

**NHS GLOUCESTERSHIRE**

**Clinical Priorities Policy  
for Commissioning Selected Services**

**A guide to the decision-making process for the  
commissioning of drugs, treatments, procedures,  
investigations, and screening and other health  
programmes that fall outside of current commissioning  
contracts**

**May 2009**

## **Introduction**

### **The role and responsibilities of NHS Gloucestershire in commissioning healthcare services**

NHS Gloucestershire (Gloucestershire Primary Care Trust) is committed to improving the health of the people of Gloucestershire, and ensuring that patients are treated at the right time, in the right place, by the right people to the right standard and for the best value.

It is the statutory duty of the NHS and its Primary Care Trusts (PCTs) ‘*to provide comprehensive healthcare within the resources available*’. This includes the responsibility to make decisions on the commissioning of healthcare services that do not fall under existing contracts, and ensuring that all decisions made are equitable and in the interest of the whole population.

Inevitably, whilst NHS Gloucestershire will do its utmost to improve the health of the people of Gloucestershire, there will be occasions when it is both reasonable and legitimate for NHS Gloucestershire to restrict or not commission a particular healthcare intervention. In such a circumstance, it is important that the process by which NHS Gloucestershire came to that decision is open and explicit. This policy document sets out that process and defines the framework within which such commissioning decisions are made.

### **NHS Gloucestershire’s commissioning policy**

In order to meet its statutory obligations, NHS Gloucestershire has developed this *Clinical Priorities Policy for Commissioning Selected Services* that aims to provide guidance to clinicians and healthcare commissioners on the PCT’s commissioning policies for selected drugs, treatments, procedures, investigations, screening and other public health programmes that are not covered by existing commissioning arrangements.

## **The scope of this policy**

The commissioning policies adopted by NHS Gloucestershire impact on the healthcare interventions that are provided to Gloucestershire residents through primary care (General Practitioner services), secondary care (hospital services), tertiary (specialist) care, and community services.

Accordingly, in the implementation of the Department of Health's policy for *Practice-Based Commissioning*, services commissioned by GPs for Gloucestershire residents must be congruent with NHS Gloucestershire's commissioning policies.

## **The structure of this policy document**

NHS Gloucestershire's *Clinical Priorities Policy for Commissioning Selected Services* addresses

1. The ethical, legal and national frameworks within which commissioning decisions are reached, and in particular
  - the evidence taken into consideration in the decision-making process.
  - how the needs of patients and the needs of the Gloucestershire community are incorporated into the decision-making process.
2. The priorities allocated to the commissioning decisions.
3. Current commissioning protocols, including
  - Drugs and therapeutic agents
  - Managing the entry of new drugs
  - The commissioning of new health technologies not covered by guidance from the National Institute for Health and Clinical Excellence (NICE)
  - Prescribing responsibility
  - NICE Guidance
  - NHS Gloucestershire's role in the implementation of NICE Guidance
  - Supporting research undertaken by the Research Councils

4. Commissioning policy exceptions
5. The healthcare interventions to be considered by the Clinical Priorities Forum
6. The process for dissemination of NHS Gloucestershire's policy decisions
7. Withdrawal of policy statements

## **Summary**

This document sets out NHS Gloucestershire's framework for making decisions regarding the funding (commissioning) of selected healthcare interventions, and prioritising their provision for Gloucestershire residents. It is hoped that this document will promote greater awareness and inform discussion between clinicians and their patients about the healthcare interventions commissioned by NHS Gloucestershire.

An electronic version of this policy will be available on NHS Gloucestershire's web site. The following supporting documents will also be available on the websites listed in Appendix 4:

- commissioning policies adopted by NHS Gloucestershire
- the procedure for primary and secondary care clinicians to apply for funding for healthcare interventions not normally commissioned by NHS Gloucestershire (Protocol for the Management of Funding 'Exceptional Treatment' Referrals – see also Appendix 3)

## Ethical framework

In reaching its decisions, NHS Gloucestershire aims to

- take into account and weigh all the relevant evidence;
- take into account the opinion of relevant clinicians;
- give proper consideration to the views of the patient or group of patients involved, and accord proper weight to their needs against other groups competing for scarce resources;
- take into account only material factors;
- act in the utmost good faith;
- make a decision that is in every sense reasonable;
- to adhere to the requirements of NHS Gloucestershire's Equality and Diversity policy through the application of the 'Equality and Diversity Impact Assessment Toolkit'.

This ethical framework has been developed to enable NHS Gloucestershire to make fair and consistent decisions that treat patients equally. It should be noted that sometimes the discretion of the Clinical Priorities Forum and NHS Gloucestershire may be restricted or overridden by National Service Frameworks; guidance from the National Institute for Health and Clinical Excellence (NICE); and NHS directions.

People have equal rights of access to health care, but there may be times when some categories of care are given priority in order to address health inequalities in the community. The Clinical Priorities Forum will not unfairly discriminate on grounds of personal characteristics such as age, sex, race, religion, lifestyle, social position, family or financial status, intelligence or cognitive functioning.

A patient's health needs will be assessed in relation to their capacity to benefit from a healthcare intervention. In the absence of evidence of health need, treatment will not generally be recommended solely because a patient requests it. Similarly, a treatment of potentially very little benefit will not be provided because it is the only treatment available. This is necessary to ensure that resources are used to provide the greatest health benefit.

The Ethical Framework is especially concerned with the following:

- evidence of clinical and cost effectiveness
- the needs of the patient(s)
- needs of the community

## **Evidence of clinical and cost effectiveness**

In order to assess the potential healthcare benefits of drug therapies, surgical procedures, investigations and screening, the Clinical Priorities Forum strives to obtain the best evidence of clinical effectiveness.

When considering clinical effectiveness the Clinical Priorities Forum will assess the potential benefits of the intervention by reference to the available evidence. This will include consideration of the primary benefits of the intervention (i.e. the direct effect of the intervention) and any secondary benefits such as the ability to benefit from further treatment as a result of the primary benefit.

Through policy development and prioritisation, the Clinical Priorities Forum will promote treatments for which there is good evidence of clinical effectiveness.

Evidence for clinical effectiveness will be sought from large-scale randomised clinical trials. If these have not been conducted or published, evidence from less authoritative sources will be considered, including controlled trials, cohort studies and case studies. Patients' evidence of clinical effectiveness will also be considered.

'Cost effectiveness' analysis is an economic evaluation that compares the cost of a health care intervention with the potential health care benefits the intervention provides, and enables an assessment to be made as to whether the intervention should be commissioned from an economic perspective. Because NHS Gloucestershire has a statutory obligation not to exceed its budget, the cost of healthcare interventions will be considered, bearing in mind that investing in one area of healthcare will inevitably divert resources from other uses. The Clinical Priorities Forum will compare the cost of treatment to its overall benefit, both to the individual and the community and it will consider technical cost-benefit calculations.

## **The clinical needs of the patient(s)**

The Clinical Priorities Forum will consider the health needs of patients according to their capacity to benefit from health care, and will take into consideration whether the intervention 'cures' a condition, alleviates or slows its progression, or prevents further deterioration in the health of the patient. So far as is possible, the Clinical Priorities Forum will respect the rights of patients to choose between different treatment

options, subject to the availability of supporting evidence of clinical effectiveness.

Where NHS Gloucestershire does not have a policy in place for a healthcare intervention, and in circumstances where an individual patient has a special healthcare problem that presents an exceptional need for treatment, NHS Gloucestershire will consider such cases on their own merits. These 'exceptional cases' are considered by NHS Gloucestershire's Interventions Not Normally Funded (INNF) Panel. The protocol and procedure for applying for 'exceptional' funding is included at Appendix 3 of this policy, and is also available electronically from the websites listed in Appendix 4.

### **Health needs of the community**

Public health is an important concern of the Clinical Priorities Forum and the Forum will seek to make policy recommendations that promote the health of the whole community. Some public health interventions are promoted by the Department of Health (such as the guidance from the National Institute for Health and Clinical Excellence, and National Service Frameworks). In other areas, policies are developed locally in consultation with local people. Effective health promotion schemes (for example, smoking cessation strategies) will be considered by the Clinical Priorities Forum. Available guidance in these areas will be considered by the Forum in order to inform its recommendations.

Sometimes the healthcare needs of the community may conflict with the needs of individuals. Decisions are difficult, for example, when expensive treatments produce little clinical benefit. Where it has been decided by NHS Gloucestershire that a treatment has a low priority and cannot generally be funded, a patient's doctor may consider that the circumstance is exceptional. As described in the section above (*The clinical needs of the patient(s)*), such requests will be considered by NHS Gloucestershire's INNF Panel (Appendix 3), and in line with NHS Gloucestershire's Policy Statement *Guidance for considering 'exceptionality' in individual cases* (Appendix 5). Where appropriate, the Clinical Priorities Forum will consult with Gloucestershire residents on such issues through representatives of the Local Involvement Networks (LINKs) and local patient groups.

<b>Legal framework</b>
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It is the statutory duty of the NHS and its Primary Care Trusts (PCTs) 'to provide comprehensive healthcare within the resources available'.

