



Methods: National Clinical Policies

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Methods: National Clinical Policies

Methods of development and approval of national clinical policies for directly commissioned specialised services

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Equality and Health Inequalities statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Introduction

National clinical commissioning policies are initiated during the Clinical build phase of policy development, where a topic is proposed, an evidence review commissioned and completed and Clinical Panel confirm whether the policy proposition reflects the evidence review produced. The second phase is the 'Impact Analysis' managed by the National Programme of Care and concludes through a Gateway at the National Programme of Care Board. The third and final stage is the 'Decision' through the Clinical Priorities Advisory Group, Specialised Commissioning Oversight Group, and Specialised Commissioning Committee.

A. CLINICAL BUILD

The **clinical build** is the first of three phases to form a national clinical commissioning policy for a directly commissioned specialised service. It is coordinated and managed by the Clinical Effectiveness Team and concludes through a Gateway managed by the Clinical Panel.

Step A1. Propose Policy Clinical Lead. A clinician who undertakes to take the proposal through each step will lead each clinical commissioning policy development.

A1.1. All clinical policy proposals will have a clinical lead. For most proposals this is the Chair or Clinical Member of a Clinical Reference Group. A clinical lead may also be identified outside of the CRG membership. The clinical lead should have detailed clinical understanding of the policy proposal and must not have a conflict of interest associated with the technology.

A1.2. Patient organisations, Royal Colleges, the industry and other organisations can initiate the formation of clinical policy proposal but they have to identify a clinical lead to make the proposal.

A1.3. Some clinical policies proposals will be initiated by NHS England either to introduce new interventions or to decommission existing interventions. In circumstances where an appropriate clinician cannot be identified who is willing to lead the proposal development a public health consultant or NHS England employed clinician will be identified as the Policy Clinical Lead. In addition the Public Health network may lead policies of a wider public health benefit.

A1.4. The proposal is submitted using the Policy Clinical Lead Proposal Form to an on line form the link to which is received by contacting the email england.CET@nhs.net. The Clinical Effectiveness Team confirms receipt of the Policy Clinical Lead Proposal Form.

Step A2. The Clinical Reference Group Endorses the Clinical Lead. The relevant Clinical Reference Group endorses that the nominated Policy Clinical Lead has the support of peers to lead the development of a proposal.

Choose an item.

- A2.1. The Clinical Effectiveness Team contacts the relevant CRG Chair by email with the Policy Clinical Lead Proposal Form.
 - A2.2. The CRG Chair confirms the CRG support for the Policy Clinical Lead having discussed with the CRG members. A confirming email is sent to the Clinical Effectiveness Team.
 - A2.3. Where a lead is nominated by NHS England the CRG membership are informed and are asked to provide assistance in building clinical involvement in the Policy Working Group.
 - A2.4. The Clinical Effectiveness Team confirms with the clinician the Policy Clinical Lead supplying the on line Preliminary Policy Proposal form link, a guide for completing the form and a Policy Proposal Reference number.
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Step A3. Production of Preliminary Policy Proposal. The Policy Clinical Lead forms the Preliminary Policy Proposal (PPP) and submits to the Clinical Effectiveness Team via the on line submission.

- A3.1. The Policy Clinical Lead completes the Preliminary Policy Proposal Form. This is likely to take some time depending in the complexity of the issue, the lead may need to secure other assistance to complete all elements of the proposal.
 - A3.2. The Policy Clinical Lead shares and agrees the final Preliminary Policy Proposal Form with the CRG Chair. The CRG Chair can give chair's action to agree but ideally should secure support from the full CRG.
 - A3.3. The Policy Clinical Lead submits the Preliminary Policy Proposal form to the Clinical Effectiveness Team to the on line submission.
 - A3.4. The Clinical Effectiveness Team confirms receipt of the PPP.
-

Step A4. The NHS England Clinical Panel Reviews the Preliminary Policy Proposal. The clinical panel (with the National Programme of Care Senior Managers) confirms that the policy proceeds into the work plan on the basis of core qualifying criteria and determines the required methodology for a fully independent evidence review proportional to the complexity of the proposal.

- A4.1. The Head of Clinical Effectiveness submits the PPP to the next available Clinical Panel having confirmed that:
 - The proposal is for a specialised commissioned service AND;
 - NICE is not undertaking an appraisal in the TA or HST programme AND;
 - The intervention is not included in tariff.
- A4.2. The Clinical Panel confirms that the policy proceeds into the work plan. The Clinical Panel can exclude a preliminary policy proposal in the following circumstances:

Choose an item.

- The Preliminary Policy Proposal has failed to identify any qualifying evidence of the intervention benefit;
- The clinical utility of implementing the intervention through national clinical policy is not well defined.

