NHS
North Hampshire
Clinical Commissioning Group

NHS NORTH HAMPSHIRE CLINICAL COMMISSIONING GROUP

The Policy for Adoption and Implementation of NICE Guidance and Policy Recommendations from the Southampton, Hampshire, Isle of Wight and Portsmouth (SHIP) Priorities Committee

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Contents

1. Introduction

NHS North Hampshire Clinical Commissioning Group (NHCCG) has a legal duty to provide funding for treatments recommended within National Institute for Health and Clinical Excellence (NICE) Technology Appraisals ('TAG's) normally within three months of the date of publication unless the treatments have been exempted by the Secretary of State. All other NICE Guidance will be considered when developing strategies and planning services. Given that demand for healthcare is greater than the resources available, prioritisation of competing needs cannot be avoided.

This policy describes the way in which NHCCG implements NICE guidance, but also the way it utilises the outputs of the SHIP (Southampton, Hampshire, Isle of Wight and Portsmouth) Priorities Committee in the setting of its commissioning priorities and the Individual Funding Request (IFR) process.

2. Policy Statement and Scope

2.1 This policy applies to any patient in circumstances where NHCCG is the responsible commissioner for their NHS care. It equally applies to any patient needing medical treatment where the Secretary of State has prescribed that the CCG is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

2.2 NHCCG will implement NICE Technology Appraisals in line with the Secretary of State's Directions. NHCCG accepts that it has a legal duty normally to make treatments available to patients whose clinical condition(s) come within the definitions listed in a Technology Appraisal within 3 months of the date of the appraisal's publication unless the treatments have been exempted by the Secretary of State. These treatments will receive the highest priority for funding.

2.3 All other NICE Guidance shall not be treated as statutory guidance, including medical technologies guidance. It will be carefully considered when developing strategies, planning services and prioritising resources. NHCCG reserves the right to depart from NICE Guidance, other than Guidance which relates to treatments for patients that are within the specific remit of the Secretary of State's Directions, if NHCCG has a good reason to do so.

3. Equality Statement

NHCCG has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHCCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, NHCCG will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

4. Guidance Notes

NICE produces the following types of guidance documents:

- Cancer service guidance
- Clinical guidelines
- Diagnostic guidance
- Interventional procedures guidance
- Medical Technologies guidance
- Public Health guidance
- Technology Appraisals guidance
- Quality Standards

Of these only Technology Appraisals are subject to guidance from the Secretary of State.

Given that demand for healthcare is greater than the resources available, prioritisation of competing needs cannot be avoided. At present it is not possible to fully implement all NICE Guidance on the grounds of affordability. This situation also applies to guidance issued by other bodies such as clinical guidelines and standards produced by the various professional bodies.

4.1 Directions versus Guidance

It is essential for decision-makers to understand the difference between Guidance and Directions. It is also essential for them to understand the nature of the different types of guidance produced by NICE.

4.1.1 NHS Directions are legally binding instructions to NHS organisations issued by the Secretary of State under section 8 of the National Health Service Act 2006.

4.1.2 NICE's *Technology Appraisals* are a specific form of Guidance published by NICE which are covered by NHS Directions issued in 2003. The Directions provide that NHS Commissioners shall make funding normally available to patients who meet the criteria set out in the Guidance. This funding should be made available within three months from the date that the Technology Appraisal Guidance has been issued unless an extension has been authorised by the Secretary of State.

4.1.3 Guidance issued to the NHS is non-binding advice which is intended to assist the NHS in the exercise of its statutory duties. It recommends steps which might be taken, factors which could be taken into account and procedures which could be followed to deliver specified steps of administration or policy. NHS bodies are entitled to take decisions which do not follow Guidance (other than NICE's Technology Appraisals) if they have a good reason to do so. The availability of resources and competing priorities can be a good reason.

4.2 Types of Guidance Produced by NICE

4.2.1 Cancer Service Guidance

Cancer service guidance supports the implementation of The NHS Cancer Plan for England, and the NHS Plan for Wales Improving Health in Wales. The focus of the cancer service guidance is to guide the commissioning of services and is therefore different from clinical practice guidelines.

Health professionals should take the NICE cancer service guidance into account when planning, commissioning and organising services for cancer patients. This guidance can be used to identify gaps in local provision and to check the appropriateness of existing services.

4.2.2 Clinical Guidelines

Clinical guidelines are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. They are based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills.

The Aim of Clinical Guidelines

Good clinical guidelines aim to improve the quality of healthcare. They can change the process of healthcare and improve people's chances of getting as well as soon as possible. Clinical guidelines can:

- provide recommendations for the treatment and care of people by health Professionals
- be used to develop standards to assess the clinical practice of individual health professionals
- be used in the education and training of health professionals
- help patients to make informed decisions
- improve communication between patient and health professional

Versions of Clinical Guidelines

NICE produces four versions of its clinical guidelines:

- the **full guideline** contains all the recommendations, plus details of the methods used and the underpinning evidence
- the **NICE guideline** presents the recommendations from the full version in a format suited to implementation by health professionals and NHS bodies
- **NICE pathway** is an online tool for health and social care professionals that brings together all related NICE guidance, quality standards and implementation tools on a topic in a set of interactive flowcharts. This can be found at:

http://pathways.nice.org.uk/

- **understanding NICE guidance** is written using suitable language for people without specialist medical knowledge

4.2.3 Diagnostic Guidance

As part of NICE's work on evaluating medical technologies, the Diagnostics Assessment Programme (DAP) focuses on the evaluation of innovative medical diagnostic technologies in order to ensure that the NHS is able to adopt clinically and cost effective technologies rapidly and consistently.

Diagnostics includes all types of measurements and tests that are used to evaluate a patient's condition, such as physiological measurements, laboratory tests and pathology tests, imaging tests, and endoscopy.

Diagnosis is the process of identifying whether the patient has a disease at the time of testing. It is performed for patients with specific complaints or in whom signs or symptoms have been noted that may indicate a disease. Tests can have several different uses in the process of diagnosis, for example:

- ruling in or out a specific disease
- general examination looking for clues to the cause of the symptoms
- staging, or additional testing to assess how advanced or severe the disease is
- monitoring a patient over time to determine changes in their condition
- screening tests to look for conditions in patients without signs or symptoms of the specific condition

The Diagnostics Assessment Programme (DAP) provides specialist capacity for undertaking complex assessments of diagnostic technologies. In many cases, the meaningful assessment of diagnostic technologies requires detailed knowledge of the post diagnosis care pathways, which results in considerable complexity.

The programme is closely linked to NICE's Medical Technologies Evaluation Programme (MTEP) and the Medical Technologies Advisory Committee (MTAC). MTAC undertakes topic selection for all medical technologies and routes appropriate diagnostics topics to the DAP.

4.2.4 Interventional Procedures Programme

NICE makes recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use.

An interventional procedure is a procedure used for diagnosis or treatment that involves one of the following:

- making a cut or a hole to gain access to the inside of a patient's body - for

example, when carrying out an operation or inserting a tube into a blood vessel
- gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body - for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth
- using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems

Where NICE has taken a view that a treatment **should not be used,** funding should not be sanctioned save in the most exceptional circumstances.

4.2.4 Medical Technologies Guidance

Medical technologies guidance is designed to help the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently.

The types of products which might be included are medical devices that deliver treatment such as those implanted during surgical procedures, technologies that give greater independence to patients, and diagnostic devices or tests used to detect or monitor medical conditions.

4.2.5 Public Health Guidance

Public health guidance makes recommendations for populations and individuals on activities, policies and strategies that can help prevent disease or improve health. The guidance may focus on a particular topic (such as smoking), a particular population (such as schoolchildren) or a particular setting (such as the workplace).

4.2.6 Technology Appraisal Guidance

Technology Appraisals are recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales, such as:

- medicines
- medical devices (for example, hearing aids or inhalers)
- diagnostic techniques (tests used to identify diseases)
- surgical procedures (for example, repairing hernias)
- health promotion activities (for example, ways of helping people with diabetes manage their condition)

4.2.7 Quality Standards

NICE Quality Standards are a concise set of prioritised statements designed to drive measurable quality improvements within a particular area of health or care.

NICE Quality Standards are derived from high quality guidance such as that from NICE or

other sources accredited by NICE. Quality standards are developed independently by NICE, in collaboration with healthcare professionals and public health and social care practitioners, their partners and service users. Information on priority areas, people's experience of using services, safety issues, equality and cost impact are also considered during the development process.

NICE Quality Standards are central to supporting the Government's vision for a health and social care system focused on delivering the best possible outcomes for people who use services, as detailed in the Health and Social Care Act (2012).

NICE quality standards enable:

- **Health professionals and public health and social care practitioners** to make decisions about care based on the latest evidence and best practice
- **People receiving health and social care services, their families and carers and the public** to find information about the quality of services and care they should expect from their health and social care provider
- **Service providers** to quickly and easily examine the performance of their organisation and assess improvement in standards of care they provide
- **Commissioners** to be confident that the services they are purchasing are high quality and cost effective and focused on driving up quality

The Quality Standards can be found at:

https://www.nice.org.uk/standards-and-indicators

5. Priorities Recommendations by the SHIP Priorities Committee

5.1 History

Up until February 2013, the SHIP (Southampton, Hampshire, Isle of Wight, Portsmouth) Priorities Committee worked on behalf of its constituent Primary Care Trust commissioners to develop and agree clinical policies using an ethical decision making framework and standard procedures. Their recommendations were advisory, but became active policy following consultation with the constituent CCGs and endorsement by the former Cluster PCT's Board of Clinical Commissioners (BoCC).

