

# 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 and NHS Improvement's values. Throughout the development of the service specifications 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, a clinical evidence review commissioned and completed, and the Specialised Services Clinical Panel confirms whether the policy proposition reflects the evidence review produced. The second phase is the 'impact analysis', managed and assured by the National Programme of Care (NPoC). The third and final phase is the 'decision', from the Clinical Priorities Advisory Group (CPAG), then the Specialised Commissioning and Health and Justice (SCHJ) Strategy Group, and then the NHS England and NHS Improvement Statutory Committee (or NHS England and NHS Improvement Board).

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

## A. Clinical build

The **clinical build** is the first of the three phases to form a national clinical commissioning policy for a directly commissioned specialised service. It is co-ordinated and managed by the relevant 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. Any clinician can nominate themselves and propose the development of a clinical policy. The clinical lead must 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 a clinical policy proposal, but they have to identify a clinical lead who does not have a conflict of interest to make the proposal.
- A1.3. Some clinical policy proposals will be initiated by NHS England either to introduce new interventions or to decommission existing interventions. In circumstances where an appropriate clinician willing to lead the proposal development cannot be identified, a public health consultant or NHS England employed clinician will be identified as the policy clinical lead. In addition, the Specialised Commissioning Public Health Network may lead policies that have a wider public health benefit.
- A1.4. A copy of the clinical lead proposal form can be obtained by contacting CET (at [england.CET@nhs.net](mailto:england.CET@nhs.net)). Once the clinical lead proposal form has been completed and sent to the CET, the CET will confirm its receipt.

### Step A2: Clinical Reference Group endorses the clinical lead

The relevant Clinical Reference Group (CRG) endorses that the nominated policy clinical lead has the support of peers to lead the development of a proposal.

- A2.1 The CET emails the policy clinical lead proposal form to the relevant CRG chair.
- A2.2 The CRG chair completes a CRG preliminary policy proposal (PPP) checklist confirming whether the CRG supports the policy clinical lead, having discussed this with the CRG members. The form is returned to the CET.
- A2.3 Where a lead is nominated by NHS England, the CRG members are informed and are asked to provide assistance in building clinical involvement in the Policy Working Group (PWG).
- A2.4 The CET confirms endorsement with the policy clinical lead, supplying the online PPP form link, a guide for completing the form and a policy proposal reference number.

### Step A3: Production of the preliminary policy proposal

- A3.1 The policy clinical lead completes the PPP form. This can take some time if the issue is complex, and the lead may need assistance to complete all elements of the proposal. Where the PPP proposes 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 submits the PPP form to the CET by an online submission.
- A3.3 The CET confirms receipt of the PPP.

### Step A4: The NHS England Clinical Panel reviews the preliminary policy proposal

The clinical panel (with the NPoC Senior Managers) confirms that the policy proposal should proceed 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 received confirmation from the clinical policy team that:
  - the proposal is for a specialised commissioned service
  - the National Institute for Health and Care Excellence (NICE) is not undertaking an appraisal in the Technology Appraisal (TA), Highly Specialised Technology (HST) or Cancer Drugs Fund (CDF) programmes

unless an interim policy statement is being considered to allow for more timely access

- the intervention is not included in tariff (unless there is a specific reason to consider an in-tariff intervention, eg to support shared care)
- the relevant NPoC senior manager (NPoCSM) has identified initial considerations regarding the equality and health inequalities issues pertaining to the new proposal.

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

- the PPP has failed to identify any qualifying evidence for the proposed intervention's benefit
- the clinical utility of implementing the intervention through a national clinical commissioning policy is not well defined.

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

For PPPs 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 to provide an urgent commissioning position
- the commissioning position of the urgent policy statement, based on the three papers provided by the clinical lead with the PPP.

The lead commissioner will then lead the 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, PPPs for all policies, policy statements and urgent policy statements follow a similar clinical panel review process. 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 three 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 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 individual funding request (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 the relative prioritisation process. Any such proposals will need to satisfy specific criteria for this to happen.
- 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 CET commissions an evidence review guided by the PPP.

A5.1 The lead commissioner from the relevant PoC with support from the clinical policy team (where it is involved) establishes the PWG, to include the policy clinical lead. The PWG is formed, in line with the terms of reference. Dates are defined for receipt of the evidence review and meetings to build the policy proposition. The PWG should work virtually (eg by teleconference) wherever possible.

