Policy for 'low priority' treatments

1 Introduction

This paper sets out the North Central London PCTs' policy on not commissioning 'low priority' treatments routinely; requests for funding such treatments should be considered individually. This policy has been drawn up in the context of the principles framework used by three of the North Central London PCTs and the new NHS Constitution.

1.1 Context

1.1.1 Why might some treatments be considered to be of 'low priority'?

We cannot support the commissioning of services and treatments that are known to be clinically ineffective,[i] nor those that are not cost effective. We also consider that treatments that may be clinically and cost effective should not be commissioned if they are unaffordable because of in-year financial pressures, or if their opportunity costs are high and funding them could thereby deny clinically and cost-effective treatments of more significant conditions for others. 'Low priority' treatments are thus those where the evidence of clinical and/or cost effectiveness is limited (or they are only clinically effective in a specific group of people or in certain clinical circumstances, when they might be funded), and/or where not funding such treatment is unlikely to have a significantly adverse effect on the patient's physical or mental health or ability to undertake everyday living activities with reasonable independence.[ii]

If resources are used for one person then those same resources are not available for someone else. So, if we give resources to one person that are disproportionate to their need or ability to benefit then we deny those resources to others who might benefit more and this would be inequitable.

In addition, if a treatment is funded for one person then that treatment should be funded for all people in similar circumstances; to do otherwise would be inequitable. Thus, if funding a large number of treatments for conditions that do not have a major impact on people's lives would reduce the amount of money available to fund clinically and cost effective treatments for conditions that have a significant effect on people's lives, then we could not use our resources to the greatest benefit of the greatest number. This principle was probably first articulated in court in an NHS context in the 'Child B' case[iii] (this is referred to in more detail in Appendix 1: the Framework of Principles).

2 What treatments might be considered to be 'low priority'?

The list of 'low priority' treatments in Appendix 2 is not exhaustive, rather, it is indicative of the types of treatments that we consider are likely to be of lower priority for funding than others and that thus we will not routinely fund. We may formally add to this list and we reserve the right to define other treatments and clinical interventions as being of 'low priority' in the light of further reviews and/or individual patient treatment funding requests and/or proposals for service developments.

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i Clinical effectiveness is the extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are intended to do – that is, maintain or improve health, and secure the greatest possible health gain from available resources [NHS Executive. *Promoting Clinical Effectiveness: a framework for action throughout the NHS*. Department of Health, 1996]

ii In contrast, a 'high priority' treatment might be one that was literally life saving or one that might reasonably relieve, or avoid, a significant disability that was far beyond what is usual in terms of causing difficulty or an inability to undertake everyday living activities

iii Sir Thomas Bingham MR in *R v Cambridge Health Authority ex p B* [1995]

The second column in the table in Appendix 2 gives an indication of circumstances in which each of the North Central London PCTs, or the North Central London Acute Commissioning Agency acting on their behalf, might consider it appropriate to fund such a treatment, subject always to consideration of all aspects of the prevailing version of the framework of principles to be found in Appendix 1. It is important to note that exceptionality is a 'threshold condition', i.e. a finding of exceptionality does not mean that the PCT responsible for a particular patient is bound to approve funding, but is the start of the process of making a decision in an individual case because the responsible PCT must balance this with the other components of the principles framework. There are two instances in this list where no such examples are given. This is because we are not aware of any robust evidence to support such treatments. However, were such evidence to be made available then, similarly, the responsible PCT be willing to consider a funding request, in the light of such evidence and balanced against all components of the framework of principles, on an individual basis.

3 Clinical effectiveness

The framework of principles (see Appendix 1) defines clinical effectiveness. It would be inappropriate to fund treatments where there was little or no evidence of clinical effectiveness or where that evidence was weak: if we fund one type of treatment where there is poor evidence of clinical effectiveness then we would be obliged to fund all treatments where there was similarly weak evidence of clinical effectiveness. We also consider that the fact that a condition may be rare and thus its treatment may be more difficult to research does not constitute a valid reason for us to accept poor quality evidence.

For some 'low priority' treatments, as far as we know, robust and convincing evidence of clinical effectiveness is lacking, although the responsible PCT would be pleased to review any good evidence that were made available as part of an individual patient treatment funding request. In other instances, there is good evidence of clinical effectiveness of the 'low priority' treatments but this must be balanced with the other principles in the framework including, but not limited to, cost effectiveness, equity and distributive justice.

4 Cost effectiveness

In assessing cost-effectiveness, we have to consider the balance between cost and benefit, whether the benefit is likely to be long-lasting, and whether the precedent of funding one treatment may require us to fund treatments for other conditions (which would also require us to consider affordability, equity and distributive justice issues, among others). The fact that a treatment may be relatively inexpensive does not mean that it is cost-effective if there is poor evidence of its clinical effectiveness. Similarly, if we agree to fund one type of treatment solely because it is inexpensive then we become obliged to fund all treatments that are similarly inexpensive: funding a large number of treatments that are individually inexpensive costs a large amount of money and this would not be available to support the use of other treatments where the evidence of clinical and cost effectiveness (and other considerations) are more convincing, or to address issues of health inequalities, and this would prevent us from using a limited budget to the maximum advantage of the maximum number of people.

5 Affordability

A multi-million pound levy has been placed on most London PCTs for 2009/10 and 2010/11 to provide deficit support for a number of acute hospital trusts. In addition, some North Central London PCTs are over their capitation position. This means that they expect to receive below-average growth in their funding in 2010/11, in addition to any impact that the current national economic situation will have on public sector spending.

Whilst all North Central London PCTs seek to achieve balanced budgets for 2009/10, there are substantial pressures against this which mean that their individual ability to achieve the statutory financial breakeven duty is likely to be compromised.

It is also now apparent that the NHS will not have a budget uplift in 2011/12 and probably for several years thereafter because of the need for the government to address national budget problems. This means that staff pay raises and any increases in costs ('medical inflation' typically runs at 5-10% each year) will have to be managed within a budget that is, effectively, frozen. North Central London PCTs are therefore having to implement savings this year and next to help mitigate this severely adverse situation.

As the resources available to PCTs are finite and they are statutorily required to balance our budget and not to overspend, they also have to take affordability into account when considering what treatments and other clinical interventions they can fund.

6 Equity

There are three components to this. The first is that, within the requirements of legislation and NHS regulations, and other than where there is good evidence that a particular characteristic (e.g. age) or lifestyle (e.g. smoking) adversely impacts the clinical and/or cost-effectiveness of treatment, the North Central London PCTs will not discriminate between people on personal or lifestyle grounds.

The second component is that health care should be allocated justly and fairly on the basis of need, and the North Central London PCTs will seek to maximise the welfare of all the people for whom they are responsible within the resources made available to them. In this context, equity means that people in equal need should have equal access to care. But everything has an opportunity cost; if resources are used for one person then those same resources are not available for someone else. So, if we give resources to one person that are disproportionate to their need or ability to benefit then we deny those resources to others who might benefit more and this would be inequitable.

In the context of an individual patient treatment funding request, PCTs also need to consider, on an individual patient basis, whether there are exceptional circumstances that might be relevant in their case. Our definition of exceptionality is provided in section 4.1 of the framework of principles (see Appendix 1). Section 4.2 of this framework defines limits to this. As noted earlier, exceptionality is a 'threshold condition' and thus any finding of 'exceptionality is the start of the process of making a decision in an individual patient's case because PCTs must balance this with the other components of the principles framework.

7 Quality and safety

PCTs are sometimes asked to fund treatments (which may or may not be considered to be 'low priority' as referred to in this document) in institutions or that are provided by people who are not within the NHS. Whilst there are good mechanisms in place to assure quality and safety in NHS organisations, this is not necessarily the case in other organisations or with individual practitioners and individual PCTs, and/or the North central London Commissioning Agency acting on their behalf, will also need to take into account the evidence for the safety and quality of the proposed treatment when considering any such funding applications.

