has yet to be settled. In other areas of law it does not mean something necessarily unique. It does not mean something unprecedented. It does not mean something rare. It obviously cannot be something regular or routine or normal. It cannot be extended to mean something that will apply to everyone else seeking a particular form of treatment, for example that they have a life threatening condition. The life threatening condition is relevant and material to the whole situation but by itself it cannot form exceptionality. There have to be additional factors. A decision made by a PCT does not set a precedent for a future decision.

PCTs in their policy documents sometimes add in further steps to be proved or definitions to be applied. Some PCT policies make it impossible to prove "exceptional circumstances". They might refuse where one patient can be likened to another. That is a policy for uniqueness, not exceptionality. If it becomes difficult, if not impossible, to envisage who and in what circumstances might be successful in overcoming these hurdles in respect of obtaining the treatment, that would be an unlawful procedure.

You should ask your PCT to explain their policy if you do not understand it.

## Examples of exceptional circumstances

- ◆ The PCT took into account care by a single parent for a disabled child which required home care.”
- ◆ Hypersensitivity to normal treatment and risk of other complications prevented full normal treatment so the PCT agreed a combination of 80% of normal treatment and the recommended treatment.
- ◆ A patient was significantly fitter and healthier than the generality of people suffering from an illness and so in regard to that particular condition and that particular treatment, was in the opinion of the consultant far likelier to respond positively to treatment.
- ◆ New evidence of a genetic test which meant increased chance of success on treatment.
- ◆ Drug taken privately had shown decrease in tumour markers. The treatment was the only proven cause of that reduction in tumour marker.

## Clinical effectiveness.

The consultant has the job of proving this. It is vital that the consultant does a proper job in the application. This is the first time that a judgment on the treatment can be properly assessed. Treatment can be prescribed in the right case even where it is not licensed.

## Getting a second consultants opinion.

This is useful when the case on clinical effectiveness is borderline and ought to be considered after a refusal when it might amount to a change in circumstances if the second consultant supports the treatment. It should also be considered if the consultant won't support an application. It's usually done through the GP and, in itself, may require a funding decision. You have a right to obtain a second opinion. You should not be too concerned that your present consultant will be upset. They have broad shoulders for that.

Importantly it will mean the PCT will find it hard to challenge two consultants. Of course, you take the risk that a second opinion might not agree with the first consultant's advice.

## Cost effectiveness.

This is the most common reason why PCTs refuse to fund. It should not be confused with a similar but different question of the cost. The PCT cannot simply refuse by saying the treatment is too expensive or too costly alone. The PCT must assess the chance of getting benefit from the use of the treatment. A treatment that does not work is expensive because it is a waste of money and of people's time.

If the PCT offers you an alternative treatment, ask it for details of the cost effectiveness of that treatment so that you can compare it with that of the treatment your consultant has advised

## Some drugs have no cost effectiveness data.

Many treatments for rarer cancer have no NICE guidance at all. This can delay the PCT decision. A lack of NICE guidance is not a lawful reason by itself for the PCT refusing to fund the treatment or delaying a decision.

The real question the PCT should be asking themselves is “Is the treatment likely to confer benefit and if so what kind of benefit and how much benefit?”

## Private treatment.

See also **Co Payments**. Sometimes a consultant will help in these cases by prescribing the treatment privately. You take the risk that if not done within **DH** guidelines you might have to pay for all the costs of your treatment. The purpose of this is to improve the evidence base for clinical effectiveness and therefore cost effectiveness in your particular case. Bear in mind that simply taking the treatment privately does not automatically mean the PCT has a duty to continue to fund it even if it works.

**IMPORTANT:** Before taking the treatment privately, notify the PCT so that they have a chance to respond to you. You might like to inform them that if the treatment works with you, you will be seeking reimbursement of the cost. On this point, you definitely need the assistance of CAB or a lawyer.

Please remember that taking the treatment privately and not telling the PCT whilst obtaining their services can prejudice your chances of a remedy in a successful judicial review at a later stage.

## Risk Share schemes.

Sometimes a pharmaceutical company offer the first few doses of a treatment free to the PCT or they offer to provide the treatment on the basis that the PCT pay only if it works with you.

