NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Commissioning Policy
Prioritisation framework for Commissioning health services

July 2010

This commissioning policy applies to patients within:
South Worcestershire Clinical Commissioning Group (CCG)
Redditch & Bromsgrove Clinical Commissioning Group (CCG)
Wyre Forest Clinical Commissioning Group (CCG)

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Commissioning Committee	Non-Executive Directors, Clinical Development, Commissioning, Finance, Public Health
Equality Impact Assessment	Equality Impact Assessment Scrutiny Panel

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1. Definitions

1.1 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.

1.2 *A* **Similar Patient** refers to the existence of a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. When the treatment meets the regional criteria for supra-CCG policy making, then the similar patient may be in another CCG with which the Primary Care Trust collaborates. The existence of one or more similar patients indicates that a policy position is required of the Primary Care Trust.

1.3 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks funding for a single identified patient for a specific treatment.

1.4 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Primary Care Trust agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

1.5 **Treatment** means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.

1.6 **Clinical circumstances** means a full history of the patient's medical condition, a full description of the patient's present medical condition and as comprehensive an assessment of the patient's future medical condition and prognosis as the Clinician treating the patient is able to provide at the time of the application.

1.7 **Clinical effectiveness** is a measure of the extent to which a treatment achieves the pre-defined clinical outcomes in a target patient population.

1.8 **Cost effectiveness** is the same as value for money although, in health care settings, it tends to imply value for money determined by means of cost effective analysis. However here it is used synonymously with value for money.

1.9 **Value for money** in general terms is the utility derived from every purchase or every sum spent.

1.10 The **IFR Panels Level 1 and 2** refer to the Panels that have delegated responsibility to make decisions on behalf of the NHS organisation concerning an individual funding request (IFR). IFR Level 3 refers to the IFR Appeals Committee.

1.11 **Case by case decision making**, in the context of priority setting, occurs when a decision maker decides to allocate NHS resources for a specified treatment for one or more specified patients as a substitute for policy making. This is generally regarded as poor practice because it avoids making an explicit policy.

1.12 **Responsible NHS Organisation** means the NHS Organisation which discharges the Secretary of State's functions under the National Health Service Act 2006 for an individual patient.

1.13 **Rule of rescue** is 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. In the healthcare setting the term has been used in a number of ways. In this document the term refers to agreeing funding treatments for patients whose prognosis is grave, on the basis that their prognosis is grave and without regard to cost or ability to benefit.

1.14 **Experimental and unproven treatments** are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. They may include the following:

- The treatment is still undergoing clinical trials for the indication in question;
- There is no evidence available to critique;
- The treatment does not have approval from the relevant government body;
- The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field;
- The treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body;
- The treatment is rarely used, novel, or unknown and there is a lack of evidence of safety and efficacy;
- There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.

1.15 A **service development** is any aspect of healthcare which the NHS organisation has not historically agreed to fund and which is likely to require additional and predictable recurrent funding. The term refers to all new developments including new services, new treatments (including medicines), changes to treatment thresholds, and quality improvements. It also encompasses other types of investment which existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms.

1.16 A **policy variation** is when an existing policy is changed which results in either increased or decreased access to treatment. When the proposal increases access (for example by lowering the threshold for treatment or adding a new indication) the policy variation is a service development and will be treated as such.

2. Scope of policy:

2.1 This policy should be considered in line with all other Worcestershire Commissioning Policies. Copies of these Commissioning Policies are available on the Worcestershire's local website at the following address: http://www.worcestershire.nhs.uk/policies-and-procedures/commissioningindividual-funding-requests-ifr/

2.2 The purpose of this document is to set out the rationale and describe the factors to be taken into account when prioritising health services in order to:

- Provide a coherent structure for rational and reasonable decision making, ensuring all important aspects are properly considered;
- Promote fairness and consistency in decision making;
- Provide a means of expressing the reasons behind the decisions made.

2.3 The document is relevant to decisions about which services and treatments are commissioned at four levels as below. The principles set out provide a clear public statement about the issues that will be considered when deciding whether or not a service or treatment will be funded.