The policy statements to date will remain in place where appropriate and extant until reviewed and replaced - an index of the policy statements from this committee is published on the South Central Commissioning Support Unit's website at:

http://www.fundingrequests.cscsu.nhs.uk/wp-content/uploads/2016/08/SHIP-HIOW-Policy-Recommendations-LOCKED-PDF.pdf

The committee was abolished just before the abolishment of PCTs in March 2013, but then re-launched in July 2014 as the SHIP Priorities Committee.

5.2 The SHIP Priorities Committee

5.2.1 Purpose and Role

The overall aim of the SHIP Priorities Committee is to:

"….provide CCGs with evidence-based, carefully considered recommendations that inform the commissioning policies of the constituent SHIP CCGs. This advice and support ensures that clinical policy remains fit for purpose, up-to-date and rigorously responsive to challenge. The Priorities Committee help SHIP 8 CCGs to choose how to allocate their resources to promote the health of the local community"

Supported by Solutions for Public Health (SPH), an NHS public health consultancy organisation, the committee will provide a generic analysis of NICE clinical guidelines with that enables CCGs to easily identify areas of their existing policy arrangements that are not aligned to NICE recommendations. A cost analysis tool is used to determine the implications of different future policy adoptions and establishes an audit trail for consequent policy decisions.

The full Terms of Reference for the SHIP Priorities Committee is shown in **Appendix A.**

5.2.2 Dealing with Recommendations/Guidelines made from Higher Authorities

The Committee recognises that its discretion may be affected by national policy and by NICE guidance and Secretary of State Directions to the NHS and is especially concerned with the following:

A: Evidence of Clinical and Cost Effectiveness

The Committee will seek to obtain the best available evidence of clinical and cost effectiveness using robust and reproducible methods. Methods to assess clinical and cost effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of the Committee. Choice of appropriate clinically and patient-defined outcomes needs to be given careful consideration, and where possible quality of life measures and cost utility analysis should be considered.

The Committee will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment that is shown to be ineffective. Issues such as safety and drug licensing will also be carefully considered. When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients' health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other sources and this will also be considered. Patients' evidence of significant clinical benefit is relevant.

The Committee will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. They will consider technical cost-benefit calculations where these can be accessed (e.g. quality adjusted life years), but these will not by themselves be decisive. The

Priorities Committee may use the ethical framework to guide context-specific judgements about the relative priority that should be given to each intervention.

B: Equity

The Committee believes that people should have access to health care on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community. However, the Committee will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, gender identity, race, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning. However, in some circumstances, these factors may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment.

C: Health Care Need and Capacity to Benefit

Health care should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. The Committee will consider the health needs of people and populations according to their capacity to benefit from health care interventions. So far as possible, it will respect the wishes of patients to choose between different clinically and cost effective treatment options, subject to the support of the clinical evidence.

This approach leads to three important principles:

- in the absence of evidence of health need, treatment will not generally be given solely because a patient requests it
- a treatment of little benefit will not be provided simply because it is the only treatment available
- treatment which effectively treats “life time” or long term chronic conditions will be considered equally to urgent and life prolonging treatments.

D: Cost Of Treatment and Opportunity Costs

Because each CCG is duty-bound not to exceed its budget, the cost of treatment must be considered. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other uses. This is known as opportunity costs and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way. The concept derives from the notion of scarcity of resources. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high.

E. Needs of the Community

Public health is an important concern of the Committee and it will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE). Others are produced locally. The Committee also supports effective policies to promote preventive medicine which help stop people becoming ill in the first place.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient’s condition, or to stop, or slow the progression of disease. Where it has been decided that a treatment has a relatively low priority and cannot generally

be supported, a patient's doctor may still seek to persuade the CCG that there are exceptional circumstances which mean that the patient should receive the treatment.

F. Policy Drivers

The Department of Health issues guidance and directions to NHS organisations, including the NHS Constitution and NHS Mandate, which may give priority to some categories of patient, or require treatment to be made available within a given period. These may affect the way in which health service resources are allocated by individual CCGs. The Committee will operate with these factors in mind and recognise that its discretion may be affected by national policy, NICE publications, Secretary of State Directions to the NHS and performance and planning guidance.

Locally, choices about the funding of health care treatments will be informed by the needs of each individual CCG.

G. Exceptional Need

There will be no blanket bans on treatment since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Each case of this sort will be considered on its own merits in light of the clinical evidence. CCGs have procedures in place to consider such exceptional cases on their merits. The Individual Funding Request route is one way and is dealt with in **Section 5.2.3** below.

5.2.3 More General Reviews

In addition, SPH will also undertake evidence reviews for chosen commissioning topics that entail:

- a comprehensive evidence review
- engagement with relevant local provider clinicians
- CCG specific activity & financial modelling to analyse the extent of variation in relevant current activity & spend between the 8 CCGs & predicts the financial impact of potential commissioning policy options

The topics for review are chosen according to the Topic Selection Process shown in **Appendix B**.

5.2.3 Relationship to the Process of Individual Funding Requests (IFRs) to CCGs

5.2.3.1 Background

The NHS Confederation document "*Priority setting: managing individual funding requests"* was drafted originally for Primary Care Trusts, but remains relevant to CCGs today. It gives a clear definition of an individual funding request as follows:

"A request to a [CCG] to fund healthcare for an individual who falls outside the range of services and treatments that the PCT has agreed to commission"

There are several reasons why a CCG may not be commissioning the healthcare intervention for which funding is sought:

- it might not have been aware of the need for this service and so has not incorporated it into the service specification

- it may have decided to fund the intervention for a limited group of patients that excludes the individual for whom the request is made
- it may have decided not to fund the treatment because it does not provide sufficient clinical benefit and/or does not provide value for money
- it may have accepted the value of the intervention but decided it cannot be afforded in the current year

Such requests should not be confused with:

- decisions that are related to care packages for patients with complex healthcare needs
- prior approvals which are used to manage contracts with providers

An important consideration for CCGs is the concept of **'exceptionality'** - the UK Faculty of Public Health has published a statement describing the concept of exceptionality:

"It is important to distinguish between an exceptional case and an individual funding request. In an exceptional case, a patient seeks to show that he or she is an 'exception to the rule' or policy and so may have access to an intervention that is not routinely commissioned for that condition. In contrast, an individual funding request arises when a treatment is requested for which the [commissioning organisation] has no policy. This may be because:

- *it is a treatment for a very rare condition for which the [commissioners have] not previously needed to make provision, or*
- *there is only limited evidence for the use of the treatment in the requested application, or*
- *the treatment has not been considered by the [commissioner] before because it is a new way of treating a more common condition. This should prompt the development of a policy on the treatment rather than considering the individual request unless there is grave clinical urgency."*

In practice, all requests for funding for an individual patient have been called Individual Funding Requests (IFRs) but these sub-categories of request should be recognised."

IFRs also need to be understood in the context of routinely funded services. Most established treatments and services are subject to routine commissioning arrangements: a portfolio of contracts and service level agreements, clinical commissioning policies, mandatory National Institute of Health and Clinical Excellence (NICE) technology appraisal guidance. This guidance note is intended to distinguish the broad types of request that may be received. These are where the request:

1. represents a service development for a cohort of patients
2. is on grounds of clinical exceptionality where there are commissioning arrangements in place
3. is on grounds of rarity and no commissioning arrangements exist
4. is for a new intervention or for use of an intervention for a new indication, where no commissioning arrangements exist

In the event that an IFR is approved, this does not necessarily set any precedent and relates to the individual patient only.

5.2.3.2 Types of Funding Request

There are two main kinds of funding request:

1. Procedures of Limited Clinical Value (Low Priority) treatments

PLCV are treatments/interventions which are not routinely funded or commissioned by the local Clinical Commissioning Groups. The Clinical Triage Panel and the Case Review Committee will consider an IFR if the clinician believes there is a strong case for a specific patient on grounds of an exceptional health need.

The IFR process is not intended to be used to consider requests which, if funded, would be provided under NHS England specialised commissioning arrangements. NHS England operates its own IFR process.

2. Threshold Dependent Procedures (TDP)

TDPs are treatments/interventions which are routinely funded or commissioned when the patient meets the defined criteria for treatment.

