CLINICAL PRIORITIES POLICY FOR COMMISSIONING SELECTED SERVICES:
A GUIDE TO THE DECISION MAKING PROCESS FOR SERVICES OR TREATMENTS WHICH ARE NOT ROUTINELY COMMISSIONED

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<td>Gail Warnes /Mary Monnington (based on previous versions)</td>
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<td>Related documents</td>
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<td>Equality &amp; Diversity</td>
<td>NHS Wiltshire is committed to promoting equality and respect for the people of Wiltshire and for our staff. Our aim is to ensure that the way we work with individuals and communities and their representatives and with our staff, challenges inequality, eliminates unlawful discrimination and helps us to identify opportunities for promoting equality and human rights and promoting good relations among our diverse communities. This enables us to improve access to our services and deliver them in an appropriate and sensitive manner to meet the needs of individuals. To achieve this we have carried out an equality impact assessment on this policy in accordance with the requirements of the Equality Act 2010.</td>
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## Consultation Route

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1. Summary

This document sets out NHS Wiltshire’s framework for making decisions on the funding (commissioning) of selected healthcare interventions, and prioritising their provision for people registered with general practices in NHS Wiltshire’s area (hereafter referred to as the people of Wiltshire).

This document is intended as a guide to clinicians and it is hoped that it will promote greater awareness of the policy and processes and support discussion between clinicians and their patients about the healthcare interventions commissioned by NHS Wiltshire.

An electronic version of this policy is available on NHS Wiltshire’s website as well as the Exceptional Funding information leaflet for patients.

This document reflects the NHS Confederation policy, Priority setting; managing individual funding requests.

This document will be reviewed and updated as clinical practice and priorities and evidence change.
2. Introduction

The role and responsibilities of NHS Wiltshire in commissioning healthcare services

NHS Wiltshire is committed to improving the health of the people of Wiltshire, 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 ‘to provide services to such an extent as considered necessary to meet all recognised requirements 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 Wiltshire is committed to improving the health of the people of Wiltshire, there will be occasions when it is both reasonable and legitimate for NHS Wiltshire to restrict or not commission a particular healthcare intervention where it is of limited clinical benefit or not a clinical imperative. Where this happens it is important that the process by which NHS Wiltshire came to that decision is open and explicit.

This policy document sets out what interventions are restricted, the criteria that apply to these interventions, the definitions of exceptional funding and the framework within which such commissioning decisions are made.

3. The national context and NHS Constitution

NHS Wiltshire has a responsibility to commission care, including treatments and medicines, for their populations within available resources. Decisions on whether to fund treatments and medicines should be taken in context of NHS Wiltshire’s available resources, ensure that care is fairly allocated to all patients and where appropriate, assessed against NHS Wiltshire’s other service priorities.

The NHS Constitution says:
“You have the right to drugs and treatments that have been recommended by NICE (National Institute for Clinical Excellence) for use in the NHS, if your doctor says they are clinically appropriate for you”.

“You have the right to expect local decisions on funding of other drugs and treatments to be made rationally followings a proper consideration of the evidence. If the local NHS decides not to fund a drug of treatment you and your doctor feel would be right for you, they will explain that decision to you”.

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) www.nice.org.uk and the Care Quality Commission www.cqc.org.uk

The National Institute for Health and Clinical Excellence (NICE)
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.

NHS Wiltshire has a responsibility to ensure Technology Appraisals AGS (TAs) are implemented within 3 months of publication. Other NICE guidance is advisory and commissioners are expected to take it into account in commissioning decisions. 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 Wiltshire implements NICE guidance is described later in this document.

The Care Quality Commission
The Healthcare Commission (previously known as the Commission for Healthcare Audit and Inspection - CHAI) is responsible for monitoring progress on the implementation of NICE guidance nationally.

4. NHS Wiltshire Commissioning Policy

In order to meet its statutory obligations, NHS Wiltshire has developed this Clinical Priorities Policy to provide guidance on NHS Wiltshire’s commissioning and clinical priorities.

The scope of this policy
This policy applies to primary care (such as General Practitioner services), secondary care (hospital services), tertiary care (specialist services), other qualified providers and community services for all patients registered with a General Practitioner within NHS Wiltshire.

5. Ethical Framework

In reaching its decisions, NHS Wiltshire aims to:

- Take into account and weigh all the relevant clinical 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 relevant to the clinical intervention and the patient;
- Act in the utmost good faith;
• Make a decision that is in every sense reasonable.

This ethical framework has been developed to enable NHS Wiltshire to make fair and consistent decisions that treat patients equally. It should be noted that sometimes the discretion of NHS Wiltshire may be restricted or overridden by NSFs; guidance from 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. NHS Wiltshire will not discriminate on grounds of personal characteristics such as age, gender, race, religion, sexual orientation, 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 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, NHS Wiltshire strives to obtain the best evidence of clinical effectiveness.

‘Clinical effectiveness’ can be defined as, ‘the application of the best knowledge, derived from research, clinical experience and patient preferences to achieve optimum processes and outcomes of care for patients. The process involves a framework of informing, changing and monitoring practice’ (Promoting Clinical Effectiveness DOH 1996).