- Strategic planning;
- Operational planning and making investment and disinvestment decisions during the annual planning round;
- Making urgent investment decisions - in-year service developments;
- Making decisions concerning specific individuals - individual funding requests

3. Background:

3.1. NHS principles have been applied in the agreement of this policy.

3.2. The nature of priority setting

3.3. The aim of commissioning is to maximise the 'allocative efficiency' of resources - i.e. to ensure that the limited resources available are deployed in a way which means that health services are overall as effective, cost-effective and equitable as possible, thereby achieving the best value for money and the maximum health gain across the whole population.

3.4. Demand for health services has always and will always outstrip the resources available. This will become ever truer as we enter a period of unprecedented financial constraint. Commissioners therefore are required to make decisions about which services and treatments can be funded by the NHS, and which cannot.

3.5. Prioritisation decisions may have profound consequences for the groups and/or individuals affected and are frequently finely balanced and/or highly emotive. It is important that they are taken with reference to consistent underlying principles, with the involvement of clinicians, patients and the public, and through a transparent process, to ensure that they are evidence based, broadly supported and can be defended at the highest level.

3.6. Legal considerations

3.7. The legal framework for the commissioning responsibilities of Commissioners is set out in regulations 3(7)-(10) of the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002. A Commissioner is under a statutory duty 'to provide comprehensive healthcare within the resources available'.

3.8. The NHS Constitution sets out a series of rights for patients. These include:

- "… the right to receive NHS services free of charge, apart from certain limited exceptions sanctioned by Parliament."
- "… the right to access NHS services. Access will not be refused on unreasonable grounds."
- "… the right to expect your local NHS to assess the health requirements of the local community and to commission and put in place the services to meet those needs as considered necessary."
- "… the right not to be unlawfully discriminated against in the provision of NHS services including on grounds of gender, race, religion or belief, sexual orientation, disability (including learning disability or mental illness) or age."
- "… the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate ."
- "… the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment, they will explain that decision to you.

3.9. However, it is well established by the courts that a Commissioner is not under an absolute obligation to provide every treatment that a patient, or group of patients, may demand. A Commissioner is entitled to take into account the resources available to it and the competing demands on those resources and may develop processes to prioritise services and treatments. The precise allocation of resources and the process for prioritising those resources is a matter of judgement for individual Commissioners.

3.10. Commissioners must therefore be able to demonstrate they have clear mechanisms in place for making decisions about relative priorities both at a strategic and at an individual case level, including a mechanism by which individuals, who might be an exception to commissioning policies, can be considered. Such an approach should enable them to be demonstrably accountable for their resource allocation decisions, particularly to the population they serve.

3.11. In making commissioning decisions, Commissioners need to take into consideration 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.

3.12. Under the Human Rights Act, a legal challenge regarding the failure of a Commissioner to fund a particular treatment would focus on whether the decision was linked to (a) affordability, (b) the overall Commissioner's priorities and (c) how those priorities were determined.

3.13. Ethical considerations

3.14. Four key ethical principles underpin clinical and public health practice as outlined below. There are tensions both within and between them and no one principle overrides any other.

Non-maleficence asserts an obligation not to inflict damage (either physical or psychological) and has often been associated with the maxim 'first, do no harm'. However, no treatment is free from the potential to cause adverse consequences: it is the balance between the benefits and harms that determines (at least in part) whether it is appropriate.

Beneficence implies an obligation to benefit individuals. Moral philosophers distinguish between 'positive beneficence' and 'utility', with the former describing benefits that can be accrued and the latter attempting to balance benefits and harms. No treatment is beneficial for everyone and utility is therefore more relevant.

Distributive justice is concerned with the provision of services in a fair and appropriate manner. Problems of distributive justice have become particularly manifested in healthcare, because of the universal mismatch between demands and resources. Two main theories of distributive justice are relevant: utilitarianism and egalitarianism. Utilitarianism seeks to maximise the overall benefit for the whole population from the resources available. Egalitarianism seeks fairness either in equality of opportunity or in equality of outcomes. There is no consensus about which of these theories most appropriately captures the ethical basis of the fair allocation of healthcare resources. The notion of 'utility' places a premium on the efficiency of a healthcare system. However, when considered alone it can allow the interests of minorities to be overridden by the majority, thereby exacerbating health inequalities. It therefore needs to be considered alongside concepts of equality to ensure that the whole population has a chance to benefit from the resources available.

Respect for autonomy acknowledges the rights of individuals to make informed choices in relation to healthcare. It is inherent in the concept of 'patient choice'. It cannot, though, be applied universally. The Commissioner receives a fixed allocation with which to commission all of the health care required by the population. Providing a few people with very expensive treatments, on the basis of personal preference, would deprive many others of more cost-effective treatments.