A4.3. The Clinical Panel determines the required methodology for evidence review:

- Very small number of publications and top 3 selected publications clearly define efficacy (or lack of efficacy). The clinical panel can state there is no need for a further clinical evidence review.
- Small number of relevant publications (circa 30 or less), high complexity, small population. The clinical panel can offer a grant for a postgraduate student (or public health trainee) to undertake the evidence review under the guidance of a representative from the Public Health England network. The individual must have completed a training package in the method of systematic evidence review.
- The intervention is a licenced drug. The Clinical Panel can refer the proposal to NICE for consideration in the NICE-CSD programme.
- The intervention is a device. The Clinical Panel can refer the proposal to NICE for a Medical Innovation Briefing (MIB).
- Clinical urgency. The Clinical Panel can refer the proposal to NICE for a Rapid Evidence Review (RER) via the Evidence Summary: unlicensed or off-label medicines team.
- Larger number of relevant publications and/or larger populations. The Clinical Panel recommends an NHS England funded independent evidence review and prioritise subject to available resources.

A4.4. The Clinical Panel defines the clinical urgency of the requirement of the policy by reviewing the clinical problem and the degree to which the intervention meets clinical need and the number and outcomes of IFR and CCU applications (The CET will provide information on IFR and CCU activity relevant to the policy proposal):

- Inclusion in annual work programme for relative prioritisation for most proposals except those with high clinical urgency.
- Inclusion in annual work programme for In Year Service Development for proposals of high clinical urgency.
- The need to form an immediate Policy Statement for proposals of Clinically Critical Urgency (and inclusion for an In Year Service Development). The Clinical Panel is likely to have recommended a NICE Rapid Evidence Review as above.

Step A5. Evidence Review Commissioned. The NHS England Clinical Effectiveness team commissions an evidence review guided by the Preliminary Policy Proposal.

Choose an item.

- A5.1. The Clinical Effectiveness Team (CET) identifies a lead public health consultant to form the Population Intervention Comparison Outcomes (PICO) framework for the commissioning of the evidence review. This is built from the information in the PPP and is tested with the clinical lead and as many members of the Policy Working Group who are available.
 - A5.2. The CET coordinates the evidence review as defined by Step 4.
 - A5.3. The CET establishes communication between the evidence review team and the Policy Clinical Lead to clarify elements of the evidence review.
 - A5.4. The CET receives the evidence review, assures the quality and prepares the document for future publication.
 - A5.5. While the evidence review is underway the meeting dates for the Policy Working Group are defined to receive the evidence review and build the policy proposition.
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Step A6. Policy Proposal Formed. Working with a Policy Working Group the Policy Clinical Lead forms a Policy Proposition built from the evidence base.

- A6.1. The Policy Clinical Lead establishes the Policy Working Group (PWG) to include a lead from the Public Health Network and a commissioner from the relevant Programme of Care.
 - A6.2. All members of the PWG are asked to complete an on-line learning package providing training on the fundamentals of evidence review, interpretation, and clinical policy formation.
 - A6.3. On receipt of the Evidence Review from the CET the PWG proceeds to form a Policy Proposition.
 - A6.4. The Policy Clinical Lead secures consensus agreement to the Policy Proposition from members of the PWG. The Policy Clinical Lead shares and agrees the final Policy Proposal with the CRG Chair. The CRG Chair can give chair's action to agree but ideally should secure support from the full CRG.
 - A6.5. The Policy Working Group, when forming the policy proposition, should consider whether the intervention requires prior approval via a web based access system. If the PWG agree such approval is required this should be included in the audit requirements section of the policy.
 - A6.6. The Head of Clinical Effectiveness submits the Evidence Summary and the Policy Proposition to the next available clinical panel.
-

Step A7. CLINICAL PANEL. The clinical panel tests whether the Policy Proposition is built on the Clinical Evidence and whether the policy proceeds into the impact analysis phase as either a 'routine' or 'no-routine' commissioning proposal.

Choose an item.

A7.1. The Clinical Panel receives the original Preliminary Policy Proposal, the Evidence Summary, and the Policy Proposition.

A7.2. The Clinical Panel determines:

- Whether the population is adequately defined.
- Whether any subpopulations are adequately defined.
- That the Policy Proposition is built on the evidence base as defined in the evidence summary.
- That the evidence presented is supportive of a 'Routine Commissioning' policy.

A7.3. If the Clinical Panel supports the Policy Proposition the CET passes the Proposition to the relevant Programme of Care to move to the second 'Impact Analysis' phase.