Through policy development and the allocation of a high priority, NHS Wiltshire will promote treatments for which there is good evidence of clinical effectiveness. Evidence of clinical effectiveness will be sought from large-scale randomised clinical trials, but 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. When assessing evidence of clinical effectiveness, the outcome measures that will be given greatest importance are those considered important by patients and clinicians.

Interventions of low clinical and/or cost effectiveness (i.e. low ratio of clinical benefit to cost) are likely to be given low priority in comparison with other national and local priorities that are proven to be clinically and cost-effective. It is impossible to give a priority if there is insufficient evidence to determine whether or not the intervention is clinically effective. If the clinical benefit derived from an intervention is low (for example, surgery for uncomplicated varicose veins) then it is likely that no NHS-funded treatment will be available.
Because NHS Wiltshire has a statutory obligation not to exceed their resource limit, the cost of healthcare interventions will be considered, as will the impact of investing in one area of healthcare that will inevitably divert resources from other uses. NHS Wiltshire will compare the cost of treatment to its overall benefit, both to the individual and the community. It may consider technical cost-benefit calculations, but these will not by themselves be decisive.

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

NHS Wiltshire 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 patient’s health. Urgent and life-saving treatment will be given the highest consideration, as will treatment that effectively treats “life time”, or chronic conditions such as arthritis, mental illness, or sensory impairment. So far as possible, NHS Wiltshire will respect the rights of patients to choose between different treatment options, subject to the availability of supporting evidence of clinical effectiveness.

Where NHS Wiltshire 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 Wiltshire will consider such a case on its own merits. These ‘exceptional cases’ are considered by NHS Wiltshire’s Exceptions Committee.

**Health needs of the community**

Public health is an important concern of NHS Wiltshire and NHS Wiltshire 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 NICE and NSFs). 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 NHS Wiltshire. Available guidance in these areas will be considered by NHS Wiltshire 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 Wiltshire that a treatment has a low priority and cannot generally be funded, a patient’s doctor may consider that the circumstance is exceptional. Such requests will be considered by NHS Wiltshire’s Exceptions Committee.

Where appropriate, through the representative of the Wiltshire Involvement Network, NHS Wiltshire may consult with local people on such issues.

**6. Legal Framework**

It is the statutory duty of the NHS and NHS Wiltshire ‘to provide services to such an extent as they consider necessary to meet all reasonable requirements within the resources available’.
Further, in making commissioning decisions, NHS Wiltshire needs 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 Wiltshire to fund/commission a particular treatment would focus on whether the decision was linked to:
(a) Unaffordability;
(b) NHS Wiltshire’s priorities; and
(c) How those priorities were decided.

NHS Wiltshire will comply with Department of Health current guidance on funding treatment abroad.

7. Prioritisation

In order to provide a clear direction on the priorities allocated to the commissioning of healthcare services, NHS Wiltshire will recommend the allocation of one of the following priorities to its service development statements:

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

**Restricted priority** indicates 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. Prior approval is required by NHS Wiltshire for individual cases.

**Low priority** indicates that the drug, treatment, procedure, investigation, or screening or other public health programme will not normally be funded by NHS Wiltshire 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.

**No priority** indicates that NHS Wiltshire 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.

8. Management of Funding Prior Approval and Exceptional Referrals

NHS Wiltshire must ensure that it provides the community with the best health care from the funds available. This includes the responsibility to make decisions for...
funding requests for interventions that are restricted (Prior Approval) or not normally funded (Exceptional), ensuring that decisions made are equitable and in the best interest of the whole population.

**Prior Approval**
Under the terms of their contract, providers may not accept restricted prior approval requests unless there is evidence that prior approval has been agreed. Before making any referrals for treatment of restricted interventions the referring clinician is required to complete the appropriate application for funding to NHS Wiltshire, with full details of how the patient meets the criteria as set out in the intervention policy statement. Application forms are mandatory as they ascertain whether the patient meets the specific criteria. If information is missing this may delay a decision being made, or even result in the application being declined due to lack of information.

Full details of the prior approval process are listed in Appendix 2.

**Exceptional Funding**
These are procedures not normally funded by NHS Wiltshire as the evidence for clinical effectiveness is limited or treatment is not considered a clinical imperative. The referring clinician should complete an application for Exceptional funding to NHS Wiltshire with supporting information. This should include robust evidence that identifies that the patient would be likely to derive significant clinical benefit from the treatment in question than might normally be expected for patients with that condition and why the patient is significantly different to the general population of patients with the condition in question. The fact that a treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality. Application forms are mandatory for exceptional funding requests.

Full details of the exceptional funding process are listed in Appendix 3.

**9. 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 SLAs and should not comprise a separate cost item. NHS Wiltshire will comply with the National Tariff and Payment-by-Results arrangements for PBR-excluded drugs.

Drugs and therapeutic agents allocated Restricted Priority should be prescribed only in the circumstances detailed in NHS Wiltshire’s policy statements. Compliance with this guidance will be audited. Drug therapies that have a Restricted Priority will generally be commissioned on a prior approval basis.