8 Ethical considerations

8.1 Autonomy

We should respect a patient's capacity to think and decide what they want for themselves, and we recognise an obligation to help people to make such decisions by providing any and all information that they need. We also recognise that we should respect their final decision, even if it is not what we think is best for them. We assume that most patients will wish to try the proposed treatments that we are being asked to fund (although this is not always the case). However, of itself, this does not mean that any individual PCT should fund such requests.

We also need to consider another aspect of autonomy, albeit not strictly the ethical aspect of this: that some treatments may enable a patient to maintain their independence and/or dignity (e.g. prolonging the time that they can continue to perform everyday living activities with relative independence) and we consider that this is a desirable objective, although it will not necessarily take precedence over other considerations. We would need to see good quality evidence that a proposed treatment might reasonably be expected to benefit the patient in this way and this must be balanced against the other components of the principles framework.

8.2 Beneficence

We recognise an obligation of beneficence, which emphasises the moral importance of 'doing good' to others, entailing doing what is 'best' for the patient or group of people, and we recognise that many treatments might be considered to do so, albeit sometimes only to a very limited extent or in special or poorly predictable circumstances (for example, it is not always possible to know that a patient is likely to respond to a treatment in the way that those in a research trial did, especially if there are aspects of their circumstances that might have led them to have been excluded from the trial or trials put forward as evidence for the effectiveness of the proposed treatment).

We also have an obligation to do good to others and our responsibility is for all people registered with North Central London GPs not just for an individual person. We therefore have to balance the impact of doing good for one person with the effect that that would have on our ability to do good for others. In considering this, we also have to recognise that all decisions set precedents: if we agree to fund this request for one person then we become obliged to fund all requests where the circumstances are similar and this would increase the cost and thus the opportunity cost which could impact on our ability to do good for others. Therefore, even where there may be some evidence that a particular treatment or clinical intervention might 'do good' for an individual, this must be balanced against the other components of the principles framework.

8.3 Non-maleficence

We recognise a duty of non-maleficence, which requires that we should seek not to harm people. However, it is important to recognise a distinction between a duty not to harm someone (which implies actively doing something that may harm them) – which we recognise as something we should not do – and not acting to prevent possible harm. We consider that there is an important difference here because it is not possible for us to prevent harm coming to everybody, and therefore we do not consider that there is an obligation for us to fund an intervention just because it might reduce the risk of some sort of harm coming to an individual.

We also need to consider whether the likely risks of a proposed treatment are balanced by its likely benefits. We also recognise that few, if any, treatments are likely to be without side effects or adverse reactions in all patients in all circumstances. Further, we need to take account of whether not funding a treatment might do the patient harm. However, we also have a duty not to harm others and funding a treatment inappropriately could do this, albeit indirectly, by denying them access to treatment that could otherwise do them greater good.

For similar reasons, a treatment of likely limited benefit and/or of relatively high cost will not necessarily be provided simply because it may be the only active treatment available.

8.4 Distributive justice

The principle of distributive justice emphasises two points: patients in similar situations should normally have access to similar health care; and when determining what level of health care should be available for one set of patients, we must take into account the effect of such a use of resources on other patients. In other words, we should try to distribute limited resources (such as time, money, intensive care beds) fairly, and based on need.

Need usually exceeds the resources available. We therefore cannot always enable every patient to have what some might think of as the ‘best possible’ care. This concept conflicts with the principles of some clinicians who, understandably, take the view that every patient should be given the ‘best possible’ care and that every therapeutic option should be tried irrespective of cost. However, if we provide the 'best possible’ care for everyone then at some time during the year there will be nothing left for others: we will be giving some patients 'everything' and others 'nothing'. We consider that such an approach would be inappropriate and that we should share resources 'fairly', this usually meaning (i) giving resources preferentially to those who are in greatest need and who can benefit the most from them, and (ii) settling for what is adequate and not necessarily what may be the ‘absolute best'. We believe that this approach is consistent with the opinion expressed by Sir Thomas Bingham in his judgment in the ‘Child B’ case.[iii]

9 Conclusion

Appendix 2 sets out a non-exhaustive, i.e. an indicative, list of the types of treatments that we consider to be of lower priority for funding than others and therefore that we will not routinely fund. We consider that this is reasonable having taken account of the various components of the framework of principles, and that it is rational in so far as other PCTs have similar lists of ‘low priority’ treatments and similar principles frameworks. By being willing to consider funding requests for such treatments on an individual basis, and to consider the possibility of exceptionality (as defined in the framework of principles) were there is good evidence for this, we believe that this is also a reasonable approach to take for organisations with finite budgets and more calls on that budget than can be accommodated within their statutory obligations.

North Central London Sector
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Appendix 1: Framework of Principles

This document describes the principles that we have applied in drawing up this 'low priority' treatments policy.

The intent of the North Central London PCTs is to improve the health and well-being of their populations and to ensure that there are good quality, appropriate health promoting and health care services for those people that need them. We wish to ensure that people receive health services that are appropriate for the 21st century.

The experience of the NHS from its inception is that demand has always outstripped supply. There is no evidence that this is changing and thus we must sometimes choose between providing one type of service or treatment over another. The North Central London PCTs are committed to focusing their resources where they are needed most.

The North Central London PCTs are responsible for the health and health care of some 1.24m people registered with local GPs, a population that is expected to grow by some 100,000 over the next few years. We are therefore responsible for the health and health care of a lot of people and the needs of those populations are different in different parts of the North Central London sector. If we spend money or allocate other resources (e.g. staff time) in one area, or for one group of people or for one individual, then those resources cannot be used for someone else. We therefore try to ensure that our resources are used to the benefit of the largest number of people. This inevitably means that it is not always possible for everyone to get exactly what they want or when they want it; we have to prioritise some services and individual treatments over others.

A PCT's decision on an individual patient treatment request[i] does not concern whether it is clinically appropriate for a patient to have the treatment recommended by their clinical adviser, but whether it is appropriate for them to fund it. This responsibility has been recognised in the courts, most notably in the 'Child B' case, when the judge said:

> "I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much the cost, particularly when a life is potentially at stake.
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> "It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients." [ii]

This observation has been quoted with approval in a number of appeal judgments on individual patient treatment requests since and remains an accurate statement of the law. In another case concerning the funding of an individual treatment,[iii] the court stated that:

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i PCTs receive a number of requests for treatments that are outside service level agreements ('TOSLAs') either because a treatment is specifically excluded from a contract (sometimes by national requirement) or because a patient or their clinician proposes treatment to be provided by an organisation or an individual with whom a PCT does not have a current contractual arrangement. Such requests are dealt with on an individual patient basis

ii Sir Thomas Bingham MR in *R v Cambridge Health Authority ex p B* [1995]

iii *R v NW Lancashire Health Authority, ex parte A, D&G* [1999]

> "…in establishing priorities, comparing the respective needs of patients suffering from different illnesses and determining the respective strengths of their claims for treatment, it is vital for an [NHS funding body] accurately to assess the nature and seriousness of each type of illness; to determine the effectiveness of various forms of treatment for it; and to give proper effect to that assessment and that determination in the application of its policy.
>
> "The [NHS funding body] can legitimately take into account a wide range of considerations, including the proven success or otherwise of the proposed treatment; the seriousness of the condition… and the costs of that treatment".