A7.4. If the Clinical Panel does not support the Policy Proposition, the Policy Clinical Lead receives written report of the clinical panel; the Clinical Lead reports back to CRG chair with a proposal that either a) the CRG needs to work up the proposal further before re-submission to clinical panel or b) CRG has demonstrably valid grounds for disputing the findings of the clinical panel. CRG Chair to decide on preferred course of action, and may need to discuss with CRG members first. The panel chair or delegate, will be available to informally give feedback / discuss should this be needed, but it must be for CRG chair to formally confirm next steps.

B. IMPACT ANALYSIS

The **impact analysis** is the second of three phases to form a national clinical commissioning policy. It is coordinated and managed by the National Programme of Care and concludes through a Gateway managed by the National Programme of Care Board..

Step B1. Receive Papers from the Clinical Effectiveness Team. There is a formal handover of the work in Phase I completed by the Clinical Effectiveness Team to the National Programme of Care Senior Team.

B1.1. The Clinical Effectiveness Team compiles the documents for handover: The initial Preliminary Policy Proposal; the Clinical Evidence Review; (including the PICO provided to the reviewer of the Evidence; the Search Criteria supporting the Evidence Review; the literature search publication list; the Evidence Summary), the Clinical Panel Report; the Policy Proposition.

Step B2. Stakeholder Testing. The National Programme of Care confirms the stakeholders have been identified and tests the work completed by the Policy Working Group.

B2.1. The Policy Working Group (PWG) prepares to test the Policy Proposition with stakeholders, including those who have already registered as having an interest in the work of the host CRG.

B2.2. The PWG considers any additional stakeholders who they would wish to contribute their views at this stage, forwarding details to the communications team.

B2.3. The draft Policy Proposition is sent out to the complete list of stakeholders (with evidence review related documentation, if one has been undertaken), together with a response form.

B2.4. If the stakeholder testing raises the issue that the evidence review undertaken did not evaluate the full evidence base the NPoC Public Health Lead will review whether the omission is material. If they determine this is the case the policy process will be returned to Phase I step 5 handed back to the Clinical Effectiveness Team.

B2.5. The PWG considers, particularly for more contentious topics, whether a formal stakeholder event should be arranged to supplement testing by email. Otherwise responses are received solely via a generic email, and acknowledged. Collated responses are sent to the Lead Commissioner.

B2.6. The PWG reviews responses, and updates the Policy Proposition as appropriate based on the feedback received.

B2.7. An Engagement Report is completed.

Step B3. Completion of Impact Analysis Reports. An Impact Assessment is completed with advice from a finance specialist. Key assumptions are debated and captured within a supporting spreadsheet. The NPoC Senior Manager establishes the work programme to complete the impact analyses.

B3.1. The Lead Commissioner confirms to the National Programme of Care Senior Manager (NPoCSM) that stakeholder testing is complete and receives their agreement to proceed to impact assessment.

B3.2. The Impact Assessment is undertaken, identifying the impact of moving from current pathways of care to the one(s) proposed in the draft Policy Proposition. A supporting spreadsheet is produced to capture workings and assumptions.

B3.3. Impact is modelled over 5 years, or by exception over 10 years. (for example if significant demographic changes are expected over an extended period)

B3.4. The NPoC Senior Manager with the NPoC Finance Lead identifies the finance support to complete the finance impact report.

Step B4. The NPOC Board Receives the Combined Impact Analysis Report.

The Board receives the draft policy proposition and supporting documentation and considers its readiness for consultation. If approved, the Board determines an appropriate length of time for the public consultation to run.

B4.1. The NPoC Senior Manager with the lead commissioner supporting the policy working group submits to the NPoC Board:

- The policy proposition;
- The combined impact analysis report;
- The engagement report;
- The CPAG coversheet (with patient benefits sections completed);
- The clinical evidence review;
- The fact sheet.

B4.2. The NPoC Board approves the impact analysis report (or returns for further work) and determines the length and scope of the public consultation.

Step B5. Public Consultation. The public consultation is undertaken, and responses collated for subsequent consideration by the PWG. Changes are made as appropriate on the basis of the feedback received and a Consultation Report is produced.

B5.1. Documentation is prepared for consultation, any amendments required by the PoC Board being actioned.

B5.2. The following documents are prepared to be included in the consultation:

Choose an item.

- Policy Proposal
- Clinical evidence review
- Engagement report
- Clinical Panel report
- Integrated Impact assessment
- CPAG Cover Sheet (Benefits)

B5.3. At the end of the consultation period, the collated consultation responses, are then forwarded to the Lead Commissioner. The PWG meets to consider consultation responses and amends the Policy Proposition and Impact Assessment as appropriate taking into account consultation responses. A Consultation Report is produced.

B5.4. Should the Policy Proposal be put on hold at this stage, a Pause Report is completed.