Drugs and therapeutic agents that have been given a Low Priority by NHS Wiltshire will be considered on an individual basis using the Exceptional Funding application.

As regards drugs and therapeutic agents that have been given No Priority by NHS Wiltshire, clinicians who feel they have a case for exceptionality should apply to
NHS Wiltshire’s Exceptions Committee using the Exceptional Funding application form. If agreed, these drugs or therapeutic agents will be commissioned on an individual basis.

**Unlicensed and off licensed drugs**
NHS Wiltshire does not generally commission the use of drugs that do not have a UK product license, outside of agreed clinical trial programmes. Any prescribing will be within trials that have received the necessary ethical approvals. Where a licensed and appropriate equivalent is available this should be prescribed and issued.

NHS Wiltshire recognises that on occasions prescribers will need to use drugs outside their licensed indications (off license). This is most common in the area of paediatrics and obstetrics where ethical approval for clinical trials is difficult to obtain. Additionally drugs will be used off license in areas where the potential treatment population is very small and trials are difficult / economically prohibitive to conduct. In these instances, NHS Wiltshire would expect there to be good published data on dosage, efficacy and safety of a medicine in the licensed area and the act of prescribing off license be considered appropriate by a recognised body of medical opinion. Exceptions continue to be governed by the earlier definitions of this policy.

Clinicians are also advised to refer to NHS Wiltshire’s policy Safe and Secure Handling of Medicines.

**Experimental and Unproven treatments**
When a treatment has not been subject to an adequate study and where it would be possible to undertake a study (even if not prioritised in the research community) the treatment is classified as experimental. NHS Wiltshire does not generally fund medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective.

**Research**
As regards clinical research, this must be funded by appropriate research-designated monies and not through budgets that NHS Wiltshire has allocated for the commissioning of health services.

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

NB: End of Trial Policy: patients will not be funded on a trial unless the trial period covers the whole of the proposed treatment. Under no circumstances will residual costs be funded after the end of a trial, the rationale for which is that it is illogical to fund patients for treatment for which the evidence (i.e. the purpose of undertaking the trial) is yet unproven.

With regard to new healthcare interventions, the treatment of rare conditions, or interventions for which there is currently little evidence of effectiveness, NHS Wiltshire may request that NHS organisations provide data to national or regional databases in order to facilitate the accumulation of knowledge and experience.
Service developments
Very occasionally an individual funding request presents a new issue which needs a substantial piece of work before the PCT can reach a conclusion upon its position. This may include wide consultation. Where this occurs the Exceptions Committee may adjourn a decision on an individual case until that work has been completed.

NHS Wiltshire does not offer treatment to a named individual that would not be offered to all patients with equal clinical need. The exceptional funding process is not used to fund service developments.

Non-GP Referrals
In order to allow GPs to manage care for their patients, clinicians should not refer directly to colleagues but should write to GPs and advise on appropriate treatment or referral unless clinically urgent or part of the original referral. This applies to referrals between consultants providing NHS care in private and NHS settings and to referrals between consultants providing private and NHS care.

If a condition can be managed in primary care, the patient should be referred back to their GP practice.

Consultant to consultant referrals directly to colleagues within or outside of the Trust are only accepted when circumstances are clinically urgent, i.e. suspected cancer or likely to lead to emergency admission within 28 days. Consultant to consultant referrals must be triaged and action authorised by an appropriate consultant and the GP notified.

All other recommendations for consultant review and referral should be forwarded to the patients’ GPs for review and decision on where to refer. Patients should be referred back to GPs with a recommendation to consider onward referral when:

- the referral is not urgent
- the referral is for a secondary condition
- the referral is not directly linked to the original presenting condition
- the original referral was to the wrong clinical team
- the referral does not meet the criteria for onward consultant to consultant referral

When referring a patient back to the GP for follow up referral, the responsibility for the patient passes to the GP. The patient must be informed that they will need to contact their GP to arrange follow up care and the GP must be given advice on treatment and/or referral to the appropriate specialty.

Referrals for a second opinion
If a patient is unhappy with the advice or care offered by the NHS provider to which they have been referred, they are entitled to seek a second opinion. NHS Wiltshire will fund referral to an alternative NHS provider, together with any subsequent treatment; provided that any intervention offered is one which is normally commissioned by NHS Wiltshire. If the above criteria are not met, then a submission as an exceptional case will need to be made to the Exceptions Committee.