Further, in making commissioning recommendations and decisions, the Clinical Priorities Forum and NHS Gloucestershire need to consider the Human Rights Act (1998), in particular:

Article 2	the right to life
Article 3	prohibition of torture and freedom from inhuman and degrading treatment
Article 8	respect for private and family life
Articles 9 & 10	freedom of thought and expression
Article 12	the right to marry and found a family
Article 14	prohibition of discrimination

Under the Human Rights Act, a legal challenge regarding the inability of NHS Gloucestershire to fund/commission a particular treatment would focus on whether the decision was linked to (a) unaffordability, (b) the PCT's priorities and (c) how those priorities were decided.

## **The national context**

A further responsibility of NHS Gloucestershire is to implement changes in the local NHS in line with the requirements of the Department of Health. NHS Gloucestershire will do this through strategy formulation, performance management and clinical governance.

The Government's strategic plan for the modernisation of the NHS (*The NHS Plan, Department of Health, 2000*) states, as a core principle, that, "The NHS will work continuously to improve quality services and to minimise errors."

*"An important means of achieving this is for healthcare agencies and professionals to establish ways to identify procedures that should be modified or abandoned and new practices that will lead to improved patient care".*

The Government and Department of Health have established 'standard-setting' organisations as key drivers for their plans for service improvement and evidence-based healthcare. The work of two of these organisations is particularly relevant to this policy: the National Institute for Health and Clinical Excellence (NICE) and the Care Quality Commission (previously the Healthcare Commission). In addition, the

National Service Frameworks that address, for example, the prevention, management and treatment of chronic diseases, are of importance.

### **The National Institute for Health and Clinical Excellence (NICE)**

National Institute for Health and Clinical Excellence (NICE) is an independent organisation responsible for providing national guidance on treatments and care. NICE guidance is available to healthcare professionals, patients and carers to help them make healthcare decisions.

Once NICE guidance is published, health professionals are expected to take it fully into account when exercising their clinical judgment. However, NICE guidance does not override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their guardian or carer.

The Chief Executive of each NHS organisation is ultimately accountable for the implementation of NICE guidance. The way in which NHS Gloucestershire implements NICE guidance is described below.

### **The Care Quality Commission**

The Care Quality Commission is responsible for monitoring progress on the implementation of NICE guidance nationally.

### **National Service Frameworks**

As part of its commitment to improving health and reducing inequalities the Department of Health has produced National Service Frameworks (NSFs). NSFs describe national standards of care, define service models, offer strategies to support implementation, and establish performance measures against which progress is measured. NSFs have been published in a number of disease areas: coronary heart disease; cancer; paediatric intensive care; mental health; older people; diabetes; long-term conditions; renal services; children, young people and maternity services.

## **2 Prioritisation**

In order to provide a clear direction on the priorities allocated to the commissioning of healthcare services, the Clinical Priorities Forum will recommend the allocation of one of the following priorities to its policy statements:

**No priority** recommends that NHS Gloucestershire does not support the use of, and will not fund, a particular healthcare intervention because the drug, treatment, procedure, investigation, or screening or other public health programme is unsafe or proven to be ineffective.

**Low priority** recommends that the drug, treatment, procedure, investigation, or screening or other public health programme will not normally be funded by NHS Gloucestershire either because it is not considered to be a clinical imperative or because the evidence for clinical effectiveness is limited. Low priority interventions will only be commissioned under exceptional circumstances.

**Restricted priority** recommends that the availability of some services or interventions may be restricted because of capacity/resource constraints, AND/OR where treatment is restricted to those patients who are most likely to benefit according to protocols put in place by doctors and other treatment providers.

**High priority** recommends that this healthcare intervention is supported by NHS Gloucestershire, and a service to deliver it will normally be commissioned.

The recommendations from the Clinical Priorities Forum will be submitted to the PCT's Professional Executive Committee for a decision on formal adoption by the PCT.

### **3 Current commissioning protocols**

#### **Drugs and therapeutic agents**

As a general principle, appropriate drug therapy (those therapies that have a *High Priority*), including high cost drugs, will be included in all commissioning arrangements for patients, i.e. appropriate drug treatment should not be excluded from Service Level Agreements and should not comprise a separate cost item.

Drugs and therapeutic agents that have been given a *Low Priority* by NHS Gloucestershire will generally be commissioned on a cost-per-case basis.

Drugs and therapeutic agents allocated a *Restricted Priority* should be prescribed only in the circumstances detailed in NHS Gloucestershire's policy statements (policy statements will be available at the websites listed in Appendix 4). Compliance with this guidance will be audited.

Drug therapies that have a *Restricted Priority* will generally be commissioned on a cost-per-case basis.

As regards drugs and therapeutic agents that have been given *No Priority* by NHS Gloucestershire, clinicians who feel they have a case for exceptionality should apply to NHS Gloucestershire's INNF Panel (see Appendix 3). If agreed, these drugs or therapeutic agents will be commissioned on a cost-per-case basis.

### **Managing the entry of new drugs and the commissioning of drugs for use outside the indications of their UK product licence ('off-label' prescribing)**

New drug therapies are constantly being developed, and this leads to pressure from both patients and the pharmaceutical industry for clinicians to prescribe them.

In addition, NHS Gloucestershire recognises that in certain circumstances prescribers will need to use drugs outside of their licensed indications (off-label). This is most common in the areas of paediatric and obstetric medicine where ethical approval for clinical trials is difficult to obtain, and for conditions where the potential treatment population is very small thus making the conduct of clinical trials difficult or economically prohibitive. In these instances, NHS Gloucestershire would expect there to be good evidence based published data on the dosage, efficacy and safety of a medicine within the licensed area, and the act of prescribing off-label should be considered appropriate by a recognised body of medical opinion.

It is the responsibility of the prescribing organisation to ensure that adequate clinical governance arrangements are in place to ensure off-label prescribing is safe, effective, a responsible action, and amenable to audit. This must include agreements about when a subsequent opinion(s) is required to prescribe off-label.

Full details of NHS Gloucestershire's policy and process for managing the entry of new drugs, and off-label prescribing, is provided in Appendix 6.

### **Informing patients of their use of medicines outside the scope of the product licence**

Patient consent must always be considered when prescribing off-label. The prescriber must consider the risk to the patient; the patient's and/or

their guardian's ability to understand the issues; and whether the proposed use of the drug therapy is well established. In the treatment of pregnant patients, the individual must be fully informed about the unlicensed nature of the prescription. Informed written consent must be obtained for novel formulations of unconventional ingredients, as described in the section above.

### **Prescribing responsibility**

Prescribing responsibility lies with the person who signs the prescription. Where there is doubt or dispute about who should take responsibility for prescribing, it must be considered to lie with the person who has clinical responsibility for the treatment of the specific illness or condition. Thus, where care is shared across primary and secondary/specialist care, responsibility will generally lie within secondary/specialist care if the latter has initiated the therapy. Commissioning arrangements will seek to allocate funding so that the most appropriate practitioner may prescribe for the patient.

A 'Traffic Light' indicator system has been developed to signify the prescribing responsibilities:

- RED = should only be prescribed in secondary/specialist care
- AMBER = may be transferred from specialist to GP shared-care arrangements when these have been negotiated and where it is suitable for a specialist and GP to share care, i.e. once therapy has been initiated and the patient stabilised on the drug in secondary or tertiary care. Ideally a shared care guideline is agreed.
- GREEN = may be initiated by GPs in primary care or specialists.

These 'traffic light' indicators will be incorporated into commissioning contracts.

### **Guidance from the National Institute for Health and Clinical Excellence (NICE)**

Currently NICE produces guidance in four areas:

- the use of new and existing medicines and treatments within the NHS in England and Wales – *Technology Appraisal Guidance*

- the appropriate treatment and care of people with specific diseases and conditions with the NHS in England and Wales – *Clinical Guidelines*
- the use of surgical or other invasive interventions for diagnosis of treatment as to their safety and effectiveness – *Interventional Procedure Guidance*
- guidance for those working in the NHS, local authorities and the wider public and voluntary sector on the promotion of good health and the prevention of ill health - *Public Health Guidance*

Since January 2002, Primary Care Trusts have been required to provide funding and resources for drug therapies and other interventions recommended by NICE Technology Appraisals. The NHS normally has three months from the date of publication for each Technology Appraisal to provide funding and resources. NICE may extend this period if there are good reasons for delay, such as lack of trained, specialist staff to implement the service.

There is currently no standard, specified time scale for the implementation of either NICE Clinical Guidelines, Public Health guidance, or guidance on Interventional Procedures, although specific advice is sometimes given by the Department of Health.

### **NHS Gloucestershire's role in the implementation of NICE Guidance**

NHS Gloucestershire will take all forms of NICE guidance into account as part of their clinical governance duty.

**Technology Appraisals:** On publication of NICE Technology Appraisal guidance, relevant primary, secondary and tertiary care practitioners should review their practices against the standards proposed by NICE, and inform NHS Gloucestershire if there are key implementation areas that cannot be delivered.