B5.5. An Equality Impact Assessment is completed.

Step B6. National Programme of Care. The National Programme of Care approves the policy documents as complete, that effective patient and public engagement has been undertaken, and the finance impact of the proposition is fully defined.

B6.1. The NPoC Senior Manager takes the policy proposition with the consultation report to the National Programme of Care.

B6.2. The NPoC Board determines whether the consultation has determined that the evidence review undertaken did not evaluate the full evidence base. The NPoC Public Health Lead will review and provide advice whether the omission is material. If the NPoC Board determines this is the case the policy process will be returned to the Clinical Effectiveness Team for resolution.

B6.3. The NPoC Board determines whether the consultation materially affects the impact analysis report or the policy proposition. Amendments are made and either approved by a return to the Board or by Chair's action.

B6.4. For policies developed with HSS involvement, the HSS team will submit the policy proposition to the Rare Diseases Advisory Group to consider for endorsement prior to step B7. This is an additional Gateway step for policies developed with HSS involvement.

Step B7. Handover to Clinical Effectiveness Team. The suite of papers are handed to the Clinical Effectiveness Team for submission to CPAG.

B7.1. The NPoC Senior Manager hands the documents back to the Head of Clinical Effectiveness. These include:

- The final policy proposition
- The engagement report
- The consultation report
- The impact analysis report
- The equality impact and assessment report

Choose an item.

- The finance model spreadsheet
- The evidence report completed by Public health
- Any comment that the NPoC Board would want CPAG to be aware of during the decision making phase.

B7.2. The NPoC Senior Manager undertakes or commissions the work to form the commissioning implementation plan, which will accompany the CPAG report to SCOG.

C. DECISION

The **DECISION** is the final stage of three phases to form a national clinical commissioning policy. It is coordinated and managed by the Clinical Effectiveness Team (CET) and concludes with the publication of the policy. There are three Gateways within this phase: Clinical Priorities Advisory Group (CPAG); Specialised Commissioning Oversight Group (SCOG); Specialised Services Commissioning Committee (SCC).

Step C1. Clinical Effectiveness Team Receives the Papers from the National Programme of Care. On completion of Phase B by the National Programme of Care Senior (NPOC) Team there is a formal handover of key documents to the Clinical Effectiveness Team (CET) to enable them to support the process of proposals reaching key governance committees.

C1.1. Phase A will have provided the CET with: The initial Preliminary Policy Proposal; the Population, Intervention, Comparators and Outcomes (PICO) provided to the reviewer of the Clinical Evidence by the Policy working Group); the Search Criteria supporting the Clinical Evidence Review; the Clinical Evidence Review (including the search strategy and literature list); the Clinical Evidence Summary; the Fact Sheet, the patient benefits section of the CPAG cover sheet, and the Clinical Panel Report.

C1.2. The Phase B handed over will include in addition: the revised final Policy Proposition; the integrated Impact Analysis Report, Finance Spreadsheet, the Engagement Report (which includes the membership list of the Policy Working Group and list of registered Stakeholders), the Consultation Report, the Equality Report, and a Public Health Lead Report (should there have been any challenges to the Clinical Evidence Review during stakeholder testing or consultation).

Step C2. Editorial Checking and Preparation. The CET checks the final policy proposition for, consistency, accuracy and to ensure that it is written in plain language. They prepare two packs of papers: a library pack (see 2.3); and an evaluation pack (see 2.4). A Summary Report is populated in preparation for the CPAG.

C2.1. An editorial staff member reviews each policy proposition and corrects formatting, language, ensures consistency and cross checks statements to ensure accuracy. The Head of Clinical Effectiveness approves the final document.

C2.2. A CPAG Summary Report is compiled and approved by the Head of Clinical Effectiveness to include; the key facts from the evidence review (including the key health metrics from the evidence review and patient benefits), the quality of evidence, service impact information that the NPOC determine needs to be considered by

CPAG. The summary report includes a section (Part II) containing the finance report with information including: budget impact and the net cost per patient over 5 years (calculated as cost to NHS England over 5 years divided by the number of patients receiving treatment over 5 years). The NHS England specialised commissioning finance team approves the cost per patient information, budget impact and also identifies and considers areas of uncertainty.