5.2.3.3 IFR Process

The process for making and managing and processing IFRs is contained within the Policy and Procedure for Individual Funding Requests (IFRs) for Treatments Concerning Clinical Commissioning Groups. This policy and the associated request forms are available at:

http://www.fundingrequests.cscsu.nhs.uk/wp-content/uploads/2016/06/IFR-Policy-and-Procedure-for-CCGs-2016-17-update-3.pdf

The full list of treatments, interventions and procedures covered by the policy (with associated referral forms for clinicians) for the Hampshire CCGs can be viewed at:

http://www.fundingrequests.cscsu.nhs.uk/clinical-commissioning-groups-hampshire/policies-guidance-ccgs-hampshire/

Any patient being considered for an IFR application should be registered with a GP practice belonging to the relevant CCG or, if not registered with any GP, lives within the geographical responsibility of the CCGs and is eligible for NHS treatment. If this is not clear then the Responsible Commissioner guidance from NHS England applies:

https://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf

where:

- the provider can meet the quality standards as per Healthcare Assurance Standards / Care Quality Commission guidelines
- **only an NHS GP, NHS Consultant or consultant in a Treatment Centre holding an NHS contract** can make a funding application. Allied health professionals and specialist nurses can also make referrals though these should normally be endorsed by a GP or consultant
- the procedure/treatment is not already purchased under existing service agreements
- Patient Choice guidelines will apply where relevant
- for a treatment covered under this policy and the CCGs hold a contract covering a relevant specialty
- the referral should be made by a consultant of the same specialty to a provider with whom the CCGs hold a contract.

Private treatment - If a patient has opted to pay for treatment and/or procedures privately, these will not be funded retrospectively and would not normally include future treatment offered by the private provider.

It is the responsibility of the requesting clinician to set out the case for funding and to provide all relevant supporting information; the requesting clinician can also include supporting information provided by the patient. A fully-completed application will normally include:

- an outline of the patient's diagnosis/problem and the clinical circumstances of the case, including any previous treatment(s) used and outcomes achieved;
- a clear statement of the referral/treatment plan proposed for the patient, to include the point at which the patient should return to local treatment pathways (or including the expected duration of the proposed treatment);
- consideration of reason(s) why the patient's needs cannot be met within existing pathways;
- a statement of the reason(s) why this treatment, which would not be offered to others with similar clinical need, is a priority for funding in the individual patient's case, i.e. what are the exceptional clinical circumstances?;
- a statement of evidence of clinical and cost-effectiveness if this is a new treatment not yet funded;
- the anticipated cost of the treatment (and associated costs) if it is outside the NHS tariff;
- the expected healthcare benefits (e.g. impact of likely outcomes on the Activities of Daily Living) if the requested treatment is provided, set against expected outcomes if the patient remains within the service or continues with treatment provided within existing CCG contracts.

All requests will be addressed by the IFR team at first before proceeding for consideration by the IFR Panel. In cases where the referral clearly does not meet the exceptional circumstances explained above will be declined with an explanation. The IFR team will approve all referrals that clearly meet the criteria set out in this policy. In cases where the referrer has not made the application on the IFR funding request form and/or has not sent all relevant information plus any supporting documentary evidence, the referrer will be invited to do so, to enable the request to proceed to Panel consideration.

Those referrals to be considered by the Panel should be exceptional within the guidelines of current policy. The Panel may also consider cases for a treatment not provided for within the policy and, where the consequences of a decision might have wider implications on commissioning policy may refer such cases back to the CCGs for consideration of future precedence. All requests, requiring a decision by the Panel together with supporting information will be submitted to the next available meeting. Papers should be circulated at least one week prior to the meeting date.

The IFR team shares its decisions via a monthly report to CCGs. Referrals leading to a possible policy change, those in an area of contention, or appeals against a Panel decision where no additional information has been provided may be considered by the Appeal Panel for the relevant CCG.

5.2.3.4 The IFR Referral Panel

In order to meet the demand from the volume of referrals, the CSU has a structure of an IFR Referral Panel and 'parent' Appeal Panels for each commissioner. It is important that all decisions made by the Panel are transparent, defendable and consistent, observing CCG corporate principles, available NICE guidance, advice from the priorities framework and the

available evidence base. After a decision has been made, a full written explanation will be provided to the referrer and patient. Where a significant number of referrals are being made in a particular area or specialty these will be flagged to CCGs and the SHIP Priorities Committee.

The Panel should consist of primary care clinicians, the IFR lead or member of the team, an Associate Director / Key Contracting Manager and a Public Health Consultant. The Panel should be chaired by a senior clinician or Public Health Consultant. Where appropriate, support should be secured from a medicines management lead and a nursing professional depending on the cases considered. A guide to membership is as follows to ensure clinical participation. The Panel will meet twice a month for which there should be a minimum of 3 clinicians/allied health professionals as a quorum. Additional members may be co-opted as the need arises.

The key task of the Panel is to consider and discuss individual cases and to decide to approve funding, reject a request or defer to seek further information. It is intended that the Panel should be represented by each of the CCGs or that CCGs delegate representation so that it acts as a decision-making body on behalf of all the CCGs in the area it represents.

5.2.3.5 Appeals

The GP/clinician has a responsibility to refer appropriately. Good working relationships should ensure that proper procedures are followed. However, the referrer may wish to appeal against a decision and this should initially be made in writing to the IFR Lead with additional supporting information/evidence. If the information provided contains new evidence the referral should be reconsidered by the original Panel. If their decision remains unchanged the referral will be directed to the relevant CCG's Appeals Panel.

The Appeals Panel for each commissioner will remain to consider appeals from referring clinicians on behalf of patients from their area. The Appeals Panel's remit will be to consider whether the process and rationale behind the IFR Panel's decision-making has been adequately followed, that all relevant information has been considered and that the decision was fair, equitable and based on the evidence available at the time. It does not take funding decisions itself and, if any new evidence is brought before it, this must be referred back to the previous Panel.

The constitution of the Appeals Panel is to be determined by the CCG but it is recommendation that it should have at least two clinical members, preferably from its governing body, and a lay member. A member of the original decision-making Panel may also attend to present the audit trail of the case being considered but would not have a vote in any decision made. Clinical colleagues may be co-opted onto any Panel depending on the subject matter.

Should the Appeal Panel return a case for reconsideration by the IFR Panel, then funding would be expected to follow. The grounds for funding decisions need to be accepted as relevant to meeting the overall healthcare needs of the population within resource constraints.
The CSU will not accept appeals instigated by a patient, their family or other non-clinical representative (e.g. local MP).

At both the initial referral and appeal stages, cases will be considered with the GP/other referring clinician being the main point of contact. The decision of the Appeals Panel is final.

5.2.3.6 Complaints

Patients have the right to raise a formal complaint with the CCG via the NHS Complaints Procedure should they be unhappy with the CSU's handling of their case (i.e. staff attitude, communication or the way in which the policy or procedure has been followed, adherence to procedure). The NHS Complaints Procedure is set out to address concerns over service provision and not funding decisions. It cannot be used to investigate or influence funding decisions and the appropriate process for appeals should be followed i.e. from the referring clinician and not the patient.

6. Clinical Commissioning Group Responsibilities and Adoption Processes

6.1 Background

The Priorities Committee uses an agreed Ethical Framework, shown in **Appendix C** to formulate policy and priority recommendations regarding health care and which involves the exercise of judgment and discretion – although there is room for disagreement both within and outwith the Committee. There is no objective or infallible measure by which such decisions can be based, however the Ethical Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community, and which can be justified by the CCGs on a consistent basis.

CCGs must show that they are acting, through the SHIP Priorities Committee, within their powers and in a reasonable way when making policy and prioritising the commissioning of services. Recommendations made by the SHIP Priorities Committee and adopted by CCGs can be challenged by Judicial Review in terms of legality, reasonableness or natural justice. The role of the Priorities Committee is to provide commissioning policy recommendations to the 8 CCGs about the interventions which it reviews. The adoption and implementation of these and NICE guidelines is the responsibility of each CCG and not the Priorities Committee. It is not binding for all CCGs to adopt the policy recommendations of the Priorities Committee or NICE guidelines *verbatim* but should a CCG choose to vary from the policy recommendations then it will need to clearly articulate its rationale for doing so and be able to justify it.

6.2 CCG Roles and Responsibilities

6.2.1 SHIP Priorities Committee Members – each member CCG can field up to a two representatives on the Priorities Committee. They should have sufficient authority and standing to ensure fully informed recommendations are developed that command the confidence of their organisations. They should also be able to supply the following specialist knowledge:

- CCG Executive with commissioning responsibility
- CCG Executive with finance responsibility
- Lay Members
- Pharmaceutical Advisor
- Specialist adviser in Public Health

Members are also responsible for communicating recommendations and any relevant issues back to their organisations in a timely manner.

6.2.2 The CCG Accountable Officer – is ultimately responsible for the prioritisation processes and adoption of policy within the CCG.

6.2.3 The CCG Lead for Innovation, Excellence & Research is responsible for the initial review and recommendations made by the Clinical Effectiveness Group to the Clinical Executive Committee concerning NICE guidelines and SHIP Priorities Committee recommendations.

6.2.4 The CCG Governing Body – the major role of the CCG Governing Body is to set the strategy of the CCG and to approve the commissioning intentions and plans. The details of such plans, and the decisions made with regard to the priorities set for those policies mentioned in this document, are the work of the Clinical Executive Committee. The Governing Body thus will act to check that the policies received from the Clinical Executive Committee are within the general strategy of the CCG and then to ratify them for adoption if appropriate.