Co-funding
Where a patient opts to pay for private care, their entitlement to NHS services
remains and may not be withdrawn. However, in order to ensure that there is no risk of the NHS subsidising private care:

- It should always be clear whether an individual procedure or treatment is privately funded or NHS funded
- Private and NHS care should be kept as clearly separate as possible
- Private care should be carried out at a different time to the NHS care that a patient is receiving
- Private care should be carried out in a different place to NHS care, as separate from other NHS patients as possible. A different place would include the facilities of a private healthcare provider, or part of an NHS organisation which has been permanently or temporarily designated for private care, such a private wing, amenity beds or a private room

To help protect the essential principles of the NHS, NHS Wiltshire will apply the following specific safeguards when making decisions:

- As with any other patient who changes between NHS and private status, patients who pay for private care in these circumstances should not be put at any advantage or disadvantage in relation to the NHS care they receive. They are entitled to NHS services on exactly the same basis of clinical need as any other patient
- The patient should bear the full costs of any private services. NHS resources should never be used to subsidise the use of private care

If funding is granted, either for a restricted intervention or on an exceptional basis, NHS Wiltshire will not reimburse the patient for any treatment received as a private patient before an application for funding was successful.

10. Dissemination

NHS Wiltshire 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 for NHS Wiltshire’s area by NHS Wiltshire and sent to clinicians and clinical governance leads at the relevant Trusts. The Acute Trusts, AWP Mental Health Trust and the Ambulance Trust are responsible for developing their own process for implementation of the guidance, and an annual audit programme will be agreed with the commissioning PCT.

NHS Wiltshire will receive the impact statement and is responsible for monitoring the implementation process and relevant audit programme.

**Policy statements**

Once adopted by NHS Wiltshire’s Clinical Commissioning Group (or NHS Wiltshire’s Board), policy statements will be sent to relevant contacts in primary and secondary care, and specialist centres; and to lay members of the Exceptions Committee.

Additionally, these documents will be published on NHS Wiltshire’s internet and paper copies are also available on request.
11. Changes to commissioning policy Statements

NHS Wiltshire will review commissioning policy statements on a regular basis. However, as new healthcare interventions are introduced and NICE Guidance is implemented, NHS Wiltshire’s commissioning policies may become out-of-date or inappropriate. In these circumstances, NHS Wiltshire will bring forward the review.

NHS Wiltshire requires provider trusts and clinicians to take the commissioning policies into account in the advice and guidance given to patients prior to making the decision to treat a patient, as set out in the NHS Contract.

Service providers will implement any revisions to the NHS Wiltshire Clinical Priorities Policy within 1 month of publication, except where serious adverse effects of interventions are published. Where this is the case immediate review or withdrawal of a commissioning policy may be required by NHS Wiltshire. All patients listed for procedures where criteria have been changed should be reviewed to ensure they are clinically appropriate to undertake that procedure with a bias to honouring the procedure if appropriate. (Treatment that has already been approved by the Prior Approvals Panel or Exceptions Committee may continue with the planned/approved care.)
Appendix 1: Flow Chart for making a request

Request for treatment not normally commissioned

Is there an agreed commissioning policy or criteria? Check Clinical Priorities Policy

Yes

Prior Approval: Apply to NHS Wiltshire on appropriate form

Request considered against criteria

Does not meet criteria – approval not given.

Request reconsidered if new evidence.

Apply as exception

Meets criteria – approval given

No

Exceptional
Apply to NHS Wiltshire on appropriate form

If found to be exceptional - individual approved

If not found to be exceptional - rejected

Can appeal:
- Not considered all factors
- Not reasonable
- Process not followed

Submit formal appeal to Appeals Panel

Request reconsidered if new evidence. Not an appeal
Appendix 2: Protocol for the Management of Funding ‘Prior Approval' Referrals

Introduction

NHS Wiltshire must ensure that it provides the community of Wiltshire with the best health care from the funds available. This includes the responsibility to make decisions for funding requests that are restricted, ensuring that decisions made are equitable and in the best interest of the whole population.

Under the terms of their contract, providers may not accept restricted prior approval requests unless there is evidence that prior approval has been agreed. Before making any referrals for treatment of restricted interventions the referring clinician is required to complete the appropriate application for funding to NHS Wiltshire.

A Prior Approvals Panel has been established to consider these requests. This is made up of three members of NHS Wiltshire’s Commissioning Team with technical advice from Medicines Management Representative, Dental Advisor and GP’s.

Non-contracted Prior Approvals will be considered under the protocol for the management of funding ‘Exceptional Treatment’ Referrals.

The Prior Approval Referral Process

The first stage of the process is for the appropriate application form to be completed by the patient’s GP and sent to NHS Wiltshire. It is recognised there may be occasions where the patients secondary or tertiary Consultant will submit an application, although this is not considered the normal route. The referring clinician must first consult the current criteria as set out in the interventions policy statement.

Application forms are mandatory as they ascertain whether the patient meets the specific criteria. If information is missing this may delay a decision being made, or even result in the application being declined due to lack of information.

It is not the responsibility of NHS Wiltshire to source information for a funding request. Incomplete applications will not be considered by the Prior Approvals Panel.

Referring bodies should also provide supporting letters from other clinicians and/or support workers involved in the patients care if available.

When the referral information is received by NHS Wiltshire it will be entered onto a database. Each complete request will then be presented to the Prior Approval Panel by a member of the Exceptions and Prior Approvals team.
The Prior Approval Decision Making Process

The Prior Approval Panel
The Prior Approval Panel will meet monthly in order to make decisions on requests received. At each meeting the Panel will receive an anonymised referral information sheet and any copies of additional correspondence which may be relevant to the decision making process. The Panel will receive and consider whether the evidence presented is in line with the Prior Approval Policy / Protocol for the circumstances around the intervention seeking approval. The Panel will only support interventions that are in line with NHS Wiltshire policies and procedures.