In this case, the court also stated that:

> "It is natural that each [NHS funding body], in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose, indeed, it might well be irrational not to have one. "

In drawing up a policy on 'low priority' treatments, we have therefore applied a number of 'principles', and balanced these against each other, in determining what we should not fund as a matter of routine. These principles are:

1 Clinical effectiveness

Our resources should be used in the most clinically effective way –

- clinical effectiveness is the extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are intended to do – that is, maintain or improve health, and secure the greatest possible health gain from available resources;[1]
- we recognise a distinction between 'evidence of lack of effectiveness' and 'lack of evidence of effectiveness', and we will seek to avoid supporting the use of interventions for which evidence of clinical effectiveness is either absent, or too weak for reasonable conclusions to be reached;
- as well as strength of evidence for a particular intervention, we will also take into account the likely magnitude of benefit and of safety for patients, as well as the number of people who can reasonably be expected to benefit from that intervention;
- when assessing evidence for clinical effectiveness, we will give greater weight to some outcome measures than to others, for example, but not limited to –
  - randomised controlled trials and large observational studies published in peer-reviewed journals are likely to provide more robust evidence for a finding than individual case reports, small case series or anecdote;
  - trials of longer duration and those with clinically relevant outcomes are likely to provide more robust evidence for a finding than those of shorter duration or those with surrogate outcomes,
  - reported levels of 'patient satisfaction' do not necessarily provide good evidence of clinical effectiveness or the likelihood of others having similar outcomes with the same or with similar treatments; and
- we will seek our own expert advice on topics as we may consider necessary.

2 Cost effectiveness

Our resources should be used in the most *cost* effective way –

- the NHS has finite resources and is required to keep within its budget, so to maximize the care that can be given to patients generally we must extract the maximum value from the money we spend and from the way in which all other types of resources are used;
- the cost of treatment is relevant because every activity has opportunity costs – if resources are used in one area they cannot be used in another, so we must seek to use all resources in the most appropriate way if the greatest number of people possible are to benefit in the greatest possible ways; and
- decisions to fund a treatment have the capacity to set a precedent – if one person or a group of people are given treatment then others in similar circumstances will expect to receive the same treatment. Thus, a decision about the treatment of one person or a group of people can have resource implications beyond that individual or group.

3 Affordability

We should only commission the services that we consider are appropriate if we have enough money or other resources to do so –

- we are statutorily required to keep within the resources available to us, that is, we are legally bound not to spend more money each year than we have been allocated; and
- if we use money or other resources on one investment then we cannot use the same resources for another. So we consider that, even if something is clinically effective and it is, compared to other interventions for the same condition, also cost-effective, this does not necessarily mean that we will be able to support its use because we may not always have enough money or other resources available or because other investments are determined to be of a higher priority.

4 Equity

Our resources should be used in an equitable way –

- within the requirements of legislation and NHS regulations, and other than where there is good evidence that a particular characteristic (e.g. age) or lifestyle (e.g. smoking) effects the clinical and/or cost-effectiveness of treatment, we will seek not to directly or indirectly discriminate between people on the grounds of[iv] –
  - age
  - gender
  - ethnicity
  - physical, sensory or learning disability
  - religious beliefs
  - sexual orientation
  - place of abode[v]
  - employment
  - financial status
  - personal lifestyle
  - social position or status;
  - suggested 'individual worth', e.g. having a particular occupation or being a parent or carer

iv This list is not exhaustive, but is intended to provide examples of the types of differences between people that the we will not use as grounds for determining whether one person or group of people should or should not receive a particular treatment, other than where there is good evidence that a characteristic is associated with poorer or better clinical or cost-effectiveness

v Other than the fact that PCTs are only responsible for the health care needs of the residents of their boroughs, for people registered with their general medical practitioners, for the provision of a range of school nursing services to children attending their local schools, and for visitors to their areas who develop a need of emergency health care whilst there

- health care should be allocated justly and fairly on the basis of clinical need, and we will seek to maximise the welfare of the largest possible number of people within the resources available to us. However, we will be willing to be flexible so that variations from this approach may (but will not necessarily always will) be made in certain circumstances, such as (but not necessarily limited to) –
  - treatment that may be 'life-saving' in acute circumstances,[vi]
  - treatment for those whose quality of life is extremely severely affected by disabling chronic condition,[vii]
  - special characteristics of an individual patient justifying treatment of higher cost than normal, e.g. where an intervention may be less cost-effective for a particular person because of a disability or other characteristic but would normally be available under the NHS and funded by this PCT to others who did not have that disability or other characteristic.

4.1 Commissioning services or treatments in individual cases

PCTs commission care for patients suffering from various clinical conditions. Care pathways are usually agreed at the beginning of the financial year as part of a PCT's budget setting process. This means that clinicians and service users can know what medical treatments they can expect and which treatments are not funded by a PCT. PCTs get better value for money by commissioning in this way. However PCTs accept that there may be individual cases where their established commissioning policies have not taken account of the particular circumstances of an individual. The North Central London PCTs are prepared to consider commissioning treatment for such individuals who can demonstrate that they have exceptional circumstances. The onus of proving exceptionality is on the patient and on the clinical team supporting the application.

If a patient or their clinician seek to show that they are 'exceptional', this will be considered on an individual basis and in comparison within the group of patients with the same clinical condition. Generally, we will consider two components to exceptionality (although the presence of one or both factors to some degree may not be sufficient to lead to a decision by a PCT that the case is exceptional) –

1. the clinical circumstances of the patient may be exceptional. For example there may be good evidence that they may reasonably be expected to respond much better than others with the same condition to the proposed treatment and they may be highly unusual in not being able tolerate the treatment usually provided for a patient with their clinical condition;
2. The patient may have exceptional personal circumstances, but these would normally need to be 'far beyond what is usual' in order to be exceptional. For example, being a carer for an elderly relative or having dependent or disabled children is unlikely to be considered in this way as it would not be 'far beyond what is usual'.

It might be possible for a patient to prove that they are exceptional because they suffer from a condition for which there is no established care pathway or no established treatment which is routinely provided.

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vi This exception does not include treatment that may prolong life or slow disease progression, rather, it refers to treatment that could be required immediately to significantly reduce the chance of someone dying within minutes or hours of the sudden onset of a life-threatening situation.

vii Such disability would be far beyond what is common, for example, it might include someone who is paralysed below the neck and dependent upon nursing care for all of their bodily functions. but it is unlikely to include someone who is disabled but who has no significant difficulty in undertaking everyday living activities

If a treatment for a condition has been considered for funding as part of the PCT's annual process and has not been approved for funding, it is not open to a patient to seek to make a case for funding for that treatment solely or substantially on the basis that they suffer from the condition or suffer from symptoms which are usually associated with that condition.

Funding will only be approved on an individual basis for exceptional patients where the proposed treatment for which funding is sought is both proved to be likely to be clinically effective and is proved to be cost effective, and subject to consideration of the other principles in this framework. For example the fact that a patient may:

- have a rare (or 'orphan') condition, does not mean that –
  - their proposed treatment should be funded simply because their condition is rare. It would be inequitable to preferentially fund those with uncommon conditions over those with more common ones,
  - we will accept a lower standard of evidence of clinical effectiveness or a different level of cost-effectiveness or other consideration in comparison with that which we would consider for people with more common conditions,
  - we will accept that the treatment, because the rareness of the condition, need necessarily be more expensive, especially as many governments grant various allowances and dispensations to manufacturers of orphan drugs to compensate for the smaller market available for their products;
- be suffering from a rare condition, does not necessarily mean that their symptoms are rare and thus require special treatment, for example for the management of pain;
- have a clinical picture that matches the accepted indications for a treatment that is not routinely funded does not, in itself, constitute exceptional circumstances. Hence, for example, a patient may not be able to tolerate the usual treatment for a chronic condition due to side effects which occur in a proportion of patients with that condition. The fact that the patient is in that cohort is highly unlikely to make the case exceptional so as to justify treatment options which are not made available to other patients;
- have already received a treatment (however this may have been funded, including by other NHS organisations) and/or to be deemed in some way to have already responded to treatment does not, in itself, constitute an exceptional circumstance or mean that they should automatically receive funding by a PCT for further such treatment or related treatment;[viii, ix]

The presence of one or more such potentially 'exceptional' factors may not be sufficient to justify a PCT agreeing to shift resources to support the requested investment as PCTs have to balance that request with all the principles in this framework.