A5.2 The CET identifies a lead from the Public Health England Specialised Services Public Health Network to form the PICO (population, interventions, comparisons and outcomes) framework for the commissioning of the evidence review. Where



involved, the clinical policy team will work with the Public Health England lead to draft the PICO. This is built from the information in the PPP and is tested with the policy clinical lead and all available members of the PWG. The CET quality assures the PICO.

- A5.3 The CET commissions the evidence review and CPAG summary report for the clinical panel from an external provider, and co-ordinates its completion.
- 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 the clinical panel.
- A5.5 The CET receives the evidence review and circulates it to the PWG for comment over five 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 from the evidence base.

- A6.1 All members of the PWG are asked to undertake online training and an assessment, led by the CET, which includes the fundamentals of an evidence review and clinical policy formation.
- A6.2 On receipt, from the CET, of the evidence review and CPAG summary report for the clinical panel, the PWG proceeds to form a policy proposition.
- A6.3 The clinical lead (or clinical policy team) secures consensus agreement to the policy proposition from members of the PWG. The clinical lead shares and agrees the policy proposition with the PWG.
- 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 agrees (following advice) such approval is required, the prior approval form should be drafted at this point and included in the audit requirements section of the policy proposition.
- A6.5. The PWG completes an initial draft of the equality and health inequalities assessment (EHIA) template, informed by previous NPoC comment at PPP stage, the clinical evidence review and PWG considerations based on sources of evidence.

- A6.6 The Head of Clinical Effectiveness submits the previous clinical panel report, evidence review, CPAG summary report for the clinical panel, draft EHIA report, draft prior approval form (where applicable) and policy proposition to the next available clinical panel.
- A6.7 Where there is no consensus in the PWG, a short summary of the points of difference is 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 it should proceed into the impact analysis phase as either a 'routine' or 'not for routine' commissioning proposition.

- A7.1 The clinical panel receives the previous clinical panel report, evidence review, CPAG summary report for clinical panel, draft EHIA report, draft prior approval form and policy proposition.
- A7.2 The clinical panel determines:
- whether the eligible population is adequately defined
  - whether any eligible subpopulations are adequately defined
  - that the policy proposition is built on the evidence base as defined in the evidence summary
  - that the evidence presented supports the proposed commissioning position
  - whether any eligibility criteria are adequately defined.
- A7.3 If the clinical panel supports the policy proposition, the CET passes the proposition to the relevant PoC (and clinical policy team where applicable) to move to the second 'impact analysis' phase.

Policy statements supported by the clinical panel will progress to stakeholder testing (Step B2.1).

For urgent policy statements supported by the clinical panel, the urgent policy statement will be drafted by the clinical lead (or clinical policy team on their behalf) in conjunction with the lead commissioner, and submitted to a subgroup of the SCHJ Strategy Group for approval, and then will progress to Step C6.2.

- A7.4 The clinical lead will receive a written report of the clinical panel's decision. If the clinical panel does not support the policy proposition, the clinical lead will report

back to the PWG. The PWG may agree that it (a) needs to work up the proposition further before re-submission to the clinical panel or (b) has demonstrably valid grounds for disputing the findings of the clinical panel. The clinical lead will discuss this with the CRG chair who considers the preferred course of action and may need to discuss this with CRG members. The PWG will receive a detailed clinical panel report outlining the clinical panel's debate and reasons for its recommendation. If the CRG chair agrees the PWG has grounds for dispute, a formal letter will be written to the NPoC for consideration. It is for the NPoC to then decide the course of action, and whether the clinical panel should be formally requested to review its recommendation.

## B. Impact analysis

The **impact analysis** is the second of the three phases to form a national clinical commissioning policy. It is co-ordinated, managed and assured by the NPoC.

### Step B1: Stakeholder testing

The NPoC confirms the stakeholders that have been identified and tests the work completed by the PWG.

- B1.1 The PWG prepares to test the policy proposition and EHIA report with stakeholders, including those that have already registered as having an interest in the work of the host CRG.
- B1.2 The PWG considers any additional stakeholders they would wish to contribute views at this stage, forwarding details to the Communications and Engagement Team. The PWG should identify any other CRGs to which the policy proposition may be relevant and that should test the documents.
- B1.3 The draft policy proposition and EHIA report is sent 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 the responses and updates the policy proposition and EHIA report as appropriate based on the feedback.
- B1.6 If the stakeholder testing raises the issue that the evidence review may not have evaluated the full evidence base, the public health lead will review whether the evidence identified was considered and excluded from the evidence review (eg because the study did not meet the PICO) and if not, whether there has been an omission that materially affects and alters the proposition. An evidence report should be completed to identify whether there has been an omission or to outline the reason for the exclusion. If they determine the full evidence base has

not been evaluated, the policy process will be returned to Step A5 and handed back to the CET.

