Methods: National Clinical Policies
This document outlines the methods implemented in the development and approval of national clinical policies for directly commissioned policies. The document details the three phases in development of a policy, from initiation of the topic to publication.
Methods: National Clinical Policies

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

Version number: v1.3

First published: November 2016 (amended August 2018)

Prepared by: Specialised Services, NHS England

Classification: (OFFICIAL)

NHS England is committed to high quality care for all, now and for future generations. We know from evidence that we cannot successfully achieve this vision without advancing equality and reducing health inequalities. Our values-based commitments embrace important legal duties in relation to equality of opportunity and reducing health inequalities. These duties are provided by the Equality Act 2010 and the Health and Social Care Act 2012. The processes for developing clinical commissioning policy outlined in Methods: National Clinical Policy comply with and abide by the agreed arrangements for Specialised Commissioning at NHS England with respect to Equalities and Health Inequalities analyses.
Introduction

National clinical commissioning policies are initiated during the ‘Clinical Build’ phase of policy development, where a topic is proposed, a clinical evidence review commissioned and completed and Specialised Services Clinical Panel confirm whether the policy proposition reflects the evidence review produced. The second phase is the ‘Impact Analysis’ managed by the National Programmes 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 (CPAG), Specialised Commissioning Oversight Group (SCOG), and Specialised Services Commissioning Committee (SSCC).

Policy statements may be developed to provide an urgent commissioning position.

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 (CET) and concludes through a Gateway managed by the Clinical Panel.

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

A1.1. All clinical policy proposals will have a Policy Clinical Lead. For most proposals this is the Chair or Clinical Member of a Clinical Reference Group (CRG). A Policy 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 who does not have a conflict of interest.

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. A copy of the Clinical Lead Proposal Form can be obtained by contacting the email england.CET@nhs.net. Once the Clinical Lead Proposal Form has been completed, the CET confirms receipt of the Policy Clinical Lead Proposal Form.
Step A2. **The Clinical Reference Group Endorses the Clinical Lead.** The relevant CRG endorses that the nominated Policy Clinical Lead has the support of peers to lead the development of a proposal.

A2.1. The CET 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 CET.

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 CET 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 CET via the online submission.

A3.1. The Policy Clinical Lead completes the PPP form. This is likely to take some time depending on the complexity of the issue, the lead may need to secure other assistance to complete all elements of the proposal. Where the PPP is proposing development of an urgent policy statement, this should be indicated on the form with a clear explanation of the rationale.

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 PPP form to the CET to the online submission.

A3.4. The CET confirms receipt of the PPP.

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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 programme on the basis of core qualifying criteria and determines the required approach for a fully independent evidence review proportional to the complexity of the proposal.

A4.1. The CET 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, HST or CDF programme AND;
• The intervention is not included in tariff (unless there is a specific reason to consider an in tariff intervention e.g., to support shared care).

A4.2. For PPPs proposing development of a clinical commissioning policy, the Clinical Panel confirms that the policy proceeds into the work programme. The Clinical Panel can exclude a PPP in the following circumstances:

• The PPP 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.

For PPPs proposing development of a policy statement, the Clinical Panel confirms whether the topic proceeds into the work programme and an indication of the timeline when the work should begin. A PWG will be established and development of the policy statement will continue from A6.1.

For PPPs submitted proposing the development of urgent policy statements, the Clinical Panel will determine:

• Whether the topic will be added to the work programme for development of an urgent policy statement providing an urgent commissioning position.
• The commissioning position of the urgent policy statement, based upon the three papers provided by the Clinical Lead with the PPP.

The Lead Commissioner will then lead development of the urgent policy statement. A rapid impact assessment will be completed. The final documentation will proceed for a decision on final investment.

In general all policies, policy statements and urgent policy statements follow a similar process of Clinical Panel review. If the nature of the product to be produced changes during the course of its development then this will be approved by Clinical Panel and the appropriate steps will apply.