Purpose
The Prior Approvals Panel is responsible for considering requests for Prior Approval for interventions specified on a restricted basis in existing NHS Wiltshire Contracts.

Requests may be referred to the Prior Approval Panel by the patient's GP. Requests directly from patients are not considered and are referred back to the patient’s own GP. Requests from appropriate referrers may contain information submitted by the patient.

The decisions of the Prior Approval Panel will be communicated directly to the referring GP with a copy to the patient (unless deemed unnecessary or not appropriate). However, the Panel will not enter into direct patient correspondence.

In fulfilling the primary purpose of the Prior Approval Panel the Panel will ensure it has adequate supporting information upon which to base its decision. In the absence of such information, decisions will be deferred until supplementary information is available to the Panel.

Scheme of Delegation
The Panel acts as a formal sub-committee of the Exceptions Committee and has the authority to authorise interventions commissioned on a restricted basis. The Panel will communicate the outcomes of its decisions to the Clinical Commissioning Group via the Exceptions Committee report, bi-annually.

Membership
The Panel will comprise three members of NHS Wiltshire’s Commissioning Team with technical advice from Medicines Management Representative, Dental Advisor and GP’s. The Exceptions and Prior Approvals Manager, or nominated deputy, will be in attendance.

The Panel will be quorate when three members are in attendance.

Informing Referrers of Decisions
If the referral is considered by the Prior Approvals Panel the final decision will be sent to the referrer within five working days after the date at which the case has been presented. The decision of the Panel will be communicated directly to the referrer with a copy to the patient (unless deemed unnecessary or not appropriate). The Panel will not enter into direct patient correspondence. The Panel and NHS Wiltshire’s PALS manager will only communicate to patients on matters of process and policy.

What decision will be made

| Clinical Policy | Priorities | Commissioning | GP055 | R2 | Approved: 28/03/2012 | Policy under review in 2015/16 | Page 17 of 29 |
There are three different decisions possible for an individual case when presented to the Panel.

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

NHS Wiltshire authorises treatment to be commenced within a 12 month period from the decision. If for any reason the approved treatment is not started within 12 months from the decision, the provider will be required to seek re-authorisation of funding from NHS Wiltshire.

Requirement for Urgent Decisions
It is recognised that on occasions urgent decisions are required. Therefore the Panel will also operate virtually e.g. using email/telephone to reach speedy decisions if it is necessary. It is important that no members of the Panel make decisions on their own.

An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of significant harm if a decision is not made before the next scheduled meeting of the Prior Approval Panel. Referring clinicians should explicitly state the urgency.

Re-representation of the Case
If the request for funding has been declined by the Panel the referrer is able to present the case providing additional information to prove that the case meets the criteria to receive restricted funding. If this information is deemed new evidence by the Exceptions and Prior Approvals Manager it will be considered at the next available meeting of the Panel. Resubmissions with additional evidence are only accepted within six months of the original application.

Appeals
In the event that the referring medical practitioner and/or patients wishes to appeal against the decision the appeals procedure set out in Appendix 4 needs to be followed. If the appeal is against the procedure then NHS Wiltshire’s normal complaints procedure is invoked.
Appendix 3: Protocol for the Management of Funding ‘Exceptional Treatment’ Referrals

Introduction

NHS Wiltshire must ensure that it provides the community of Wiltshire with the best health care from the funds available. This includes the responsibility to make decisions for funding requests for procedures not normally funded by NHS Wiltshire as the evidence for clinical effectiveness is limited or treatment is not considered a clinical imperative, ensuring that decisions made are equitable and in the best interest of the whole population.

An Exceptions Committee has been established to consider these requests. This is made up of a range of health professionals, NHS Wiltshire managers, a Patient and a lay representative, and will be chaired by the Director of Nursing and Medical Director.

The Referral Process

The first stage of the process is for the Exceptional Funding application form to be completed by the patient’s GP and sent to NHS Wiltshire. It is recognised there may be occasions where the patients secondary or tertiary Consultant will submit an application. The referring clinician must first consult the current policy statements.

Requests to the Exceptions Committee for treatment to be funded by NHS Wiltshire should be submitted on the grounds that the patient is suffering from a presenting medical condition for which NHS Wiltshire has no policy or the patient is suffering from a presenting medical condition for which NHS Wiltshire has a policy but where the patient’s particular clinical circumstances falls outside what the PCT has agreed to fund.

Application forms are mandatory as they ascertain whether the patient has exceptional circumstances and must be fully completed. If information is missing this may delay a decision being made, or even result in the application being declined due to lack of information.

It is not the responsibility of NHS Wiltshire to source information for a funding request. Incomplete applications will not be considered by the Exceptions Committee.

Referring bodies should also provide supporting letters from other clinicians and/or support workers involved in the patients care if available.

