Methods: Commissioning through Evaluation
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This document outlines the methods implemented in the development and implementation of schemes falling within the Commissioning through Evaluation programme for directly commissioned specialised services.

**Author:** NHS England  
**Publication Date:** 23 June 2017  
**Target Audience:** External stakeholders with an interest in the Commissioning through Evaluation programme, including patient organisations, industry and professional organisations.

**Additional Circulation List**

**Description:** This document outlines the methods implemented in the development and implementation of schemes falling within the Commissioning through Evaluation programme for directly commissioned specialised services.

**Cross Reference:** Methods: National Service Specifications, Methods: National Clinical Policies

**Superseded Docs (if applicable):** N/A

**Action Required:** N/A

**Timing / Deadlines (if applicable):** N/A

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**Document Status**

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Methods: Commissioning through Evaluation

Methods of development and implementation of schemes falling within the Commissioning through Evaluation programme for directly commissioned specialised services

First published: June 2017

Prepared by: Clinical Director, Specialised Services, NHS England

Classification: (OFFICIAL)

Equality and Health Inequalities statement

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

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

NHS England’s Commissioning through Evaluation (CtE) programme enables valuable new clinical and patient experience data to be collected for treatments that are not currently routinely funded by the NHS, but nonetheless show significant promise for the future. CtE schemes may also be initiated where there is a funded treatment and/or established clinical practice within specialised NHS care, but for which significant questions of clinical or cost effectiveness remain. Patients recruited as part of time limited CtE schemes formally consent to data about their care and outcomes being used as part of a formal national evaluation programme.

Data collected via a CtE scheme is considered alongside published data from research trials to inform the development of NHS England’s clinical commissioning policies for directly commissioned specialised services (see ‘Methods – National Clinical Policies’).

Proposals for new CtE schemes are co-ordinated by NHS England’s clinical reference groups (CRGs) during the ‘Topic Selection’ phase and the Clinical Panel then determines which schemes go forward for implementation. The second phase is the patient ‘Recruitment’ phase which is overseen by a Steering Group involving clinicians and patient representatives. The third and final ‘Analysis’ phase is undertaken in partnership with the National Institute for Health and Care Excellence (NICE) and concludes with the publication of a final scheme evaluation report.

A. TOPIC SELECTION

Topic selection is the first of three phases to develop and implement a new Commissioning through Evaluation scheme. Potential new schemes are put forward by the clinical reference groups (CRGs) and are considered by the Clinical Panel for inclusion in the Commissioning through Evaluation programme.

Step A1. Topic identification. The clinical reference groups (CRGs) co-ordinate the identification of services that might benefit from a new CtE scheme.

A1.1. The clinical reference group (CRG) receives advice on the timetable for identifying topics for new CtE schemes.

A1.2. Topics are identified through discussion by the CRG.

A1.3. The CRG ensures that the following criteria are met:

- The topic falls within NHS England’s direct commissioning responsibilities for specialised services.
- The treatment or care pathway shows significant promise as a potential future routine NHS treatment approach.
- A clinical commissioning policy has been published confirming the treatment is not routinely commissioned (NRC) for the topic concerned or the topic represents an area of specialised care where there are significant remaining questions of clinical or cost effectiveness, and/or outcomes in the routine clinical setting.
Key questions of clinical and/or cost effectiveness remain that will not be answered by current or planned clinical trials.

Meaningful new outcome data can be gathered within the likely timescale of a CtE (typically 1-2 years).

A1.4. The CRG Chair liaises with other chairs to clarify whether or not it is the CRG best placed to lead on the development of a CtE proposal and/or other CRGs that may wish to have active involvement.

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**Step A2. Proposal development.** The lead CRG completes an initial draft proposal and submits this to the next available Programme of Care Board meeting for consideration.

A2.1. The lead CRG completes a Commissioning through Evaluation New Proposal Proforma, gaining the input of other CRGs identified in step A1.4, as appropriate.

A2.2. Completed proformas are submitted to the next available Programme of Care Board for consideration of their readiness for onward consideration by the Clinical Panel.