C2.3. The **library pack** is compiled to include:

- The Provisional Policy Proposal
- PICO provided to the reviewer of the Clinical Evidence, which includes the search criteria and the literature search publication list
- Clinical Evidence Review
- Integrated Impact Analysis Report
- Finance Spreadsheet
- Engagement Report
- Consultation Report (full)

C2.4. The **evaluation pack** is compiled to include:

- Summary Report Part I (evidence and service impact)
- Summary Report Part II (finance)
- Clinical Evidence Summary
- Fact Sheet
- Clinical Panel Report
- Consultation Report
- Public Health Lead Report
- Equality Report
- Final Policy Proposition

Step C3. Clinical Priorities Advisory Group

In Year Service Developments (IYSDs). The members of CPAG receive the evaluation pack including Summary Report II. CPAG then considers the clinical patient benefit and financial impact that would be delivered through implementation of the policy. CPAG will make a commissioning recommendation for approval by SCOG. For clinical policies to be considered through the IYSD route they would have to satisfy the factors stated in the IYSD policy (see In Year Service Development Policy).

Appraisal of Cost/Benefit (Annual Prioritisation). The members of CPAG receive the evaluation pack (except the Summary Report II and the financial information it contains). CPAG then considers the patient benefit that would be delivered through implementation of the policy. CPAG then determines the relative patient benefit of all the policy proposals being considered as part of annual relative prioritisation process. This is done without reference to the costs of implementation. Policy Propositions are allocated in equal proportion into one of three categories of patient benefit: low, medium, and high.

- C3.1. CPAG members receive the evaluation pack a minimum of two weeks before the annual prioritisation meeting. Members are asked to identify any questions of interpretation before the meeting and consider their opinion for each proposition into the three categories.
- C3.2. The CPAG meeting begins with a discussion and questions about each of the final policy propositions. Members of the CET, NPOC Senior Managers, and Head of Acute and Mental Health Programmes are in attendance to support CPAG discussion and to provide answers to questions raised. The library pack is available at the meeting for reference if required.
- C3.3. In the next part of the meeting the CPAG Chair asks each individual CPAG member for their view of the relative patient benefit for each of the policy propositions: low, medium or high.
- C3.4. The CET next separates all the proposals into 5 groupings, depending on the consensus of CPAG determined by the Chair. These 5 groupings are needed to take account of the differences in opinions across the members and are an intermediate grouping pending final allocation of policy proposals in equal proportion to low, medium and high patient benefit categories:
- Low
 - Low/Medium
 - Medium
 - Medium/High
 - High
- C3.5. The number of available positions in the three categories (low/medium/high) is determined by the total number of policies presented. An equal number of policies will be placed in each group. Where policies clearly provide low or high benefit they are placed in the corresponding category. If there is any uncertainty they will be placed in either the low/medium or medium/high category. The members then focus on the Low/Medium and Medium/High grouping and move them through deliberative debate filling the available slots in each category of low, medium or high. An equal number of proposals are now placed in each category.
- C3.6. All members review the allocations together as a group to determine whether any further adjustment is required.
- C3.7. The Chair calls a close to the discussion on patient benefit.

Step C4. Clinical Priorities Advisory Group – Application of Relative Cost (Annual Prioritisation). The cost per patient is identified and matrix of cost and benefit is formed and presented to CPAG members.

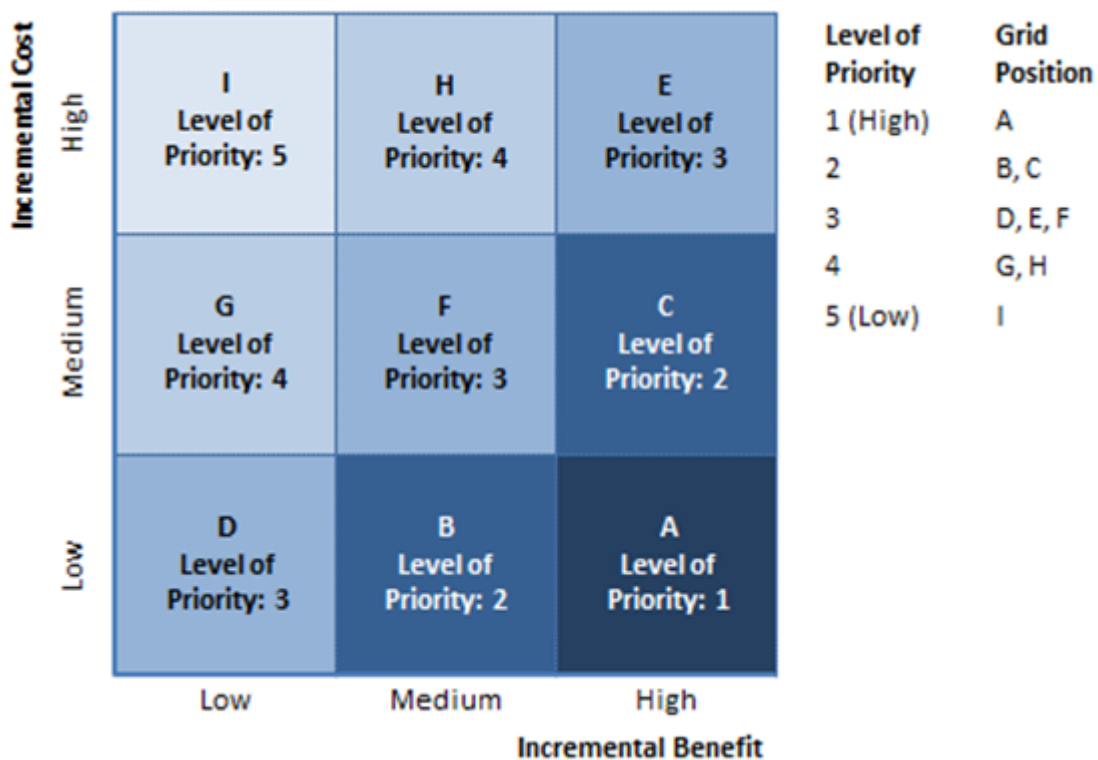
- C4.1. While CPAG members are in recess the CET with finance analytical support determine three cost per patient ranges that will result in equal dividing of the propositions into three categories of cost; low, medium and high.