When the referral information is received by NHS Wiltshire it will be entered onto a database. Each complete request will then be presented to the Exceptions Committee.

The Decision Making Process

The Exceptions Committee

The Exceptions Committee will meet monthly in order to make decisions on requests received. At each meeting the Committee will receive an anonymised
application and any copies of additional correspondence which may be relevant to the decision making process. The Committee will receive and consider the clinical and cost effectiveness evidence briefing available supporting the requested treatment. The Committee will normally only support treatments with at least moderate level evidence of effectiveness. The committee will also consider any evidence pertaining to the level of cost-effectiveness of the treatment.

The Rule of Rescue
The Exceptions Committee shall take care to avoid adopting the “the rule of rescue” approach. The observation that human beings, in situations where an individual’s life is at risk, have the proclivity to take action to rescue the individual regardless of the cost and the chances of success. Action taken, therefore, is in part about meeting the emotional needs of the decision maker. In the healthcare setting the term has been used in a number of ways. In NHS Wiltshire the term refers to agreeing funding for treatments for patients whose prognosis is grave on the basis that their prognosis is grave and without regard to cost or ability to benefit.

The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

Purpose
The Exceptions Committee is responsible for considering requests for exceptions to the existing Commissioning Policies of NHS Wiltshire.

Requests may be referred to the Committee by the patient’s GP. Requests directly from patients are not considered and are referred back to the patient’s own GP. Requests from appropriate referrers may contain information submitted by the patient.

The decisions of the Committee will be communicated directly to the referring GP with a copy to the patient (unless deemed unnecessary or not appropriate). However, the Committee will not enter into direct patient correspondence.

In fulfilling the primary purpose of the Exceptions Committee, the Committee will ensure it has adequate supporting information upon which to base its decision. In the absence of such information, decisions will be deferred until supplementary information is available to the Committee.

Scheme of Delegation
The Committee acts as a formal sub-committee of the Clinical Commissioning Group and has the authority to make exceptions to the Commissioning Policies of NHS Wiltshire and thus commit financial resources within the frameworks agreed. The Committee will communicate the outcomes of its decisions to the Clinical Commissioning Group meetings bi-annually.

Membership

* This is defined as good quality observational control or case control studies or better i.e. controlled trials. This is based on the levels recommended by NICE.
The Committee will comprise the following members or delegates:

- Director of Nursing/Medical Director – Chair
- Clinical Commissioning Group Representative – GP
- Senior Commissioning Representative
- Independent Lay Member – lay representative
- Commissioning Finance representative
- Medicines Management representative

In attendance:

- Exceptions Manager

The Committee will be quorate when three members are in attendance, one of whom should be an Executive Director of NHS Wiltshire.

**Informing Referrers of Decisions**

If the referral is considered by the Exceptions Committee the final decision will be sent to the referrer within five working days after the date at which the case has been presented. The decision of the Committee will be communicated directly to the referrer with a copy to the patient (unless deemed unnecessary or not appropriate). The Committee and NHS Wiltshire’s PALS manager will only communicate to patients on matters of process and policy.

**What decision will be made**

There are three different decisions possible for an individual case when presented to the Committee.

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

NHS Wiltshire authorises treatment to be commenced within a 12 month period from the decision. If for any reason the approved treatment is not started within 12 months from the decision, the provider will be required to seek re-authorisation of funding from NHS Wiltshire.

**Requirement for Urgent Decisions**

It is recognised that on occasions urgent decisions are required. Therefore the Committee will also operate virtually e.g. using email/telephone to reach speedy decisions if it is necessary. It is important that no members of the committee make decisions on their own and is recommended that the virtual Committee will be quorate with, three members of the Exceptions Committee.

An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of significant harm if a decision is not made before the next scheduled meeting of the Exceptions Committee. Referring clinicians should explicitly state the urgency.

**Re-representation of the Case**
If the request for funding has been declined by the Committee the referrer is able to re-present the case providing additional information to prove exceptionality. If this information is deemed new evidence by the Exceptions Manager and the Director of Nursing it will be considered at the next available meeting of the Committee. Resubmissions with additional evidence are only accepted within six months of the original application.

Appeals
In the event that the referring medical practitioner and/or patients wishes to appeal against the decision the appeals procedure set out in Appendix 4 needs to be followed. If the appeal is against the procedure then NHS Wiltshire’s normal complaints procedure is invoked.
Appendix 4: Appeals Procedure for the Clinical Priorities Policy of NHS Wiltshire

Introduction

The Appeals Panel (the Panel) is established as a formal sub-committee of NHS Wiltshire Board to consider appeals by a referring Medical Practitioner and/or their patient against a decision of NHS Wiltshire’s Exceptions Committee. The clinician who referred the case can appeal within 28 days of receiving the decision of the Committee. They must state the grounds for the appeal in writing. If new and relevant information about a case is presented, the case will be reviewed as a new case, not an appeal.

