

Standard Operational Framework For Prior Approvals

July 2021

Document Summary

This operating framework for Prior Approvals applies to any patient for whom NHS Commissioners in Herefordshire and Worcestershire, to be referred to hereafter as “the Commissioners”, is the “Responsible Commissioner”.

The Commissioners consider 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 status, marital status, religion or disability, save 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.

A Glossary to terminology used in this policy can be found in Appendix 1.

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1.0	Full Review	Adoption of policies from NHS Herefordshire Clinical Commissioning Group and NHS Worcestershire Clinical Commissioning Groups, which were already fully aligned (V1.2 of previous document)	Fiona Bates & Helen Bryant	September 2019
1.1	Minor	Application of new commissioning policy template, no change to policy statement, no requirement to update Clinical Commissioning Executive Committee as Template already approved. Change of Executive Lead to Ruth Lemiech	Helen Bryant & Jennie Hammond Helen Bryant	July 2021

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Circulated to the following individuals/groups for comments:

Name	Date	Version Reviewed
Policy Alignment Task & Finish Group, which includes	14 th August 2019, 22 nd October 2019	Version 1.0
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1. Introduction and Background

- 1.1 Clinical Commissioning Groups (CCGs) were created by the Health & Social Care Act 2012 and established in accordance with the rules set out in the National Health Service Act 2006, as the statutory bodies charged with the function of commissioning healthcare for patients for whom they are statutorily responsible.
- 1.2 The CCG receives a fixed budget from NHS England to enable it to fulfil this duty. It has a statutory responsibility to maintain financial balance¹ and, as part of discharging this obligation, must decide how and where finite local resources are allocated.
- 1.3 The need for health care is always greater than the resources available to a CCG to meet the demand. Therefore, it is evident that it will not be possible for the CCG to commission all the health care that is needed or wanted by the population it serves and, as a result, it will need to prioritise its commissioning intentions based on the needs of the local population.
- 1.4 In carrying out these functions, the CCG will act with a view to securing that health services are provided in a way which promotes the NHS Constitution among patients, staff and members of the public. Patients have a right to expect that the CCG will assess and prioritise the health requirements of the local community and commission the services to meet those needs as considered necessary. In discharging its obligations under this policy, in particular, the CCG acknowledges that patients also have a right to expect that local decisions on the funding of treatments which have not been considered by the National Institute for Health and Care Excellence (NICE) in its technology appraisal programme will be made rationally following the proper consideration of evidence.
- 1.5 Those with the responsibility for health care budgets have to make decisions about priorities at three levels: when developing strategic plans (the main priorities), when deciding year on year which investment and disinvestments to make, and at the individual patient level.
- 1.6 The CCG has developed a series of Clinical Commissioning Policies to provide guidance to patients and clinicians on a range of interventions or treatments that require a CCG decision before NHS funded treatment can be provided. All policies and related Standard Operating Procedure documents are published on the CCG website: www.herefordshireandworcestershireccg.nhs.uk
- 1.7 The CCG has reviewed their Clinical Commissioning Policies to ensure that they reflect, or are more detailed than, the NHS England Evidence Based Interventions recommendations.
- 1.8 There are two categories of CCG decision making:
 - treatments that are not routinely commissioned; which require the submission of, and CCG agreement to, an Individual Funding Request. For more information about this process, please review the CCG Individual Funding Request Standard Operating Procedure document.
 - treatments that are funded as part of a specific pathway for patients who meet the clinical eligibility criteria for that treatment/intervention; which require the submission of, and CCG agreement to, a Prior Approval request. This document provides guidance on this process.