We also take the view that whilst we will broadly follow a system for assessing clinical and cost-effectiveness and take affordability, equity and other factors into consideration, especially where a treatment is of extremely high cost, whether or not it is for a rare condition, we will not make an exception just because the condition is rare or is a more common condition which, for a particular patient, has manifested itself in some way which makes the condition difficult to treat.

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viii We consider that it would be inequitable to fund in such circumstances alone and that such funding requests should be considered individually against the principles in this framework

ix Related to this, we will not reimburse costs or fees that patients or their family or friends or others may have incurred in their choosing to undergo investigation or treatment outside the NHS

4.2 A limit to the consideration of individual cases:

Whilst we will be willing to consider possible exceptionality in making individual patient treatment and population-based service funding decisions, if we consider that there is no realistic possibility of a treatment or a service being proved to be clinically effective, cost-effective, affordable, equitable to fund, or reasonable to fund on other grounds, we will not normally be prepared to look at the case as an individual one based on alleged exceptionality. However, we will be willing to consider an individual case if there is compelling evidence that the anticipated cost of the proposed treatment in that individual case is significantly less than the anticipated cost of treating other patients with the same condition who could benefit from the same proposed treatment, or if there is compelling evidence that the outcome for an individual patient is very likely to be significantly and beneficially greater. We will also be willing to keep a 'no exceptions' policy on any such treatment or service under review and be willing to reconsider our general approach to commissioning such treatment in the light of new and compelling evidence.

Similarly, it may be that, in some circumstances, a PCT will not fund treatment for a particular condition, even if the condition is medically recognised as an illness requiring intervention categorised as medical and/or curative, rather than merely cosmetic or a matter of convenience or lifestyle, but we may – as appropriate – consider some treatments as service developments and deal with them en bloc by tender or as part of a service level agreement negotiation with a provider rather than as an individual patient treatment request.

Further, whilst we consider that people should generally be able to access health and health care services on the basis of equal need, we note that –

- there may be occasions or circumstances when some categories of care or specific interventions will be given priority in order to help address health inequalities in the community;
- health and health care services should be allocated justly and fairly on the basis of both need and capacity to benefit, in order to maximise benefits to the population within the resources available. However, in the absence of evidence of health need or reasonable capacity to benefit, treatment will not generally be given solely because an individual person or a group of people request it. Similarly, a treatment of likely limited benefit and/or of relatively high cost will not necessarily be provided simply because it may be the only active treatment available;
- sometimes the needs of the wider population conflict with the needs of individuals, especially when an expensive treatment may possibly produce some clinical benefit but only for a relatively limited time. For example, such a treatment may do something to improve a patient's (or group of patients') condition to some extent or slow the progression of disease but not change the ultimate outcome, i.e. it will not 'cure'. However, more people may gain greater benefit if the same money or other resources were used for other purposes, even if that may not be in the best interests of an individual or smaller group of people; and
- we cannot always enable every patient to have what some might think of as the 'best possible' care. This concept conflicts with the principles of some clinicians who, understandably, take the view that every patient should be given the 'best possible' care and that every therapeutic option should be tried irrespective of cost.[x] However, if we provide the 'best possible' care for everyone then at some

[x] Whilst clinicians have a direct legal duty of care to their patients, NHS funding bodies only have a 'target duty' (i.e. 'something to be aimed for') and are not legally required under sections 1 and 3 of the National Health Service Act 2006 to provide the 'best' or 'most expensive' treatment available

time during the year there is likely to be nothing left for others: we will be giving some patients 'everything' and others 'nothing'. We consider that this would be inappropriate and that we should share resources fairly, this usually meaning (i) giving resources preferentially to those who are in greatest need and who can benefit the most from them, and (ii) settling for what is adequate and not necessarily for what may be the 'absolute best'.

5 Quality and safety

The services we commission should be safe and of high quality to minimise risk to people and to minimise waste –

- high quality care can be thought of in terms of doing the right thing, in the right way, to the right person, at the right time and doing it right first time; and
- failing to do this risks harming people and wasting finite resources (and thus harming other people by denying them access to services that can no longer be afforded).

Thus, we will need to be satisfied that any service provider has adequate quality and safety mechanisms in place. Generally, these will have to be equivalent to NHS governance mechanisms, and we will expect all standards set by the relevant health and social care standards bodies to be met in full.

6 Ethics

The approach that we take to determining health and health care priorities should take account of ethical considerations, specifically[2] –

- *respect for personal autonomy* – which requires that we help people to make their own decisions (e.g. by providing important information), and respect those decisions (even when we may believe that a patient's or a group of people's decision may be inappropriate), noting that this does not require us to fund a specific treatment just because someone wants it, but only if it satisfactorily meets sufficient other criteria in this framework and that this does not require us to fund a treatment in a particular place other than as the patient may be entitled to under the requirements of the national 'Patient Choice' initiative or other NHS regulations;

  and, we recognise that some treatments may enable a patient to maintain their independence and/or dignity, e.g. prolonging the time that they can continue to perform everyday living activities with relative independence, and we consider that this is a desirable objective, although it will not take precedence over other considerations in this framework;
- *beneficence* – which emphasises the moral importance of 'doing good' to others, entailing doing what is 'best' for the patient or group of people,[xi] although this will not take precedence over other considerations in this framework and must be balanced with an equal obligation for us to seek to 'do good' for all of the people in the population for which we are responsible;
- *non-maleficence* – which requires that we should seek not to harm patients, and, because most treatments carry some risk of doing some harm as well as good, the potential goods and harms and their probabilities must be weighed to decide

xi The question of who should be the judge of what is 'best' is often interpreted as focusing on what an objective assessment by a relevant health professional would determine as in the patient's best interests, with the patient's own views being considered through the principle of respect for patient autonomy, the two only conflicting when a competent patient chooses a course of action that might be thought of as not in their best interests

what, overall, is in a patient's or group of patients' best interests. We will also consider whether not funding a particular treatment or service might 'do harm', but it must also be noted that we have a duty of non-maleficence to others – we could indirectly harm others because a decision to fund treatment for one person or group of people could prevent others from receiving other care of proven clinical and cost-effectiveness, so this consideration in the context of an individual treatment or service will not take precedence over other considerations in this framework; and

- *distributive justice* – which recognises that time and resources do not allow every patient to have the 'best possible' treatment and that decisions must be made about which treatments can be offered within a health care system. This principle of justice emphasises two points:
  - people in similar situations should normally have access to similar health care, and
  - when determining what level of health care should be available for one group, we must take into account the effect of such a use of resources on others (i.e. the opportunity costs).

7 General principles

In determining which treatment priorities to focus on, we will use mechanisms that –

- *follow technology appraisal guidelines (TAGs) from the National Institute for Health and Clinical Excellence (NICE)* where they exist and where the circumstances of patients meet NICE TAG criteria precisely and in full;
- *are based on good quality evidence* – using both local data (to enable effective targeting) and the results of high-quality research, including systematic literature reviews in peer-reviewed publications, and including clinical guidance from national health-professional bodies (to enable us to support care that is appropriate for the largest number of people possible);
- *are transparent*, i.e. the reasoning behind our decisions made should be clear and available to anyone who wishes to see them (as long as patient confidentiality is preserved);
- *are ethical*, i.e. that meet principles of fairness and appropriateness and that seek to provide the greatest good for the greatest number of people whilst not discriminating against people who, because of their personal circumstances (e.g. a disability) would benefit from treatment provided in a less cost-effective way than were their circumstances otherwise to be similar to those of others with the same condition; and
- *are managerially robust*, i.e. that follow due process and can be seen to have done so.