3.15. Procedural considerations

3.16. A further consideration, procedural justice, places a premium on ensuring that the processes by which decisions are reached have legitimacy. Processes should have all four of the following characteristics, in order to ensure that decision-makers are accountable for their 'reasonableness'.

Publicity. Decisions about limits on the allocation of resources should involve patients and the public. This includes not only the decisions themselves, but also the

grounds for making them. It does not, however, require that all the criteria for decision-making should be established in advance: rather, there should be room for the development of 'case-law'.

Relevance. The grounds for decisions are those that fair-minded people would agree are relevant to meeting healthcare needs, especially when there are constraints on resources. In particular, 'relevance' focuses on the importance of deliberation about the limits of the common good and acknowledges that such 'deliberative democracy' should involve both the decision-makers themselves and those whom the decisions may affect.

Revision and appeals. There must be opportunities for challenging decisions and mechanisms for resolving disputes. There should be systems in place for revising decisions when new, or additional, evidence becomes available or new arguments are put forward.

Regulation. There should be either voluntary or public regulation of the process of decision-making to ensure that it has all three of the above characteristics (publicity, relevance and opportunities for revisions and appeals).

4. Relevant National Guidance and Facts

4.1. Local strategic and financial context

4.2. The Commissioner is working to a strategic plan with eight priorities, agreed by the Board after extensive consultation with clinicians, patients and the public. These are:

1	Staying Healthy
2	Maternity
3	Children and young people
4	Mental health
5	Falls prevention
6	End of life care
7	Long term conditions
8	Planned care

4.3. Each of these priorities has a series of initiatives, and which have involved a small investment in order to deliver transformational change in the way in which health services are arranged and thereby realise revenue savings of £60M by 2013/14. The Commissioner's funding is therefore entirely committed and there is no funding available for additional services or treatments unless:

- A convincing case can be made that they will also facilitate transformational change and realise savings at least as great as any investment required;
- They meet one of the criteria in paragraph 4.9 - a small contingency has been set aside for the developments expected under these categories.

4.4. Operational planning cycle

4.5. Where possible, all decisions about funding for service developments, new treatments and new indications for existing treatments should be made through the annual operational planning process to ensure that their relative merits are weighed against each other. The operational planning round should also actively consider the

potential for disinvestment in existing services with reconfiguration and redistribution of funding to other services.

4.6. Those services approved for review will be required to work up a full business case describing the expected benefits before they can be approved for implementation. As a rule the expectation is that any service or treatment requiring investment will need to demonstrate that, through care pathway redesign, they can release at least the same amount of funding from another service in order that implementation is cost neutral. Prioritisation between different services in the care pathway will be carried out with reference to the commissioning principles set out in Section 5.0.

4.7. The Commissioner will adopt the approach that each life is of equal value and that decisions about funding for treatments shall be primarily based on the clinical and cost effectiveness of the proposed treatment and whether the cost can be justified given the financial consequences for other services. The needs of a population for a range of treatments may outweigh the needs of a group of patients or an individual for a particular treatment.

4.8. Decision making must:

- Be guided by the clear commissioning principles set out in this prioritisation framework.
- Have the involvement of patients, the public and other healthcare specialists to provide them with the opportunity to influence the development and range of services/treatments commissioned.
- Be transparent and subject to scrutiny and review through the governance arrangements of the Commissioner.
- Produce a reasonable balance of health care provision across all health services: health promotion and community development; preventative services such as immunisation and screening; primary care, community care, secondary and tertiary care.
- Produce a reasonable balance of health care provision across care programmes – e.g. circulatory diseases, cancers, mental health etc. As a general rule, the Commissioner should look to invest in those programmes which are relatively underfunded, disinvest in those which are overfunded Invest in programmes that are underfunded, and redesign care through investment and disinvestment within the same programme.

4.9. **In year service developments**

4.10. Service developments will only be considered routinely through the operational planning process detailed above. An in-year ad hoc decision to fund new services or treatments outside of this process exposes The Commissioner to the following risks:

- Compromises its ability to deliver the statutory duty to achieve financial balance;
- Distortion of priorities for service development agreed through the LOP process;
- Inequitable provision, as in-year service developments elevate the needs of one group of patients above that of others outside of the context of the prioritisation framework.