NICE Technology Appraisal Guidance will be given a High Priority by NHS Gloucestershire. The drug therapy or intervention will be commissioned by NHS Gloucestershire within the three-month time scale, and will generally be provided to patients who meet the entry criteria specified in the NICE Guidance. (Details of the interventions that fall within this category can be found at the NICE website: [www.nice.org.uk](http://www.nice.org.uk).) If there is local need, or if additional evidence becomes available in the period following the issue of NICE Guidance, NHS Gloucestershire may extend or amend the eligibility criteria defined

by NICE. In such circumstances, a commissioning policy will be developed through the Clinical Priorities Forum.

Where an individual patient is receiving a drug therapy as a result of a commissioning decision made by NHS Gloucestershire's INNF Panel, and prior to the release of a NICE Technology Appraisal for that therapy, the patient should continue to receive the therapy during the three-month lead-in period that normally applies to the introduction of NICE Technology Appraisals.

Where an individual patient is receiving a drug therapy as a result of a commissioning decision made by NHS Gloucestershire's INNF Panel, and this therapy is subsequently not recommended by a NICE Technology Appraisal, the prescriber should review the patient's case. In instances where risk to the patient has been identified by NICE, and either NICE recommend withdrawal of treatment or the PCT considers that the risk outweighs the potential benefit, then treatment should be withdrawn as soon as possible to be replaced by a clinically effective alternative if available. If the principal issue in the NICE Guidance is lack of cost-effectiveness, but the patient is deriving clinical benefit, then the patient should continue to receive the therapy whilst a clinically- and cost-effective alternative is sought.

**Clinical Guidelines:** Although not mandated for implementation, NICE Clinical Guidelines usually correspond to clinicians' professional guidelines. NHS Gloucestershire will therefore disseminate Clinical Guidelines to the relevant service providers and take into account local resources and conditions when considering implementation. However, because these types of guidance are considered by the Department of Health to reflect 'best practice', primary, secondary and tertiary care practitioners should review their practices against the standards proposed by NICE, and inform NHS Gloucestershire if there are key implementation areas that cannot be delivered.

**Public Health Guidance** is NICE guidance on the promotion of good health and the prevention of ill health for implementation by those working in the NHS, local authorities and the wider public and voluntary sector. As with NICE's Clinical Guidelines, NICE Public Health guidance is not mandated for implementation but health and social care organisations should review and revise their practices against the recommendations made by NICE.

**Interventional Procedures Guidance:** NICE Interventional Procedures Guidance has similarities with licensing procedures, and informs health

professionals and the public whether procedures are safe and effective. If they are not safe and effective, NHS Gloucestershire will not commission them. Safe and effective interventional procedures will be commissioned in appropriate clinical circumstances, and where the necessary resources and specialist skills are available.

### **Treatment for patients outside of the eligibility criteria in NICE Guidance**

If a Trust wishes to vary the entry criteria for access to a specific healthcare intervention for all patients or a selected group of patients from that stipulated in NICE Guidance, then a proposal must be brought to the Clinical Priorities Forum in order that an appropriate policy can be developed (see Appendix 2 for details of this process).

If a Trust wishes to provide a treatment for an individual patient who does not meet the eligibility criteria specified in NICE Guidance, then an application should be made to NHS Gloucestershire's INNPF Panel. Details of the procedure are given in Appendix 3 and are available electronically on the websites listed in Appendix 4.

### **Research**

Clinical research must be funded by appropriate research-designated monies and not through budgets that NHS Gloucestershire has allocated for the commissioning of health services.

However, in line with Health Service Guideline (HSG (97) 32) (29 May 1997), NHS Gloucestershire will meet the treatment costs of patients entered into Research Council-funded trials. Treatment costs, including Excess Treatment Costs, will be negotiated through the PCT's normal commissioning procedures.

With regard to new healthcare interventions, the treatment of rare conditions, or interventions for which there is currently little evidence of effectiveness, NHS Gloucestershire may request that NHS organisations provide data to national or regional databases in order to facilitate the accumulation of knowledge and experience.

## **4 Commissioning Policy exceptions**

NHS Gloucestershire has developed a policy to guide the PCT in its consideration of 'exceptionality' in individual applications for health care interventions that are not normally commissioned. This policy (*Policy*

*Statement Guidance for considering 'exceptionality' in individual cases*) is provided in full in Appendix 5.

Requests for treatments outside of current commissioning policies are considered by the PCT's INNPF Panel, and the terms of reference and procedure for making applications to that Committee are given in Appendix 3.

It should be noted that NHS Gloucestershire will not fund interventions retrospectively.

## **5 Clinical Priorities Forum - work programme**

At the start of each financial year, the Clinical Priorities Forum will draw up a priority list of health technologies, drugs and procedures that it will consider over the next 12 months. The list could include

- new interventions that are identified by members of the Clinical Priorities Forum as potential treatment priorities for the residents of Gloucestershire;
- commonly recurring requests to the INNPF Panel;
- high cost medicines where their commissioning might have a significant cost impact on NHS Gloucestershire and the health community;
- drugs, technologies and procedures currently commissioned where new evidence regarding their effectiveness is published;
- drugs, technologies or procedures that are not included in NICE's assessment programme, OR drugs, technologies or procedures where NICE will not release guidance for at least six months.

In addition, healthcare providers and Gloucestershire residents can request that the Clinical Priorities Forum considers the development of a policy for a specific healthcare intervention.

There are four main reasons why healthcare providers working within a particular clinical area might need to make a presentation to the Forum:

1. Clinicians requiring extra funding for a service, additional to the allocation in the Service Level Agreement. Requests for this

reason typically arise because there has been an advance in healthcare that requires extra funding. (Sometimes the extra expense falls mainly to the GP's drug budget but it is still extra cost to the NHS and therefore prioritisation principles need to be applied).

2. To enable NHS Gloucestershire's Clinical Priorities Forum to support a clinical decision to fund a new treatment or procedure as a priority against another treatment or procedure when no further funding is available.
3. To brief the Forum about health care services that are, and are not, being carried out in order to help in making decisions about the extent and need for future commissioning services.
4. To implement a technology outside of NICE Guidance.

The information required by the Clinical Priorities Forum is detailed in Appendix 2, and clinicians wishing to bring a proposal to the Forum should contact the New Technologies and Drug Therapies Manager at NHS Gloucestershire to make the necessary arrangements.

## **6 Dissemination**

On behalf of NHS Gloucestershire, the Clinical Priorities Forum will disseminate policies regarding the commissioning of specific services as follows:

### **NICE Guidance**

Following the release of NICE or other Department of Health guidance, an impact statement will be produced by the relevant provider organizations. Provider organisations are responsible for developing their own process for implementation of the guidance. The Gloucestershire NICE Technology Appraisal Guidance Group will receive copies of the impact statement, and are responsible for monitoring the implementation process.

### **Policy statements**

Once adopted by NHS Gloucestershire's Professional Executive Committee (or NHS Gloucestershire's Board), policy statements will be sent to relevant contacts in primary and secondary care, and specialist centres; and to lay members of the INN Panel.

Additionally, these documents will be published on the relevant intranets. Paper copies are also available on request. See Appendix 4 for website details.

## **7 Withdrawal of commissioning policy statements**

NHS Gloucestershire's Clinical Priorities Forum will review each commissioning policy statement after a period of two years. However, as new healthcare interventions are introduced and NICE Guidance is implemented, NHS Gloucestershire's commissioning policies may become out-of-date or inappropriate. In these circumstances, the Clinical Priorities Forum will bring forward the planned review date. Where evidence of serious adverse effects is published, immediate review or withdrawal of a commissioning policy may be instigated by NHS Gloucestershire.

## **8 Implementation Plan**

The Clinical Priorities Policy for Commissioning Selected Services will take effect from 1<sup>st</sup> July 2009, following approval by the Board of NHS Gloucestershire. Current funding applications will be entered into the new process at the most appropriate point to ensure that unnecessary delays are not introduced. The Clinical Priorities Forum and its supporting infrastructure will be fully established by 30 September 2009.

The interim schedule of special commissioning arrangements (Appendix 7), which the list of Interventions that are Not Normally Funded contained within NHS Gloucestershire's previous INNF Policy, will apply until it is reviewed by the Clinical Priorities Forum and any changes are agreed by the PEC. The schedule at Appendix 7 also highlights the list of commissioning policies that are currently prioritised for development (eg bariatric surgery, assisted conception, botulinum toxin A, cancer screening, deep brain stimulation). Other policies that are prioritised for development are: gender reassignment, lymphoedema, functional electrical stimulation, anti VEGF treatments for visual impairment and new high cost medicines. The list of priorities will be reviewed by the Clinical Priorities Forum.

A Communications Plan to support the implementation of the new policy and to communicate the role of the Clinical Priorities Forum will be developed and implemented during June 2009.

## APPENDIX 1

### CLINICAL PRIORITIES FORUM Draft Terms of Reference

#### **Aim**

The NHS Gloucestershire Clinical Priorities Forum will support the decision-making process for the commissioning of health care services, treatments and/or interventions for Gloucestershire residents. It will provide a multi-agency forum to enable review of the prioritisation of clinical services; to discuss commissioning intentions, and to provide guidance to clinical colleagues on service delivery issues that may arise.