8 Accountability

We will be accountable for our decisions, through –

- *publicity* – decisions and their rationale will be publicly accessible, i.e. the processes and the principles behind them will be 'transparent',
- *reasonableness* – our decisions and their rationale should reflect an 'even-handed' and 'sensible' interpretation of how we should ensure both value for money and equitable access to the services that we commission for the varied health needs of the population, within the resources available to us;
- *an appeal process* – there may be objections from individuals or from groups to decisions made on recommendations made by a PCT and these will be dealt with

by the PCT responsible for the individual patient using their own appeal and/or complaints mechanisms; and

- *enforcement* – there will be regulation of these processes by the PCT to ensure that these various conditions are met.

9 Ensuring probity

People involved in making decisions using this framework will be bound by the 'Seven Principles of Public Life' defined by the Nolan Committee. These are:

- **selflessness** – holders of public office should act solely in terms of the public interest. They should not do so in order to gain financial or other benefits for themselves, their family or their friends;
- **integrity** – holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might seek to influence them in the performance of their official duties.;
- **objectivity** – In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.;
- **accountability** – holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office;
- **openness** – holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands;
- **honesty** – holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest; and
- **leadership** – holders of public office should promote and support these principles by leadership and example.

10 Developing this framework

The principles described in this document will be developed:

- in the light of our experience and that of other organisations, especially to ensure a fair and ethical approach;
- in response to new scientific evidence coming to light concerning the effectiveness of health and health care interventions;
- as public values and perceptions change; and in response to changes in legislation and regulatory requirements.

REFERENCES

1 NHS Executive. *Promoting Clinical Effectiveness: a framework for action throughout the NHS*. Department of Health, 1996

2 Parker M, Hope T. Ways of thinking about medical ethics. In *Ethics*. The Medical Publishing Company Ltd. 2000

Appendix 2: A list of 'low priority' treatments that will not be funded routinely but only on consideration of individual patient circumstances, i.e. on a 'prior approval' basis

Treatment that will not be routinely funded	Potential exceptions, but subject to consideration on an individual patient basis and in the context of all of the criteria in the framework of principles in this document	Comment
Ventilation tube (grommet) insertion for otitis media with effusion (glue ear)	Children between the ages of 3 and 12 years at the time of the proposed treatment who have otitis media with effusion (OME) where: ■ there has been a period of at least three months watchful waiting from the date of the first appointment with an audiologist or GP with special interest in ENT **AND** the child is placed on a waiting list for the procedure at the end of this period, **AND** ■ OME persists after three months **AND** the child suffers from at least one of the following: • at least 5 recurrences of acute otitis media in a year • evidenced delay in speech development • educational or behavioural problems attributable to persistent hearing impairment together with a hearing loss of at least 25dB particularly in the lower tones (low frequency loss) • a significant second disability, e.g. Down syndrome, when, in addition to the above age criterion, where there is OME, a proposal to insert grommets is made by the multi-disciplinary team managing the patient and they agree that (i) hearing aids have been tried and failed or are considered to be wholly inappropriate, (ii) this is a practical proposition with a very low likelihood of extrusion. For children with cleft palate, in addition to the above	■ the evidence of effectiveness is limited ■ surgery may resolve glue ear and improve hearing in the short term compared with non-surgical treatment, but there is less certainty about long-term outcomes and large variation in effect between children ■ a Cochrane review showed that the benefits of grommets in children is small compared with myringotomy or non-surgical treatment.[a] The effect of grommets on hearing diminished during the first year. It recommended an initial period of watchful waiting for most children with OME. ■ there continues to be debate about how best to select children for surgery and there is a high rate of spontaneous resolution of glue ear, particularly in younger children ■ the Scottish Intercollegiate Guidelines Network (SIGN) recommend that children under three years of age with persistent bilateral otitis media with effusion and hearing loss of =<25 dB but no speech and language, development or behavioural problems can be safely managed with watchful waiting.[b] If watchful waiting is being considered, the child should undergo audiometry to exclude a more serious degree of hearing loss.

a Cochrane review: Grommets for hearing loss associated with otitis media with effusion. January 2005

b SIGN. Diagnosis and management of childhood otitis media in primary care. February 2003

	age criterion, a proposal to insert grommets is made by the multi-disciplinary team managing the patient and they agree that (i) hearing aids have been tried and failed or are considered to be wholly inappropriate, (ii) grommet insertion is to be undertaken at the time of primary closure of the cleft palate NOTE: the insertion of ventilation tubes is not considered to be a low priority treatment when the procedure is a key component of of another procedure such as repairing the tympanic membrane.	Children with persistent bilateral otitis media with effusion who are over three years of age or who have speech and language, developmental or behavioural problems should be referred to an otolaryngologist.
Tonsillectomy and adenoidectomy (separately or in combination)	■ In children, where there is significant severe impact on quality of life indicated by at least seven episodes of tonsillitis in the preceding year, or five episodes/year in each of the preceding two years, or three episodes/year in the preceding three years, and documented evidence of absence from school or attendance at GP or other health care setting. [c] ■ obstructive sleep apnoea confirmed by overnight oxygen saturation monitoring ■ In adults with proven recurrent group A streptococcal pharyngitis (GAHSP)[d] ■ Quinsy associated with tonsillitis, requiring 2 or more hospital visits ■ Patients with tonsillar enlargement causing upper airway obstruction	■ A revised Cochrane systematic review in 2008,[e] concluded that Adeno-/tonsillectomy is effective in reducing the number of episodes of sore throat and days with sore throats in children, the gain being more marked in those most severely affected. ■ SIGN national guideline on management of sore throat and indications for tonsillectomy published April 2010 recommended watchful waiting is more appropriate than tonsillectomy for children with mild sore throats. ■ It should be noted, that those considering tonsillectomy or adenotonsillectomy for themselves or their children, and those advising them, should be aware of two important uncertainties which may affect their treatment decisions. They must acknowledge some uncertainty about whether or not their symptoms

[c] Adapted from Management of sore throat and indications for tonsillectomy. A national clinical guideline. SIGN Publication Number 117. April 2010

[d] Tonsillectomy versus watchful waiting in recurrent streptococcal pharyngitis in adults: Randomised controlled trial. BMJ 2007;334(7600):939-41..

[e] Burton MJ, Glasziou PP. Tonsillectomy or adeno-tonsillectomy versus non-surgical treatment for chronic/recurrent acute tonsillitis. Cochrane Database of Systematic Reviews 2009, Issue 1. Art. No.: CD001802. DOI: 10.1002/14651858.CD001802.pub2.