4.11. The following are considered exceptional grounds for agreeing a service development outside of the operational planning process:

- There is a serious threat to the safety of a service requiring urgent interim support measures to avoid or manage a healthcare crisis;

- There has been an infectious disease outbreak, environmental incident or other major incident that requires emergency procurement of additional healthcare capacity;
- A treatment has been recommended by a National Institute of Health and Clinical Excellence (NICE) Technology Appraisal thereby requiring implementation within the statutory three month period;
- There is a statutory requirement to fund a new service or treatment;
- There is an individual funding request for a patient there is genuine evidence of individuality or exceptionality – see below.

4.12. **Individual funding requests**

4.13. Requests for funding of new services and treatments for specific individuals will be considered through the ***Worcestershire's local Commissioning Policy - Individual Funding Requests (IFR) – Operating Framework***. The key consideration is whether there is genuine evidence of individuality or exceptionality in relation to the case in question. Assuming this can be demonstrated, individual funding requests should be considered with reference to the core commissioning principles listed in section 5.0 of this document.

5. Commissioning Policy

5.1 The Commissioner considers all lives of all patients whom it serves to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related to the patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

5.2 The principles set out below underpin all prioritisation decisions and are expected to be applied universally.

Principle 1: The Commissioner has legal responsibility for its healthcare budgets and its primary duty is to live within the budget allocated.

Principle 2: The Commissioner has a responsibility to make rational decisions in determining the way in which it allocates resources and to act fairly in balancing competing claims on resources between different patient groups and individuals.

Principle 3: Competing patient and service needs should have a fair chance of being heard and, as such, all potential calls on new and existing funds should have the opportunity to be considered against other competing service developments within the resources.

Principle 4: The principles driving prioritisation at all levels should be consistent.

Principle 5: Health services are commissioned on the basis of evidence of clinical effectiveness, cost effectiveness, impact on health and affordability. Access to services should be on the basis of equal access for equal clinical need. Individual patients or groups should not be distinguished on the basis of age, gender, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status

(including responsibility for dependants), intellectual/cognitive functioning or physical functioning. The Commissioners have a responsibility to address health inequalities between groups within their populations. There are proven links between social inequalities and inequalities in health, access to health care and health needs. In making commissioning decisions, priority may be given to interventions targeting health needs in sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

Principle 6: The Commissioner should only invest in new services and treatments which are of proven clinical and cost-effectiveness unless it does so in the context of well designed, sufficiently powered and properly conducted clinical trials.

Principle 7: The Commissioner must ensure that it demonstrates value for money and appropriate use of NHS funding based on the needs of the population it serves.

Principle 8: All NHS commissioned care should be provided as a result of a specific decision to support the proposed treatment or service. Third parties have no mandate to pre-commit resources from The Commissioner's budgets unless directed to do so by the Secretary of State.

Principle 9: The Commissioner should strive to provide equal treatment to individuals in the same clinical circumstances, The Commissioner should therefore not offer to one patient a treatment which cannot be afforded for, and openly offered to, all patients with similar clinical circumstances.

Principle 10: Decisions relating to the funding of new treatments or new indications for established treatments should be considered as potential service developments and not through the process for managing individual funding requests

Principle 11: All services and treatments should be prioritised on the basis of:

- Strength of evidence of benefit – i.e. the level of confidence in the potential gains. Where possible evidence should come from methodologically sound systematic reviews such as those produced by Cochrane, meta-analyses or large high quality randomised controlled trials. The Commissioner will not, unless in truly exceptional circumstances, support new interventions for which evidence of clinical effectiveness is either absent or too weak for reasonable conclusions to be reached.
- Clinical effectiveness - the size and probability of any potential benefit to an individual (e.g. in terms of deaths prevented, quality of life years gained).
- Health impact – the total health gain to the population.
- Cost effectiveness – where a new service or treatment is not cost saving or cost neutral. The Commissioner will broadly follow the QALY/ICER system recommended by NICE for assessing the clinical and cost effectiveness of an intervention. However, in adopting commissioning policies for particular interventions, the Commissioner may choose to deviate from the strict financial limits identified by NICE if there are compelling reasons to do so. The Commissioner may conclude that an intervention is not cost effective even if it is proven to be clinically effective in extending the lives of patients.
- The nature of the underlying condition and treatment: life-saving and preventative treatments will be given a higher priority than treatment that influences the quality but not the length of life.