6.2.5 The CCG Clinical Executive Committee and Clinical Effectiveness Group

- is accountable to the Governing Body, advises and implements strategy and policy, makes recommendations to the Governing Body across all the business of the CCG and develops a common approach to commissioning strategies. As such, the Clinical Executive Committee will receive the outputs of the initial review and recommendations made by the **Clinical Effectiveness Group (CEG)** with regard to SHIP Priorities Committee statements and NICE guidelines, with a view to approving the wording ready for the Governing Body to ratify at their next meeting. Any alterations agreed to the wording of recommendations should be accompanied with a full justification of the changes to be made, which might include additional evidence or legal advice to support it. The Clinical Executive Committee should also inform the Governing Body of those recommendations that it could not approve, again accompanied with justification. The CEG uses the monthly NICE Resource Planner and NICE Digest from NICE as a reference point for review by the CEG and for horizon scanning for future publications. The CEG also receives the results of audit and review at providers as to the application of restrictions on those treatments under the IFR/PLCV processes.

The Terms of Reference of the CEG are shown in **Appendix E**.

6.2.6 The CCG Audit and Governance Committee - oversees the work of the other committees of the CCG to seek assurance that the clinical, financial and corporate governance mechanisms are in place and working. As such, this should include the oversight of the effectiveness of the processes that support the prioritisation of commissioning decisions within the CCG and thus the work of the Clinical Executive Committee and Clinical Effectiveness Group.

6.3 Progressing the Outputs of the SHIP Priorities Committee, the IFR Process and NICE

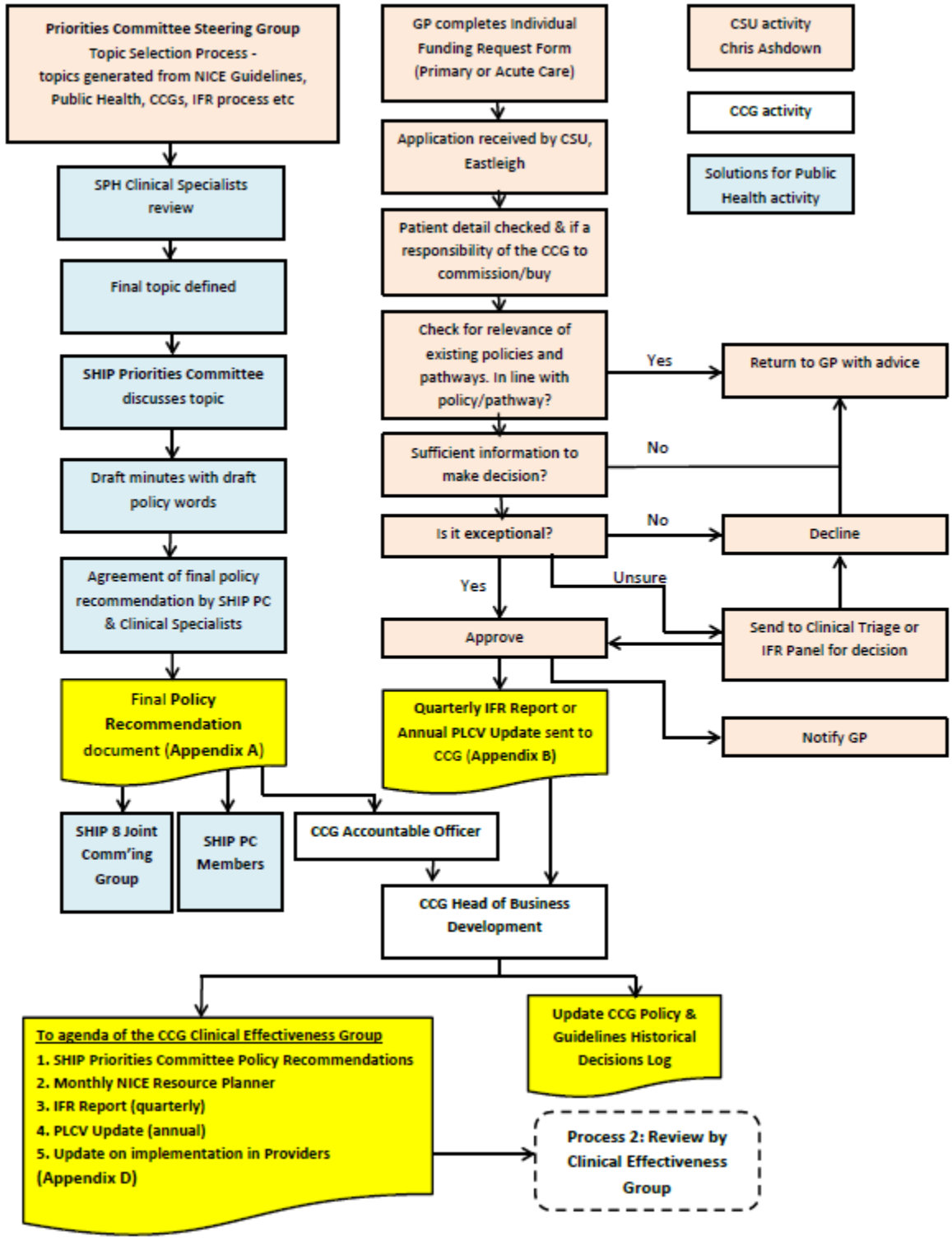
The process for progressing the outputs of SHIP Priorities Committee and IFR decisions is shown in **Process 1** below.

The process for progressing the outputs of NICE, SHIP Priorities Committee and IFR decisions to review by the CCG Clinical Effectiveness Group is shown in **Process 2**

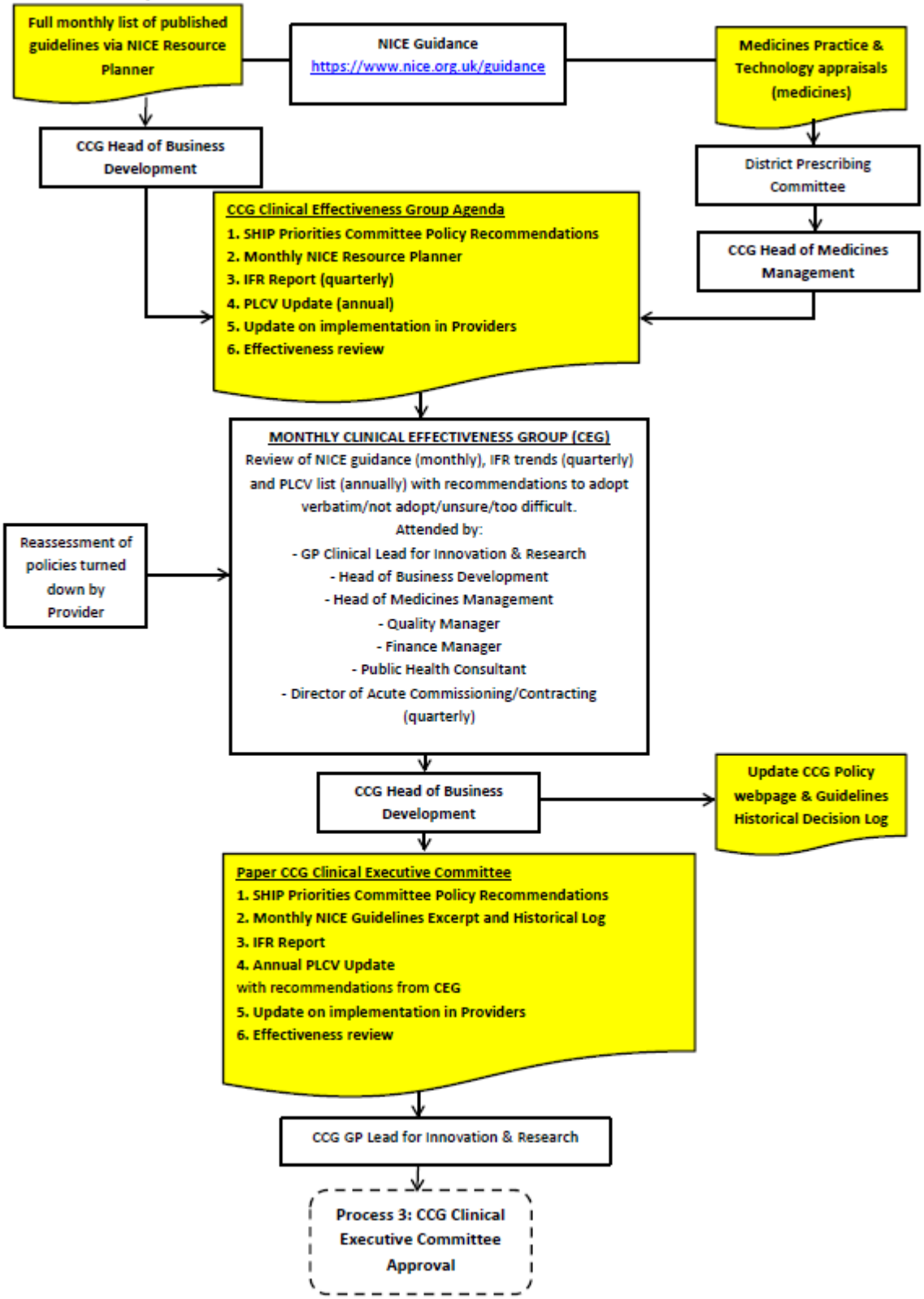
below.

The process for progressing the recommendations of the Clinical Effectiveness Group to the Clinical Executive Committee and CCG Governing Body are shown in **Process 3** below.