		are primarily due to their tonsils and realise that adeno-/tonsillectomy is not a panacea for all types of sore throat. There is also uncertainty about the likelihood that these will continue in the future, which is only partly predictable from the frequency and severity of symptoms they have experienced in the past. ■ Grommets and adenoidectomy represents a trade off between benefits and harms; adenoidectomy on its own is of unknown effectiveness[f]
Cochlear implants	Normally, Cochlear implants will only be funded where the patient meets the criteria of the National Institute for Health and Clinical Excellence technology appraisal guideline on this treatment precisely and in full and then only if the least expensive implant available is used assuming that this is clinically appropriate	A cochlear implant in one ear is recommended as a possible option for everyone with severe to profound deafness if they do not get enough benefit from hearing aids after trying them for 3 months. Cochlear implants in both ears are recommended for the following groups with severe to profound deafness only if they do not get enough benefit from hearing aids after trying them for 3 months and the implants are placed during the same operation: ■ children ■ adults who are blind or have other disabilities which mean that they depend upon hearing sounds for spatial awareness. In all cases, if more than one type of cochlear implant is suitable, the least expensive should be used.
Varicose veins, reticular veins, telangectasia	■ substantial skin changes including varicose eczema, lipodermatosclerosis, moderate to severe oedema; ■ intractable ulceration secondary to venous stasis; ■ bleeding from a varicosity that has eroded the skin or they	■ symptoms attributable to varicose veins are common but their relationship to visible trunk varices is not clear[g]

f Clinical Evidence. Review of adenotonsillectomy. 2005

g Bradbury A, Evans C, Allan P et al. What are the symptoms of varicose veins? Edinburgh vein study cross sectional population survey. *Br Med J* 1999;318:353-356

	have bled and are at risk of bleeding again; or ■ recurrent phlebitis (more than one documented episode) ■ severe and persistent pain and swelling interfering with activities of daily living and requiring chronic pain management ■ severe symptoms attributable to the venous disease not acceptably relieved by 6 months documented conservative management including compression hosiery and exercise	■ most patients with varicose veins are never harmed by them and good explanation and reassurance are fundamental.[h] ■ the National Institute for Health and Clinical Excellence has published detailed guidance on what treatment should be considered for varicose veins and when[i] ■ treatment for reticular veins and telangectasia is generally considered to be cosmetic (see section on cosmetic surgery)
Dental implants	■ major loss of tissue as a result of trauma or cancer surgery ■ significant congenital abnormalities, such as cleft lip and palate and hypodontia, where the abnormality or the process of correcting it, make it impossible for other prostheses to be used ■ significant neuromuscular disorders and other conditions (e.g. Parkinson's Disease, Bell's palsy), which make it impossible for patients to manage conventional dentures ■ some oral mucosal conditions, e.g. Sjogren's syndrome ■ severe jaw atrophy or alveolar bone resorption making retention of conventional dentures impossible	Primary predictors of implant failure are poor bone quality, chronic periodontitis, systemic diseases, smoking, unresolved caries or infection, advanced age, implant location, short implants, acentric loading, an inadequate number of implants, and absence/loss of implant integration with hard and soft tissues. Inappropriate prosthesis design also may contribute to implant failure[j,k] Implant treatment for patients who have undergone irradiation to the maxilla and/or mandible has a significantly higher failure rate.[k] Patients who are over 60 years of age, smoke, have a history of diabetes or head and neck radiation, or are postmenopausal and on hormone replacement therapy experience significantly increased implant failure compared with healthy patients.[k]
Surgical treatment of carpal tunnel syndrome	■ symptoms persisting after conservative therapy with local corticosteroid injection and/or nocturnal splinting ■ significant neurological deficit present, e.g. sensory	

h Campbell B. Clinical Review- Varicose veins and their management. BMJ 2006;333:287-292 (5 August)

i NICE 2001. Referral Advice: A guide to appropriate referral from general to specialist services.http://www.nice.org.uk/nicemedia/pdf/Referraladvice.pdf

j Porter JA, von Fraunhofer JA. Gen Dent. 2005 Nov-Dec; 53(6):423-32

k Moy PK, Medina D, Shetty V, Aghaloo TL. Int J Oral Maxillofacial Implants. 2005 Jul-Aug; 20(4):569-77

	blunting, muscle wasting, or weakness of thenar abduction ■ severe symptoms that significantly interfere with everyday living activities	
Hysterectomy for menorrhagia (heavy menstrual bleeding)	■ documented medical contra-indication to Minera® coil insertion when other treatments have failed or are contraindicated ■ severe anaemia, unresponsive to transfusion or other treatment whilst a Mirena trial is in progress ■ recent sexually transmitted infection (if not fully investigated and treated) ■ distorted or small uterine cavity (with proven ultrasound measurements) ■ genital malignancy ■ active trophoblastic disease	NICE has published clinical guidelines on menorrhagia which do not necessarily require a prior trial of treatment before hysterectomy. These guidelines include recommendations on the use of other procedures, currently covered by NICE interventional procedures guidance, which should be considered in the context of a patient pathway for managing menorrhagia
Cosmetic surgery, including minor skin surgery	■ suspicion of malignancy ■ significant adverse effect on activities of daily living ■ significant disfigurement ■ major weight loss leaving significantly excessive skin folds ■ severe, post-pubertal gynaecomastia ■ congenital facial anomalies ■ significant post-surgical or radiotherapy deformity ■ following severe trauma ■ These conditions, which might cause skin hypopigmentation are not considered to be a low priority • mycosis fungoides • lymphoma • sarcoidosis • regressed menaloma • genital lichen sclerosis • tuberose sclerosis • leprosy	This includes (but is not limited to) – – abdominoplasty – breast reduction/augmentation – face lifts and similar facial surgery, including blepharoplasty – acne treatment other than with drugs – skin flap excision, e.g. after substantial weight loss – pinnaplasty – removal or obliteration of benign skin lesions including, but not limited to – • benign pigmented moles • comedones • corn/callouses • lipomas • milia • molluscum contagiosum • sebaceous, epidermoid or pilar cysts • seborrhoeic keratoses

		• basal cell papillomas • skin tags (including anal tags) • spider naevae and other telangiectasia • warts • xanthelasma • neurofibromata • rosacea – rhinoplasty – treatment of skin hypopigmentation (this exclusion includes conditions such as vitiligo but not those listed in the second column) treatment of erythema for cosmetic purposes – surgical treatment of rhinophyma – skin resurfacing – botulinum toxin or other treatment for the appearance of skin-ageing – scar revision or excision (including keloid scarring) – liposuction and other surgical treatments of excess fatty tissue or contouring (e.g. buttock lift) – male pattern baldness treatment – hair removal or obliteration for hirsuitism – tattoo removal – cosmetic genital surgery
Wisdom tooth (third molar) removal	■ unrestorable caries ■ non-treatable pulp and/or periapical pathology ■ cellulitis ■ abscess and osteomyelitis	See NICE guidance[l]

l http://www.nice.org.uk/nicemedia/pdf/wisdomteethguidance.pdf (accessed 8 February 2010)

	■ fracture of tooth, ■ internal / external resorption of the tooth or adjacent teeth ■ disease of follicle including cyst / tumour ■ tooth/teeth impeding surgery or reconstructive jaw surgery ■ when a tooth is involved in or within the field of tumour resection ■ plaque formation and pericoronitis depending on severity and frequency of episodes.	
Male circumcision and other genital surgery for cosmetic or non significant functional problems	■ scarring of the opening of the foreskin making it non-retractable (i.e. pathological phimosis). This is unusual before 5 years of age ■ recurrent, significantly troublesome episodes of infection beneath the foreskin ■ restoration of functional anatomy after female circumcision to facilitate childbirth where mutilation renders this hazardous	Female circumcision is prohibited by under the Prohibition of Female Circumcision Act 1995
Ganglions	■ significant pain or dysfunction unrelieved by aspiration or injection ■ in patients presenting with significant skin breakdown, significant nail deformity, or repeated episodes of drainage caused by distal interphalangeal joint mucous cysts ■ diagnostic uncertainty	
Dupuytren's contracture	■ function of hand is significantly impeded or deformity is significantly disabling so that everyday living activities cannot be undertaken and surgery is likely to resolve this	
Trigger finger	■ the patient has failed to respond to conservative measures (e.g. hydrocortisone injections); or ■ the patient has significant fixed deformity	A Cochrane review has shown that corticosteroid injections can be effective for the treatment of trigger finger, but evidence is limited by being based on two small studies in secondary care, and there were only data available for effectiveness of up to four months. The authors concluded that the initial treatment for patients should be corticosteroid injection rather than