- Affordability - the overall cost and therefore the financial consequences to other services.
- Any relevant legal requirement or national directive.
- Alignment with national priorities - as set by the Department of Health.

Principle 12: Interventions of proven effectiveness will be prioritised above funding research and evaluation.

Principle 13: Because The Commissioner's capacity to meet the needs for research and evaluation is insufficient, research has to be prioritised and therefore not all treatments can be investigated. The NHS has neither the capacity nor the resources to undertake good research into all experimental treatments. Proposals for research have to be prioritised and those who propose research projects cannot expect automatic access to funding however worthwhile an individual research proposal may appear to be.

Principle 14: If treatment is provided within the NHS, which has not been commissioned in advance by The Commissioner, the responsibility for ensuring ongoing access to that treatment lies with the body which initiated treatment.

Principle 15: At the conclusion of any clinical trial, patients entered into the trial are entitled to be informed about the outcome of the trial and to share any benefits that result from having been in the trial. This duty, which falls on the party conducting the trial, will include, for example, ensuring access to treatment identified as beneficial in the trial or to other appropriate care or benefits.

Principle 16: NHS funds should never be used to subsidise private treatment.

Principle 17: All commissioned services should be part of agreed care pathways and delivered by healthcare providers who comply with the relevant quality requirements including Care Quality Standards and performance monitoring.

Principle 18: Respect for autonomy and individual choice are important, however they should not have the consequence of promoting interventions that are not clinically and/or cost effective as this would jeopardise the opportunity for other patients to receive treatments where clinical and cost effectiveness is established.

6. Clinically Exceptional Circumstances

6.1 If there is demonstrable evidence of a patient's clinically exceptional circumstances, the referring practitioner should refer to the Worcestershire's local "Individual Funding Request Policy" document for further guidance on the process for consideration.

For a definition of the term "clinically exceptional circumstances", please refer to the **Definitions** section of this document.

7. Documents Which Have Informed This Policy

- Worcestershire's local: Individual Funding Request Process

- Worcestershire's local: Prioritisation Framework for the Commissioning of Healthcare Services

- West Midlands Strategic Group Commissioning Policy 1: Guiding principles and considerations to underpin priority setting and resource allocation within collaborative commissioning arrangements

- West Midlands Strategic Group Commissioning Policy 4: Use of cost-effectiveness, value for money and cost effectiveness thresholds

- West Midlands Strategic Group Commissioning Policy 16: Prior Approval

- West Midlands Strategic Group Commissioning Policy 9: Individual funding requests

- The National Health Service Act 2006, The National Health Service (Wales) Act 2006 and The National Health Service (Consequential Provisions) Act 2006 : Department of Health - Publications

- Department of Health, World Class Commissioning Competencies, December 2007, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080958

- Department of Health, The NHS Constitution for England, March 2010, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113613

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

- West Midlands Specialised Commissioning Group – Commissioning Policy W/M 8 In-Year Service Developments and the Commissioner's approach to treatments not yet assessed and prioritised Version 1 April 2010

- West Midlands Specialised Commissioning Group – Ethical Framework to support priority setting and resource allocation within collaborative commissioning arrangements Version 1 April 2010

Equality impact assessment report

1. Name of policy or function – Prioritisation Framework for Commissioning Health Services

2. Responsible Manager – Dr Richard Harling, Director for Public Health, NHS Worcestershire

3. Date EIA completed – 22nd July 2010

4. Description of aims of function/policy
To set out the principles and the factors to be taken into account when prioritising health services in order to provide a coherent structure for rational and reasonable decision making, promote fairness and consistency and provide a means of expressing the reasons behind the decisions made.

5. Results of Initial Screening Equality Impact Assessment

Initial Equality Impact Assessment	
Equality Group	**Assessment of Impact**
Race	Low
Gender	Low
Disability	Low
Age	Low
Sexual Orientation	Low
Religion or Belief	Low
Human Rights	Low

6. Decisions and or recommendations (including supporting rationale)
None to be taken.

7. Equality action plan (if required)
Not required.

8. Monitoring and review arrangements (include date of next full review)

Department	Acute Commissioning
Directorate	Delivery
Director	Mr Simon Hairsnape
Report produced by and job title	Dr Richard Harling, Director of Public Health, NHS Worcestershire
Date report produced	22/07/2010
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