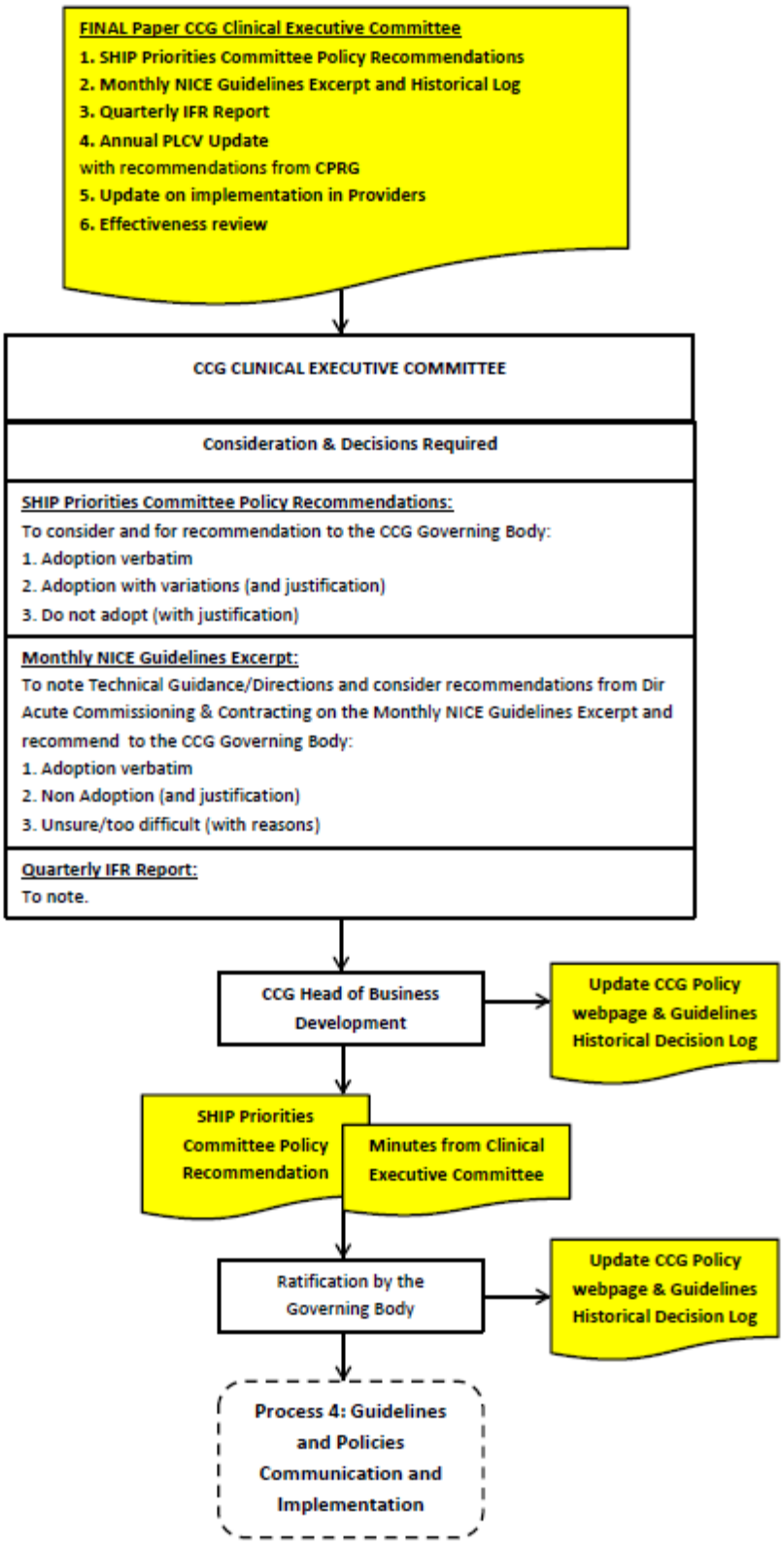
Process 1: SHIP Priorities Committee Policy Recommendations and Individual Funding Requests



Process 2: North Hampshire CCG NICE Guidelines/Instructions and SHIP Priority Recommendations Review by Clinical Effectiveness Group



Process 3: CCG Clinical Executive Committee Approval



7. Onward Communications

7.1 The minutes of each of the CCG committees mentioned above should record the full extent of the discussions with regard to the recommendation being considered, and these should be published in the normal way.

7.2 An indexed log should be kept by the CCG of all policies adopted and this should be published on the CCG's policy page of the public-facing website at:

http://www.northhampshireccg.nhs.uk/documents/

7.3 Notification to providers of the adoption of SHIP policy statements by the CCG is via the Head of IFRs, who acts to instruct CSU contract managers to notify providers of the new wording and the intention to vary the current contract via a Letter of Variation. It is then the responsibility of the provider contracts department to notify the individual clinicians responsible for the service. It is also best practice for the CCG to notify the provider in addition of the intention to adopt new or revised policy statements.

7.4 The CCG Clinical Bulletin is used to communicate those policies relevant to Primary Care implementation and those policies whose pathways are of interest to referring Primary Care physicians.

8. Implementation of NICE Guidance

8.1 The regulations surrounding the adoption of the different NIVE guidelines are discussed in Section 4.1 above. Provider contracts take account of a limited percentage – the NICE uplift - to meet the estimated costs of implementation in secondary care. The assumptions used to estimate the reserve involve a significant degree of financial risk. Moreover, this reserve is top-sliced from any growth monies at the beginning of the year. Thus, the cost of funding NICE recommendations has a direct impact upon the ability to fund competing priorities for service development. In light of the above factors it is essential that interventions approved by NICE are used only in accordance with the published criteria. The secondary care clinician should provide evidence that the criteria are met.

8.2 If published NICE guidance is likely to have significant resource implications for the local NHS, implementation may be delayed for a period of 3 months from the date of publication. This is to enable the necessary administrative arrangements to be put in place. However, the CCGs accept that delayed implementation may not be appropriate for rapidly progressive conditions where delay is likely to compromise the clinical outcome significantly.

The NICE reserve does not cover the costs of implementation of NICE guidance in primary care. The funding for this is included within the annual uplift to primary care prescribing budgets.

As per Department of Health guidance, the above does not preclude commissioners from funding health interventions that are not subject to finalised NICE guidance or are currently in the NICE process awaiting guidance. Appropriate procedures for consideration should still be taken.

8.3 Most Technical Guidance are new medicines and as such are managed by the District Prescribing Committees (DPCs) – see Section 9 below. Take up to the local formulary is tested by the CCG Medicines Management Team and any deviations are reported to the CEG.

8.4 Application of the restrictions and prior approval/threshold management processes

surrounding PLCV and TDP procedures/treatments are monitored by the frequency and type of applications made to the IFR Team and subsequently by review of clinical notes at the provider to test the adequacy of compliance with the policies. Any significant deviation from the expected results of review will be reported to the CEG and recommendations made as to remedial actions to the Clinical Executive Committee and thence taken up with the provider. Current capacity issues within the CCG again limit the number of clinical reviews that can be undertaken.

8.5 Currently, uptake and implementation of NICE guidance is reported at the Clinical Quality Review Meetings with providers but capacity issues limit the ability of the CCG to test uptake, the implementation of guidance and the effectiveness of the application of guidance within the patient population. Trusts must, however, aim to provide the best evidence as reasonably practicable as to the implementation and effectiveness of guidelines. It is the aspiration of the CCG to develop its' capability in this regard.

9. Managing Entry of New Medicines

Relevant District Prescribing Committees (DPCs) or Area Prescribing Committees (APCs) are responsible for considering whether new drugs and preparations are suitable for local use. The DPCs/APCs are joint bodies formed with members from provider and commissioners. The use of drugs not approved by DPCs/APCs is not generally supported.

If a referrer wishes to propose that a drug or preparation be considered for use by clinicians locally, a formal application should be made to the Chief Pharmacist. Additions to the formulary should represent a significant advance over current therapy. The application should be supported by any relevant published research evidence. The application forms can be found at the front of the Joint Formulary file.

There is no reserve to meet the costs of introducing new drugs (other than those approved by NICE) within the financial year. If a new drug is supported by the DPC/APC and agreed formally by the commissioners, the costs of its introduction will need to be met from existing resources. This applies equally whether the drug is prescribed within secondary care or in primary care. Where the costs cannot be absorbed, the addition of the drug to the Formulary may need to be deferred until resources allow. Cost pressures on the secondary care drugs budget are negotiated through the annual Operating Plan.

Appropriate drug therapy is commissioned as an integral part of patient care. Individual drugs should not be excluded from contracts as a separate cost item.

It is anticipated that a large number of new drugs either implemented following NICE guidance or the area Prescribing Committee arrangements will be commissioned by NHS England Specialised Services and not directly by CCGs.

10. Policy Monitoring

10.1 In addition to the Integrated Governance Committee, the effectiveness of this policy will be monitored by the Business Development team by checking to ensure the correct procedures have been followed. Any learning points and trends will be identified and recommendations made to the IGC. Any changes required will be made by the Business Development Manager. The application and impact of this policy will be monitored by the North Hampshire CCG Integrated Governance Committee.

11. Policy Review

11.1 The policy will be reviewed twelve months after first approval and thence every two

years or on request by the relevant committees.