		surgery, and other non-invasive interventions such as splinting may also be appropriate first-line interventions.[m]
Bartholin's cysts	■ significant infection and/or rapid growth causing significant pain that is unresolved by non-surgical treatment	
Hyperhidrosis	■ significant focal hyperhidrosis and a 1–2 month trial of aluminium salts (under primary care supervision to ensure compliance) has been unsuccessful in controlling the condition ■ intolerance of topical aluminium salts despite reduced frequency of application and use of topical 1% hydrocortisone	
Dilatation and curettage for heavy menstrual bleeding in women aged under 40 years		There is no evidence that this procedure has any therapeutic value
Surgical treatment of chronic sinusitis	■ suspected complications, e.g. periorbital infection ■ suspected sinonasal tumour ■ ENT referral may be appropriate if there is: – recurrent or chronic sinusitis of uncertain cause – unremitting or progressive facial pain – a trial of intranasal corticosteroids for three months has been ineffective – a significant anatomical abnormality	NHS Clinical Knowledge Summaries advise a trial of intranasal corticosteroids for 3 months for treatment in the first instance.[n] Sinus puncture and irrigation has a poor diagnostic yield, and carries the risk of secondary contamination.[n] Only short-term benefit seen in patient refractory to medical management treated with balloon catheter dilation of sinus ostia.[o]

m Peters-Veluthamaningal C, van der Windt DAWM, Winters JC, Meyboom- de Jong B. Corticosteroid injection for trigger finger in adults. *Cochrane Database of Systematic Reviews* 2009, Issue 1. Art. No.: CD005617. DOI: 10.1002/14651858.CD005617.pub2.

n http://www.cks.nhs.uk/sinusitis/management/quick_answers#-369973 (accessed 8 February 2010)

o NICE Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis. IPG 273 NICE September 2008.

Temporo-mandibular joint (TMJ) dysfunction		There is little evidence available on the safety and efficacy of surgery for this condition. Conservative therapy includes self care practices e.g. eating soft foods, jaw stretching, ice packs, and pain relief. Stabilisation splints (bite guards) are the most widely used treatments for TMJ disorders. Failure to respond to conservative treatment is not an indication to proceed to irreversible treatments such as TMJ replacement. There is limited evidence of effectiveness and no agreed diagnostic classification scheme for TMJ replacement
Minor oral surgery for retained roots	Symptomatic retained roots may be removed in the dental surgery under local anaesthetic. Referral to a specialist may be necessary : ■ where anatomical or pathology considerations make the extraction difficult, ■ where the patient has medical complications, ■ where the operator does not have the relevant training or experience, or ■ where previous attempts at extraction have failed	GDC guidelines indicate that 'particular care must be taken when referring patients for treatment under general anaesthesia or sedation' It is also in line with minor oral surgery management and referral guidelines: A Handbook for PCTs and Primary Care Professionals.[p]
Varicocoele	■ persistent discomfort or pain despite adequate conservative management	There is no evidence that treating varicocoele can help male sub-fertility problems
Refashioning scars	■ following severe burns or severe trauma and/or where there is a significant difficulty in undertaking everyday living activities, including severe psychosocial problems following facial scarring	
Complementary medicine of all types	■ there is some evidence that some forms of complementary treatments can be effective in certain conditions	

p Minor oral surgery management and referral guidelines: A Handbook for PCTs and Primary Care Professionals, Sue Gregory, 2006

Reversal of sterilisation	■ extreme personal circumstances, e.g. establishing a stable relationship with a new partner following the death of the patient's partner and all children when there are no children living with the patient and their new partner	Most studies are retrospective and success rate variable.[q] The Royal College of Obstetricians and Gynaecologists guidelines on male and female sterilisation advise that men and women requesting sterilisation should understand that the procedure is intended to be permanent, they should be given information about the success rates associated with reversal, should this procedure be necessary.[r]
Treatment of ME/chronic fatigue syndrome outside NHS service level agreements		No evidence has been forthcoming from units purporting to specialise in this condition to support claims of treatment success. Clinical guidance from the National Institute for Health and Clinical Excellence provides information for health care providers on how this condition could be managed, but do not place any obligation on service commissioners[s]
Implantable cardiac defibrillators	Funding will be made available for patients who meet the criteria of the NICE technology appraisal guideline on the use of implantable cardiac defibrillators precisely and in full[t]	This NICE technology appraisal guideline appraisal does not cover the use of implantable defibrillators for non-ischaemic dilated cardiomyopathy.

q Yossry M, Aboulghar M, D'Angelo A, Gillett W. In vitro fertilisation versus tubal reanastomosis (sterilisation reversal) for subfertility after tubal sterilisation. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Art. No.: CD004144. DOI: 10.1002/14651858.CD004144.pub2.

r Royal College of Obstetricians and Gynaecologists (RCOG). Male and female sterilisation. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Jan. 114 p.

s http://www.nice.org.uk/nicemedia/pdf/CG53FullGuidance.pdf (accessed 8 February 2010)

t http://www.nice.org.uk/nicemedia/pdf/TA095guidance.pdf (accessed 8 February 2010)

Knee washout for osteoarthritis	Referral for arthroscopic lavage and debridement should not be offered as part of treatment for osteoarthritis, unless the person has knee osteoarthritis with a clear history of mechanical locking i.e (not gelling, 'giving way' or X-ray evidence of loose bodies)	NICE issued full guidance to the NHS on Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis in August 2007.[u] Subsequent to this, a more specific recommendation was made as part of the the clinical guideline on osteoarthritis published in February 2008 on the indication for which arthroscopic lavage and debridement is judged to be clinically and cost-effective[v]
Apicectomy	• Presence of periradicular disease, with or without symptoms in a root filled tooth, where non surgical root canal re-treatment cannot be undertaken or has failed, or where conventional re-treatment may be detrimental to the retention of the tooth. For example, obliterated root canals, small teeth with full coverage restorations where conventional access may jeopardise the underlying core. It is recognised that non-surgical root canal treatment is the treatment of choice in most cases • Presence of periradicular disease in a tooth where iatrogenic or developmental anomalies prevent non surgical root canal treatment being undertaken • Where a biopsy of periradicular tissue is required • Where visualisation of the periradicular tissues and tooth root is required when perforation, root	The Faculty of Dental Surgery of the Royal College of Surgeons has published guidelines outlining the indications for surgical endodontics[w] Literature shows that the success rate of apical surgery on molar teeth is low and should not be routinely undertaken[x]

[u] National Institute for Health and Clinical Excellence - Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis - Guidance issue date: 22 August 2007. http://www.nice.org.uk/IPG230

[v] National Institute for Health & Clinical Excellence (NICE), Clinical guideline CG59 The care and management of patients with Osteoarthritis, February 2008 www.nice.org.uk/cg59.

	crack or fracture is suspected • Where procedures are required that require either tooth sectioning or root amputation • Where it may not be expedient to undertake prolonged non surgical root canal re-treatment because of patient considerations	
Unilateral bone anchored hearing aids for unilateral deafness (implanted one side) Bilateral bone anchored hearing aids (implanted both sides)	Unilateral bone anchored hearing aids for unilateral deafness : Severe unilateral conductive deafness in children • case by case basis centred on the child's audiometric data, development and communication needs[y] • a trial period with a sufficiently powerful bone anchored hearing aid on a headband is recommended before a decision on implantation	Bone anchored hearing aids are only appropriate for patients with conductive or mixed deafness for whom air conduction hearing aids are ineffective or inappropriate. Comprehensive patient assessment and a trial of bone conductor technology as well as extensive counselling are all essential before the implantation of bone anchored hearing aids. There is evidence for the clinical effectiveness of unilateral bone anchored hearing aids in selected groups of patients. The evidence base for use of bilateral bone anchored hearing aids is weak.