A4.3. The Clinical Panel determines the required approach for an 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.
• The intervention is a licenced drug or is expected to be licensed shortly. The Clinical Panel can refer the proposal to NICE for consideration in the NICE Commissioning Support Programme (CSP). Topics which enter the CSP will follow the associated NICE methods and will re-enter this process at Step B3 (Approval by the Programme of Care Board). This will include step A7.
• The intervention is a device. The Clinical Panel can refer the proposal to NICE for a Medical Innovation Briefing (MIB).
• The Clinical Panel can refer the proposal to the recognised independent provider (procured by NHS England for this work) or to NICE for a Rapid Evidence Review (RER) via the Evidence Summary: unlicensed or off-label medicines team, subject to available resources.

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

• Inclusion in the work programme for most proposals except those with high clinical urgency.
• Inclusion in the work programme for proposals of high clinical urgency to be considered outside of the relative prioritisation process.
• The need to form an Urgent Policy Statement for proposals considered to be clinically urgent (to be considered outside the relative prioritisation process).

Step A5. Evidence review commissioned. The NHS England CET commissions an evidence review guided by the PPP.

A5.1. The Lead Commissioner from the relevant Programme of Care establishes the Policy Working Group (PWG) to include the Policy Clinical Lead. While the evidence review and CPAG Summary Report for Clinical Panel are underway, the PWG is formed, in line with the Terms of Reference, and the meeting dates are defined to receive the evidence review and build the policy proposition. The PWG should work virtually (e.g., by teleconference) wherever possible.

A5.2. The CET identifies a lead from the Public Health England Specialised Services Public Health Network 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 Policy Clinical Lead and as many members of the Policy Working Group who are available. The CET quality assures the PICO.

A5.3. The CET commissions the evidence review and CPAG Summary Report for Clinical Panel from an external provider and coordinates completion as defined by Step 4.

A5.4. The CET establishes communication between the evidence review team and the Policy Clinical Lead to clarify elements of the evidence review and CPAG Summary Report for Clinical Panel.
A5.5. The CET receives the evidence review and circulates to the PWG for comment for 5 working days. The CET quality assures the evidence review and CPAG Summary Report during this period.

Step A6. **Policy Proposition Formed.** Working with a PWG the Policy Clinical Lead forms a policy proposition built from the evidence base.

A6.1. All members of the PWG are asked to attend a training session, led by CET, providing training on the fundamentals of an evidence review, interpretation of the evidence, and clinical policy formation.

A6.2. On receipt of the evidence review and CPAG Summary Report for Clinical Panel from the CET, the PWG proceeds to form a policy proposition.

A6.3. The Clinical Lead secures consensus agreement to the policy proposition from members of the PWG. The Clinical Lead shares and agrees the final policy proposition with the CRG Chair. The CRG Chair can give chair’s action to agree but ideally should secure support from the full CRG.

A6.4. The PWG, 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 the prior approval form should be drafted and this point and included in the audit requirements section of the policy.

A6.5. The Head of Clinical Effectiveness submits the evidence review, CPAG Summary Report for Clinical Panel, the draft prior approval form (where applicable) and the policy proposition to the next available Clinical Panel.

A6.6. Where there is not consensus in the PWG, a short summary of the points of different are prepared and submitted to the 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 ‘not for routine’ commissioning proposition.

A7.1. The Clinical Panel receives the original PPP, the PICO, the evidence review, the CPAG Summary Report for Clinical Panel, the draft prior approval form 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 the proposed commissioning position.
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.

For policy statements supported by Clinical Panel, the policy statement will progress to stakeholder testing (Step B2.1).

For urgent policy statements supported by Clinical Panel, the urgent policy statement will be drafted by the Clinical Lead in conjunction with the Lead Commissioner and submitted to a subgroup of SCOOG for approval and will progress to Step C6.2.