C4.2. CPAG receives the Summary Report Part II and the proposals are allocated to each of the three cost categories identifying those that may straddle categories due to uncertainties regarding the cost calculations.

C4.3. A three by three 9-box matrix is populated (Figure A). All proposals are thus now presented in five levels of equivalent cost-benefit per patient. Level I is the highest benefit at lowest cost, Level V is the lowest benefit at highest cost.

C4.4. The **unadjusted cost-benefit list** is locked at this point.

Figure A Three 9-box matrix



Step C5. Clinical Priorities Advisory Group – Consideration of the Strategic Principles (Annual Prioritisation). The members of CPAG consider whether the relative priority of any of the propositions should be considered for adjustment based upon NHS England’s strategic principles. Any adjustment is supported by a narrative of the reasons for the adjustment.

C5.1. The strategic principles that should be considered include:

- The intervention should benefit the wider health and care system
- The intervention should advance parity between mental and physical health

- Consider the benefit of stimulating innovation
- Reduce health inequalities

C5.2. Once each proposition is reviewed an **adjusted cost-benefit list** is locked at this point.

Step C6. Specialised Commissioning Oversight Group – Consideration of Budget Impact

In-Year Service Developments. SCOG receives the in-year service development recommendation from CPAG and determines the budget/affordability impact and makes a final decision on the commissioning position. The associated Commissioning Implementation Plans are considered and approved.

Annual Prioritisation Products. SCOG receives the unadjusted and adjusted cost-benefit assessment from CPAG, determines the available resource for discretionary investment, and makes investment recommendations to the SSCC. The associated Commissioning Implementation Plans are considered and approved.

C6.1. The Clinical Director presents the unadjusted and adjusted (using NHS England's strategic principles) cost-benefit assessment from CPAG, and the narrative for the adjustments. The budget impact for each of the propositions is presented, and the total budget impact for each of the 5 levels of cost-benefit is presented.

C6.2. SCOG considers whether they support or reject the adjustments on individual propositions forming a **revised adjusted cost-benefit list**. The budget impact of the revisions to the levels is reviewed.

C6.3. SCOG confirms the available discretionary spend. The proposals within each of the cost-benefit levels are recommended for funding in order, the best value level first, until the available funding is exhausted. The members determine whether propositions from the cost-benefit level that could not all be afforded (the **marginal level**) should be considered and recommend to the SCC for funding or whether CPAG should be asked to prioritise items within this level.

C6.4. SCOG considers the associated Commissioning Implementation Plans and approves these, where agreed. Feedback is provided to the NPoC Senior Managers where further amendments are required to individual Plans prior to implementation, should SSCC approve the adoption and publication.

Step C7. Specialised Services Commissioning Committee – Board Approval

In-year Service Developments. The SSCC receives and endorses the decisions by SCOG.

Annual prioritisation. The SCC receives the cost-benefit level assessments, receives the recommendations from SCOG and determines the final investment.