#### **Objectives of the Clinical Priorities Forum**

1. To review presented evidence for the clinical effectiveness of drugs, treatments, procedures, investigations, screening and other clinical programmes in order to advise the Professional Executive Committee of NHS Gloucestershire on priorities for investment and service redesign
2. To promote and support effective, equitable and transparent health care decision making
3. To enable a range of stakeholders in Gloucestershire to understand the context within which prioritisation is determined and to support decision making around commissioning.
4. To enable clinical, ethical and economic perspectives on health care issues to be considered
5. To offer members and other clinicians a forum in which they are able to discuss key issues affecting patient care, within their own organisation and/or the wider health community
6. To allow members to bring to the attention of the Group any strategic developments that may impact on health care delivery

#### **Membership**

CEO or nominated representative - as Chair	NHS Gloucestershire
GP (Chair of PEC) and/or Chair of Clinical Quality Commissioning Group	NHS Gloucestershire

Medical Director (Commissioning)	NHS Gloucestershire
Medical Director (Provider)	Gloucestershire Care Services
Director of Business Development and Performance	NHS Gloucestershire
Director of Clinical Development (Director of Nursing Gloucestershire Care Services)	NHS Gloucestershire/ Gloucestershire Care Services
Director of Public Health	NHS Gloucestershire
A Practice Based Commissioning Lead Clinician	GP
Director of Nursing	Gloucestershire Hospitals NHS Foundation Trust
Medical Director	Gloucestershire Hospitals NHS Foundation Trust
Director of Clinical Strategy	Gloucestershire Hospitals NHS Foundation Trust
Director of Nursing	<sup>2</sup> gether NHS Foundation Trust
Medical Director	<sup>2</sup> gether NHS Foundation Trust

### Co-opted members (as appropriate)

Clinical Leads from other care providers (eg GWAS) or clinical networks
Clinicians and/or Managers from service delivery areas
Professional Pharmacy Leads
Clinical Audit Managers
Research Managers
NHS Gloucestershire Commissioning Leads

### Secretary

TBA
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## **Support**

NHS Gloucestershire will co-ordinate the provision of the necessary information to the Clinical Priorities Forum through the Clinical Quality Commissioning Group (CQCG) .

All members or their representatives will be responsible for communicating the work and decisions of this Forum within their respective organisations.

## **Quoracy**

For a meeting to be quorate, five members are required - to include the Director of Public Health, a relevant clinician, a relevant provider representative, the Director of Business Development and Performance, or their nominated deputies.

## **Representation**

Members may delegate their place on the Forum if unable to attend a meeting only if their representative has been appropriately briefed and has designated responsibility to take decisions. A Clinician must be represented by another clinician.

## **Accountability**

The Forum is accountable to the individual organizations from which the representatives are drawn. The Forum will make recommendations to the Professional Executive Committee of NHS Gloucestershire. The Professional Executive Committee will decide whether to adopt the commissioning policies developed through the Clinical Priorities Forum, using the powers delegated to it by the Board of NHS Gloucestershire.

The Chair of the Forum will be an Executive Director of NHS Gloucestershire (TBA), and will have a designated Deputy.

## **Invitations and minutes**

Minutes, agendas, and invitations to attend meetings of the Clinical Priorities Forum (for information purposes) may be provided to:

- Medical Director of the Strategic Health Authority
- Medical Director of the Ambulance Trust
- Social Services Department, Gloucestershire County Council
- Other primary and community care Committees, such as LMC, VCS

**Meeting Schedule**

Meetings of the Clinical Priorities Forum will be held every 3 months (to be reviewed).

**Review**

The Terms of Reference will be reviewed within 6 months of the Forum being established and then on an annual basis.

## **APPENDIX 2**

### **Advice for Presenters to the Clinical Priorities Forum**

#### **Presentation of new drugs, technologies or procedures to the Clinical Priorities Forum**

Gloucestershire Clinical Priorities Forum is being set up to support the NHS Gloucestershire health system to make difficult priority decisions about what health care should be provided to its residents when resources are limited and services are under increasing pressure.

The Clinical Priorities Forum considers at a local level, whether new drugs and treatments, or treatments that are not routinely available should be funded, as well as discussing pressure points in local services and the impact of service developments. Using an ethical framework to support its decision making process, the Clinical Priorities Forum makes recommendations to the NHS Gloucestershire Professional Executive Committee, which is responsible for making the final decision using the powers delegated to it by the Board of NHS Gloucestershire.

The Clinical Priorities Forum does not consider individual cases.

Presenters should note that the Clinical Priorities Forum makes a recommendation only. Funding is allocated on an annual basis through the commissioning process– the Clinical Priorities Forum links to this process. In-year funding may be agreed where appropriate.

**The “envelope” of resources for each directorate area/clinical area**  
NHS Gloucestershire cannot decide the relative priority for every type of health care intervention. Nor is it desirable that it should. It is more appropriate that each directorate has scope to decide about priorities within its own area of expertise. The clinicians in each area closely involved with patients’ care are generally in the best position to decide about priorities.

#### **What should the presentation include?**

A background paper should be submitted to the Clinical Priorities Forum by the date requested, and address the following:

#### **Background**

- An introduction to the drug/technology

- Is this a new innovation or a new indication for an existing drug/technology?

### **NICE guidance (if appropriate)**

- A summary of NICE recommendations
- What are the differences between guidance and current practice?
- What are the clinical and service implications of the guidance?
- What are the financial implications of the guidance\*?

### **Current practice**

- Is the drug/technology currently being used in Gloucestershire?
- How many patients are treated?
- What are the current criteria for treatment?

### **Proposal for consideration**

- Outline of proposed usage of drug/technology
- Any staffing or service implications?
- Briefing on drug/technology/indication not being carried out (if applicable)

### **National Priorities**

- Is the drug/technology a National Priority?
- Has National guidance been issued in this area?
- Is National guidance in the pipeline?

### **Local Priorities**

- How can this treatment be funded within the current allocation of resource? (i.e. How can this new treatment substitute another treatment that is of less value within current resources?)
- Where does the treatment rank in terms of other priorities within your specialty?

### **Evidence of effectiveness**

- Data from research studies should be presented and a list of references provided
- What are the benefits (both short term and long term potential benefits)?
- What is the size of the benefit?
- Do any sub-groups of patients benefit more than others?
- How many patients will benefit?

### **Cost-effectiveness**

- Data from economic evaluations should be presented and a

list of references provided

- Cost per QALY (Quality Adjusted Life Year) should be shown where available

### **Equity**

- How does the treatment compare with those (of the same general type) from other clinical areas? (e.g. life extending treatments from two different clinical areas)?

### **Patients Choice**

- What are the views of individual patients, and patient groups?

### **Implications of not using this treatment**

- What are the alternatives for treatment?
- Are patients at risk if this treatment is not used? If yes, how?

### **Audit process for NICE guidance**

- How will you audit the implementation of the NICE guidance in terms of adherence to the recommendations and its cost?

### **Financial Impact**

A financial impact statement (see below) should be completed and presented by the relevant finance department.

## Financial Impact Statement

Name of Guideline, Innovation, Drug or Health Technology Assessment:		
Trust:	Division/Directorate:	Specialty:
Change in practice, if any. Please include any procedure or drug this innovation will replace		
Proposed Timetable for implementation – e.g. introduction with effect from a certain date or over a number of years		
Major commissioners affected (so that we can work with them to find a consistent approach). If the data can be split over the main commissioners please do this, if not, then please list the commissioners here.		
'Work group' Involved – if applicable. If this has been discussed at a 'work group' meeting please give date of meeting and/or reference in minutes.		
Has this been discussed by Directorate/Division/Trust? If so please give date and result of discussion.		
Form completed by / contact for queries:	Name	Position
Tel	E-mail	Date
Notes:		

<b>Data over years.</b> There is likely to be a build up of activity and/or costs over a number of years, as very few innovations will be implemented in full from the beginning of a year. The full year effect will be the activity or costs when and if the innovation is fully implemented.			
Please give the number or cost for the Trust as a whole. The amount attributable to each Commissioning PCT will be necessary.			
<b>Number of patients</b> expected to be treated - this may build up over a period of years.	Current Year		
	Next Year		
	Full Year		
<b>Total (Gross) Cost</b> – this may include staff, drugs, equipment etc. Again it would be useful to show the total costs for the Trust and the amount that would be required from each Commissioner. This may simply be in the same proportion as the number of patients	Current Year		
	Next Year		
	Full Year		
<b>Cost Savings</b> from ceasing previous treatment – if applicable	Current Year		
	Next Year		
	Full Year		
<b>Net (Additional) Cost</b> – i.e. Total or Gross Cost less Savings. If the new procedure replace a more expensive one this will be Net Savings.	Current Year		
	Next Year		
	Full Year		
<b>Any funding already agreed</b> – please say if some of this has already been recognised by NHS Gloucestershire or other Commissioners. Please say which PCTs have agreed funding.	Current Year		

## APPENDIX 3

### Protocol for the consideration of 'Exceptional Treatment' (Interventions Not Normally Funded)

#### INTRODUCTION

NHS Gloucestershire must ensure that it provides the community of Gloucestershire with the best health care from the funds available. This includes the responsibility to make decisions regarding individual funding requests that do not fall under existing contracts, and ensuring that decisions made are equitable and in the interest of the whole population (see NHS Gloucestershire's *Clinical Priorities Policy for Commissioning Selected Services*). An Interventions Not Normally Funded (INNF) Panel has been established to consider these individual requests. The membership of this committee includes health professionals, NHS Gloucestershire Directors and is chaired by a Lay Member.