12. Documents which have informed this policy

NHCCG's Commissioning Policy: Ethical Framework for priority setting and resource allocation

Department of Health Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislatio n /DH_4083088

Department of Health, The National Health Service Act 2006 (amended by NHS Health and Social Care Act 2012) , The National Health Service (Wales) Act 2006 and The National Health Service (Consequential Provisions) Act 2006
http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_06410 3

Department of Health, The NHS Constitution for England, July 2009,
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAn dGuidance/DH_093419

The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009
http://www.npc.co.uk/policy/resources/handbook_complete.pdf

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

Appendix A Terms of Reference for the SHIP Priorities Committee

SOUTHAMPTON, HAMPSHIRE, ISLE OF WIGHT AND PORTSMOUTH CCGs (SHIP) PRIORITIES COMMITTEE

TERMS OF REFERENCE

1. INTRODUCTION

1.1. The Priorities Committee operates as an advisory body to the eight Clinical Commissioning Groups [CCGs] across SHIP. Its role is to provide them with evidence based, carefully considered recommendations to inform the commissioning policies of the constituent CCGs.

2. FUNCTIONS OF THE PRIORITIES COMMITTEE

Aim

2.1. To make recommendations, using the agreed Ethical Framework and taking into account stakeholder views, to SHIP CCGs on the appropriateness of commissioning and funding of selected healthcare interventions (e.g. specific treatments, procedures and care pathways).

Objectives

- To receive and scope potential topics to be considered by the Committee
- To receive evidence appraisals and service reviews, as agreed by the Committee
- To take account of relevant expert and patient perspective
- To consider the information they receive, in accordance with the SHIP Ethical Framework
- To develop recommendations on commissioning policy, with regards to the topics presented to the Committee, to be then considered by the constituent CCGs
- To provide reports on advice issued and activity to commissioning organisations on a regular basis

3. MEMBERSHIP AND PROCESS

Roles and responsibilities of committee members

3.1. The overall role of all members is to actively contribute to the discussions and recommendations of the Committee. All members should have a named deputy of similar standing and expertise; all are expected to attend training relating to the Priorities Committee role, as required. Employed members should have this role included in their job description/ job plan. The Committee members are recruited as:

(a) Members representing NHS organisations. They should have sufficient authority and standing to ensure fully informed recommendations are developed that command the confidence of their organisations. These members are also

responsible for communicating recommendations and any relevant issues back to their organisations.

AND

(b) Members performing specialist advisory roles, due to their background or expertise in a particular area; for example clinical, public health, finance, contracting/IFRs, pharmaceutical

3.2. All members and observers attending a Priorities Committees will be asked to declare any conflict of interest to the Committee secretariat (annually) or to the Committee Chair, in a meeting.

Membership

3.3. The Priority Committee will draw its membership from the following sources:

- Independent Chair
- Up to two members per member CCG. These members will supply the following specialist knowledge:
    - CCG Executive with commissioning responsibility
    - CCG Executive with finance responsibility
    - Lay members
    - Pharmaceutical Advisor
    - Special adviser in Public Health
- Medical Director of an NHS provider organisation:
- Legal / ethics advisor
- Contracting/IFR Advisor

Chairing of Committee

3.4. The Priorities Committee will have an independent Chair and a named deputy Chair. The Chair will be agreed by the Chairs of the relevant CCGs and will have an agreed job description. The Deputy Chair will be a Priorities Committee member, elected by the Committee members.

Quoracy

3.5. The Priorities Committee meetings will be considered quorate if, as a minimum, the following members (or their deputies) are present:

- representation from at least six of the eight Clinical Commissioning Groups
- one Director of Commissioning **or** Director of Finance
- at least two GPs
- one Specialist in Public Health
- one lay member

3.6. A non-quorate meeting will not have power to take decisions, but may still make recommendations on topics discussed. Their "draft recommendations" will be circulated via e-mail to all Committee members, seeking a majority approval. If no consensus can be reached in this manner, then that item will be re-considered at the next quorate Priorities Committee meeting.

Decision-making

3.7. The Committee's recommendations are made by a consensus of voting members, at a quorate meeting. On occasions, a vote is taken; a simple majority decides. In the event of no majority, the Chair has the casting vote.

4. MEETING LOGISTICS

4.1. The Priorities Committee will meet bi-monthly, However, if it is clear in advance that a meeting will not be quorate, the meeting may be cancelled. Meeting location will usually be in Southampton.

4.2. The meetings will be managed and administered by the Priorities Committee secretariat, who are responsible for generating the agenda and sending out papers for each Priorities Committee meeting. The papers will be distributed to Committee members five working days in advance of each meeting. The Priorities Committee secretariat will also circulate papers to an agreed list of non-member recipients, for information.

4.3. The Chair has executive authority to finalise the agenda.

4.4. Minutes will be drafted by the Priorities Committee secretariat and reviewed by at least one Committee member who has been delegated this responsibility the Committee. Draft minutes will be circulated to and approved at the next quorate meeting.

4.5. The arrangements with, and functions of ,the Priorities Committee secretariat in supporting the work of the Priorities Committee are set out in a Service Level Agreement, agreed with the lead CCG on behalf of the SHIP CCGs.

5. GOVERNANCE AND RELATIONSHIP WITH COMMISSIONING ORGANISATIONS

5.1. The Committee's core function is to provide CCGs with evidence-based recommendations on commissioning priorities and policies, using the agreed SHIP Ethical Framework.

5.2. The CCGs fund the infrastructure and provide operational support to the Committee and are core members of the Priorities Committee.

5.3. Committee members who are representatives of commissioning or provider organisations are responsible for making decisions and recommendations at the Committee on behalf of their organisation and for reporting back, through appropriate routes, to their organisation.

5.4. CCG representatives are responsible for ensuring Committee commissioning recommendations are taken to appropriate decision-making groups for discussion and for formal adoption.

5.5. Reports on the operation and activity of the Priorities Committee should be taken to appropriate senior groups within each organisation at least annually. It is for each CCG to determine the group/committee which should receive reports from the Priorities Committee.

Appendix B Topic Selection for the SHIP Priorities Committee

TOPIC SELECTION FOR THE SHIP PRIORITIES COMMITTEE

1. INTRODUCTION

The SHIP 8 Joint Commissioning Group has responsibility for topic selection and these topics then go forward for scoping and the commission and receipt of evidence reviews via the SHIP Priorities Committee.

2. SOURCES OF TOPIC REQUESTS

Correct topic selection is key to ensuring appropriate stakeholder engagement into the priorities framework. Both providers and commissioners will have different reasons for requesting areas of healthcare technology to be reviewed and critically appraised. CCGs will require a point of reference for receiving topic requests and to ensure that all stakeholders are aware of the process involved.

It is expected that topics will come from the following sources:

- NHS Trusts
- CCGs
- Public health
- IFR process

3. TOPIC SELECTION

It is recommended that the SHIP8 will properly define the topics and the Priorities Committee would then decide the appropriate scope for review. This will have a direct effect on the level of analysis required and help commissioners in 'getting the question right'. Input from the selected provider of topic reviews will assist commissioners in scoping appropriately and that the outcome of any review in terms of a robust policy statement matches their needs. This means defining the review correctly is essential.

Follows is the topic selection proforma used by the previous PCT Priorities Committees which covered the old South Central SHA region and sets out the areas of priority using a balanced scorecard. This could be adapted or amended to reflect current purposes.

Topic/TRF Reference:
Date:
Decision: Refer to work programme: Yes/No
Scoping: Is additional scoping required? Yes/No (If yes, record the scoping agreed and the arrangements for this)

1. Population	**Score**
The larger the patient population (across south central), the more priority will be given for evaluation. Population: **Score 1-2:** 0 - 100 **Score 3-4:** 101 – 1000 **Score 5+** 1001+ NB Smaller populations will not automatically be excluded as they will still be judged on the remaining criteria Weight can also be given for issues relating to specific sub-groups of patients, either clinically defined or affected by issues of equality and diversity	
2. Disease Severity	
Higher priority will be given to conditions resulting in greater health impact (mortality, morbidity and quality of life). This criterion should take into account: life expectancy, state of health prior to and after treatment, how far the individual is away from perfect health and health states that incur social stigma. **Score 1** Minor quality of life (QoL) impact, no disability **Score 2** Definite QoL impact but no significant mortality **Score 3** QoL impact, some morbidity/disability or modest increase in mortality **Score 4** Intermediate mortality impact or significant disability or QoL impact on patient or carers **Score 5** Significant mortality risk or very severe impact on QoL, very significant morbidity, very significant impact on carers/parents/family, impaired ability to reach full potential	
3. Resource Impact	
Consideration of the potential resource impact of the topic, including cost of implementation and any additional service, facilities or staff required. **Score 1-2:** likely to be cost neutral	

Score 3-4: Moderate cost impact **Score 5:** Significant cost impact (either as a high cost or as potential for disinvestment)	
4. Claimed Therapeutic Benefit	
Consideration of the extent to which the technology is claimed to offer therapeutic benefit over the currently available options. **Score 1-2:** Little potential additional therapeutic benefit compared to existing care **Score 3-4:** Moderate potential additional benefit **Score 5:** Significant potential additional benefit	
5. Risk of not reviewing	
Consideration of the risk PCTs will be exposed to if they do not review the topic and agree a commissioning policy. **Score 1-2:** Low risk – no evidence that clinicians or patients are wishing to use this technology. **Score 3-4:** Moderate risk – low level of demand. Requested use by individual clinicians only, not supported by clinical consensus. Little evidence of demand by patients. **Score 5:** High risk – evidence of significant support from clinicians (eg business case submitted) and/or generating significant number of IFRs and/or showing 'technology creep' into routine practice etc. And/or evidence of variation in practice between providers or PCTs.	