¹ Section 223H National Health Service Act 2006@ Financial duties of clinical commissioning groups: expenditure

2. Scope of the Prior Approval Process

- 2.1 This document is part of a suite of locally endorsed Commissioning Policies. Copies of these Commissioning Policies are available on the following website address: www.herefordshireandworcestershireccg.nhs.uk
- 2.2 This document applies to all patients for whom Herefordshire & Worcestershire CCG has responsibility including:
- People provided with primary medical services by GP practices which are members of the CCG and
 - People usually resident in the area covered by the CCG and not provided with primary medical services by any CCG.
- 2.3 In this document, any reference to “treatment” is a reference to a health care intervention provided or proposed to be provided by a clinician of any discipline.
- 2.4 The Prior Approval Process is not designed to create policy or to sanction funding requests which may result in precedent being set to provide the same or similar treatment to an identifiable group of patients. Therefore, where there is an identifiable group of patients who may all benefit from the proposed treatment but who are not currently included within a specific clinical commissioning policy, the requesting clinician should be advised that the request cannot be considered through the Prior Approval process and that an outline business case for a service development must be submitted to one of the following groups for further consideration:
- *The relevant Care Planning Programme Group*
 - The Medicines Prescribing Committee
 - The Clinical Commissioning Policy Collaborative
- Services or treatment pathways that are commissioned by NHS England, have a separate NHS funding decision making process that local commissioners (CCGs) are not a part of. Clinicians should use the appropriate NHS England forms to make an application for funding. If a funding request is made to the CCG for NHS England commissioned services, it will be sent back to the requesting clinician with advice on accessing the correct process. NHS England will only accept a funding request from the treating clinician, normally a specialist.
- 2.5 Prior Approvals are required where the local commissioning policy has clear clinical eligibility criteria that has been agreed by the Commissioner and Provider clinicians to ensure that patients are treated at an appropriate stage in their treatment pathway/disease progression.

3. Applying for Prior Approval

- 3.1. All Prior Approval requests will be considered in accordance with this policy. The following paragraphs provide further details on how they will be managed. The Prior Approval process is summarised in **Appendix 2** of this document.
- 3.2. GPs must submit patient referrals for specialist consideration of a treatment/intervention using the correct referral form. These are accessible via the practice EMIS system and are compatible with e-RS. Clinical commissioning policies provide detail regarding necessity for and availability of specific forms.
- 3.3. Upon receipt of a GP referral form, secondary care clinicians will assess and review the circumstances of the referral and arrange a patient consultation where the requirements for GP referral are met.
- 3.4. Patients will be reviewed during their consultation to ensure that they meet the requirements of the relevant clinical commissioning policy.
- 3.5. Where a clinical decision is made by the provider to offer a patient a treatment/intervention that is subject to prior approval, in accordance with commissioning policy arrangements, prior approval must be made before the patient is accepted for treatment (TCI Date or Pre-Operative Assessment)
- 3.6. A Prior Approval application must be made through completion of the appropriate **Prior Approval form**, which is available via the CCG Prior Approval system, Blueteq.

All Prior Approval applications will be submitted by the secondary/tertiary care clinician intending to undertake the treatment/intervention or their nominated representative (e.g. their medical secretary or junior clinical colleague) and must include the Patients Local Hospital Identifier number as standard. N.B. the Blueteq process is compliant with GDPR requirements

- 3.7. All details contained in a Prior Approval application are the responsibility of the treating clinician; validated by the inclusion of the individual clinician's GMC number on each application.
- 3.8. Prior Approval applications made by GPs, patients, or other sources e.g. Members of Parliament will be acknowledged but cannot be accepted.
- 3.9. Any Prior Approval application received not using the correct form, or not adequately completed will be returned to the clinician/nominated representative, with a request to review and resubmit the request using the appropriate proforma or completing any missing information.

4. Making a Prior Approval Decision

Prior Approval applications which meet the relevant clinical criteria for NHS funding (in accordance with policy) will automatically be approved following completion and submission on Blueteq

4.1 Any Prior Approval application made for a patient that does not meet the clinical eligibility criteria for automatic approval will require submission to the Commissioner for review (CCG Review).

4.2 The Commissioner's Prior Approvals Team will review and respond to all applications that are submitted for "CCG Review" within **2 working days** of submission.

The CCG Review will provide one of the following responses:

- *Request additional supporting information*, where there is insufficient clinical information to determine compliance with the policy
- *Approve Prior Approval Request*, at which point the CCG will provide the requesting clinician/organisation with a Unique Identification Number (UIN) to confirm funding is approved.