- C7.1. The SSCC receives the unadjusted and revised adjusted cost-benefit list. They receive the recommendations for investment from SCOG and the recommendation for CPAG prioritisation of policy and service specification propositions within the marginal level.
 - C7.2. The SSCC considers the recommendations and makes a final decision on investment and considers whether to ask CPAG to prioritise propositions in the marginal level.
 - C7.3. The CET works with the Gateway and communications team to complete the final stages of policy approval for publication and accompanying communications.
 - C7.4. The final clinical policies are published on the NHS England website.
 - C7.5. A communication circular and accompanying provider letter will be drafted detailing the clinical policies which are due for publication and confirming the date of publication for distribution to local commissioning teams. This will reflect the relevant elements of the agreed Commissioning Implementation Plan.
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Glossary

CCU	Clinically Critically Urgent.
CET	Clinical Effectiveness Team (NHS England)
CPAG	Clinical Priorities Advisory Group
CRG	Clinical Reference Group
CSD	Commissioning Support Documents
HST	Highly Specialised Technology
IFR	Individual Funding Request
MIB	Medical Innovation Briefing
NPOC	National Programme of Care
PPP	Preliminary Policy Proposal
PWG	Policy Working Group
RER	Rapid Evidence Review
SCOG	Specialised Commissioning Oversight Group
SSCC	Specialised Services Commissioning Committee
TA	Technology Appraisal

Appendix A

A GUIDE TO CREATING CLINICAL POLICIES



NHS England directly commissions specialised services for the whole population of England to ensure that everyone has access to treatments and services which are effective and a good use of NHS resources. **Clinical policies** are used to determine the commissioning position on new treatments and technologies for patients or revise existing treatments and technologies. They form a critical part of NHS contracts and hold providers (hospitals, healthcare providers) to account for the treatment they deliver to patients. Clinical policies are developed via the work of the **Clinical Reference Groups (CRGs)** following a standard process called the **Clinical Policy Pipeline**, that has three phases.

Phase A Clinical Build

The **clinical build** is the first of three phases to form a national clinical commissioning policy for a directly commissioned specialised service. It concludes through a Gateway managed by the Clinical Panel where a 'Policy Proposition' is confirmed to be built from clinical evidence. The second phase is the 'Impact Analysis' concludes through a Gateway at the National Programme of Care Board. The third and final stage is the 'Decision' through the Clinical Priorities Advisory Group, Specialised Commissioning Oversight Group, and Specialised Commissioning Committee.

A clinician who undertakes to take the proposal through each step is identified to lead each clinical commissioning policy development.

The relevant CRG endorses that the nominated **Policy Clinical Lead** has the support of peers

The Clinical Lead forms the **Preliminary Policy Proposal (PPP)**

The **Clinical Panel** confirms that the policy proceeds and determines the required methodology for a proportional to the complexity of the proposal.

An **Evidence Review** is commissioned guided by the Preliminary Policy Proposal

What is a Clinical Policy

- A document **endorsed by NHS England's Board**, that describes the commissioning position how a particular treatment or technology within specialised services and in what circumstances people will receive the treatment, reflecting NHS England's values and principles and taking in to account stakeholder views.
- The contents of a clinical policy are a **mandated** NHS England commissioning position and must be followed by all healthcare providers.
- A policy is developed when there is **no relevant guidance published by NICE** (Technology Appraisal Guidance or Highly Specialised Technology Assessment). If NICE guidance is published on an existing clinical commissioning policy topic, it will either replace, or be incorporated into the policy.

Evidence Review

Evidence Reviews can follow different routes

Licenced Drugs	Commissioning Support Documents (CSD)
Clinically urgent	Rapid Evidence Review (RER)
Medical Technology	Medical Innovation Briefing (MIB)
Limited Evidence Base	Public Health England Evidence Review
Complex Evidence Base	Independent Evidence Review

Working with a **Policy Working Group** the Policy Clinical Lead forms a **Policy Proposition** built from the evidence base

The **Clinical Panel** tests whether the Policy Proposition is built on the Clinical Evidence and whether the policy proceeds either a **'routinely'** or **'not routinely'** commissioned proposal.

The proposal moves to the impact analysis Phase B.



Phase B Impact Analysis

The **impact analysis** is the second of three phases to form a national clinical policy. It is coordinated and managed by the National Programme of Care (NPOC) team and concludes through a Gateway managed by the relevant Programme of Care Board. During this phase, the draft proposition is subject to informal stakeholder testing, impact assessment, formal public consultation and an equality assessment. A Commissioning Implementation Plan is developed to consider in advance the timing and method of implementation if the proposition is then approved during Phase C (Decision).

There is a formal handover of the work in Phase A completed by the Clinical Effectiveness Team to the National Programme of Care Senior Team in NHS England

Stakeholder Testing. The NPOC confirms the stakeholders have been identified and tests the work completed by the Policy Working Group (PWG). The responses are reviewed and the Policy Proposition updated. An Engagement Report is completed

An **Impact Assessment** is completed. Key assumptions are debated and captured. The financial Impact is modelled over 5 years.