A7.4. The Clinical Lead will receive a written report of the decision by Clinical Panel. If the Clinical Panel does not support the policy proposition, the Clinical Lead will report back to the CRG chair with a proposal that either a) the PWG needs to work up the proposal further before re-submission to Clinical Panel or b) PWG has demonstrably valid grounds for disputing the findings of the Clinical Panel. The CRG Chair will decide on the preferred course of action, and may need to discuss with CRG members first. The Clinical 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 decide next steps and confirm with the CET.
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. Stakeholder Testing. The National Programme of Care confirms the stakeholders have been identified and tests the work completed by the PWG. For NICE CSP topics, documents for stakeholder testing will be submitted to the relevant Programme of Care for distribution to stakeholders however, responses received as a result will be submitted to NICE for consideration.

B1.1. The 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.

B1.2. The PWG considers any additional stakeholders who they would wish to contribute their views at this stage, forwarding details to the communications team. The PWG should identify any other CRGs to which the policy proposition may be relevant to test the documents.

B1.3. 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.

B1.4. 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 via a generic email, and acknowledged. Collated responses are sent to the Lead Commissioner.

B1.5. The PWG reviews responses, and updates the policy proposition as appropriate based on the feedback received.

B1.6. If the stakeholder testing raises the issue that the evidence review undertaken did not evaluate the full evidence base the Public Health Lead will review whether the evidence identified was excluded from the evidence review (for example, because the study did not meet the PICO) and if not, whether an omission has been made and whether this material. An evidence report should be completed to identify whether an omission has been made or to outline the reason for the exclusion. If they determine this is the case the policy process will be returned to Phase I step 5 and handed back to the CET.

B1.7. An Engagement Report is completed. For policy statements, on completion of stakeholder testing, the statement will progress to step B6, for sign off by the National Programme of Care board and progression to the Decision phase.
Step B2. 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.

B2.1. The Lead Commissioner confirms to the NPoC that stakeholder testing is complete and receives their agreement to proceed to impact assessment.

B2.2. The NPoC Senior Manager with the NPoC Finance Lead identifies the finance support to complete the finance impact report.

B2.3. 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. The Finance Lead works with the Lead Commissioner, the Clinical lead and Public Health lead to agree assumptions. A supporting spreadsheet is produced to capture financial workings and assumptions which are included in the assessment.

B2.4. Impact is modelled over 5 years, or by exception over 10 years, for example, if significant demographic changes are expected over an extended period.

B2.5. Section II of the CPAG Summary Report is compiled by the Finance Lead, 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.

Step B3. 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. Products developed by the NICE CSP will re-enter the process at this stage.

B3.1. The NPoC Senior Manager with the Lead Commissioner supporting the PWG submits to the NPoC Board:

- The policy proposition;
- The evidence review.
- The CPAG coversheet for Clinical Panel;
- The engagement report;
- The impact analysis report;
- The prior approval form (where applicable)

B3.2. The NPoC Board approves the impact analysis report (or returns to the Finance Lead for further work, in conjunction with relevant PWG
members) and determines the length and scope of the public consultation.

B3.3. The financial model should be approved by the Head of Finance (Specialised Services) or nominated deputy prior to consultation.

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**Step B4. Public Consultation.** The public consultation is undertaken, and responses collated for consideration by the PWG. Changes are made as appropriate on the basis of the feedback received and a Consultation Report is produced. Policy statements will not undergo this step and will progress to Step B6.

B4.1. Documentation is prepared for consultation, taking into account any amendments required by the NPoC Board.

B4.2. The following documents are prepared to be included in the consultation:

- Policy proposition
- Evidence review
- CPAG Summary Report for Clinical Panel
- Clinical Panel report
- Engagement report
- Impact analysis report

B4.3. 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.

B4.4. If any comments identify that the evidence review undertaken did not evaluate the full evidence base the Public Health Lead will review whether the evidence identified was excluded from the evidence review (for example, because the study did not meet the PICO) and if not, whether an omission has been made and whether this material. The Public Health Lead will complete an evidence report to identify whether an omission has been made or to outline the reason for the exclusion. If they determine this is the case the policy process, the CET will identify whether the evidence review can proceed with an addendum or whether the policy should return to an earlier stage of the process.

B4.5. Should the policy proposition be put paused or stopped at this stage, a Status Change Report is completed.