- B1.7 An engagement report is completed. For policy statements and those policies not progressing to public consultation, on completion of stakeholder testing, the statement/policy will progress to Step B6, for sign off by the NPoC and progression to the decision phase.
- B1.8 Once the outcome of the stakeholder testing has been reviewed, the PWG will complete part A of the specialised commissioning 13Q assessment form for the policy proposition to determine whether public consultation is required. The assessment is reviewed and confirmed by the relevant NPoCSM in consultation with the Communications Team. The Patient and Public Voice Assurance Group (PPVAG) chair, with support from the Communications and Engagement Team, will review part A of the 13Q assessment form. The Communications Team may request further information at this stage, to fully understand the implications of the policy and the feedback received through stakeholder testing. If the chair agrees with the NPoCSM assessment that the policy proposition does not present any potentially negative impacts, they will confirm to the NPoCSM that public consultation is not required. The policy proposition will then proceed to the NPoC and then the CPAG in line with the specification development process.

If the PPVAG chair has any concerns about potential patient impact, then part B of the 13Q assessment form will be completed and discussed at the next PPVAG meeting. The PPVAG will provide assurance on the decision on the requirement to undertake public consultation and, if considered required, the length of that consultation. The outcome is reported to the relevant NPoCSM.

## Step B2: Completion of impact analysis reports

An impact assessment is completed with advice from a finance specialist. Key assumptions are debated and captured in a supporting spreadsheet. The NPoCSM 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 its agreement to process the impact assessment.
- B2.2 The NPoCSM 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 the financial workings included in and assumptions made in the assessment.
- B2.4 Impact is modelled over five years, or by exception over 10 years; for example, if significant demographic changes are expected over an extended period.
- B2.5 The finance lead completes section II of the CPAG summary report containing the finance report, this includes the budget impact and the net cost per patient over five years (calculated as cost to NHS England over five years divided by the number of patients receiving treatment over five years). The NHS England Specialised Commissioning Finance Team approves the cost per patient information and budget impact and identifies and considers areas of uncertainty.

## Step B3: NPoC receives the combined impact analysis report

The NPoC receives the draft policy proposition and supporting documentation, and considers its readiness for progression to the CPAG or public consultation.

- B3.1 The NPoCSM with the lead commissioner supporting the PWG submits the following to the PoC:
- clinical panel report
  - policy proposition
  - evidence review or three supporting evidence papers (for some policy statements)
  - evidence report (where applicable)
  - CPAG summary report for clinical panel
  - EHIA report
  - engagement report
  - impact analysis report
  - prior approval form (where applicable).
- B3.2 The NPoC approves the impact analysis report (or returns it to the finance lead for further work in conjunction with relevant PWG members).

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

B3.4 The NPoCSM or lead commissioner drafts the commissioning implementation plan.

## Step B4: Public consultation

The public consultation is undertaken (if required) and responses collated for consideration by the PWG. Changes are made as appropriate on the basis of the feedback received, and the engagement report is updated. Policy statements will not go through this step and will progress to Step B6.

B4.1 Documentation is prepared for consultation, actioning any amendments required by the NPoC.

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
- EHIA 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 these and amends the policy proposition, EHIA report and impact assessment as appropriate, taking into account the consultation responses. The feedback is included in the engagement report.

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

- B4.5 Should the policy proposition be paused or stopped at this stage, a status change report is completed.
- B4.6 The NPoCSM or lead commissioner finalises the draft commissioning implementation plan, draft circular and provider letter, which will accompany the suite of documents for sign off by the NPoC (see Step B5) and may accompany the CPAG summary report to the SCHJ Strategy Group as required.