## Why pay privately or Risk Share?

The point is to be able to assess whether you benefit from the taking of the treatment and to improve the clinical effectiveness evidence.

## Clinical Trials.

When you have been on a clinical trial and the treatment has worked, you should continue to have the treatment provided to you. This is because there are Ethical Approvals for trials and European Regulations on the issue. Contact CAB or a lawyer.

## Clinical Negligence.

This is an area which requires a lawyer's advice. It needs proper evidence from a consultant. Where there may have been negligence which has led to delay, or deterioration, or has limited the treatment that can be given, the negligence might amount to an exceptional circumstance. Another point is that if the PCT have been negligent, they should provide proper and full mitigation of loss with the recommended treatment.

## Human Rights

This is a different aspect of law. The legal test here is not simply whether you are exceptional within the PCT policy. The PCT have a duty to comply with Human Rights legislation and should not interfere with your human rights. The PCT have to prove they comply with human rights legislation. You have a right to a private and a family life under article 8 of the European Convention on Human Rights ("ECHR"). The test here is to take all matters in the round and see if the decision so affects your private or family life that it cannot be justified by the PCT as proportionate.

There may be particular situations where the right to life (article 2 ECHR) and the right not to suffer inhuman and degrading treatment (article 3 ECHR) apply. You may also have been given a legitimate expectation of treatment from the whole set of circumstances of your case. These points need legal assistance. The Courts have yet to lay down clear guidance on how these apply in every NHS setting.

## What if I have been refused already?

If an Application about your treatment has already gone through the exceptional panel of your PCT and your case has been refused, you should ask the PCT for the **Reasons for refusal**, a copy of the **Application**, a copy of the **Minutes** of the PCT meeting which decided to refuse and copies of the **Documents** the panel who decided had with them when making their decision.

If you have already been refused, and you did not know about the process you can write a letter explaining you were not aware of the Application. The PCT might treat it as grounds for a fresh Application.

If not, then you have to Appeal.



Refusal of an application is not an end to the PCT process.

The PCT may have to conduct an appeal if you challenge their refusal of your application. Most PCTs do this although there is no legal requirement on them to do so. They do not conduct it on the merits of the decision but rather on whether their process in coming to a decision was followed and it was a fair and rational process.

Do not assume merely because the PCT panel are in a position of power and authority that they will always get it right. You might be surprised how poor their management of your case is. In poorly run PCTs these can be a source of reasons for an appeal. With the Minutes, you will see what went on in the meeting. You may be surprised at how ill informed and how prejudiced some PCT panels are.

## **Set out your grounds for appeal.**

There are examples in the appended documents below. You are challenging the PCT on their procedure and fairness and rationality.

## **Can I attend the appeal?**

Possibly. Ask the PCT for their policy on this. You are more likely to be allowed to attend the appeal than the application panel.

## **What happens if I win the appeal?**

If you win, you usually go back to the application stage. You may have put in new evidence. In extreme cases where the treatment should obviously have been provided, the Chief Executive of the PCT can step in and order funding.

## **A New Application Panel?**

The PCT usually send the application back to the same people who made the first decision. PCTs often state it is impossible to obtain new panel members quickly. However, although it will delay things you might wish to ask for a fresh panel because of bias in the way the people on the original panel unfairly conducted the original meeting. Even the fairest minded people could not put that kind of criticism out of their mind when being asked to reconsider a case.

## **Legal Implications.**

If the appeal has failed, ask for the appeal panel refusal reasons, the minutes and copies of the documents they had when they decided. You should take legal advice from a CAB or lawyer. When the appeal has failed, you should consider bringing a judicial review of the case. JR should be begun "promptly" or within a maximum time limit of 3 months from the appeal decision.

Ask your CAB or lawyer if you qualify for Legal Aid.

## **Judicial Review ("JR").**

If you intend to go to court on the matter, telling the PCT about your intention to seek JR can persuade a PCT Senior manager to have an in depth look at the case and reconsider the matter. This is sometimes enough when it is plain that the application panel have made mistakes.