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**Step A3. Programme of Care Board review.** The appropriate national Programme of Care (PoC) Board considers proposals and agrees which may go forward for initial consideration by the Clinical Panel.

A3.1. The relevant national PoC Board considers proposals submitted by its CRGs for potential new CtE schemes.

A3.2. Feedback is provided to CRGs where proposed schemes are either not supported, or require further work before resubmission.

A3.3. Supported scheme proposals are forwarded to the Clinical Effectiveness Team (CET) for inclusion in the agenda of a future Clinical Panel meeting. Proposals are marked at this stage for the Clinical Panel’s ‘Debate/Co-Production’.

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**Step A4. Clinical Panel initial review (first submission).** The Clinical Panel undertakes an initial assessment of the new scheme proposals supported by the relevant PoC Board.

A4.1. New CtE scheme proposals are considered by the Clinical Panel against available programme funding.

A4.2. Feedback is provided for those schemes which are consequently

i. not supported as they fall outside of the planned remit of the CtE programme, or

ii. where further work would be required before resubmission, or

iii. not deemed of sufficient priority against available funding.

A4.3. Schemes prioritised for potential implementation, and for which programme funding would potentially be available, are notified to the
Senior PoC Manager for further refinement before a second submission to the Clinical Panel.

**Step A5. Proposal development with NICE.** New CtE proposals supported in principle by the Clinical Panel for potential investment are further developed and refined, in partnership with the National Institute for Health and Care Excellence (NICE).

A5.1. As a minimum, the Clinical Lead from the CRG, a public health representative and the lead commissioner meet with NICE to further develop the proposed scheme including:

- Refining the evaluation questions that would be answered by the CtE scheme, together with supporting data to be collected for each patient.
- Detailing key trials which may impact on the CtE project either by going live or delivering influential results during the CtE timeline.
- Detailing the planned patient numbers and likely scheme timescales.
- Defining the patient selection criteria.
- Proposing the number of participating centres, together with a supporting rationale.
- Defining the criteria to be used to select participating centres. **NB** These need to reasonably differentiate between applying centres rather than use criteria that all or most providers are likely to be able to meet.
- Clarifying a suitable and value-for-money database arrangement that fulfils required data and information governance requirements, together with any other proposed ancillary data sources.
- Exploring details of proposed data controllers, processors, contract holders and authors of research ethics applications.

A5.2. Working with a finance lead, a suitable pricing mechanism is identified or, by exception, derived for activity to be undertaken under the scheme. This should be benchmarked where possible to ensure value for money and supported with a realistic forecast spending profile.

A5.3. The *Commissioning through Evaluation New Proposal Proforma* is updated accordingly by the Lead Commissioner and is now marked as ‘Prioritisation Decision Required’, ready for second submission to the Clinical Panel.

A5.4. NICE is provided with an opportunity to submit any additional comments they may wish the Clinical Panel to consider.
Step A6. Clinical Panel formal review (second submission). The Clinical Panel undertakes a further assessment of proposals that have been updated following input from NICE, and makes a determination of whether programme funds should now be allocated to enable implementation.

A6.1. Updated CtE scheme proposals are considered by the Clinical Panel against available programme funding. This includes the consideration of any additional comments submitted by NICE.

A6.2. Feedback is provided for those schemes which are consequently either:
   i. not supported as they have failed to demonstrate an implementable scheme that would generate sufficiently valuable new evaluation data, or
   ii. where further work would be required before resubmission, or
   iii. are not of sufficient priority against available funding.

A6.3. Schemes prioritised for implementation (and for which programme funding will be made available) are notified to the Senior PoC Manager, the Head of Acute Programmes (or Specialised Mental Health, as appropriate), local commissioning teams and NICE.
B. RECRUITMENT

Schemes agreed by the Clinical Panel now progress to implementation, focussing during the second phase on the recruitment of a planned number of patients, falling within the agreed patient selection criteria. This is undertaken by selected participating centres, with agreed data regularly submitted.

Step B1. Commissioning through Evaluation Chair appointment. A scheme Chair is appointed ahead of the Steering Group being established.