## Step B5: National Programme of Care

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

- B5.1 The NPoCSM submits the following documents to the NPoC:
- policy proposition
  - evidence review or three supporting evidence papers (for some policy statements)
  - CPAG summary report (including sections 1 and 2)
  - clinical panel report
  - engagement report (includes consultation)
  - impact analysis report
  - EHIA report
  - evidence report (where applicable)
  - draft commissioning implementation plan, including draft circular and provider letter.
  - prior approval form (where applicable).
- B5.2 The NPoC considers 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 on whether the omission is material. If the NPoC determines this is the case, the policy process will be returned to the CET for resolution.
- B5.3 The NPoC determines whether the consultation materially affects the impact analysis report or the policy proposition. Further amendments are made if required and will be resubmitted for NPoC approval.



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 (RDAG) to consider endorsement prior to Step B6. This is an additional gateway step for policy propositions developed with HSS involvement.

## Step B6: Handover to CET

The suite of papers is handed to the CET for submission to the CPAG.

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

- final policy proposition
- evidence review or three supporting evidence papers (for some policy statements)
- CPAG summary report (with sections 1 and 2 completed)
- engagement report (includes consultation)
- impact analysis report
- EHIA report
- finance model spreadsheet
- evidence report completed by public health lead (where applicable)
- draft commissioning implementation plan, draft circular and provider letter
- any comment that the NPoC would want the CPAG to be aware of during the decision-making phase
- prior approval form (where applicable).

## C. Decision

The **decision** is the last of the three phases to form a national clinical commissioning policy. It is co-ordinated and managed by the CET and concludes with the publication of the policy. There are three gateways within this phase: CPAG; SCHJ Strategy Group; and NHS England and NHS Improvement Statutory Committee or NHS England and NHS Improvement Board.

### 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 English. It prepares two packs of papers: a library pack (see Step 1.2) and an evaluation pack (see Step 1.3). A summary report is populated in preparation for the CPAG meeting.

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 appendices
- commissioning implementation plan, draft circular and provider letter
- CPAG summary report section 2 (for policies entering prioritisation only)
- prior approval form (where applicable)

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

- policy proposition
- evidence review or three supporting evidence papers (for some policy statements)
- CPAG summary report section 1 (evidence and service impact) and section 2 (finance) (for IYSDs) **or** CPAG summary report section 1 (for policies entering prioritisation)
- clinical panel report
- engagement report
- evidence report

- EHIA report.

C1.3 The library pack and evaluation pack are submitted to the Head of Acute Programmes of Care/Mental Health/Cancer/Genomics/Gender; Director of Finance (or nominated deputy) and Clinical Programmes Director, and Head of Quality Surveillance to confirm assurance in advance of the deadline. If any amendments are required, the packs will be returned to the NPoCSM for resolution before the deadline provided. The commissioning implementation plan, which forms part of the library pack, is approved by the relevant Head of Programmes and Clinical Programmes 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. If any amendments are required, the packs will be returned to the NPoCSM for resolution before the deadline provided.

## Step C2: Clinical Priorities Advisory Group

### **Service developments considered outside the relative prioritisation process.**

The CPAG members receive the evaluation pack including the summary report sections 1 and 2. The CPAG then considers the clinical patient benefit and financial impact implementation of the policy would deliver. The CPAG will make a commissioning recommendation for approval by the SCHJ Strategy Group. 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 policy.

**Appraisal of cost/benefit (relative prioritisation).** The CPAG members receive the evaluation pack (except the summary report section 2 and the financial information it contains). The CPAG then considers the patient benefit implementation of the policy would deliver. The CPAG then determines the relative patient benefit of all the policy propositions being considered as part of the relative prioritisation process. This is done without reference to the costs of implementation. Policy propositions are allocated in equal proportion to one of three patient benefit categories: low, medium and high.

C2.1 CPAG members receive the evaluation pack a minimum of one week before the relative prioritisation meeting. Members are asked to identify questions to help clarify their interpretation before the meeting and to consider which of the three categories each proposition should be allocated. Assurance from all parties

outlined in the CPAG summary report, as gained in Steps 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, NPoCSMs and heads of relevant programmes are in attendance to support the 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 patient benefits for each of the policy propositions: low, medium or high.
- C2.4 The CET next separates all the propositions into five groups, depending on the consensus of the CPAG determined by the chair. The grouping needs to take account of the differences in opinions between members and is 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 propositions presented. An equal number of propositions will be placed in each group. Where propositions clearly provide low or high benefit they are placed in the corresponding category. If there is any uncertainty, they are placed in either the low/medium or medium/high category. The members then focus on the propositions in the low/medium and medium/high groups and move them through deliberative debate, filling the available slots in each category of low, medium or high. An equal number of propositions are in each category.
- C2.6 All members review the allocations as a group to consider and agree whether any further adjustment is required or not.
- C2.7 The chair calls a close to the discussion on patient benefit.