This protocol presents a three-staged approach to the process of considering these requests. A flow chart outlining the process is provided in Addendum 1.

#### STAGE ONE – Application to NHS Gloucestershire

The referrer (the GP, consultant, or person managing the clinical care of the patient) must first consult NHS Gloucestershire's current commissioning policy statement(s), and/or Interventions Not Normally Funded list, to establish that the patient is ineligible for the treatment requested.

If the patient's clinician assesses that funding will not normally be available, the next step in the process is for a standard funding application form (Addendum 3) to be completed. Completion of the form must be undertaken by the GP, consultant, or person managing the clinical care of the patient, in liaison with the patient. **To avoid misunderstandings, and losing time in the resolution, the form requires the signature of both the clinician and the patient (or their carer/guardian).**

Completed applications should be posted, faxed or e-mailed to the address specified on the form.

Requests for exceptional funding must be submitted on the standard application form; this is to ensure that NHS Gloucestershire and/or the

INNF Panel receives all the information, and only that information, needed to reach a decision. The information required includes the following:

- Name of GP/consultant making application
- Patient's name, address and date of birth
- Brief and relevant health history
- Treatment/intervention requested
- Information on alternative treatment(s) available
- Proposed provider of treatment
- Costings (if available/known) and length of treatment (number of treatment episodes, length of in-patient stay, etc)
- Evidence that the proposed treatment is likely to result in improved health for the patient
- Implications for patient if treatment is not funded
- Reasons why the patient's case is 'exceptional'

If the information requested is not supplied, consideration of the application will be delayed whilst the information is collected from the clinician. It is not the responsibility of NHS Gloucestershire to complete sections of the form on behalf of applicants. Where appropriate, supporting letters from other clinicians (specialists, other experts or other health or social care professionals involved in the patient's care) should also be provided.

The same application form is to be used for requests for equipment, drugs, surgery or other treatments that fall outside of existing commissioning contracts.

It should be noted that NHS Gloucestershire does not fund interventions retrospectively.

## **STAGE TWO – Initial assessment of the application**

When the application is received by NHS Gloucestershire, it will be reviewed to

1. Agree that the healthcare intervention or equipment request is not currently commissioned
2. Assess whether the application demonstrates sufficient exceptionality to warrant its consideration by the INNF Panel

The latter assessment is guided by NHS Gloucestershire's Policy Statement *Guidance for considering 'exceptionality' in individual cases.*

Where an application suggests that exceptional funding may be warranted, the case will be taken forward to the INNF Panel for a decision.

## **STAGE THREE - The decision-making process**

### **The INNF Panel**

The INNF Panel will meet ten times a year in order to make decisions on individual funding requests received. At each meeting the Panel will receive an anonymised application form and anonymised copies of any additional correspondence or reports which may be relevant to the patient's case. When relevant, the Panel will receive and consider a briefing of the evidence-base supporting the requested treatment or intervention, prepared by NHS Gloucestershire's New Technologies and Drug Therapies Manager. The Panel will normally only support treatments with at least **moderate level** evidence of effectiveness<sup>1</sup>. The Panel will also consider any evidence pertaining to the level of cost-effectiveness of the treatment or intervention requested.

### **Purpose**

The INNF Panel is responsible for considering requests for exceptions to the current commissioning policies of NHS Gloucestershire.

Requests may be referred to the Panel by the patient's managing clinician; requests received directly from patients without the endorsement of their managing clinician will not be considered and will be referred back to the patient's GP. However, patients may submit information to support their case alongside the application form that is completed by their managing clinician.

The decisions of the Panel will be communicated directly to the referring clinician and/or the patient's GP (if this is not the same person). Decisions are not communicated directly to the patient unless requested to do so by agreement between the patient and their managing clinician and indicated on the signed application form. The PCT exercises caution in communicating the Panel's decisions to patients because these may potentially cause distress or require interpretation that can best be addressed by their managing clinician.

In fulfilling the primary purpose of the INNF Panel, the Panel will ensure it has adequate information upon which to base its decisions. This may

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<sup>1</sup> This is defined as good quality observational control or case control studies or better i.e. randomised or controlled trials. This is based on the levels of evidence recommended by NICE.

be information over and above that provided by the patient's managing clinician (for example, a second opinion may be requested). In the absence of such information, decisions will be deferred until supplementary information is provided to the Panel.

### **Scheme of Delegation**

The Panel acts as a formal sub-committee of the NHS Gloucestershire Board. It has the authority to make exceptions to the Commissioning Policies of NHS Gloucestershire and thus commit financial resources within the frameworks agreed. The Panel will report its decisions to a meeting of the NHS Gloucestershire Board on a quarterly basis in an anonymised form.

### **Membership**

The INNF Panel will comprise the following members:

- Lay Representative (Chair)
- Lay Representative (Vice Chair)
- Chair of the Professional Executive Committee or their nominated representative (a medically qualified member of the Board or PEC)
- Director of Public Health or their nominated deputy
- Director of Strategy Development and Corporate Services or their nominated deputy
- Director of Business Development and Performance or their nominated deputy
- Medical Director (Commissioning) or their nominated deputy
- The New Technologies and Drug Therapies Manager will be co-opted as necessary to report on the evidence for the clinical and cost effectiveness of interventions requested, but will not have any role in the decision-making process.

The Panel will be quorate when three members are in attendance, of whom one must be a lay representative; one must be an Executive Director of the PCT; and one must be the Chair of the Professional Executive Committee, or his/her representative (a medically-qualified member of the PCT's Board or Professional Executive Committee).

Note that the Chief Executive of NHS Gloucestershire cannot be delegated as a member of the INNF Panel because of their role as Chair of Appeals Panels that consider contested decisions or processes.

In usual circumstances, it is not considered appropriate for patients, or their representatives, to attend the meeting of the INNF Panel where their case is discussed. However, as noted above, patients are invited to submit information in support of their application for consideration by the Panel.

### **Informing applicants of the process**

Applicants will be sent an acknowledgement letter when their application is received by NHS Gloucestershire. Following initial assessment, the applicant will be informed in writing as to whether their request is to be taken to the INNF Panel and/or whether additional information is required.

The INNF Panel meets a minimum of 10 times a year, and cases will be considered at the earliest possible meeting. Applicants and, where agreed, patients, will be informed of the Panel's decision within 15 working days of the Panel meeting.

### **What decision will be made**

The INNF Panel can make one of three different decisions regarding individual cases:

1. Agree to fund/support the request
2. Defer a decision pending further information/investigation
3. Refuse to support/fund the request

### **Requirement for Urgent Decisions**

It is recognised that on occasions urgent decisions are required. In such instances, the INNF Panel will consider cases outside of scheduled meetings, using fax/e-mail/telephone conference facilities as necessary. However, despite urgent circumstances, no members of the INNF Panel can make decisions on their own, and urgent decisions should be delegated by the Chair of the INNF Panel to, as a minimum, an Executive Director of NHS Gloucestershire, the Chair of the Professional Executive Committee (or designated deputy) and a lay representative.

### **Re-presentation of the case**

If the request for funding has been refused by the Panel, the applicant can re-present the case if there is additional information to suggest exceptionality. If this information is deemed 'new evidence' by the Director of Public Health and/or the Director of Strategy Development and Corporate Services or their nominated deputies, it will be considered at the next available meeting of the Panel.

## **Appeals**

In the event that the applicant and/or patient wishes to appeal against a decision made by the INN F Panel, then the Appeals Procedure set out in Addendum 2 must be followed.