The **NPOC Board** receives the draft proposition and supporting documentation and considers its readiness for consultation. If approved, the Board determines the appropriate length of time for the public consultation to run

In Year Service Development

The great majority of policy propositions should follow the path to 'relative prioritisation' with decisions of investment being made once a year. Propositions that are cost neutral or cost saving, clinically urgent or low cost can be considered 'In Year'. Those which seek additional resource can be considered 'In Year' if the following three criteria are met:

- It is very likely that the proposed service would have been supported by NHS England in the last annual commissioning round, as it represents as **high or higher priority** than other service developments which were approved
- The proposed service to be developed is both **highly clinically effective and has a cost benefit priority level that is being commissioned by NHS England**; and the evidence is robust enough to achieve a high level of certainty
- The proposed service is **affordable** in the current financial year and for the foreseeable future.

Levels of Consultation

- Level 1:** Minor changes – no further consultation
- Level 2:** Medium changes that are broadly supported by stakeholder engagement - up to 6 week consultation, limited engagement activity during the live consultation
- Level 3:** Significant changes that are broadly supported by stakeholder engagement - up to 10 weeks consultation to include some proactive engagement activities during the live consultation period
- Level 4:** Significant change with some contentious aspects 12 week consultation to include some proactive engagement activities during the live consultation period
- Level 5:** Highly contentious/ high volume impact on numbers of stakeholders/ high levels of dissent/ high financial implications/ high media or political profile. 12 week consultation plus an extensive range of pre and during engagement activity

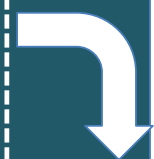
Categories of Consultation Outcome

- Category 1.** Recommendation for approval with no significant service change or convergence cost to implement product. **Category 2.** Recommendation for approval with potential for service change or convergence costs that requires further analysis and discussion
- Category 3.** Recommendation for further development as the revisions required are substantial, require service reconfiguration, and/or have a known convergence cost and may need further consultation before approval.

A **public consultation** is undertaken, and responses collated. Changes are made as appropriate on the basis of the feedback received and a **Consultation and Equality Report** is produced.

The NPOC approves the policy documents as complete, that effective patient and public engagement has been undertaken, and the finance impact of the proposition is fully defined.

The suite of papers are handed to the Clinical Effectiveness Team for submission to CPAG



Phase C Decision

The **decision** is the final stage of three phases to form a national clinical commissioning policy. It is coordinated and managed by the Clinical Effectiveness Team (CET) and concludes with the publication of the policy. There are three Gateways within this phase: Clinical Priorities Advisory Group (CPAG); Specialised Commissioning Oversight Group (SCOG); Specialised Commissioning Committee (SCC).

On completion of Phase B there is a formal handover of key documents to the Clinical Effectiveness Team (CET).

The final policy proposition is checked for consistency, accuracy and to ensure that it is written in plain language. A **library pack** and an **evaluation pack** is prepared. A **Summary Report** is populated in preparation for the CPAG.

The **Clinical Priorities Advisory Group (CPAG)** receives the evaluation pack for all the propositions to be considered for relative prioritisation. As a group they determine the relative patient benefit of each proposition in Low, Medium, and High.

The **Cost per Patient** is determined and the propositions equally divided by rank into the highest, medium, and lowest cost.

A 3x3 matrix is then established with cost on the Y axis and patient benefit on the X axis.

Cost per patient

The cost to NHS England over 5 years divided by the number of patients receiving the treatment over the 5 years.

Evaluation Pack

- Summary Report Part I (evidence and service impact)
- Summary Report Part II (finance)
- Clinical Evidence Summary
- Clinical Panel Report
- Consultation Report
- Public Health Lead Report where required
- Equality Report
- Final Policy Proposition

Publication

In Year Service developments are published throughout the year. Relative prioritisation decisions are published as soon after the SSCC as possible. A circular, with a letter to providers, is distributed to the local commissioning teams to support the introduction of the new clinical policy.

Incremental Cost		Incremental Benefit			Level of Priority	Grid Position
		Low	Medium	High		
High	I Level of Priority: 5	H Level of Priority: 4	E Level of Priority: 3	1 (High)	A	
Medium	G Level of Priority: 4	F Level of Priority: 3	C Level of Priority: 2	2	B, C	
Low	D Level of Priority: 3	B Level of Priority: 2	A Level of Priority: 1	3	D, E, F	
				4	G, H	
				5 (Low)	I	

The **relative priority** is determined into 5 levels. Level 1 having the lowest cost and highest benefit, level 5 the highest cost and lowest benefit.

The members of CPAG consider whether the relative priority of any of the propositions should be considered for adjustment based upon NHS England's strategic principles.

SCOG receives the cost-benefit assessment, determines the available resource for discretionary investment, and makes recommendations to the SSCC.

The **SSCC** receives the priority order, and makes the investment decisions.