Role of the Appeals Panel

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

- Followed NHS Wiltshire’s own procedures and policies
- Considered all relevant factors and did not take into account immaterial factors
- Made a decision that was not so unreasonable that it could be considered irrational or perverse in the light of the evidence presented

Membership

The Panel shall be chaired by a Non-Executive Director appointed by the Chair of NHS Wiltshire. The Panel shall comprise a minimum of three persons none of whom should have sat on the Exceptions Committee for the case under consideration. To be quorate there shall be at least one Non-Executive member together with at least one Clinical Commissioning Group member and a lay representative. The Panel Chair may co-opt onto the Panel a medical practitioner, nurse or other healthcare professional with relevant healthcare expertise.

Appeals Secretary

The servicing and administrative support to the Panel will be undertaken by a member of NHS Wiltshire’s staff (the Appeals Secretary) with responsibility for Patient Advice and Liaison Service 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 Medical Practitioner and/or patient will be supplied with all the documents available to the Panel at least 21 days before the hearing.

Evidence available to the Appeals Panel

a) Documents
i) All documents that were available to the Exceptions Committee together with the Committee’s decision and reasons;

ii) Any further information that has come to light since the Exceptions Committee’s decision.

b) Representations

i) The 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) At the absolute discretion of the Chair of the Panel the patient will be entitled to attend the hearing and to make oral representations either personally or by their chosen representative (who should not be legally qualified).

Referral back to Exceptions Committee

If further relevant information or evidence is presented following the Exceptions Committee’s original decision the case will be referred back to the Exceptions Committee. In such circumstances, this is not considered an appeal.

Referral to Independent Assessor

Where it is clear that there is a dispute on the facts 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 shall provide a written report to the Chair of the Panel within 6 weeks. If, as a result of the appeal, the case is referred back to the Exceptions Committee for re-determination the Exceptions Committee shall be bound by the assessor’s determination in the absence of any fresh relevant evidence.

Time for Appeal Hearing

Meetings will be called under the direction of the chair or chief executive as soon as possible after an appeal has been received. Unless there are circumstances making this impossible, the Panel hearing will take place a maximum of 6 weeks after the date of receipt of the appeal.

Appeal Decision

If the Panel is not satisfied that the Exceptions Committee’s decision was valid it shall recommend a new decision to NHS Wiltshire’s Board, in part II. If the Panel decides to refer back for further consideration by the Exceptions Committee, the Committee shall convene a meeting within 6 weeks to review the case. Subsequent actions should include the following:

a. Notifying the patient or their representative of the Panel’s decision within three working days;

b. Notifying other organisations which have an interest in that decision;

c. Recommending action to the Board and/or Executive Committee of the measures which should be adopted to improve the process in order to ameliorate the effects in similar future cases. This may include referral of the current policy for scrutiny and re-evaluation.
Authority

The Panel is authorised by NHS Wiltshire’s Board to seek any information it requires from members of the Exceptions Committee who are directed to co-operate with any such request. The Panel is also authorised by NHS Wiltshire’s 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

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 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 Wiltshire’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 Wiltshire will be informed:

i) How their appeal will be handled;
ii) 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.

Adapted from the process set up by Kennet and North Wiltshire PCT January 2004, which was subjected to legal review
Appendix 5: Documents which have informed this policy

http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_064103

Department of Health, The NHS Constitution for England, July 2009,

NHS Confederation Priority Setting Series, 2008,
http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx

Department of Health, Guidance on NHS patients who wish to pay for additional private care, March 2009
## Appendix 6: Non GP Referrals

<table>
<thead>
<tr>
<th>No.</th>
<th>Type of Referral</th>
<th>Source of referral</th>
<th>Definition</th>
<th>Agreed referral protocol</th>
<th>Actions based on 18 weeks policy</th>
</tr>
</thead>
</table>
| 1.  | Urgent referral  | Within trust       | Urgent defined as:  
- suspected cancer;  
- life, limb or sight threatening;  
- conditions affecting pregnancy where either the health of the mother or baby are compromised;  
- and in cases where any delay will have a serious adverse effect on the patient’s health.  
All urgent referrals should be notified to the original referring GP. | Accept | Continuation of previous wait |
|     | Other provider of NHS care (NHS hospital, NHS treatment centre, private provider) | | | | |
|     | Provider of private care (NHS hospital, private provider) | | | | |
| 2.  | Same condition  | Within trust       | Internal referrals within the same specialty relating directly to the original reason for referral, i.e. patient has associated symptoms  
Internal referrals to other specialties which relate to the presenting condition where a specialist opinion is required for the wider management of the patient and where it is reasonable to assume that the opinion/further management can only be provided by secondary care and where this is part of an agreed local pathway.  
Secondary condition or where referral is only loosely associated with original problem or referrals to the wrong clinical team.  
Referrals from other NHS providers only to be accepted when referred on as a tertiary referral for complexity on an agreed pathway  
Referrals from private providers should go back to GP for further discussion regarding onward treatment | Accept | Continuation of previous wait |
|     | Other provider of NHS care (NHS hospital, NHS treatment centre, private provider) | | | Accept | Continuation of previous wait |
|     | Provider of private care (NHS hospital, private provider) | | | | |
| 3.  | Different condition | Within trust | Referral for secondary condition, loosely associated problem or where original referral was to the wrong clinical team | Not accepted | Clock start if new referral from GP |
|     | Other provider of NHS care (NHS hospital, NHS treatment centre, private provider) | | | Back to GP | |
|     | Provider of private care (NHS hospital, private provider) | | | | |
4. **Second opinion**  
   All providers  
   Not accepted  
   Back to GP  
   Clock start if new referral from GP