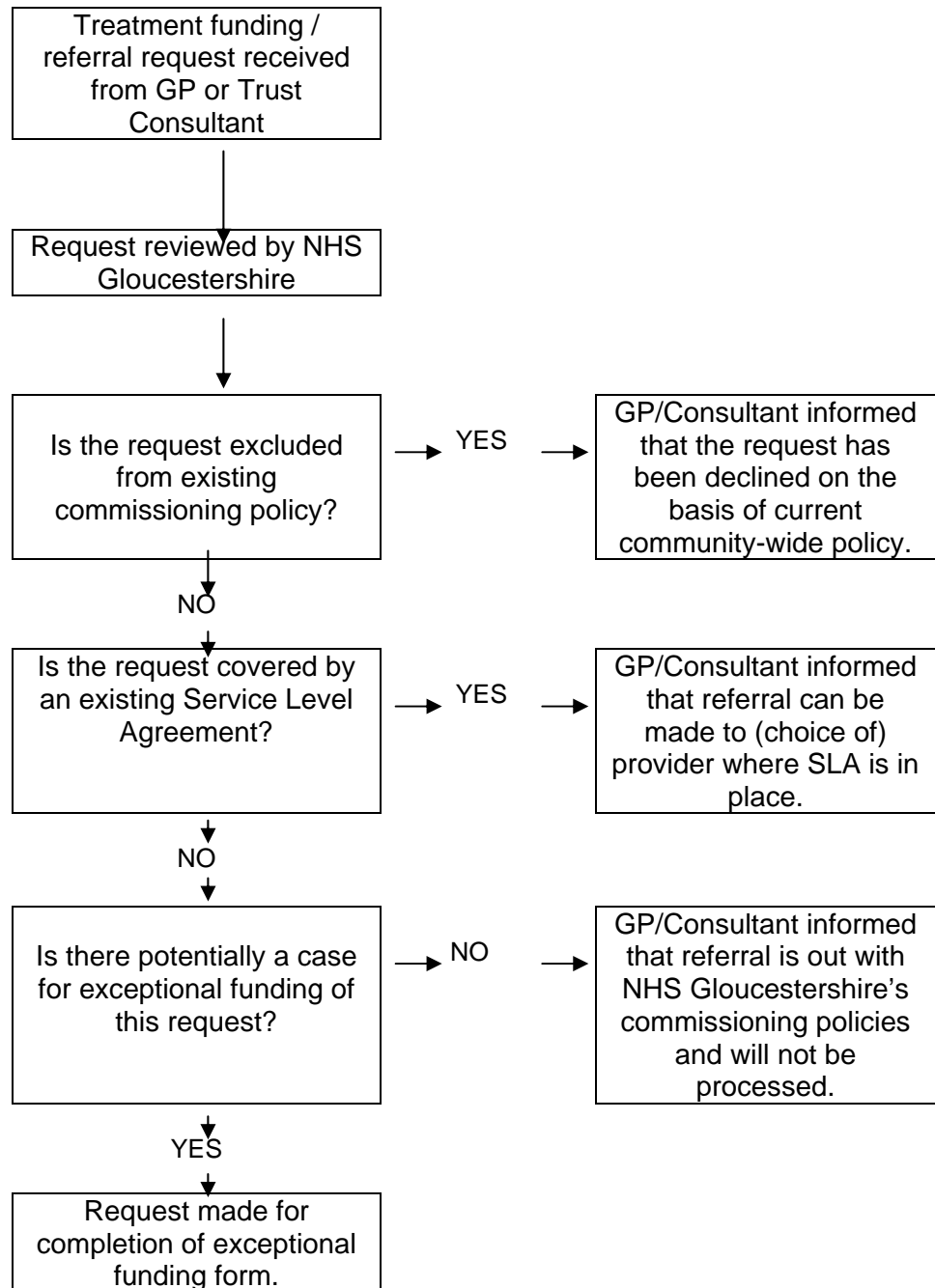
If the appeal is against the procedure followed by the INN F Panel when considering the case, then NHS Gloucestershire's usual Complaints Procedure is invoked.

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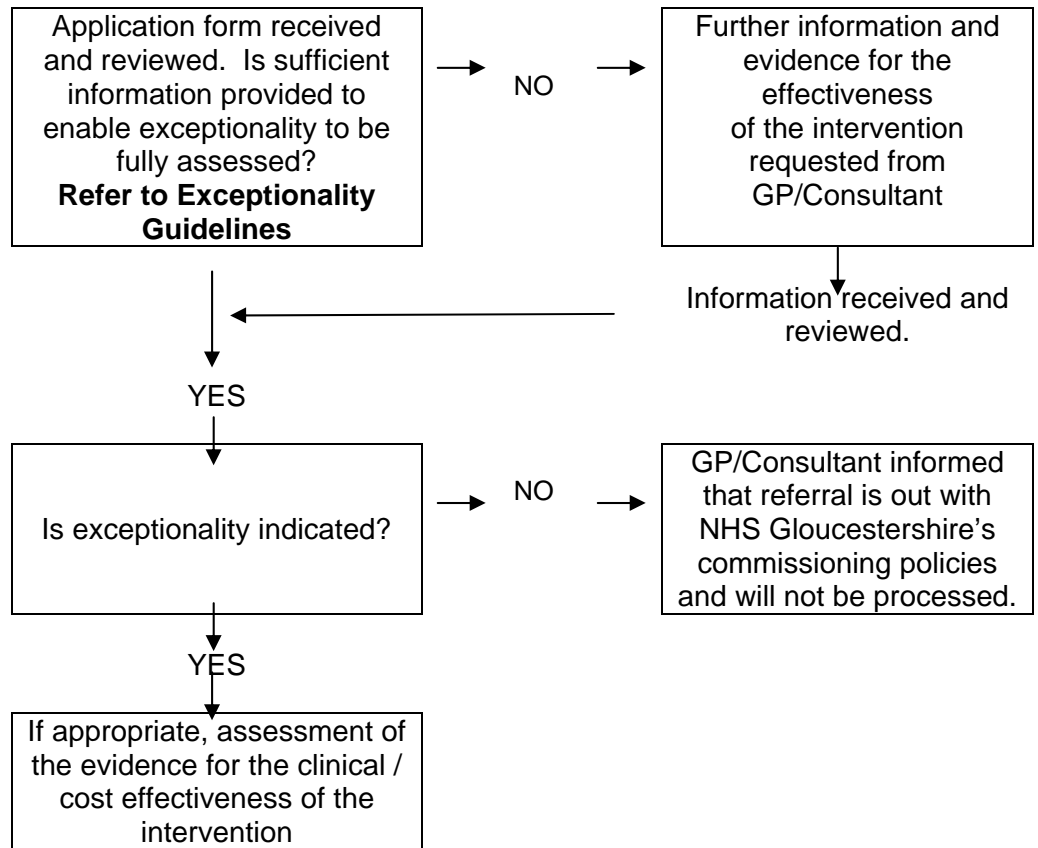
# Addendum 1

## INNF Panel - flow chart of the decision-making process

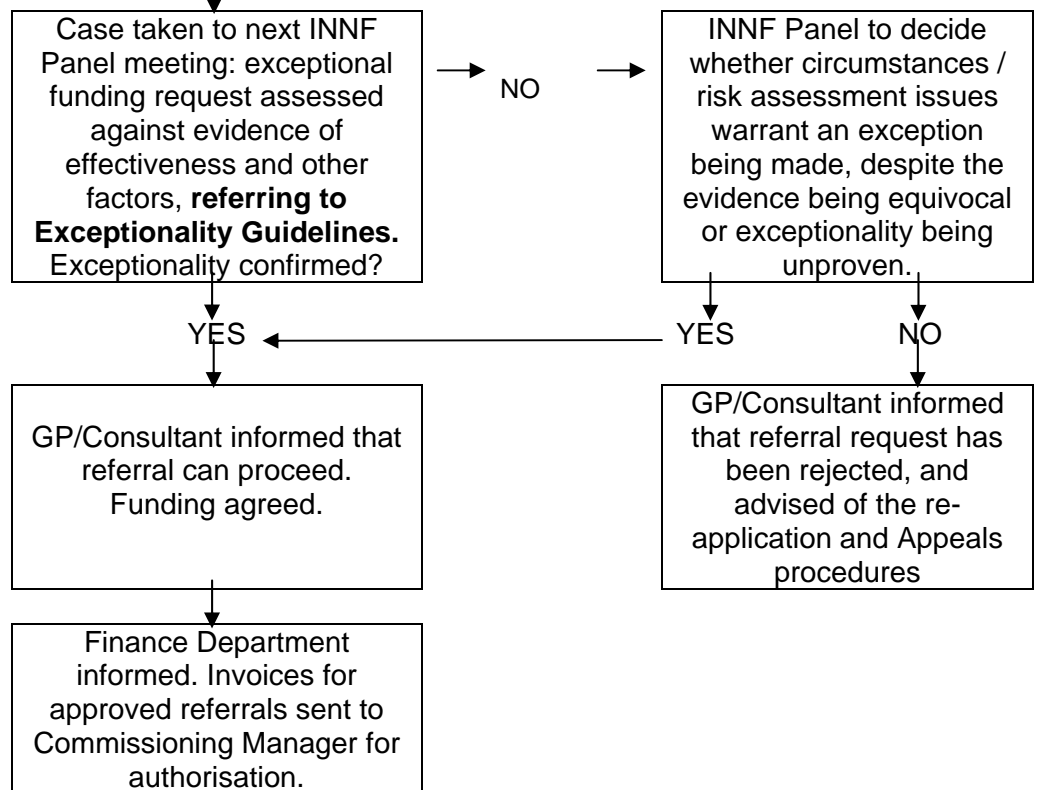
### STAGE ONE



**STAGE TWO**



**STAGE 3**



## **Addendum 2**

### **Appeals Procedure for the Clinical and Commissioning Policies of NHS Gloucestershire**

#### **Introduction**

The Appeals Panel is established as the Appeals Panel for the Board to consider appeals by the applicant/Medical Practitioner and/or their patient against a decision of NHS Gloucestershire's INNF Panel.

#### **Role of the Appeals Panel**

The Appeals Panel's role is independently to assess whether the INNF Panel's decision was valid in terms of process, factors considered and criteria applied. In making its decision the Appeals Panel must consider whether the INNF Panel has:

- Taken into account and weighed all the relevant evidence
- Given proper consideration to the claims of the patient and accorded proper weight to their claims against other groups competing for scarce resources
- Taken into account only material factors
- Acted in good faith
- Made a decision that is reasonable.