## Step C3: Clinical Priorities Advisory Group – application of relative cost (relative prioritisation)

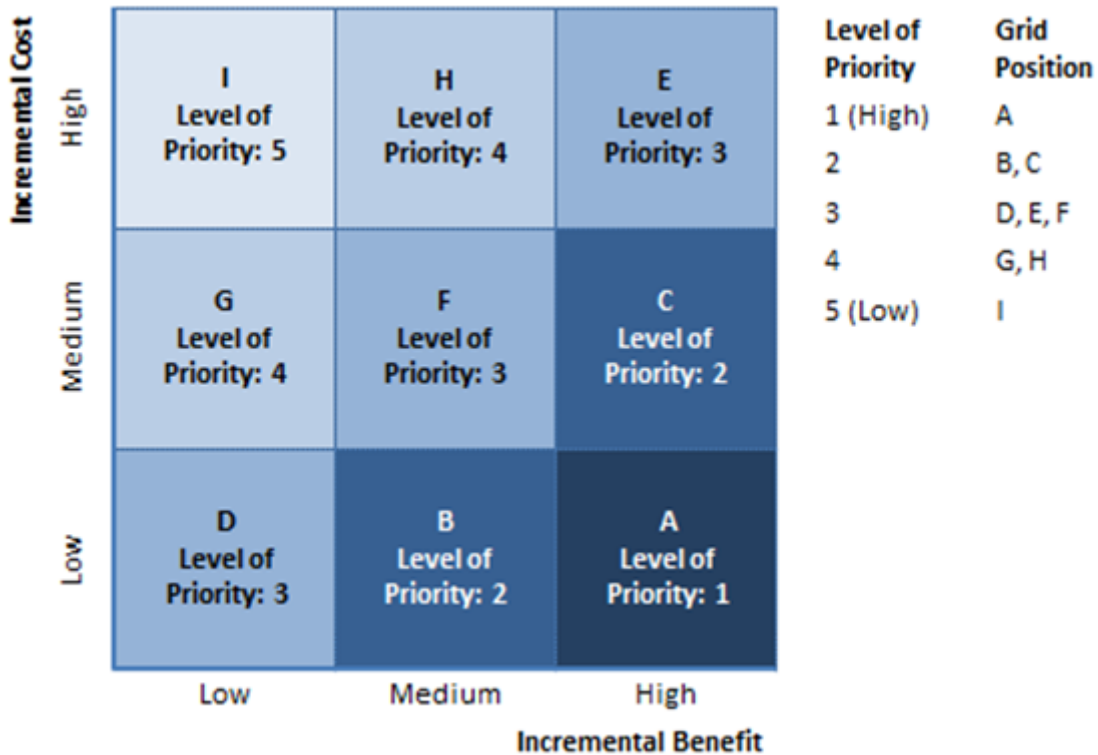
C3.1 While CPAG members are in recess, the finance analysts will determine three cost per patient ranges that will equally divide the propositions into three categories of cost – low, medium and high – based on the information received.

C3.2 A three by three nine-box matrix is populated (see Figure A below). All propositions are then presented according to five levels of equivalent cost–benefit per patient. Level 1 is the highest benefit at lowest cost; level 5 is the lowest benefit at highest cost.

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

C3.3 If it is clear that propositions in a number of levels can be considered for funding within the available resource (eg levels 1 and 2), and it is clear that all those lying in the next level (eg level 3) could not be considered in totality but some might, then the original clinical benefit category for each proposition in that level would be referred to. Those propositions in the highest categories falling within the available resource would be recommended for funding. The remaining propositions in that level and those positioned in, for example, levels 4 and 5, would not be recommended for funding.

Figure A: Three nine-box matrix



## Step C4: Clinical Priorities Advisory Group – consideration of the strategic principles (relative prioritisation)

The CPAG members consider whether the relative priority of any of the propositions should be considered for adjustment based on 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 has been reviewed, an **adjusted cost–benefit list** is locked at this point.

## Step C5: Specialised Commissioning Health and Justice Strategy Group – consideration of budget impact

### **Service developments considered outside the relative prioritisation process.**

The SCHJ Strategy Group receives the service development recommendation from the CPAG, determines the budget/affordability impact and makes a final decision on the commissioning position. The associated commissioning implementation plans are considered and approved. This includes not for routine clinical commissioning policies.