[w] Royal College of Surgeons of England. Guidelines for surgical endodontics. RCS 2001 http://www.rcseng.ac.uk/fds/publications-clinical-guidelines/clinical_guidelines/documents/surg_end_guideline.pdf (Accessed October, 2010)

[x] Molar apicectomy with amalgam root-end filling: results of a prospective study in two district general hospitals. Wesson CM. Gale TM. British Dental Journal. 195(12):707-14; discussion 698, 2003 Dec 20

[y] Bone anchored hearing aids for children and young people: Guidelines for professionals working with deaf children and young people: Guidelines for professionals. National Deaf Childrens Society. March 2010

Autologous Cartilage Implantation (ACI)	If conservative treatment and arthroscopic treatment has failed and is part of a clinical trial in accordance with NICE technology appraisal recommendations	ACI has been most commonly used as a treatment for cartilage defects in the knee, there are few studies of its use in other joints. NICE concluded ACI is not recommended for treating knee problems caused by damaged articular cartilage, unless it is used in studies that are designed to produce good-quality information about the results of the procedure. These results should include measuring any improvement in patients' quality of life, and the benefits and risks of ACI over a long period of time. If ACI is offered as part of a clinical study, the doctor should explain that there are uncertainties about the long-term benefits of this procedure and the possible risks, such as locking of the knee, infections and not being able to fully straighten the leg.[z] There is insufficient evidence to support use of ACI in ankle joint cartilage defects. [aa,bb]

[z] NICE Technology appraisal TA089, May 2008 http://guidance.nice.org.uk/TA89

[aa] Whittaker P et al. Early results of autologous chondrocyte implantation in the talus. *J Bone Joint Surg Br* 2005; 87-B: 179-83. Available at: http://www.jbjs.org.uk/cgi/reprint/87B/2/179?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=whittaker&fulltext=chondrocytes&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT

[bb] Regence. [online]. *Autologous chondrocyte transplantation.* Medical policy no. 87. 2009. Available at http://blue.regence.com/trgmedpol/surgery/sur87.html [Accessed 17 October 2010]

Injections for non-specific back pain		• NICE CG88 (2009) guideline states injections of therapeutic substances should not be used for non specific low back pain [cc] • An updated Cochrane review[dd] concluded there was insufficient evidence to support or refute the use of injections for subacute and chronic low back pain without radicular pain
Spinal Fusion for chronic low back pain	Fusion surgery for chronic low back pain may be considered if: • severe pain continues despite an 'active rehabilitation programme' (cognitive intervention combined with exercises is recommended when available) that has been undertaken for 2 years[ee],[ff]	NICE guidelines recommend the patient is referred to a specialist spinal surgical service if spinal fusion is being considered and to give due consideration to the possible risks for that patient.

[cc] NICE CG88 (2009) – Low Back Pain http://www.nice.org.uk/nicemedia/pdf/CG88NICEGuideline.pdf

[dd] Staal JB,de Bie RA,de Vet HC,Hildebrandt J,Nelemans P: Injection therapy for subacute and chronic low back pain: an updated Cochrane review. Spine, Jan 2009, vol./is. 34/1(49-59), 0362-2436;1528-1159 (2009 Jan 1)

[ee] Airaksinen O, Brox JL, Cedraschi C, Hildebrandt J, Klaber-Moffett J, Kovacs F, Mannion AF, Reis S, Staal JB, Ursin H and Zanoli G. European Guidelines for the Management of Chronic Non-Specific Low Back Pain. November 2004, Amended June 2005. On behalf of the COST B13 Working Group on Guidelines for Chronic Low Back Pain.

[ff] Brox J et al. Four-year follow-up of surgical versus non-surgical therapy for chronic low back pain. Ann Rheum Dis. 2009

Spinal cord stimulation	Spinal cord stimulation will be considered as a treatment option for adults with chronic pain of neuropathic origin who: • continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management, and • who have had a successful trial of stimulation as part of the assessment by a multidisciplinary team experienced in chronic pain assessment and management of people with spinal cord stimulation devices, including experience in the provision of ongoing monitoring and support of the person assessed.	• NICE Technology appraisal TA159[gg] • Spinal cord stimulation is not recommended as a treatment option for adults with chronic pain of ischaemic origin except in the context of research as part of a clinical trial
Surgical discectomy (standard or micro), percutaneous discectomy, coblation therapy and laser discectomy for lumbar disc herniation	Surgical discectomy (standard or micro) will be considered for a carefully selected group of patients with • symptoms and confirmatory signs of lumbar radiculopathy • disc herniation confirmed on magnetic resonance imaging at a corresponding level and side to the symptoms • who have not responded to conservative treatment for over 6 weeks[hh] [ii]	Surgical discectomy for carefully selected patients with sciatica due to a prolapsed lumbar disc appears to provide faster relief from the acute attack than non-surgical management. However, any positive or negative effects on the lifetime natural history of the underlying disc disease are unclear[jj] At present, unless or until better scientific evidence is available, automated percutaneous discectomy, coblation therapy and laser discectomy should be regarded as research techniques[jj]

[gg] NICE Technology Appraisal TA159 - Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. Issue date October 2008. http://www.nice.org.uk/nicemedia/live/12082/42367/42367.pdf

[hh] Weber H. Lumbar disc herniation. A controlled, prospective study with ten years of observation. Spine 1983 8(2): 131-40

[ii] Weinstein JN, Torteson TD, Lurie JD et al. Surgical vs Nonoperative Treatment for Lumbar Disk Herniation. JAMA 2006 296

Surgery for snoring • laser-assisted uvulopalatoplasty (LAUP) • uvulopalatopharyngoplasty (up3) • radiofrequency ablation of soft palate (RFA)		Evidence of objective reductions in snoring sound parameters for UP3, LAUP, RFA and Pillar implants was limited and equivocal. [kk] NICE recommends that RFA should not be used without special arrangements for audit, consent and research.[ll] In the management of primary snoring it should be highlighted that, given the absence of risk to health from snoring without apnoea or hypopnoea, and an absence of excessive daytime sleepiness, the patient is effectively being treated to decrease the social disturbance caused to their bed partner and family
Caesarean section for non clinical reasons		There is a close benefit/risk ratio for caesarean section for non clinical reasons. Caesarean section rates are progressively rising in many parts of the world. One suggested reason is increasing requests by women for caesarean section in the absence of clear medical indications. There is no evidence from randomised controlled trials, upon which to base any practice recommendations regarding planned caesarean section for non-medical reasons at term[mm]. Maternal request is not on its own an indication

[jj] Gibson JA, Waddell G. Surgical interventions for lumbar disc prolapse. Cochrane Database of Systematic Reviews 2007, Issue 2

[kk] Main C, Liu Z, Welch K, Weiner G, Jones SQ, Stein K. Surgical procedures and non-surgical devices for the management of non-apnoeic snoring: a systematic review of clinical effects and associated treatment costs. *Health Technol Assess* 2009;**13**(3).

[ll] Radio frequency ablation of the soft palate for snoring. IPG124. National institute for Health and Clinical Excellence. May 2005.

[mm] Lavender T, Hofmeyr GJ, Neilson JP, Kingdon C, Gyte GML. Caesarean section for non-medical reasons at term (Review). The Cochrane Collaboration 2009, Issue 3. Available at http://onlinelibrary.wiley.com/o/cochrane/clsysrev/articles/CD004660/pdf_fs.html [Accessed 30th September 2010]

		for CS and specific reasons for the request should be explored, discussed and recorded. When a woman requests a CS in the absence of an identifiable reason, the overall benefits and risks of CS compared with vaginal birth should be discussed and recorded[nn]

[nn] National Institute for Health and Clinical Excellence. Caesarean section (CG13). London: NICE; April 2004. Available at: http://guidance.nice.org.uk/CG13 [Accessed 30th September 2010]