#### **Membership**

The Appeals Panel will be chaired by the Chief Executive of NHS Gloucestershire (or his/her deputy). The Appeals Panel will comprise a minimum of three persons none of whom should have sat on the INNF Panel for the case under consideration. There will be at least one Non-Executive or lay member and at least one PEC member. The Chair may co-opt onto the Appeals Panel a medical practitioner, nurse or other healthcare professional with relevant healthcare expertise. The Communications Manager should be in attendance at Appeals Panels.

### **Appeals Panel Secretary**

The servicing and administrative support to the Panel will be undertaken by a member of NHS Gloucestershire staff (the Appeals Secretary) who will be responsible for managing the administration of the appeal from receipt of the letter of appeal through to the notification of the decision.

### **Evidence available to the Medical Practitioner and/or Patient**

The applicant/Medical Practitioner and/or patient will be supplied with all the documents available to the Appeals Panel at least 7 days before the appeal hearing.

### **Evidence available to the Appeals Panel**

#### a) Documents

- i) All documents that were available to the INNF Panel, together with the Minutes of the meeting that recorded the Committee's decision and reasons
- ii) Any further information that has come to light since the INNF Panel's decision

#### b) Representations

- i) The applicant/Medical Practitioner and/or patient must supply to the Appeals Secretary a statement in support of the appeal, together with any supporting documents, at least 7 days before the hearing
- ii) The patient is entitled to attend the hearing and to make oral representations either personally or through their chosen representative (who should not be legally qualified)

### **Referral back to INNF Panel**

If further relevant information has come to light since the INNF Panel's decision, the Appeals Panel may at its absolute discretion refer the case back to the INNF Panel.

### **Referral to an Independent Assessor**

Where the facts of a case are in dispute, the Chair of the Panel may, either before or at the hearing, refer the dispute to an independent assessor, chosen by the Chair, for determination. The assessor will provide a written report to the Chair of the Panel within six weeks. If, as a result of the appeal, the case is referred back to the INNF Panel for

re-determination, the INNF Panel will be bound by the assessor's determination in the absence of any new relevant evidence.

### **Time for Appeal Hearing**

Unless there are circumstances which make this impossible, the Panel hearing will take place a maximum of six weeks after the date of receipt of the appeal in order to give sufficient time to obtain relevant information.

### **Appeal Decision**

If the Appeals Panel is not satisfied that the INNF Panel's decision was valid it will recommend a new decision to the Board of NHS Gloucestershire. If the Panel decides to refer the case back to the INNF Panel for further consideration, the INNF Panel will convene a meeting within six weeks to review the case. The appellant will be informed of the Appeals Panel's decision within 5 working days.

### **Authority**

The Panel is authorised by the Board of NHS Gloucestershire to seek any information it requires from members of the INNF Panel who are directed to co-operate with any such request. The Panel is also authorised by the Board to obtain legal advice and to secure the attendance of other appropriate persons with relevant experience and expertise if it considers this necessary.

### **Confidentiality**

Appeals Panel members are bound by the Code of Confidentiality in respect of all written material and verbal discussions concerning the appeal. All papers are to be collected at the end of the Appeals Panel's sitting except those required by an executive member for subsequent action. Any member who does not attend the sitting is responsible for returning all papers to the Appeals Secretary for shredding.

### **Complaint**

If a complaint is made about the handling of an appeal, NHS Gloucestershire's complaints procedure can be invoked at any stage. If the complaint relates to the impact of a commissioning policy on an individual then the complaints procedure will only be implemented once the Panel has reached a final decision.

A complainant contacting NHS Gloucestershire will be informed:

- i) of how their appeal will be handled
- ii) of their right of recourse to the complaints procedure

- iii) that, if an appeal decision is found to be properly and reasonably reached, an Independent Review Panel cannot overturn that finding.

## Application Form to the INNF Panel for consideration of an individual case exception to NHS Gloucestershire's commissioning policies

The following form must be completed when applying for funding for treatments which are not usually commissioned by NHS Gloucestershire. Further information about the application process is provided in the *Protocol for the consideration of 'Exceptional Treatment' referrals* available on NHS Gloucestershire's website.

This application is submitted by:

Managing clinician (GP, Consultant, etc)  
 PRINT NAME: \_\_\_\_\_ SIGNATURE: \_\_\_\_\_

Patient (or carer/parent/guardian)  
 PRINT NAME: \_\_\_\_\_ SIGNATURE: \_\_\_\_\_

Date: \_\_\_\_\_

The completed form should be sent in confidence with a covering letter, and any other supporting documents, to:

Director of Strategy Development and Corporate Services  
 NHS Gloucestershire

**1. GP/Consultant/Clinician making the application**

<b>Name:</b>	
<b>Address:</b>	

**2. Patient's name, address and date of birth**

<b>Name:</b>	
<b>Address:</b>	
<b>DOB:</b>	
<b>NHS</b>	

<b>Number:</b>	
<b>Hospital Number:</b>	

**3. Brief history including patient's current health status and any other relevant health care problems**

**4. Summary of previous interventions this patient has received for this condition**

**5. Details of the treatment/equipment for which funding is requested**

**For drug requests, please state if it is licensed for this indication** YES

NO

**6. What are the intervention goals and expected outcomes following treatment?**

**7. Is any alternative treatment/equipment available? Is this alternative commissioned by NHS Gloucestershire? Why is this alternative not appropriate for the patient?**

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**8. Proposed provider of the treatment (include any alternative providers, if appropriate)**

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**9. Cost (if information available) and length of treatment, if known**

<b>Cost: £</b>	<b>Length of Treatment:</b>
<b>Preferred start date (and reason)</b>	

**10. Evidence that the treatment proposed has the potential to result in health improvement for the patient, including recent evidence of effectiveness/NICE guidance etc.** *(A policy not to commission a service/therapy usually reflects a lack of evidence of effectiveness, or evidence of limited benefit balanced against adverse effects. Please provide details of research/clinical evidence that supports this particular application. Reference to articles and copies of reports may be attached).*

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**11. Implications for the patient if proposed treatment is not funded**

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**12. Proof of 'Exceptionality' - rationale for bringing this case to the INNF Panel (see NHS Gloucestershire's Policy Statement). For applications for funding to treat cosmetic problems, accompanying photographic evidence is also requested. (NB It is the applying clinician's responsibility to obtain consent from the patient for photographic evidence to be used for this purpose.)**

**13. Patient's submission in support of their case:**

Has the patient been asked to submit accompanying information in support of their case?

Yes:  No:

If so, is the submission: attached to this application  being provided separately

**Communication of the decision:**

Tick the box below if it has been discussed and agreed with the patient that the decision of the INNF Panel should be communicated direct to the patient (to the address provided at the top of this form) as well as to yourself.

## **APPENDIX 4**

NHS Gloucestershire's Interventions Not Normally Funded List and Commissioning Policies can be accessed through the following website:

**[www.nhsglos.nhs.uk](http://www.nhsglos.nhs.uk)**

The PCT is in the process of developing Commissioning Policies to support the Clinical Priorities Policy. These will be made available on the NHS Gloucestershire Internet site once in place.

## APPENDIX 5

### Policy Statement Guidance for considering 'exceptionality' in individual cases

**Date of Issue: July 2009**

**Revised:**

**Review Date : July 2010**

NHS Gloucestershire has developed the following guidance to aid decision-making in individual cases where a decision to fund would mean deviating from a general policy.

#### **Background**

A patient's doctor may consider that a patient's condition presents an exceptional need for treatment. This might happen in circumstances where

- NHS Gloucestershire does not have a commissioning policy in place for a healthcare intervention OR
- it has been decided by NHS Gloucestershire that a treatment has a low priority and cannot generally be funded OR
- an individual has a special healthcare problem

NHS Gloucestershire will consider such individual cases on their own merits through the PCT's INNFP Panel.

#### **Guidance for considering 'exceptionality' in individual cases**

##### **Definitions** (from the Oxford English Dictionary)

- **"Exception"** : A particular case which falls within the application of a rule, but to which the rule is not applicable.
- **"Exceptional"** : Of the nature of or forming an exception; unusual or special.

#### **General guidelines:**

1. It is necessary to consider the underlying reasons behind the policy decision not to commission a particular intervention in order to determine whether to fund an individual case. A particular healthcare intervention may not have been commissioned for a number of different reasons, such as safety, effectiveness or cost.
2. When considering an individual case the INNPF Panel should expect to see evidence that demonstrates why those underlying reasons do not apply.

For example, where a healthcare intervention has not been commissioned because of concerns over its effectiveness, consideration will be given to evidence (eg draft NICE guidance) that shows that the benefit from the treatment for the individual patient would be significantly greater than would be expected for an average patient<sup>\*</sup>, or for the defined cohort or patient population who may benefit.