B4.6. An Equality Impact Assessment is completed.

B4.7. The NPoC Senior Manager or Lead Commissioner forms the commissioning implementation plan, draft circular and provider letter, which will accompany the suite of documents for sign off at PoC board (see Step B5) and will eventually accompanying the CPAG report to SCOG.
Step B5. **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.

B5.1. The NPoC Senior Manager submits the following documents to the National Programme of Care Board:

- Policy proposition
- Evidence review
- CPAG Summary Report (including Sections 1 and 2)
- Clinical Panel report
- Engagement report
- Impact analysis report
- Consultation Report
- Equality impact assessment
- Evidence report (where applicable)
- Draft commissioning plan, including draft circular and provider letter.
- Prior approval form (where applicable)

B5.2. 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 CET for resolution.

B5.3. The NPoC Board determines whether the consultation materially affects the impact analysis report or the policy proposition. Further amendments are made if required and either approved by a return to the Board or by Chair’s action.

B5.4. For policies developed with Highly Specialised Services (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.

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**Step B6. Handover to CET.** The suite of papers are handed to the CET for submission to CPAG.

B6.1. The NPoC Senior Manager hands the documents back to the Head of Clinical Effectiveness. These include:

- The final policy proposition
- The evidence review
- The CPAG Summary Report (with Sections I and II completed)
- The engagement report
- The impact analysis report
- The consultation report
- The equality impact assessment report
- The finance model spreadsheet
- The evidence report completed by Public health
- The draft commissioning plan, draft circular and provider letter.
- Any comment that the NPoC Board would want CPAG to be aware of during the decision making phase.
- Prior approval form (where applicable)

Papers will be submitted to the individuals identified on the CPAG Summary Report (Head of Acute Programmes of Care/Mental Health; the Director of Finance (or nominated deputy) and the Operational Delivery Director) to confirm assurance in advance of the deadline. Any amendments required will be returned to the NPoC Senior Manager for resolution before the deadline provided.

B6.2. Papers are submitted to the Head of Acute Programmes of Care/Mental Health; Director of Finance (or nominated deputy) and Operational Delivery Director, to confirm assurance in advance of the deadline. Any amendments required will be returned to the NPoC Senior Manager for resolution before the deadline provided.

B6.3. Once assurance has been confirmed, the papers will then be submitted to the Head of Clinical Effectiveness to confirm assurance in advance of the deadline. Any amendments required will be returned to the NPoC Senior Manager for resolution before the deadline provided.
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 CET and concludes with the publication of the policy. There are three Gateways within this phase: CPAG; SCOG; SSCC.

Step C1. 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 1.2); and an evaluation pack (see 1.3). A Summary Report is populated in preparation for the CPAG.

C1.1. The library pack is compiled to include:

- Agreed PICO provided to the reviewer of the Clinical Evidence, which includes the search criteria and the literature search publication list
- Impact Analysis Report
- Finance Spreadsheet
- Engagement Report and appendix
- Consultation Report Appendix (appendix of consultation responses)
- Commissioning Plan, draft circular and provider letter
- CPAG Summary Report Part 2 (for policies entering prioritisation only)
- Prior approval form (where applicable)

C1.2. The evaluation pack is compiled to include:

- Policy proposition
- Evidence review
- CPAG Summary Report Part I (evidence and service impact) and Part II (finance) (for IYSDs) OR CPAG Summary Report Part 1 (for policies entering prioritisation)
- Clinical Panel Report
- Consultation Report
- Evidence Report
- Equality Impact Assessment Report

C1.3. The library pack and evaluation pack are submitted to the Head of Acute Programmes of Care/Mental Health; Director of Finance (or nominated deputy) and Operational Delivery Director, to confirm assurance in advance of the deadline. Any amendments required will be returned to the NPoC Senior Manager for resolution before the deadline provided. The Commissioning Plan, which forms part of the Library pack, is approved by the Head of Acute Programme of Care/Mental Health and Operational Delivery Director.