**Relative prioritisation products.** The SCHJ Strategy Group receives the unadjusted and adjusted cost–benefit assessment from the CPAG, determines the available resource for discretionary investment and makes investment recommendations to the NHS England and NHS Improvement Statutory Committee (or NHS England and NHS Improvement Board). The associated commissioning implementation 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 the 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 five levels of cost–benefit is presented.
- C5.2 The SCHJ Strategy Group considers whether it supports or rejects the adjustments on individual propositions and forms a **revised adjusted cost-benefit list**. The budget impact of the revisions to the levels is reviewed.
- C5.3 The SCHJ Strategy Group considers the associated commissioning implementation plans and approves these, where agreed. Feedback is provided to the NPoCSMs where further amendments to individual plans are required before implementation, should the NHS England and NHS Improvement Statutory Committee (or NHS England and NHS Improvement Board) approve the adoption and publication.

## Step C6: NHS England and NHS Improvement Statutory Committee (or NHS England and NHS Improvement Board) – approval

### **Service developments considered outside the relative prioritisation process.**

The NHS England and NHS Improvement Statutory Committee (or NHS England and NHS Improvement Board) receives and endorses the SCHJ Strategy Group decisions.

**Relative prioritisation.** The NHS England and NHS Improvement Statutory Committee (or NHS England and NHS Improvement Board) receives the cost–benefit level assessments and the SCHJ Strategy Group recommendations, and determines the final investment.

- C6.1 The NHS England and NHS Improvement Statutory Committee (or NHS England and NHS Improvement Board) receives the SCHJ Strategy Group investment recommendations and the recommendation for CPAG prioritisation of policy and service specification propositions.
- C6.2 The NHS England and NHS Improvement Statutory Committee (or NHS England and NHS Improvement Board) 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 due for publication and confirming the date of publication, will be extracted from the appendix of the commissioning implementation plan for distribution to local commissioning teams. This will reflect the relevant elements of the agreed commissioning implementation plan.



## Glossary

|        |   |
|--------|---|
| CDF    | Cancer Drugs Fund                         |
| CET    | Clinical Effectiveness Team (NHS England) |
| CPAG   | Clinical Priorities Advisory Group        |
| CRG    | Clinical Reference Group                  |
| EHIA   | Equality and health inequalities          |
| HST    | Highly specialised technology             |
| IFR    | Individual funding request                |
| MIB    | Medical innovation briefing               |
| NPoC   | National Programme of Care                |
| NPoCSM | National Programme of Care Senior Manager |
| PPP    | Preliminary policy proposal               |
| PPVAG  | Public and Patient Voice Assurance Group  |
| PWG    | Policy Working Group                      |
| RDAG   | Rare Disease Advisory Group               |
| RER    | Rapid evidence review                     |
| SCHJ   | SHCJ (Strategy Group)                     |
| 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' and concludes through a Gateway managed by the National Programmes of Care. The third and final stage is the 'Decision' through the Clinical Priorities Advisory Group, Specialised Commissioning and Health & Justice (SCHJ) Strategy Group, and NHS England and Improvement Statutory Committee (or Board).

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 PPP.

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.



#### What is a Clinical Policy

- A document **endorsed through NHS England and Improvements governance committees**, 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

|                       |                                       |
|-----------------------|---------------------------------------|
| Clinically urgent     | Three paper review                    |
| Medical Technology    | Medical Innovation Briefing (MIB)     |
| Limited Evidence Base | Public Health England Evidence Review |
| Complex Evidence Base | Independent Rapid Evidence Review     |

# A GUIDE TO CREATING CLINICAL POLICIES



## 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 Programmes of Care (NPoC) and concludes through a Gateway managed by the relevant Programme of Care. During this phase, the draft proposition is subject to informal stakeholder testing, impact assessment, formal public consultation and an equality and health inequality 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 NPoC 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 captured. The financial Impact is modelled over 5 years.

The **NPOC** receives the draft proposition and supporting documentation. The Patient and Public Assurance Group (PPV AG) have considered the level of stakeholder engagement and whether public consultation is required.

### 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** may be undertaken, and any responses collated. Changes are made as appropriate on the basis of the feedback received and a **Consultation Report** and a **final Equality Report** are 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



# A GUIDE TO CREATING CLINICAL POLICIES



## 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 and Health & Justice (SCHJ) Strategy Group, and NHS England and Improvement Statutory Committee (or Board).