B1.1 If a suitable CtE Steering Group is not already in place, a new role of scheme Chair is advertised. Potential candidates are also identified by the CRG and signposted to the application process.

B1.2 Interested parties are asked to complete and submit an online Commissioning through Evaluation Chair Application Form within an agreed timescale.

B1.3 Applicants are then subject to an appropriate (usually telephone based) interview and assessment process prior to appointment, which will typically involve the Clinical Director, the Programme of Care Clinical Chair or CRG Chair, and Head of Acute or Mental Health Programmes or Senior Programme of Care Manager.

B1.4 The appointed Chair is confirmed, and receives a formal letter of appointment detailing their term of appointment and arrangements for sessional reimbursement.

Step B2. Formation of the CtE scheme Steering Group. A steering group is established in line with core Terms of Reference.

B2.1 Where a suitable steering group does not already exist, the newly appointed Chair, working with the lead commissioner of the CRG, now formally establishes a scheme Steering Group, in line with the Commissioning through Evaluation Steering Group Terms of Reference.

B2.2 The Steering Group ensures that a suitable mechanism is established to gain the input, as appropriate, of interested suppliers and/or manufacturers and ensure that they are kept informed of the progress of the CtE scheme.

B2.3 A meeting schedule is established, with meetings held at least twice a year for the duration of the scheme. Some or all meetings may be held by teleconference to facilitate involvement and ‘attendance’ given the likely geographical spread of members. However, the Chair should ensure that this approach enables active participation from all core members.
Step B3. Confirming an External Assessment Centre and Database Provider.

As part of their independent evaluation role, NICE select and appoint an External Assessment Centre (EAC) and database provider to support scheme analysis.

B3.1. NICE recruits a suitable EAC and database provider, working within its own governance processes to undertake the selection process.

B3.2. The EAC may act as the database provider where a de novo database is the most appropriate option in terms of value for money, information governance and/or data management and ownership.

B3.3. Where a separate database provider is proposed outside of the EAC, for example the use of an existing clinical database, NICE will need to satisfy itself that the database arrangement is fit for purpose in respect of its use for the CtE scheme. This will include the identification of any additional costs, assurance on information governance requirements and clarification of data access and ownership.

B3.4. A detailed information governance assessment should be completed at this stage (led by NICE) and should map and document data flows between all parties to assess and mitigate risks.

B3.5. Any additional costs to be incurred by NHS England, beyond those identified in the original scheme proposal, are agreed in advance with the Head of Acute Programmes.

B3.6. The appointed EAC and database provider is/are confirmed to the CtE Chair and the lead commissioner.

B3.7. A representative of the EAC is invited to join the scheme steering group.

Step B4. Completion of scheme documentation. Key documents are developed in preparation for the scheme to ‘go live’.

B4.1. The Steering Group meets to develop and complete a range of draft core documentation to enable and support the implementation of the scheme. This includes:

- Final scheme evaluation questions to be answered in the scheme final report (see Phase C, analysis). This will include any approach to assessing costs and/or cost effectiveness as part of the evaluation.
- Detailed data measures for submission by participating centres, including mandatory fields which will include the reporting of serious incidents.
- Patient selection criteria.
- Planned scheme recruitment numbers and recruitment timescale.
- The criteria to be used to select participating centres. NB Criteria need to be suitably discriminatory to enable applying centres to
be assessed and ranked in order to identify those best placed to participate. Advice may be required from NHS England’s commercial team.

- Quality assurance measures that participating centres will need to demonstrate compliance with, both ahead of them going live as a centre and on an ongoing basis during the recruitment phase, together with an associated proforma for completion.
- NHS England communications plan.
- A draft contractual schedule detailing the obligations of participating centres to include:
  i. monitoring process for returns to EAC, commissioners and the national team on a monthly basis
  ii. that payment is contingent on data completeness into EAC system
  iii. recruitment stopping criteria outlined as either 80% of the centre or national total
  iv. obligations for any patients erroneously added to a waiting list beyond the agreed scheme activity or outside of the agreed selection criteria
  v. that annual activity plans and payment is confirmed by contract variation.
- A patient information letter or leaflet to provide information on the scheme.
- A patient consent form.
- Arrangements for ethical approval and/or Caldicott guardianship notification.