C1.4. Once assurance has been confirmed, the library pack and evaluation pack will then be submitted to the Head of Clinical Effectiveness to confirm assurance in advance of the deadline. Any
amendments required will be returned to the NPoC Senior Manager for resolution before the deadline provided.

Step C2. Clinical Priorities Advisory Group

Service developments considered outside the relative prioritisation process. The members of CPAG receive the evaluation pack including Summary Report Part I and 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 SCOOG. For clinical policies to be considered through this route they would have to be confirmed as cost neutral or cost saving or satisfy the factors stated in the Service Development.

Appraisal of Cost/Benefit (Relative Prioritisation). The members of CPAG receive the evaluation pack (except the Summary Report Part 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 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.

C2.1. CPAG members receive the evaluation pack a minimum of two weeks before the relative 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. Assurance from all parties outlined in the CPAG Summary Report, as gained in Step C1.3 and C1.4, is confirmed.

C2.2. 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.

C2.3. In the next part of the meeting the CPAG Chair leads a deliberative debate on the relative patients' benefits for each of the policy propositions: low, medium or high.

C2.4. 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

C2.5. 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.

C2.6. All members review the allocations together as a group to determine whether any further adjustment is required.

C2.7. The Chair calls a close to the discussion on patient benefit.

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**Step C3. Clinical Priorities Advisory Group – Application of Relative Cost (Relative Prioritisation).** The cost per patient is identified and matrix of cost and benefit is formed and presented to CPAG members.

C3.1. While CPAG members are in recess the finance analysts will determine three cost per patient ranges that will result in equal dividing of the propositions into three categories of cost; low, medium and high, based upon the information received.

C3.2. 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.

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

If it is clear that proposals within a number of levels can be considered for funding within the available resource (for example levels 1-3) and it is clear that all those lying within the next level (for example level 4) could not be considered but come might then all the propositions within the remaining levels (for example level 4 and 5) would return for a re-run of the relative prioritisation methodology.
Figure A  Three 9-box matrix

Step C4. Clinical Priorities Advisory Group – Consideration of the Strategic Principles (Relative 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.

C4.1. 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

C4.2. Once each proposition is reviewed an adjusted cost-benefit list is locked at this point.

Step C5. Specialised Commissioning Oversight Group – Consideration of Budget Impact

Service developments considered outside the relative prioritisation process. SCOG receives the service development recommendation from CPAG and determines the budget/affordability impact and makes a final decision on the commissioning position. The associated Commissioning
Plans are considered and approved. This includes not for routine clinical commissioning policies.

**Relative 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 Plans are considered and approved.

C5.1. The Medical 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.

C5.2. 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.

C5.3. SCOG considers the associated Commissioning 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 C6. Specialised Services Commissioning Committee – Board Approval**

**Service developments considered outside the relative prioritisation process.** The SSCC receives and endorses the decisions by SCOG.

**Relative prioritisation.** The SSCC receives the cost-benefit level assessments, receives the recommendations from SCOG and determines the final investment.

C6.1. The SSCC receives the recommendations for investment from SCOG and the recommendation for CPAG prioritisation of policy and service specification propositions.

C6.2. The SSCC considers the recommendations and makes a final decision on investment.

C6.3. The CET works with the communications team to complete the final stages of policy approval for publication and accompanying communications.

C6.4. The final clinical policies are published on the NHS England website.

C6.5. The communication circular and accompanying provider letter, detailing the clinical policies which are due for publication and confirming the date of publication, will be extracted from the appendix of the Commissioning Plan for distribution to local commissioning teams. This will reflect the relevant elements of the agreed Commissioning Plan.
Glossary

CET  Clinical Effectiveness Team (NHS England)
CPAG  Clinical Priorities Advisory Group
CRG  Clinical Reference Group
CSP  Commissioning Support Programme
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
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.

**What is a Clinical Policy**

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.

### Evidence Reviews can follow different routes

- **Licensed 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**

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.

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.

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.

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

### Incremental Cost vs. Incremental Benefit

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<th>Level of Priority</th>
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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.

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.

- 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