Remember also that the High Court is only interested in the lawfulness of the decision. It is not there to decide on the merits. What that means is that even if the court thought that they personally might have provided you with the treatment, if the PCT decision was lawful, the court will not interfere.

## **The Ombudsman. The Strategic Health Authority, Healthcare Commission.**

You can make complaints about the PCT to these bodies. This is unlikely to get you the treatment in time for it to be useful to you and so Judicial review will usually be a better option. If you are not eligible for legal aid and you cannot afford lawyers for Judicial Review it might be worth complaining to the Ombudsman with your consultants support and asking her to bypass the normal procedures and intervene urgently (which she has the power to do). The Ombudsman can recommend the PCT reviews or changes to a decision if maladministration or a service failure leading to injustice is proven.

In theory the SHA and the Secretary of State can intervene in individual cases but rarely do so.

## **Publicity. The Press. The Media.**

Publicity can be very useful in the right circumstances. Publicity is useful in getting a higher level of management to look at the case. The Press are mainly interested when the PCT has not followed their own procedures properly or if there are tragic personal circumstances. If the PCT panel were not doing their job properly, then you have a story which is of interest to the public. After all, we are all paying for the PCT to manage things properly. Using the Press is sometimes the first step.

Letters you might use are found in Appendix 1 – 5.



# Checklist.



## Application

1. Have you got the PCT policy and procedure documents?
2. Has your consultant written a full enough application letter?
3. Have you written your full application letter with full family history?
4. If it applies, have you given the PCT notice of consent for your friend or lawyer to access your information from the PCT?

## Appeal

5. Have you got the written reasons for the PCT panel refusal of application?
6. Have you got the PCT minutes of the exceptional panel meetings?
7. Have you got the PCT appeal process information?

## Taking it further

8. Have you got the PCT appeal panel refusal?
9. Have you got access to CAB or a lawyer who might help you?
10. Have you contacted the Press or your MP?



## Appendix 1 - Letter for copies of information and documents which the PCT hold on you, after your consultant's application was refused.

Your Address  
 Your e-mail address  
 Your Contact Telephone Numbers

To:  
 Name of Manager at Your PCT  
 Name of PCT (e.g. Salford Primary Care Trust)  
 Address of PCT

Dear Sir/Madam

Freedom of Information Act 2000 Section 1 (1) (a) and (b)

Data Protection Act 1998 Section 1 (1), Section 4 (4) and Schedule 2.

I am writing to request that you inform me promptly and in any event within 20 working days of any and all information held by you in regard to my medical history. Please include any application made in regard to treatment or proposed treatment on me. If you hold such information I give my consent for processing of sensitive information and ask that copies be sent to me as soon as possible. I seek copies of (1) My Medical Records including any scan results and X-Rays (2) Any documents received by you in regard to an application made in my name for funding for a drug known as [name of drug] including any letters sent by my consultant [name of consultant] and any documents considered by the [name of PCT] in the application including (3) copies of the policy and procedure used by [name of PCT] in considering my application and (4) a copy of the written record of decision made by [name of PCT] and any reasons given for refusal in my application and (5) a copy of any minutes of the committee or panel of [name of PCT] which considered my application and (6) a copy of the appeal procedure and policy of the [name of PCT].

These should include copies of any e-mail communication as well as letters and any handwritten notes of communications in regard to me and my application and any decision made in regard to me and my application.

Please provide means by which the identities of the panel members who were involved in the decision to refuse might be known, if not by name then by reference to number or letter, and any relevant qualifications they might have.

This is so that (i) it can be verified that this was a properly constituted panel and (ii) so that none of those involved in the initial decision take part in any appeal from their decision.

Please identify the date or dates, on which the panel were authorised to meet, consider and decide on my case. Please confirm that the panel members actually met on one occasion when a final decision was taken.

Please do/do not make anonymous my name or my family identity in this application and appeal process.