Note:	The Provider must record the UIN on their Patient Administration System to ensure that the activity is not part of monthly contractual challenges in line with the NHS Standard Contract SC29
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- *Decline Prior Approval request*, as the request does not meet the requirements of the policy.

4.3 Where an application on Blueteq is incomplete, the entered details will be held on the Prior Approvals system pending clarification/completion of all relevant clinical criteria and should be submitted as soon as this information is available.

5. Requesting Reconsideration of a Prior Approval Application

5.1 If a Prior Approval request is declined by the CCG, the treating clinician can either:

- Submit additional clinical information not previously provided as part of the original Prior Approval Request under the terms of a “CCG Review”;

OR

- Submit an Individual Funding Request application for the patient, if there is sufficient evidence that the patient is experiencing exceptional clinical circumstances to other patients covered by the same local commissioning policy and the same clinical eligibility criteria.

6. Recording an Endorsed Prior Approval Application

- 6.1 The Prior Approvals system will provide the requesting clinician/organisation with a Unique Identification Number (UIN) to confirm funding is approved. This will be communicated as part of the Prior Approval application audit trail.

The format of a UIN will be:

XXX-NNNNN – where the first 3 characters denote the CCG organisation code and the remaining numbers are a sequential number.

- 6.2 The Unique Identification Number (UIN) is specific to:
- The patient
 - The Provider Organisation
 - The intervention/treatment
- 6.3 The Provider must record the UIN on their Patient Administration System to ensure that the activity is not part of monthly contractual challenges in line with the NHS Standard Contract SC29.
- 6.4 A UIN cannot be transferred to another Provider if the patient decides to move to another Provider Organisation for treatment. If this happens, the patient's original Provider must contact the CCG to cancel the Prior Approval application and the new Provider must review the patient's clinical presentation against the appropriate commissioning policy and clinical eligibility criteria and make an application for Prior Approval funding in line with the process described in section 4 of this document.

7. Documents which have informed this Operating Procedure

- NHS Herefordshire & Worcestershire: Individual Funding Request Operating Procedure
- NHS Herefordshire & Worcestershire: Prioritisation Framework for the Commissioning of Healthcare Services
- WM01 – Ethical Framework
- WM02 – Orphan Drugs
- WM03 – Patients Leaving Industry Sponsored Trials
- WM05 – NICE Guidance
- WM07 – Choice
- WM08 – In Year Service Developments
- WM09 – Individual Funding Requests (to be read with local process document)
- WM10 – Patients Leaving Non Commercially Funded Trials
- WM11 – Patients Leaving a CCG Funded Trial
- WM12 – Patients Changing Responsible Commissioner
- WM13 – NHS Private Interface
- WM14 – Experimental Treatments
- WM15 – Trial of Treatment
- NHS Constitution, updated 27th July 2015
- 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: <https://bulger.co.uk/dacorumhealth/dacom/PDF%20Documents/WCC%20competencies.pdf>
- Department of Health, The NHS Constitution for England, Updated October 2015: <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>

- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009,
- NHS Confederation Priority Setting Series, 2008,