B4.2 Draft scheme documentation is reviewed and if appropriate supported by the CRG prior to submission to the Programme of Care Board (PoC).

B4.3 Draft scheme documentation, supported by the CRG, is submitted by the lead commissioner to the PoC Board for final sign off.

B4.4 The PoC Board meets to review and where appropriate sign off scheme documentation.

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**Step B5. Centre selection.** The agreed number of centres are selected and confirmed in line with the agreed criteria.

B5.1. Where participating centres have not been pre-selected the opportunity to participate in the scheme is appropriately advertised to all potential providers in line with advice from NHS England’s commercial team. NB Pre-selection will be by exception only and agreed in advance by the Clinical Panel.
B5.2. Interested providers formally express an interest in participating in the scheme in response to the invitation.

B5.3. Interested parties submit their applications within an agreed timetable, detailing how they meet or exceed the centre selection criteria.

B5.4. Submissions are assessed with a final decision reached by a panel including (and administered by) the lead commissioner, Regional Clinical Directors of Specialised Commissioning and the Deputy National Clinical Director Specialised Commissioning, or their nominated clinical deputy, as Chair. Providers will normally be selected primarily on the basis of those best meeting or exceeding the centre selection criteria. However, an adjustment may be made where selection on relative ranking alone would result in a significantly inequitable geographical distribution of centres, at the panel’s discretion.

B5.5. The lead commissioner ensures timely notification of the decision made to both successful and unsuccessful centres.

B5.6. Annual allocations are calculated for each region based on the distribution of centres and the expected associated activity profile.

B5.7. NHS England’s local specialised commissioning teams are informed of the final selection made and ensure that suitable contractual agreements are put in place with all selected centres, detailing the obligations of participation. This will include the regular and timely submission of required data returns, including follow-up data beyond the recruitment phase of the scheme, and responsible communication with interested patients and/or families on the parameters, aims and limitations of the scheme.

B5.8. Annual activity plans are confirmed by the lead commissioner and issued to each participating centre through a contract variation notice issued by the relevant local commissioning teams.

B5.9. The final list of participating centres is made available on NHS England’s website and the scheme effectively goes live.

B5.10. A Clinical Leads group is established with representation from all participating centres, to act as a source of information and feedback and to help co-ordinate consistent scheme implementation.

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**Step B6. Routine scheme oversight.** The Steering Group meets on a regular basis to ensure effective oversight and delivery of the agreed scheme.

B6.1 The scheme steering group meets regularly, acting within its agreed terms of reference. Its primary focus is ensuring that scheme implementation and recruitment is successful, that any risks are identified and that mitigating actions are taken as required. This includes the review of any known clinical incidents relating to the CtE procedure, ensuring these have been reported through the appropriate serious incident (SI) routes.
B6.2 Subgroups and/or short life working groups are established as required. This includes a data group which is established to provide a robust overview of data collection, analysis and evaluation requirements and delivery. This group is supported by the External Assessment Centre (EAC). The Chair and Lead Commissioner should ensure that clear Terms of Reference are established for each group, with clear reporting to the Steering Group and clarity on governance requirements where material issues arise.

B6.3 Regular calls are held with the clinical leads from each participating centre to provide information and to ensure early escalation of any risks requiring mitigation.

B6.4 The steering group’s work is informed by quarterly reports provided by the EAC, via NICE, summarising data submissions by all participating centres.

B6.5 Where individual centre submissions do not meet contractual requirements, the Lead Commissioner works with local commissioning teams to supplement the efforts of the EAC to improve data completeness. This may ultimately include non-payment for activity undertaken in the absence of associated data submission, and/or the removal of a centre from the scheme.