Yours Sincerely

 **Appendix 2 - Letter to Consultant (before making an application).**

Your Address  
Your e-mail address  
Your Contact Telephone Numbers

To:  
Name of Consultant  
Address of Consultant

Dear Sir/Madam

I am writing to you following the meeting we had on [date] at [name of place]. You said you would support my application for [name of drug]. Thank you for that. I have been made aware of advice for you on how to make an application through a booklet written for consultants and available through downloading of a PDF document on the following Internet website:- [www.southernlaw.co.uk](http://www.southernlaw.co.uk)

In that booklet there are examples of the kind of information required by a PCT in a letter from a consultant. I know that in all probability you will have to complete the PCT pro forma or application form but there is nothing to stop you from providing further information. I would like you to provide that further information of the type which is of help to the PCT panel who must decide my application.

At the meeting we had I gave you the details of my private and family life. Here is a short account of my current family, my relationships and my commitments to them. It can be seen that the decision in this application will affect them as well as me in terms of their health and well being.

I know it is a lot of work to make these applications. I am very grateful to you for that. If for any reason you are unable to provide the information the PCT require then please let me know how I can help you find it and provide it to the PCT.

In the meeting we had I noted that you said that the clinical evidence is not extensive and there is no guidance from NICE on the [name of drug]. I would like a second clinical opinion to assist in this application. This is because we need to have as much clinical evidence as possible. This application is the only one I will probably be able to make. I think it needs the best chance possible. Can you help me find the right person to help provide a second opinion? In this way I think that the PCT will have the best clinical information available.

Do you know of any tests that can be done such as genetic tests or markers which could help identify those more likely to benefit from the drug? Are you willing to prescribe the drug so that I can take it and prove that it works?

If not, could you please refer me to a consultant that would be willing to consider treating me privately?

If you cannot support this application then please let me know as soon as possible as I will need to obtain a further clinical opinion.

Yours Sincerely

 **Appendix 3 - Letter to Consultant (after making an application which was refused).**

Your Address  
Your e-mail address  
Your Contact Telephone Numbers

To:  
Name of Consultant  
Address of Consultant

Dear Sir/Madam

I am writing following the application you have made on my behalf to the [name of PCT] for [name of drug]. Thank you very much for the support you have given.

I understand that the decision from the [name of PCT] was unsuccessful. I intend to appeal the decision.

It is not too late to provide further information to the PCT.

I have received a copy of the letter written by you to the [name of PCT]. I have also received copies of the minutes of the meeting. It is plain they did not contact you to clarify areas of uncertainty. I would like you to add the information required by the PCT when they make the appeal decision in accordance with their own policy and procedure. I have highlighted the areas where they require specific information on the clinical effectiveness and cost effectiveness of this drug.

I have written to the PCT with details of my private and family life.

One of the issues raised by the PCT is the lack of evidence of cost effectiveness. I would like you to provide evidence if possible of the effect that the [name of drug] has already had on me. This is because we need evidence that in my particular case the drug is likely to be cost effective. As you know, since making the application I have taken the drug privately and the scan tests show that the tumour has stabilised and not grown as before and the blood markers are reduced. Would you be prepared to say this is "significant"?

This application and appeal is the only one I will probably be able to make. I think it needs the best chance possible.

If you cannot support this application or appeal then please let me know as soon as possible as I will need to obtain a further clinical opinion.

Yours Sincerely

 **Appendix 4 - (Letter notifying PCT of legal representative/friend)**

Your Address  
Your e-mail address  
Your Contact Telephone Numbers

To:  
Name of PCT Manager  
Address of PCT

Dear Sir/Madam

Let [name of PCT] be hereby notified that:-

- (1) I have appointed [name of legal representative/friend] as my representative in my application and appeal against [name of PCT] for funding for [name of drug].
- (2) By this letter I, [Your full name, date of birth, address] give my consent and permission that all information and documents in regard to my application and appeal and treatment be released by [name of PCT] to [name of legal representative/friend].

Signed .....

Dated .....

 **Appendix 5 - (Letter of appeal)**

Your Address  
Your e-mail address  
Your Contact Telephone Numbers

To:  
Name of PCT Manager  
Address of PCT  
Dear Sir/Madam

Dear Sir/Madam

Please take this letter as formal notice that I appeal the decision of the committee/panel of [date] which decided to refuse to fund [name of drug].