8. Appendices

Appendix 1 – Glossary of Terms

Term	Definition
Annual Commissioning Plan	The <i>Annual Commissioning Plan</i> is a document prepared by the Commissioner which defines the healthcare interventions that will be commissioned for defined categories of patients in each financial year. Locally, this is known as the <i>Commissioning Intentions</i> .
Annual commissioning round	The <i>annual commissioning round</i> is the process by which major funding decisions are taken, including the allocation of new money coming into the NHS. This involves a complex process of prioritisation which involves a series of decisions. This process occurs during the months of October to March for the following financial year.
Clinical effectiveness	<i>Clinical effectiveness</i> is a measure of how well a healthcare intervention achieves the pre-defined clinical outcomes of interest in a real-life population under real-life conditions.
Clinical trial	<p>A <i>clinical trial</i> is a research study in human volunteers to answer specific health questions. Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol.</p> <p>The ethical framework for conducting trials is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials.</p>
Cost effectiveness	<i>Cost effectiveness</i> is an assessment as to whether a healthcare intervention provides value for money.
Efficacious	A treatment is <i>efficacious</i> where it has been shown to have an effect in a carefully controlled and optimal environment. However, it is not always possible to have confidence that data from trials which suggest that treatments will be efficacious will translate into clinically meaningful health gain and more specifically the health gain of interest. This is the difference between disease oriented outcomes and patient oriented outcomes. For example, a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy, but this relationship might not be borne out in reality.
Exceptional	<i>Exceptional</i> means out of the ordinary, unusual or special.
Exceptional clinical circumstances	<i>Exceptional clinical circumstances</i> are clinical circumstances pertaining to a particular patient which can properly be described as rare or 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.

Term	Definition
Experimental and unproven treatments	<p><i>Experimental and unproven treatments</i> are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. The reasons may include the following:</p> <ul style="list-style-type: none"> • The treatment is still undergoing clinical trials for the indication in question. • The evidence is not available for public scrutiny. • 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.
GP Referral Form	<p>A GP referral form has been designed for use where a local commissioning policy requires evidence that a patient complies with elements of a treatment pathway before referral can be made for a more specialist opinion/access to a more specialist pathway.</p> <p>The referral form will be available for download to the practice system (e.g. EMIS) and is to be used in lieu of a referral letter. Where appropriate, the referral form can be linked to the e referral system (e-RS).</p> <p>The completion and submission of this form does not constitute the CCG giving Prior Approval for an intervention.</p> <p>For more information see “Prior Approval” definition.</p>
Healthcare intervention	<p>A <i>healthcare intervention</i> means any form of healthcare treatment which is applied to meet a healthcare need.</p>
In-year service development	<p>An <i>in-year service development</i> is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner 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.</p>
NHS commissioned care	<p><i>NHS commissioned care</i> is healthcare which is routinely funded by the patient’s responsible commissioner. The Commissioner has policies which define the elements of healthcare it is and is not prepared to commission for defined groups of patients.</p>
Prior Approval	<p><i>Prior Approval</i> is a process in which treating clinicians demonstrate how a patient meets set threshold criteria prior to listing for that patient for surgery for procedures which the commissioner routinely commission in line with agreed clinical eligibility criteria and which are noted within agreed contracts.</p> <p>The completion and submission of a GP Referral Form for the patient does not constitute the CCG giving Prior Approval for an intervention.</p> <p>For more information see GP Referral Form definition.</p>
Priority setting	<p><i>Priority setting</i> is the task of determining the priority to be assigned to a service, a service development, a policy variation or an individual patient at a given point in time.</p>

Term	Definition
	Prioritisation is needed because the need and demands for healthcare are greater than the resources available.
Rule of rescue	<i>Rule of rescue</i> 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. 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 the West Midlands 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.
Service Development	A <i>Service Development</i> is an application to the Commissioner to amend a commissioning policy to provide that a particular healthcare intervention should be routinely funded for a defined group of patients. 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 that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms. Equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. However, where investment is made outside of the annual commissioning round, such investment is referred to as an <i>in-year service development</i> .
Strategic planning	<i>Strategic planning</i> is the process by which an organisation determines its vision, mission, and goals and then maps out measurable objectives to accomplish the identified goals. The outcome is a <i>strategic plan</i> which sets out what needs to be done and in what time scale. Strategic planning focuses on what should be achieved in the long term (3, 5, 7, or 10 year time span) while operational planning focuses on results to be achieved within one year or less. Strategic plans should be updated through an annual process, with major re-assessments occurring at the end of the planning cycle. Strategic planning directs how resources are allocated.
Treatment	<i>Treatment</i> 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.
Value for money	<i>Value for money</i> in general terms is the utility derived from every purchase or every sum spent.

Appendix 2 – Summarised Process For Prior Approval Requests

Summarised Process For Consideration Of Prior Approval Applications