B6.6 The Lead Commissioner works with the scheme Chair to ensure regular (at least 6 monthly) progress reports are provided to the ‘parent’ CRG(s) and PoC Board. These need to include, as a minimum, updated forecasts on recruitment and expenditure, and the identification of any risks to implementation and associated mitigation. Additional reports may be required to support NHS England’s governance requirements e.g. update reports to the Clinical Panel or Specialised Commissioning Oversight Group (SCOG).

B6.7 The lead commissioner works closely with the finance lead to ensure quarterly updates are available to support budget setting and forecasting, nationally and locally.

B6.8 The Chair and Lead Commissioner take responsibility for regular updates being provided to industry and/or suppliers with a legitimate direct interest in the scheme. Wherever possible, this will be accomplished via a collective call to ensure equitable and simultaneous provision of information to all suppliers, reduce the risk of perception of any undue unilateral influence and efficient use of Chair and Lead Commissioner time.

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**Step B7. Changes to scheme scope.** Potential changes to the originally agreed scheme scope are carefully considered and go through an appropriate governance process for approval and onward communication.

B7.1. Potential changes to the scope or status of any scheme during this phase are formally considered by the steering group and a
consensus (or majority agreed) proposal put forward to the Clinical Panel. These changes might include (but are not restricted to):

- changes to the planned numbers of patients to be recruited to the scheme, or the planned recruitment timetable
- a change to the patient selection criteria or included patient cohorts
- changes to the evaluation questions or supporting data measures
- a change to the database provider
- a change to the scope or continuation of the scheme on the basis of published or anticipated research findings which overlap with the evaluative aims of the scheme
- changes to the number of participating centres or to add or remove a provider from the list of participating centres
- any changes that would have an impact on in-year or overall scheme costs (either costs associated with patient treatment or scheme analysis costs)
- a proposal to cease patient recruitment and move to Phase C
- closure, partial closure or amendment of the scheme due to concerns identified from the reporting of serious incidents.

B7.2. Requested changes are summarised in a scheme Commissioning through Evaluation Scheme Change Report, completed by the Lead Commissioner on behalf of the steering group, and submitted to the Clinical Effectiveness Team (CET) for inclusion in the next available Clinical Panel meeting.

B7.3. Although NICE is a core member of the scheme steering group, they are additionally provided with an independent opportunity to comment on any change proposals given their formal role in producing the scheme evaluation report. NICE’s comments are submitted alongside the steering group’s change form submission.

B7.4. A change report is mandatory at the point at which the recruitment phase is planned to close.

B7.5. The Clinical Panel receives and considers change proposals and make their determination, which is formally minuted and confirmed to the PoC Senior Manager, CtE Clinical Lead and Lead Commissioner.

B7.6. Explicit consideration is given by the Clinical Panel Chair as to how any decisions need to be communicated to internal and external partners.
**Step B8. Closure of the recruitment phase.** Once the planned number of patients have been recruited, the recruitment phase is brought to a formal close, working closely with participating centres to ensure clear messaging to potentially affected patients.

B8.1 The Steering Group should ensure active ongoing monitoring of recruitment against planned patient numbers, agreeing in advance any proposed changes to the planned patient numbers or recruitment timetable with the Clinical Panel.

B8.2 At least six months before the expected completion of recruitment, or by the point at which 80% recruitment has been achieved, whichever is earliest, the Lead Commissioner should work pro-actively with participating centres to manage the closure of the recruitment phase. This will usually be coordinated via the calls with Centre Clinical Leads.

B8.3 The Lead Commissioner should provide clear written communication to each participating centre of both remaining funded activity per centre and the need to carefully manage patient listing within this allocation. Centres should be reminded that they will be responsible for arranging separate (non-NHS England) funding for any activity falling outside of the agreed scheme allocation. Any re-allocation of activity plans between centres within the national scheme total will be carefully managed and communicated by the Lead Commissioner.

B8.4 Local commissioning teams should receive an explanatory *Specialised Services Circular*, and all provider correspondence should be copied to the relevant local commissioning team(s) to ensure consistent messaging.