5. **Referral from A&E – referrals only for a symptomatic condition directly related to presentation at A & E**  
   All providers of A&E care  
   Patient reviewed via emergency department and referred on to a specialty as a direct result of their presentation at A & E when further intervention or significant specialist dressings are expected  
   If non symptomatic, patient to be referred back to GP. Consultant referral will not be accepted within A & E.  
   Accept referral  
   Back to GP  
   Clock start on date of A&E referral

6. **Referral from A&E – not trauma related**  
   All providers of A&E care  
   Patient reviewed via emergency department and referred on to a specialty as a result of non-trauma related injury.  
   Not accepted  
   Back to GP  
   Clock start on date of GP referral

7. **Self Referral**  
   Patients  
   Referral should be initiated by a GP except where a defined patient self referral pathway has been agreed between GPs and consultants for an explicit condition.  
   Not accepted  
   Back to GP  
   New clock start if referred

8. **Bilateral procedure**  
   Where GP refers for a bilateral procedure this has been agreed. When one side only is referred a formal request is required prior to a secondary procedure  
   Back to GP for GP to assess when patient Ready, Willing & Able.  
   Clock start

9. **Military patients**  
   GP referrals from Military Medical Centres  
   Patient referred via Senior Medical Officer  
   Accept referral  
   Clock start

10. **Midwife referrals**  
    Antenatal referrals only. (If the referral doesn’t relate to pregnancy, send back to GP)  
    Accept referral  
    Clock start

11. **Extended Scope Physiotherapists (ESP) onward referral**  
    ESPs employed by the Community Services Provider  
    Onward referrals to an Orthopaedic surgical team  
    Accept referral  
    Clock management in line with 18 week RTT guidelines

12. **Dental referrals**  
    As per agreed NHS dental pack  
    Dated 18/05/10

13. **Ophthalmology referrals**  
    Referrals accepted only via GP’s/PCT  
    Do not accept referrals from Opticians.  
    Accept referral from GP/PCT only  
    Clock start
## Equality & Diversity Impact Assessment

<table>
<thead>
<tr>
<th>Title of Document</th>
<th>Clinical Priorities Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the policy new or existing?</td>
<td>Existing</td>
</tr>
<tr>
<td>Date policy was created</td>
<td>December 2006</td>
</tr>
<tr>
<td>Does this policy contain the Trust's statement on Equality?</td>
<td>Yes - Section 5</td>
</tr>
<tr>
<td>Date policy is due to be reviewed</td>
<td>01/04/2013</td>
</tr>
<tr>
<td>Who was/will be consulted over this policy?</td>
<td>NHS Wiltshire Clinical Commissioning Group &amp; Lead Commissioning Managers</td>
</tr>
<tr>
<td>What is the main purpose of this policy</td>
<td>As a guideline to the decision-making process relating to commissioning of treatments and services outside the current commissioning arrangements</td>
</tr>
<tr>
<td>Is this policy contractual?</td>
<td>It forms part of our contracts with Hospital Trusts</td>
</tr>
<tr>
<td>Who is this policy aimed at or who will be affected by it?</td>
<td>Service Providers, GPs, General Public</td>
</tr>
<tr>
<td>What are the likely implications for the Trust of this policy?</td>
<td>Exceptions Committee and prior approval decisions are made in accordance with NHS Wiltshire’s Clinical Priorities Policy</td>
</tr>
<tr>
<td>What, if any, are the resource implications of this policy?</td>
<td>As a guide to managing non-contracted expenditure</td>
</tr>
<tr>
<td>What is the legislation, ethic or other guiding principle behind this policy?</td>
<td>To provide comprehensive healthcare within the resources available</td>
</tr>
<tr>
<td>Is this policy likely to have an adverse effect on any specific group taking into account: sex, gender, ethnicity, colour, national origin, and disability, physical or mental health?</td>
<td>No</td>
</tr>
<tr>
<td>Could this policy discriminate directly or indirectly against any staff group with reference to Sex, Race Disability Discrimination acts or the Regulations on Religion or Belief and Sexual Orientation? If so how?</td>
<td>No</td>
</tr>
<tr>
<td>If this policy could be discriminatory in any way, what actions will be taken to remedy this?</td>
<td>Feedback noted and policy adjusted in consultation with the Clinical Commissioning Group.</td>
</tr>
<tr>
<td>Where will this policy be stored and how will it be accessed?</td>
<td>Stored electronically within NHS Wiltshire. Accessed via NHS Wiltshire’s web site and via the Exceptions Manager</td>
</tr>
</tbody>
</table>