3. By definition, 'exceptional' may not necessarily be predicted or spelled out in advance. However, where a cohort of patients can be identified with characteristics that suggest a greater capacity to benefit from a healthcare intervention than the usual population with the health care problem, this cohort will be identified in the commissioning policy.
4. The fact that a patient's clinical features match 'accepted indications' for a treatment which is not normally provided is not, in itself, sufficient reason to deviate from the general policy.
5. The fact that the treatment is (or is likely to be) effective for a particular patient is not, in itself, sufficient reason to deviate from the general policy.
6. It is for the requesting clinician to demonstrate why the patient should be considered as an exception to the general policy.
7. If cost of the treatment was not a factor in the development of NHS Gloucestershire's commissioning policy (eg, the treatment is not commissioned for reasons of lack of effectiveness and/or concerns

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\* Where a commissioning policy has been developed for a healthcare intervention, an 'average patient' is a patient who shares characteristics with the cohort of patients who were considered when the policy was developed and therefore an 'average patient' does not necessarily share characteristics with the general population.

about the safety of the treatment) then the personal circumstances<sup>\*\*</sup> of the patient will not be taken into consideration when deciding whether the case demonstrates exceptionality.

8. If cost of the treatment was a factor in the development of NHS Gloucestershire's commissioning policy, then the personal circumstances<sup>\*\*</sup> of the patient will be taken into consideration when deciding whether the case demonstrates sufficient justification for deviating from the general policy. As the Court said in *Rogers v Swindon PCT* at paragraph 77:

“77. We see nothing arbitrary or irrational about that approach. It could properly involve a decision by a trust which was subject to financial constraints and which decided that it could not fund all the patients who applied for funding for Herceptin treatment, to make the difficult choice to fund treatment for a woman with, say, a disabled child and not for a woman in different personal circumstances.”

9. The INNF Panel will consider the need for expert advice and will seek appropriate advice where it considers necessary. Such advice may be sought in respect of any element of the case including (but not limited to) clinical effectiveness, cost effectiveness, the extent to which the individual is different from the 'average patient' and the extent to which that particular individual is likely to gain greater benefit than the 'average patient'.
10. Where an individual's circumstances are such that they are different from the average patient and are likely to gain greater benefit than the average patient or where the circumstances are otherwise found to be exceptional, the INNF Panel should continue to consider cost effectiveness and clinical effectiveness.
11. When considering cost effectiveness following a finding that the individual's circumstances are 'exceptional' then the INNF Panel will consider the appropriate approach. Such approach shall generally be less restrictive than the required case for funding an intervention as part of the PCT's commissioning contracts.

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<sup>\*\*</sup> When reviewing personal circumstances, reference will be made to the Ethical Framework described in Gloucestershire PCT's Commissioning Policy framework.

12. All factors relevant to the individual's case will be considered individually and together in order for the INN Panel to decide whether the totality of the factors means that the PCT should depart from its policy not to fund the particular intervention.

## **APPENDIX 6**

### **NHS Gloucestershire**

#### **Policy on the commissioning of new drug treatments**

##### **Introduction**

NHS Gloucestershire does not generally commission the use of drugs that do not have a UK product licence, outside of agreed clinical trial programmes. Drugs that are awaiting licensing or extension to an existing licence for a new indication should not be prescribed until they have been licensed and subject to either local (through this policy via Clinical Forum) or national (through National Institute for Health and Clinical Excellence (NICE)) critical appraisal.

Typically, NHS Gloucestershire will await a decision from NICE before proceeding to make a decision to introduce a new drug into widespread use on the basis that they have greater resources to evaluate the benefits and costs associated with a new drug, and are likely to have access to a wider range of materials including manufacturers' unpublished evidence. However there may be occasions when it would be inappropriate to await guidance from NICE, eg where NICE appraisal is not expected within a reasonable time frame, and in this instance the Forum will proceed to its own evaluation.

The aim of this policy is to ensure that requests to prescribe new drug treatments are properly appraised at an early stage in order to allow NHS Gloucestershire to reach a conclusion on whether:

- the treatment should be introduced on an unrestricted basis with immediate effect; or
- the treatment should be introduced through the next service level agreement; or
- the treatment should not be introduced at this stage, or
- the treatment should be introduced on a restricted basis

taking into account all relevant factors including the financial constraints of the organisation and the impact on the provision of other services and competing priorities.

A drug may have clearly evidenced health benefits that coincide with current priorities or may be one of many promising new treatments for which there are only limited effectiveness and safety data available. In other cases, whilst the treatment may appear to be effective, the impact to existing services of providing the treatment during a current financial year may be disproportionate and it would be sensible to use the local delivery planning process to implement the treatment during the next financial year.

## **Application**

Newly licensed drug treatments, requests for use of a drug outside its product license and requests for the use of unlicensed drugs e.g. melatonin, should be considered under the terms of this policy where requests for funding for the use of the drug are likely to be received (or have been received). Thus the proposed use of the drug is likely to be outside of the terms of a service level agreement. It will also apply to drugs which, although they have been licensed, are still awaiting critical appraisal, either nationally or locally.

This policy will not apply to the well-established use of certain drugs that reflect established custom and practice and are unlikely to ever receive either a licence or appraisal for that particular indication because clinical trials are unlikely to take place due to small patient numbers or ethical constraints such as those that exist in the areas of paediatrics and obstetrics, and are used under the terms of existing Service Level Agreements

## **Approach**

The New Technologies and Drug Therapies Manager and a pharmacist member of the medicines management team will be responsible for co-ordinating the evaluation of new treatments and reviewing the evidence and licensing position and presenting that information in a balanced and objective manner to the Clinical Forum. The New Technologies and Drug Therapies Manager and a pharmacist member of the medicines management team will also identify the position of other relevant bodies such as the Department of Health, NICE, Cancer Networks etc. and any clinical guidance provided.

The Clinical Priorities Forum will consider the evidence pertaining to the treatment including, where relevant, the following:

1. Safety
2. Clinical effectiveness
3. Cost effectiveness
4. Licensing position
5. Likelihood of NICE appraisal and timescale
6. Any other relevant information or guidance
7. Current treatments commissioned for the particular illness

before reaching a decision on whether or not the treatment should be commissioned, and if so, at what stage.

The first consideration shall be patient safety; can the drug be introduced safely taking into account the known risks and the extent to which it is appropriate to expect patients to take informed decisions about the balance of risk in the context of their disease. If the drug does not satisfy this test it shall not be introduced. However, if the risks to patient safety can be managed through selection criteria or otherwise, the Clinical Priorities Forum may proceed to consider the general clinical and cost effectiveness issues. It is noted that some risks will remain unknown at this point and it is the balance of risk, known and unknown, against the potential benefits that will be considered.

If the evidence allows the Clinical Priorities Forum to arrive at a conclusion on cost effectiveness, taking into account the alternative treatments available and the impact of the disease on the patient, then it can do so.

If, as is likely at this stage of a drug's introduction, the evidence as to cost effectiveness is unclear the Clinical Priorities Forum may, at its discretion, adopt an approach of not introducing, introducing or introducing the drug on a restricted basis. Introduction on a restricted basis may be appropriate where, although the evidence as to the cost effectiveness is equivocal, the clinical effectiveness evidence indicates either:

- differential impact can be discerned between different cohorts of potential recipients
- different cohorts of patient can be identified by reason of risk to them or potential benefit to be derived from the intervention.

Examples of the former would be where the evidence suggests that, although a wider group may potentially benefit from the drug, a narrower group shows evidence of better outcomes.

Examples of the latter would be where there is no differential in apparent impact, but a rational distinction can be made in terms of limiting the financial risk to NHS Gloucestershire between those at a greater or lesser risk of adverse outcome without the intervention.

## **Exceptions**

If the Clinical Priorities Forum concludes that a particular treatment will not be commissioned with immediate effect or only on a restricted basis, they will go on to consider whether NHS Gloucestershire should consider deviating from this approach in individual cases.

When considering whether or not to allow for deviating from the commissioning policy, the Clinical Priorities Forum must have regard to the underlying reasons behind that policy. They will consider and record their view on the circumstances in which it may be possible to envisage deviating from the policy and funding a particular patient. This does not mean that the Clinical Priorities Forum will necessarily define the exceptional circumstances to the policy.

Where concerns are primarily related to patient safety it may be that it is not possible to envisage any circumstances in which it would be safe for the treatment to be given to any patient. In such a case it may be appropriate to decline to fund all applications without considering exceptions. In others it may be possible to mitigate safety concerns through the careful screening of patients.

Where concerns relate to the clinical effectiveness or cost effectiveness of a particular treatment, it may be possible to identify sub-groups of patients where commissioning would be appropriate. Where a decision is made not to commission a new drug treatment because of the financial constraints and competing priorities, NHS Gloucestershire's INNF Panel will consider exceptions to the policy in the usual way.

## **Review**

NHS Gloucestershire recognises that decisions are often required to be taken in respect of new drug treatments at a stage where limited information is available in the public domain. It is important, therefore, that any policy decision is reviewed as and when new information becomes available. This will normally be at a time when a licence application is granted and when NICE have issued their appraisal but may be at any stage, and may arise from an individual case. The INNF Panel may, in considering an application for an exception, make a

recommendation for a review of the policy as a result. Where the policy does not admit formal exceptions, the INNF Panel can consider applications on an individual basis on the basis that the policy should be changed or disapplied in the individual circumstance. Such cases will be rare and will require cogent evidence, particularly in cases where the original decision was taken on patient safety grounds.

As and when further information becomes available it should be presented to Clinical Priorities Forum to allow them to review the policy decision.