On completion of Phase B there is a formal handover of key documents to the CET.

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

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.

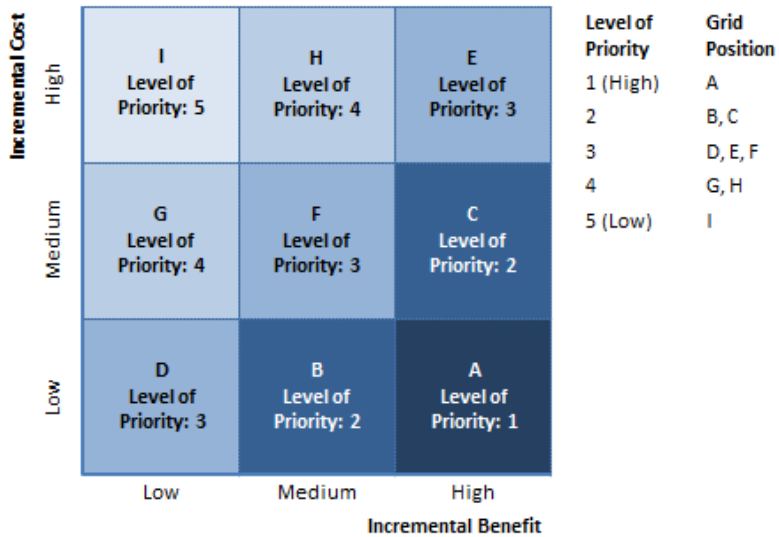
**Cost per patient**  
The cost to NHS England over 5 years divided by the number of patients receiving the treatment over the 5 years.

### Evaluation Pack

- CPAG Summary Report section I (evidence and service impact)
- CPAG Summary Report section II (finance) – for IYSD topics
- Clinical Evidence Summary
- Clinical Panel Report
- Consultation Report
- Public Health Lead Report where required
- Equality Health Inequality Impact Report
- Final Policy Proposition

### Publication

In Year Service developments are published throughout the year. Relative prioritisation decisions are published as soon after the NHS England and Improvement Statutory Committee/Board meeting 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.



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.

**SCHJ Strategy Group** receives the cost-benefit assessment, determines the available resource for discretionary investment, and makes recommendations to the Statutory Committee/Board.

The **Statutory Committee/Board** receives the priority order, and makes the investment decisions.

## Appendix B:



### Change notice for published specifications and products

#### Amendment to the published products

|                     |                                     |
|---------------------|-------------------------------------|
| <b>Product name</b> | Methods: National clinical policies |
| <b>Ref no</b>       | 06181                               |

#### Description of changes required

| Describe what was stated in original document                | Describe new text in the document  | Section/ paragraph to which changes apply | Describe why document change required   | Changes made by                             | Date change made |
|--|--|---|---|---|------------------|
| NHS England governance structures and committee names listed | Board and committee names have been updated to reflect the NHS England and NHS Improvement governance structure as of 1 April 2019. Specialised commission | Throughout                                | The names of boards and committees have been updated to reflect the new structures implemented following the move to joint working of NHS England and | Donna Hakes, Head of Clinical Effectiveness | 05/2020          |

| Describe what was stated in original document              | Describe new text in the document  | Section/ paragraph to which changes apply | Describe why document change required  | Changes made by                             | Date change made |
|--|--|---|--|---|------------------|
|  | committee names have also been amended.  |   | NHS Improvement as of 1 April 2019.  |   |                  |
| Outline of stakeholder engagement and consultation process | 13Q assessment and associated consultation decision making and processes described.  | B1.8                                      | A new approach to stakeholder testing and public consultation agreed with PPVAG.   | Donna Hakes, Head of Clinical Effectiveness | 05/2020          |
| Equality impact assessment process detailed                | Completion of the equality and health inequalities assessment form is an iterative process starting at the beginning of policy proposition development and is revised based on stakeholder | Throughout                                | A new equality and health inequalities assessment form has been introduced for use throughout NHS England and NHS Improvement. | Donna Hakes, Head of Clinical Effectiveness | 05/2020          |
| Appendix A   | Various text changes to align with changes above   | Appendix A                                | The appendices have been updated to reflect changes in the text outlined above.  | Donna Hakes, Head of Clinical Effectiveness | 05/2020          |

This publication can be made available in a number of other formats on request.

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