The grounds of appeal are as follows:- (examples only – you might wish to take advice before sending)

Grounds

The panel were not properly constituted because they failed to have any oncologist.

The panel did not properly meet and breached PCT policy.

The panel failed to consider material evidence [name these].

The panel wrongly and improperly took into account immaterial matters [list these].

The panel applied too strict a test in that it required me to prove something which is impossible to prove.

The wording of the PCT policy is ambiguous and too stringent in one interpretation.

The PCT have failed to consider me as part of a group which presented in May 2003 with advanced metastatic disease but instead have wrongly narrowed and reduced the field of comparators to a cohort of patients who would present at today's date. I can thus never comply with the restrictive interpretation of "cohort of patients". This is an unlawful test.

Panel members expressed their own personal views which were unfair and biased.

The panel have misapplied the law. The panel refused on the basis of a lack of NICE guidance. It is the case that the PCT are not allowed in law to refuse simply on the basis of lack of NICE guidance.

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The panel wrongly failed to take all matters together “in the round”. Instead the panel wrongly looked at each element in a checklist format and took the approach that any one element missing from their checklist entitled them to refuse. The panel should have considered my case and all the factors in it cumulatively.

The PCT failed to take proper account and place proper weight on the clinical evidence from my GP, Consultant and Pharmacist.

The PCT have wrongly ignored a risk share programme that was cost neutral.

The PCT have failed to consider the fact that I have taken the drug privately and therefore demonstrated with my excellent results that I am exceptional. Most patients who take the drug do not respond as well.

Please also note that I require a decision as a matter of urgency. This is because of the nature of my condition. Without the drug my prognosis is poor and the condition will deteriorate rapidly. I have only [number of months] without the drug.

There have already been serious delays in the decision making process by the [name of PCT]. [Set out details of delays].

Please also note that I intend to take judicial review proceedings in the event of a refusal to fund.

Please also note that in the event that the [name of PCT] continue to refuse the drug and that upon appeal the drug is funded, I intend to seek reimbursement of the payments I have already made from [date] in the total sum of [£.....].

Yours Sincerely

## Useful Contacts

### Kate Spall

Pamela Northcott was the first patient in Wales to win NHS funding for Nexavar, after a long campaign by her daughter, Kate Spall. After Pamela's death from kidney cancer in August 2007 Kate founded the Fund to help other cancer patients access treatments denied by their local PCT. Kate was Patient Expert for the N.I.C.E appraisal of 4 kidney cancer drugs and has provided briefings for treatment debates in Parliament and has to date won funding for over 80 exceptional cases for kidney, liver, lung, sarcoma and brain cancer patients. Please contact her at:

Email: [kate@pamelanorthcottfund.org.uk](mailto:kate@pamelanorthcottfund.org.uk)

Website: [www.pamelanorthcottfund.org.uk](http://www.pamelanorthcottfund.org.uk)

### Rose Woodward

Is a Kidney Cancer patient and specialises in access to kidney cancer treatments.

Please contact her at:

Kidney Cancer Support Network, 46-48 King Street, Cambridge CB1 1LN Fax: **01223 507095**

Website: [www.kidneycancersupportnetwork.co.uk](http://www.kidneycancersupportnetwork.co.uk)

### Bowel Cancer UK

Bowel Cancer UK to date, with the support of lawyers working pro-bono on our behalf and patients' local media and MPs, has helped over a hundred people gain access to treatments they were previously denied on the NHS. We now have 30 lawyers working on our and our patients' behalf – which means we can help even more people. Please contact on:

Email: [pcp@bowelcanceruk.org.uk](mailto:pcp@bowelcanceruk.org.uk) or call our press office on 020 7381 9711

Website: [www.bowelcanceruk.org.uk](http://www.bowelcanceruk.org.uk)

### Sarcoma UK

Supporting patients with bone and soft tissue sarcomas and GIST. Please contact:

Email: [info@sarcoma-uk.org](mailto:info@sarcoma-uk.org)

Website: [www.sarcoma-uk.org](http://www.sarcoma-uk.org)