4. ROLLING WORK PROGRAMME

In order to ensure there is a continuous review mechanism available as part of any effective commissioning cycle, it is important that the selection of appropriate topics is a standing item on the SHIP8 agenda and that a 'call for topics' is regularly circulated to all stakeholders which should include all acute and community trusts, local authority public health partners, and the Commissioning Support Unit.

In addition to this there should be a notification to all stakeholders of proposed topics that have been selected to allow for engagement in both the scoping and review process. It is suggested that these are channelled through the Commissioning Support Unit and discussed by the following working group on a virtual basis ahead of each SHIP8 meeting. This 'virtual working group' should comprise:

Chief Officer, Fareham & Gosport and Southeastern Hampshire CCGs
Clinical Chair, Fareham & Gosport CCG
Consultant in Public Health, Southampton City Council
Head of IFRs, South Commissioning Support Unit

A short paper will then be available at each SHIP8 meeting at which topics are proposed and agreed and these are then forwarded to the proposed provider of evidence reviews for discussion on scoping, stakeholder engagement and evidence review. The ‘question’ will be confirmed by the Priorities Committee at each of its meetings.

Appendix C The SHIP Priorities Committee Ethical Framework

SOUTHAMPTON, HAMPSHIRE, ISLE OF WIGHT AND PORTSMOUTH CLINICAL COMMISSIONING GROUPS

ETHICAL FRAMEWORK

1. BACKGROUND

1.1. The Priorities Committee is a committee of representatives of the following organisations:

- Fareham and Gosport CCG
- North East Hampshire and Farnham CCG
- North Hampshire CCG
- Portsmouth CCG
- Southampton City CCG
- South Eastern Hampshire CCG
- West Hampshire CCG
- Isle of Wight CCG

1.2. It includes the eight Clinical Commissioning Groups (CCGs) as well as lay members, clinicians and managers. The purpose of the Priorities Committee is to advise the member Clinical Commissioning Groups about the health care interventions and recommended commissioning policies that should be considered.

1.3. CCGs are under a statutory duty to promote the health of the local community. They are also under a duty not to exceed their annual financial allocation. These legal requirements mean that, from time to time, difficult choices have to be made. The Priorities Committee will help SHIP8 CCGs to choose how to allocate their resources to promote the health of the local community. Individual cases are considered by each respective PCT.

1.4. This Ethical Framework is based upon the South Central wide ethical framework, updated in September 2010, and its preceding versions. Its purpose is to support decision making process of the Priorities Committee and to offer a decision framework for constituent CCGs.

2. PURPOSE OF THE ETHICAL FRAMEWORK

2.1. The purpose of the ethical framework is to support and underpin the decision making processes of constituent organisations and their Priorities Committee to support consistent commissioning policy through:

- providing a coherent structure for discussion, ensuring all important aspects of each issue are considered;

- promoting fairness and consistency in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity;

- providing a means of expressing the reasons behind the decisions made;

- reducing risk of judicial review by implementation of robust decision-making processes that are based on evidence of clinical and cost effectiveness and an ethical framework;

- supporting and integrating with the development of CCG commissioning policies.

2.2. Formulating policy recommendations regarding health care priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and outwith the Committees. Although there is no objective or infallible measure by which such decisions can be based, the Ethical Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community. The Committee recognises that its discretion may be affected by national policy and by National Institute for Health and Clinical Excellence(NICE) guidance and Secretary of State Directions to the NHS.

2.3. The Ethical Framework is especially concerned with the following:

A: Evidence o**f Clinical and Cost Effectiveness**

2.4. The Committee will seek to obtain the best available evidence of clinical and cost effectiveness using robust and reproducible methods. Methods to assess clinical and cost effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of the Committees. Choice of appropriate clinically and patient-defined outcomes needs to be given careful consideration, and where possible quality of life measures and cost utility analysis should be considered.

2.5. The Committee will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment that is shown to be ineffective. Issues such as safety and drug licensing will also be carefully considered. When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients' health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other sources and this will also be considered. Patients' evidence of significant clinical benefit is relevant.

2.6. The Committee will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. They will consider technical cost-benefit calculations where these can be accessed (e.g. quality adjusted life years), but these will not by themselves be decisive. The Priorities Committee may use the ethical framework to guide context-specific judgements about the relative priority that should be given to each intervention.

B: Equity

2.7. The Committee believes that people should have access to health care on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community. However, the Committees will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, gender identity, race, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning. However, in some circumstances, these factors may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment.

C: Health Care Need and Capacity To Benefit

2.8. Health care should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. The Committee will consider the health needs of people and populations according to their capacity to benefit from health care interventions. So far as possible, it will respect the wishes of patients to choose between different clinically and cost effective treatment options, subject to the support of the clinical evidence.

2.9. This approach leads to three important principles:

- In the absence of evidence of health need, treatment will not generally be given solely because a patient requests it;
- A treatment of little benefit will not be provided simply because it is the only treatment available;
- Treatment which effectively treats “life time” or long term chronic conditions will be considered equally to urgent and life prolonging treatments.

D: Cost Of Treatment and Opportunity Costs.

2.10. Because each CCG is duty-bound not to exceed its budget, the cost of treatment must be considered. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other uses. This is known as opportunity costs and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way. The concept derives from the notion of scarcity of resources. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high.

E. Needs of the Community

2.11. Public health is an important concern of the Committee and it will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE). Others are produced locally. The Committee also supports effective policies to promote preventive medicine which help stop people becoming ill in the first place.

2.12. Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient’s condition, or to stop, or slow the progression of disease. Where it has been decided that a treatment has a relatively low priority and cannot generally be supported, a patient’s doctor may still seek to

persuade the CCG that there are exceptional circumstances which mean that the patient should receive the treatment.

3. POLICY DRIVERS

3.1. The Department of Health issues guidance and directions to NHS organisations, including the NHS Constitution and NHS Mandate, which may give priority to some categories of patient, or require treatment to be made available within a given period. These may affect the way in which health service resources are allocated by individual CCGs. The Committee will operate with these factors in mind and recognise that its discretion may be affected by national policy, NICE publications, Secretary of State Directions to the NHS and performance and planning guidance.

3.2. Locally, choices about the funding of health care treatments will be informed by the needs of each individual CCG.

4. EXCEPTIONAL NEED

4.1. There will be no blanket bans on treatment since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Each case of this sort will be considered on its own merits in light of the clinical evidence. CCGs have procedures in place to consider such exceptional cases on their merits.

Date of Issue:	**16 July 2014**

Appendix D Glossary

TERM	DEFINITION
Budgetary impact	*Budgetary impact* is the total cost to NHCCG of providing a treatment or service. The greater the budgetary impact, the greater the opportunity cost.
Exceptional	*Exceptional* means out of the ordinary, unusual or special.
Experimental and unproven treatments	*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. The reasons may include the following: • 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 whether the claims made for a treatment can be justified.
Healthcare intervention	A *healthcare intervention* means any form of healthcare treatment which is applied to meet a healthcare need.
NHS commissioned care	*NHS commissioned care* is healthcare which is routinely funded by the patient's responsible Clinical Commissioning Group (CCG) or by the NHS Commissioning Board (NHSCB). Both CCGs and the NHSCB have policies which define the elements of healthcare which each CCG and the NHSCB is and is not prepared to commission for defined groups of patients.
NHS Directions	*NHS Directions* are instructions issued by the Secretary of State who has powers under NHS primary legislation to give directions to all NHS bodies (other than NHS Foundation Trusts) including NHCCG which place a legal requirement on NHS bodies to act in accordance with the Direction.

NICE's Technology Appraisals	*NICE* publish a specific form of Guidance termed *Technology Appraisals*. This Guidance is covered by NHS Directions issued in 2003. The Directions provide that primary care trusts shall make funding available to patients who meet the criteria set out in the Guidance. This funding should be made available within three months from the date that the Technology Appraisal Guidance has been issued unless an extension has been authorised by the Secretary of State.
NICE's Clinical Guidelines	*NICE's Clinical Guidelines* are a form of NHS Guidance. They are not covered by NHS Directions.
NICE's Guidance on Interventional Procedures	*NICE's Guidance on Interventional Procedures* are a form of NHS Guidance. They aim to provide information about the safety of new interventional procedures. They are not covered by NHS Directions.
NICE Guidance on Medical Technologies	*NICE's Guidance on Medical Technologies* is a form of NHS Guidance. They aim to provide information about the cost benefits of specific medical technologies. They are not covered by NHS Directions.
Non- Statutory Guidance	*Non-Statutory Guidance* is written Guidance which is issued by any public or private body other than the Secretary of State or a body authorised by the Secretary of State (or by another directly relevant part of government). NHS bodies are not required to have regard to non-statutory guidance in their decision-making but are entitled to do so.
Statutory Guidance	*Statutory Guidance* is written guidance issued by the Secretary of State or a body authorised by the Secretary of State (or by another directly relevant part of government). NHS bodies are required to have regard to statutory guidance in their decision-making. Statutory Guidance is intended to assist public authorities in the exercise of their statutory duties. It suggests steps which might be taken; factors which could be taken into account and procedures which could be followed to deliver specified steps of administration, or policy delivery. NHS bodies are entitled to depart from statutory guidance if they have a good reason to do so. However: • the NHS body should always record that it has considered the statutory guidance as part of its decision making processes, and • the NHS body should always record the reason or reasons why it has departed from the course of action recommended in the Guidance.