B8.5 Working closely with the communications team, additional briefings and information should be used to inform patients, all affected providers, including those who are not participating centres but nonetheless provide linked services, and the wider public, for example through the NHS England website.

B8.6 A *Commissioning through Evaluation Scheme Change Report* is completed and submitted to the Clinical Panel to secure formal agreement to the closure of the recruitment phase.
C. ANALYSIS

Scheme analysis is the final phase during which data submitted by participating centres informs the conclusions reached on the agreed evaluation questions. The phase culminates in the publication of a final scheme report by NICE. Evaluation data is fed into the ‘business as usual’ process for the development of Clinical Commissioning policy for directly commissioned specialised services.

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Step C1. Submission of follow-up data by participating centres. Participating centres continue to submit required data including follow-up measures for all patients treated during the recruitment phase of the scheme.

C1.1. During the analysis phase, participating centres continue to submit required data including key follow-up measures. Data submissions may continue for a number of months or years beyond the close of the recruitment phase, depending on the follow-up data measures agreed.

C1.2. The External Assessment Centre (EAC), via NICE, continue to provide quarterly data updates to the Steering Group and data working group.

C1.3. Where individual centre submissions do not meet contractual requirements, the Lead Commissioner works with local commissioning teams to supplement the efforts of the EAC to improve data completeness. This may ultimately include direct contact with the Provider Chief Executive and/or Medical Director and non-payment for activity undertaken in the absence of associated data submission.

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Step C2. Analysis. Once all data has been submitted, the EAC undertakes a final analysis in line with the agreed scope of the scheme.

C2.1. Once all reasonably expected data has been received, the EAC undertake the final scheme analysis within the parameters agreed with NICE.

C2.2. An interim analysis may be undertaken where agreed as part of the scope of the scheme.

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Step C3. Evidence review. An accompanying clinical evidence review is undertaken for inclusion in the final evaluation report.

C3.1. NICE undertakes an evidence review to support the overall evaluation process. This provides an up-to-date position on the evidence of clinical, and in some cases, cost effectiveness of the procedure or treatment from peer reviewed, published literature.

C3.2. Where alternative sources of clinical evidence are to be used to support the evidence review, this will have been detailed in the scheme scope or have been subject to a change report agreed by
the Clinical Panel. This is to ensure that the evidence review can be used as part of a subsequent clinical commissioning policy review process, if deemed appropriate.

**Step C4. Production and publication of the scheme evaluation report.** NICE oversees the drafting of the scheme evaluation report, ahead of its publication.

C4.1. NICE draft the *Scheme Evaluation Report* directly responding to the evaluation questions posed as part of the scope of the scheme. This includes a summary evidence review, scheme analysis of the clinical and economic evidence and a note of any other key themes fed back from participating centres which might need to be taken into account in any future roll out of the service, if routinely commissioned.

C4.2. The draft report is shared at least once with all members of the Steering Group for comment. If appropriate, relevant industry and/or manufacturers may be given an ‘in confidence’ opportunity to comment on any issues of fact in the draft document. Editorial rights are retained by NICE as the report authors.

C4.3. The final report is confirmed as ready for publication by NICE and forwarded to NHS England as a completed document.

C4.4. The report will feed into NHS England’s process for the development of Clinical Commissioning Policies for directly commissioned specialised services (see *Methods: National Clinical Policy*). For this reason, the report will be subject to a final assurance process undertaken by a small working group agreed by the Clinical Panel, prior to publication (including on NHS England’s website).

C4.5. The report completion process, including the completion of the supporting scheme analysis and evidence review, will typically take a total of three to six months following the conclusion of data submissions from participating centres.

C4.6. An interim version of the report may also be produced, in agreement with NHS England.
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<th>Description</th>
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<td>CET</td>
<td>Clinical Effectiveness Team</td>
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<td>CRG</td>
<td>Clinical Reference Group</td>
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<td>CtE</td>
<td>Commissioning through Evaluation</td>
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<td>EAC*</td>
<td>External Assessment Centre</td>
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<td>NICE</td>
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*External Assessment Centres are centres commissioned by NICE to provide a range of evidence assessment and development services.*