Appendix E ToR Clinical Effectiveness Group

TERMS OF REFERENCE FOR THE CLINICAL EFFECTIVENESS GROUP

1.0 INTRODUCTION

1.1 The CCG has an obligation to implement Technical Appraisal Guidance (TAG) and consider all guidance and advice issued by National Institute for Health and Care Excellence (NICE), which is the independent organisation responsible for providing national guidance and quality standards on the promotion of good health and the prevention and treatment of ill health. This would include:

NICE Guidance	**NICE Advice**
Cancer Service Guidelines (CSG)	Evidence summary: Medicines Prescribing Briefings (ESMPB)
Clinical Guidelines (CG)	Evidence summary: New Medicine (ESNM)
Medicines Practice Guidelines (MPG)	Evidence summary: Unlicensed/off label medicine (ESU)
Diagnostics Guidance (DG)	Key Therapeutic Topic (KTT)
Highly Specialised Technologies (HST)	
Interventional Procedure Guidance (IPG)	
Medical Technology Guidance (MTG)	Medtech Innovation Briefing (MIB)
Quality Standards (QS)	
Technology Appraisal Guidance (TAG)	

1.2 The 2010 NHS Constitution states that patients "have the right to drugs and treatments that have been recommended by NICE Technology Appraisal for use in the NHS, if their doctor says they are clinically appropriate". Regulations under The Health and Social Care Act 2012 are in force, stating that Clinical Commissioning Groups have a statutory duty to provide funding for NICE Technology Appraisals (TAGs) not later than three months from the date of publication.

1.3 NICE guidance is based upon the best available clinical evidence on what works and is cost effective evidence. There is an expectation that health professionals will take national guidance fully into account as part of their clinical practice, it is intended to support clinician's skill and knowledge.

1.4 With the exception of TAGs, the CCG also has a responsibility for reviewing all the guidance being issued and deciding which are appropriate to be adopted and to what extent, and subsequently to ensure that commissioned services are complying with these decisions so that the CCG can:

- ensure patients and service users receive the best and most appropriate treatment
- ensure the NHS resources are used to provide the most clinically and cost effective treatment
- ensure equity through consistent application of NICE guidance

1.4 CCGs are also required to monitor the uptake and implementation of the specified guidelines by providers and for providers to demonstrate the effectiveness of the guidelines implemented.

2.0 PURPOSE AND RESPONSIBILITIES

2.1 The CCG Clinical Effectiveness Group (CEG) is a sub-committee of the Clinical Executive Committee, and as such has no powers or authority apart from those delegated to it by the Clinical Executive Committee (CEC).

2.2 The purpose of the CEG is to alert the Clinical Executive Committee to new TAGs as they are communicated by NICE, to review and make recommendations to the CEC as to the adoption of NICE guidelines and SHIP policy recommendations, to monitor the uptake and implementation of TAGs/SHIP policies by providers within 3 months and to monitor the effectiveness of TAGs and SHIP policies within providers.

2.2 Therefore, the specific responsibilities of the CEG is to:

i. receive SHIP Priorities Committee Policy Recommendations ('recommendations') and monthly NICE guidelines ('guidelines') excerpts in order to review and make recommendations to the CEC for individual polices/guidelines to be adopted verbatim, to be adopted with justifiable changes or not to be adopted by the CCG or by its commissioned providers

ii. to receive reports on the potential impact (positive and negative) of new guidance issued or to be issued in the future, which might include:

Anticipated impact:	**Review undertaken by:**
Clinical effectiveness	CCG Quality Team
Equality	
Quality	
Local health needs and the capacity of the local population to benefit	HCC Public Health
Impact of national policy drivers	CCG Commissioning Team
Service delivery impacts (direct or to other linked services)	
Cost effectiveness and opportunity costs	CCG Finance Team

Source: SHIP Priorities Committee Ethical Decision Making Framework

so as to evaluate potential resource requirements for implementation plans of NICE guidance for the local health needs to assess what, if any, additional funding may required

iii. to detail all activities for the forthcoming year based on the forward planning estimate(s) of costs for implementing technology appraisals and the future resource requirements for clinical guidelines and public health guidance

iv. receive monitoring reports as to the uptake of recommendations/guidelines by providers and make recommendations and any remedial action required of them with regard to timeliness of uptake or deviations from agreed business cases

v. receive reports as to the effectiveness of recommendations and guidelines as adopted by providers

vi. receive annually the Procedures of Limited Clinical Value (PLCV) Report from our Commissioning Support Unit (CSU) and to make recommendations to the CEC as to which procedures should appear on the PLCV list and the criteria by which they are applied in practice

vii. receive quarterly the Individual Funding Request (IFR) Report and make recommendations to the CEC as to the appropriate management of the arrangements for applying restrictions and the monitoring of outcomes

viii. to maintain a database of all NICE guidance issued and a log of decisions made by the CCG with regard to each aspect of guidance

ix. furnish the CEC with supporting papers and briefings as required to support the purpose of the CEG, that includes:
    - papers in support of 2.2i above
    - papers in support of 2.2vi above
    - summary notes and actions of meetings

4 MEMBERSHIP, QUORUM AND ATTENDANCE

4.1 The CEG will comprise of the following:

- GP Clinical Lead for Innovation and Research (Chair)
- Head of Medicines Management (Deputy Chair)
- GP Lead for Medicines
- Head of Business Development
- Quality Manager
- Deputy Chief Finance Officer
- Public Health Consultant/Specialist
- Director of Acute Commissioning and Contracting

(Members should make arrangements for a deputy to attend if they are unable to attend themselves).

4.2 The Committee will be chaired by the GP Lead for Innovation and Research.

4.3 The CEG has the power to invite others to attend (including other CCG employees, members of the CEC ie GP members and/or the CSU) when it believes this would provide it with relevant and necessary expertise and experience that otherwise would not be available to it. There is also the opportunity for the CEG to use the expertise of the CCG clinical leadership in the review of any guideline or policy on a virtual basis.

4.4 The quorum of the group will comprise the Chair (or Deputy Chair) and two further members of the Group.

5 FREQUENCY

5.1 Meetings shall be held on a monthly (except for August when there will be no meeting) basis and in time for papers to be produced for the CEC.

5.2 Additional meetings may be called by the Committee Chair if required.

6 MANAGEMENT

6.1 Decisions with regard to the recommendations it makes will be made on the basis of consensus. The group itself has no decision making authority bestowed upon it.

6.2 The agenda and papers for the meeting will be produced by the Business Development function of the CCG at least five days prior to each meeting. The agenda will be agreed with the Chair prior to papers being circulated.

6.3 Summary notes and actions will be circulated within seven days after the meeting and the final version sent to the CEC administrator.

7 REPORTING, COMMUNICATIONS AND INVOLVEMENT

7.1 The summary notes and actions will be signed as final by the Chair and sent to the administrator of the CEC for inclusion in a regular CEC agenda item called 'Recommendations from the Clinical Effectiveness Group'.

7.2 Reporting to the CCG Governing Body will be via the minutes of the CEC. Any specific questions asked of the CEG will be answered separately.

7.3 Where risks are highlighted, they will be reported via the Quality Committee Risk Register by the Quality Manager.

7.4 Involvement of interested parties, such as local patients, public and clinicians will be considered as appropriate and engaged/consulted with through the normal CCG routes when required.

7.5 Communications with provider organisations with regard to decisions on recommendations and/or guidance will be via the Chair and supported by the Head of Individual Funding Requests at the CSU.

8 CONFLICTS OF INTEREST AND DUTY OF CANDOUR

8.1 The CCG's rules on conflicts of interest as set out in the CCG Constitution, Standing Orders and Codes of Financial Procedures, and the CCG's Business Conduct and Management of Conflicts of Interest Policy, apply to the work of this Committee.

8.2 Committee members shall act in accordance with the recommendations of the Francis report, particularly with regard to the duty of candour in whichever way it may apply to the Committee, whether directly or indirectly through its role as a committee of the CCG.

9 EQUALITY AND DIVERSITY

9.1 The CEG will also, as part of its horizon scanning role, ensure that it is regularly updated on NICE's Equality Objectives and Equality Programme, currently set out at: http://www.nice.org.uk/media/F94/B5/NICEsEqualityObjectivesEqualityProgramme2 013-2016.pdf

and NICE's Equality Scheme, currently set out at:

http://www.nice.org.uk/aboutnice/howwework/niceequalityscheme.jsp

and will consider how this may influence the local implementation of NICE Guidance.

10 ADMINISTRATION

10.1 Administrative support to the Committee will be provided by the Business Development function of the CCG.

11. REVIEW

11.1 These Terms of Reference will be reviewed at least annually.

Date Approved:
Date ratified by:
Date for Review:
Reviewed:
Date Revision Approved: