NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

COMMISSIONING SUPPORT PROGRAMME

Standard operating procedure

April 2018

1. Introduction

The Commissioning Support Programme (CSP) at NICE supports the development of NHS England's specialised services clinical commissioning policies. This document describes the main stages and key principles of the programme that underpins the work done by CSP. It is intended to ensure that robust, quality-assured documents are produced in a transparent, consistent and timely way, with engagement from targeted stakeholders.

2. Remit of the Commissioning Support Programme

The aim of the programme is to provide objective information to support decision-making by NHS England on specialised services clinical commissioning policies for licensed or soon-to-be licensed medicines. The core work of the programme is:

- summarising and grading the evidence base
- coordinating the work of a policy working group on behalf of NHS England
- producing a draft policy proposition and testing the proposition with stakeholders
- providing an impact assessment of implementing the draft policy proposition in NHS clinical practice in England.

None of the programme's outputs include a formal recommendation or final commissioning position on a medicine. The responsibility for deciding which medicines should be prioritised for funding remains with NHS England, following the process outlined in NHS England's Methods: National Clinical Policies.

2.1 Criteria for referral of a topic to the programme

For a medicine to be referred to the programme by NHS England it has to fulfil all the following criteria:

- It is, or would be, directly commissioned by NHS England, that is, it is a specialised service as defined by the Health and Social Care Act 2012.
- It has, or will have when the final clinical policy is published, a UK marketing authorisation for the indication of interest.
- The new medicine (or new indication for an existing medicine) is listed in UK PharmaScan.
- It is available in England, or will be when the final clinical policy is published.
- The indication has not been selected for, or previously assessed by, the NICE technology appraisal or highly specialised technology programmes. When a planned new indication for a medicine is being considered for technology appraisal or highly specialised technology evaluation, referral to the CSP cannot occur until the topic selection process is complete (see section 2 of the NICE guide to the processes of technology appraisal).

2.2 Key audiences

- NHS England, to inform and support decision-making.
- Patients and the public, to help inform treatment choices.
- Clinicians and managers and those responsible for implementing a new technology.
- Pharmaceutical companies.

3. Process overview

The process for the CSP forms part of NHS England's overall process for developing a clinical commissioning policy. NHS England's policy development process includes 3 key phases: clinical build, impact analysis and decision. The CSP process supports the clinical build and impact analysis phases, and has no input or

involvement in the decision phase. This standard operating procedure should therefore be read with NHS England's publication: Methods: National Clinical Policies.

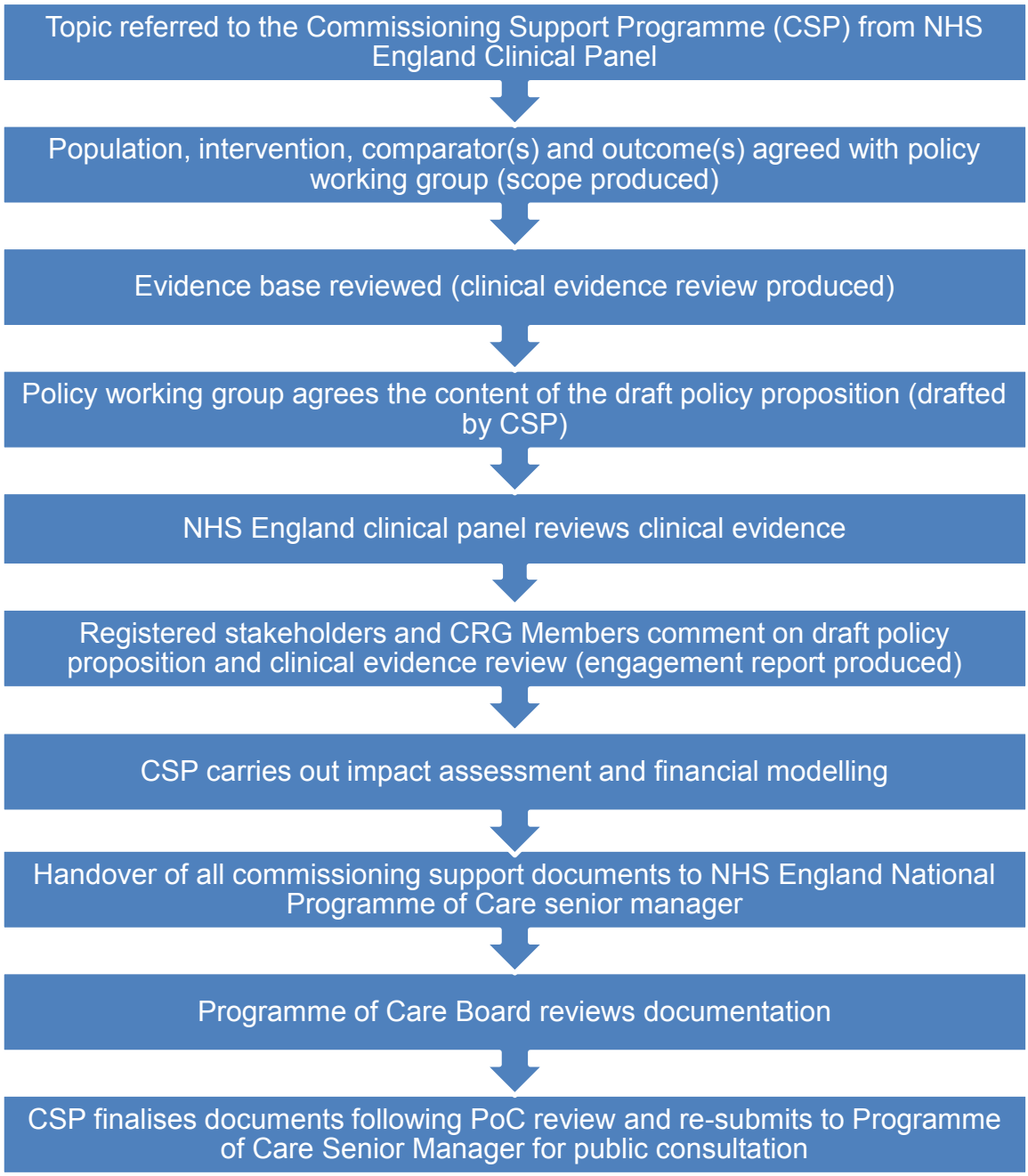
3.1 NICE CSP outputs

For each topic considered by the programme, NICE produces 9 outputs:

- scope
- clinical evidence review
- draft policy proposition (NHS England template)
- integrated impact assessment (NHS England template)
- budget impact model (costing template, Excel format)
- stakeholder engagement report (NHS England template)
- table of comments and responses following stakeholder engagement
- Clinical Priorities Advisory Group (CPAG) summary of benefits for Clinical Panel consideration (NHS England template)
- CPAG summary report parts 1 and 2 (NHS England template).

The timeline for the outputs fits with the overall process as set out in NHS England's Methods: National Clinical Policies.

Figure 1 Overview of the Commissioning Support Programme process



4 Stages of the Commissioning Support Programme work

4.1 Referral to the Commissioning Support Programme

Topics must be referred to the CSP by NHS England's Specialised Commissioning clinical panel before they are scheduled into the CSP work programme. The process by which topics are identified and prepared for consideration by the clinical panel is detailed in Methods: National Clinical Policies. Once the clinical panel decides that a

topic is suitable for referral to the CSP, the details of the topic are passed to the CSP project manager. NHS England also supplies the names of the clinical lead and lead commissioner at this stage.

In addition, topics may be identified through the NICE horizon scanning and topic selection process that supports the NICE technology appraisal and highly specialised technology evaluation programmes. If a decision has been made that the technology is not suitable for technology appraisal or highly specialised technology evaluation (see section 2 of the NICE guide to the processes of technology appraisal), and the technology is a specialised service, NICE topic selection will inform the CSP. However, the CSP cannot start work on a topic until it has been referred by NHS England's clinical panel. Therefore, the CSP submits preliminary licensing (from UK PharmaScan) and trial information for these topics directly to NHS England's clinical panel for consideration. The CSP has no further involvement until the topic is referred back to the programme from the clinical panel.

4.2 Confirmation of the topic in the Commissioning Support Programme

Once a topic is referred to the programme by NHS England's clinical panel, the CSP allocates the topic a CSP ID number. This is additional to the unique reference number (URN) assigned to the topic by NHS England. The CSP identifies topics using both the URN and CSP ID numbers from this point onwards. The CSP contacts the company to:

- Check contact details and ask for permission to store and use these for the duration of NICE's involvement with the topic.
- Ask for preliminary information about the technology, the (anticipated) indication and offer an opportunity for a brief meeting via teleconference to discuss the CSP process. Information gathered at this stage will enable the CSP project manager to consider potential start dates for the topic (see section 4.5.1).

The title of the topic (including the name of the medicine and the disease area) is published on the NICE website.

4.3 Formation of a policy working group

The CSP receives the names of the NHS England clinical lead and lead commissioner, public health lead, a pharmacy lead and a finance lead at the time that a topic is referred to CSP from clinical panel. CSP refers all new topics to its Patient Involvement Programme (PIP) who will then suggest a maximum of 3 patient organisations to invite to join the policy working group. CSP shares this information with the lead commissioner for the topic, to gain their endorsement. The CSP also works with the clinical lead to identify additional clinical experts to join the group.

The CSP contacts all members of the group to ask for permission to use their contact details for the duration of the CSP's involvement with the topic. At first contact, the CSP provides all members of the group with instructions for setting up a NICE Docs account; this software is used by NICE to share and receive documents safely and securely to avoid any breaches of confidentiality. The group members are asked to sign an agreement not to disclose any confidential information, or any information about the development work for the topic that would not otherwise be in the public domain.

4.4 Scoping

The scope sets out the focus for the review of the clinical evidence base on which the draft policy proposition will be based. NICE develops the scope, outlining the population, intervention, main comparator and outcomes of interest. The scope should identify the outcomes of greatest importance to patients and their carers. NICE ensures the accuracy of the scope by robust internal quality assurance processes, and by seeking comment from members of the policy working group. The company is also given the opportunity to comment on the scope before it is finalised.

The remit of the CSP is for licensed, and soon-to-be licensed indications only. If the policy working group is interested in expanding the topic to include unlicensed use of a medicine, the CSP contacts NHS England to discuss whether it is appropriate for NICE to continue working on the topic.

4.5 Company submission

The company is invited to provide an evidence submission for the indication under consideration.

The company submission comprises 3 sections:

- preliminary information
- clinical evidence summary and
- resource impact analysis.

The preliminary information section of the submission asks for a brief explanation of the technology, its proposed position in the treatment pathway, and for details of the disease area and epidemiology.

The clinical evidence summary section of the submission asks for details of the published clinical evidence base. It asks for a description of the key strengths and limitations of the full evidence base. The details, including the results of any unpublished studies that have been notified to the CSP in advance should be included in this section (see also section 4.5.2). This information is used by the CSP to inform the clinical evidence review and to complete the summary documentation that goes to CPAG (that is, part 1 of the Clinical Priorities Advisory Group summary report, see section 3.1).

The impact assessment section of the submission asks for details about a number of assumptions relating to the impact assessment (sometimes referred to as financial modelling or budget impact assessment) work (see section 4.11). The company is asked to provide the CSP with best estimates for each element; where there is uncertainty, this should be declared.

4.5.1 Timeline for submission

Following initial contact between CSP and the company (see section 4.2), the CSP will consider potential start dates for the core work for the topic. This will take into consideration CSP capacity constraints and any information from NHS England's clinical panel regarding the priority of the topic, in addition to regulatory timelines (if applicable). It will also take into account the availability of policy working group members. Once a start date is confirmed, the CSP will notify the company.

In advance of any submission deadlines, the CSP will issue a draft scope to the company, and will aim to do this up to 6 months in advance of starting the core work

for the topic. This scope will be based on the (expected) indication for the medicine. It should be noted, however, that the draft scope has not been signed off by the policy working group at this stage; the final scope may be different as a result of comments from the PWG and the company. The CSP's ability to provide advance notice is dependent on a number of factors including:

- the timing of the referral from NHS England's clinical panel to the CSP (for example, if the CSP is asked to prioritise a topic to start as soon as programme capacity allows, it may not be possible to give advance notice to the company The CSP will work with the company where this occurs);
- the availability of information about the indication (particularly the population for whom the medicine is intended);
- CSP capacity.

Shortly before the evidence review starts, the CSP sends an invitation to participate to the company and the final scope is issued. The company is given **2 weeks** from the date of the invitation to participate to submit to the CSP. All evidence must be submitted by this deadline to be included in the work for the topic.

4.5.2 Submitting unpublished evidence

In line with NHS England's requirement that the clinical priorities advisory group (CPAG) should only consider clinical effectiveness evidence that has been published in a peer-reviewed journal (or will have been published at the time that CPAG considers the clinical benefit of the medicine), academic-in-confidence evidence cannot be accepted in an evidence submission.

In exceptional circumstances, the CSP will consider accepting unpublished clinical evidence if it is from a draft version of the European public assessment report or if all of the following conditions are met:

- the evidence relates directly to an outcome in the scope
- there is no other published evidence for the outcome
- the evidence is written in draft manuscript form

- the company confirms that the manuscript has been accepted for publication and will be published prior to the date that the medicine will be considered by CPAG. Confirmation of acceptance to a journal, and a confirmed publication date, is required.

If a company considers that a case can be made for submitting academic-in-confidence evidence, the company should discuss this with the CSP as soon as possible, in any case before the submission deadline.

NICE will inform NHS England of the confirmed publication date when submitting any academic in confidence evidence contained within the documents.

4.5.3 Submitting commercially sensitive information

Commercial-in-confidence information is only accepted if it relates to regulatory timelines. If at the time of submission, the anticipated acquisition cost of the medicine has not been set, the use of a dummy variable is acceptable and may be updated later when a list price has been confirmed. The CSP process does not require an accurate acquisition cost, since the NHS England clinical commissioning policy development process includes a commercial negotiation stage after the handover of all documents from NICE to NHS England. The CSP is not involved in any discussions about commercial discounts. If a patient access scheme exists for the medicine, the acquisition cost, and not the existing discount, should be used in the evidence submission.

4.5.4 Late receipt of evidence

Late receipt of evidence will delay consideration of the topic at CPAG. If a delay is expected, the company should contact the CSP project manager to discuss revised timelines.

4.5.5 Non-submission

If a company does not wish to submit evidence, the topic will continue according to the timelines set by CSP. The evidence base will be informed by a systematic search of published information done by NICE. Where a company has declined to participate, CSP will not contact the company throughout the remainder of the process.

4.6 Clinical evidence review

The clinical evidence review, written by the CSP, reviews the clinical effectiveness and safety evidence on the medicine, together with information on the disease and epidemiology and the medicine's place in the treatment pathway. The CSP carries out the review according to methods of evidence assessment set by NHS England.

The CSP offers the policy working group and the company the opportunity to comment on a draft version of the review approximately 6 weeks after the submission deadline and before it is considered at the policy working group meeting (see section 4.7). The timeframe for returning comments is 5 working days from the date that the CSP project manager sends out the documents.

Once the document has been reviewed by the policy working group, it is signed off by NICE CSP and submitted to NHS England's Clinical Effectiveness Team for quality assurance prior to being considered at clinical panel.

4.7 Policy working group meeting

The policy working group meets to consider the clinical evidence review and to agree a recommendation for the draft policy proposition. The CSP manages this meeting and arranges the time and location; it attempts to set the date at least 6 weeks in advance. The meeting will be in person, usually at the NICE office in London or Manchester, depending on the location of the majority of policy working group members.

The clinical lead, lead commissioner and public health lead should be present for the policy working group meeting to be quorate. In the absence of the chair (clinical lead), the meeting will be rearranged. If a lead commissioner or public health lead is unavailable on the day of a meeting, the CSP will arrange a separate meeting with them and the clinical lead, to ensure that the discussions are quorate.

Company representatives (no more than 2 per organisation) are invited to the meeting to answer any questions from the policy working group about the evidence base. The company will be asked to leave the meeting once the evidence base and assumptions for the costing template (section 4.11) have been discussed.

Members of the NICE team working on the topic ensure that the working group covers all that is necessary to prepare the draft policy proposition.

The discussions will include:

- the benefits of the technology under consideration
- the place of the technology in the treatment pathway
- clinical criteria for starting and stopping treatment with the new technology
- any changes to the existing treatment pathway
- activity projections for the disease and new technology
- estimated comparator use.

This list is not exhaustive and will depend on the topic.

Conflict of interest declarations are not taken by NICE at this meeting, because these are requested by NHS England when people are recruited to a policy working group.

Prior to the meeting, NICE CSP will arrange a teleconference with the clinical lead, lead commissioner and public health lead to discuss arrangements for the policy working group meeting. This teleconference is referred to as the pre-meet and will usually be arranged to take place in the week prior to the policy working group meeting.

4.8 Draft policy proposition

After the policy working group meeting, the CSP drafts a policy proposition, based on the discussions at the meeting. This document contains the policy working group's view of whether the medicine should be routinely commissioned or not. This is not a final recommendation, but a summary of the working group's considerations. As such, it may be overturned by NHS England clinical panel at a later stage (see section 4.9).

The rationale in the draft policy proposition must be based on the available clinical evidence, as summarised in the clinical evidence review (section 4.6). The draft policy proposition should detail the expected position of the medicine in the treatment pathway. When appropriate, it should give starting or stopping criteria for treatment.

The draft policy proposition is sent to the policy working group for review approximately 2 weeks after the meeting. At the same time, it is sent to the company for an opportunity to check the factual accuracy of statements relating to the clinical evidence base. The timeframe for responding to the CSP (for both the policy working group members and the company) is 5 working days.

4.9 Clinical panel gateway

Once the draft policy proposition has been agreed by the clinical lead, lead commissioner and public health lead, the CSP completes the CPAG summary report for clinical panel. This is a 'plain English' summary of the information in the clinical evidence review. NICE ensures that there is no new information in this report that has not been included in the clinical evidence review. The CPAG summary report for clinical panel summarises the clinical benefits of the draft policy proposition. Specific measures of benefit include survival, progression-free survival, mobility, self-care, usual activities, pain, anxiety or depression, replacing a more toxic treatment, dependency on caregiver or supporting independence, safety, delivery of the intervention. Other health metrics appropriate to the intervention or the disease area that have been identified during the evidence review and considered important by the policy working group are also included in this report.

The clinical evidence review, draft policy proposition and CPAG summary report for clinical panel are submitted to NHS England's clinical effectiveness team for quality assurance, and then to clinical panel. This is the clinical panel gateway; for more information see Methods: National Clinical Policies.

The CSP is required to submit papers to the clinical panel at least 3 weeks before the panel meeting. The clinical panel's decision on whether the draft policy proposition can proceed to the next point in the process is given to the clinical lead in writing (copied to CSP), approximately 3 weeks after the meeting.

4.10 Engagement report and comments table

The documents are circulated by NHS England to registered Clinical Reference Group stakeholders and CRG members for a 2-week stakeholder engagement exercise to get feedback on the draft policy proposition and the clinical evidence review. The documents circulated are:

- the clinical evidence review
- the draft policy proposition and
- the CPAG summary report for clinical panel.

Comments from registered stakeholders are submitted to the NICE CSP team directly. After the closing date, the CSP produce a brief engagement report for NHS England, summarising the feedback received and any actions taken to address the comments.

Comments that require further discussion are sent via email to members of the policy working group for discussion and resolution. Any amendments to the documentation following the stakeholder engagement exercise are agreed by the clinical lead. The CSP will action the amendments.

Policy working group responses to individual comments received at stakeholder engagement are collated into a table by the CSP. As this document contains the names of individuals who have commented, it is not distributed externally.

The revised documents (that is, the clinical evidence review, draft policy proposition and CPAG summary for clinical panel) are sent to the company for information.

4.11 Impact assessment report and costing template

The CSP carries out an impact assessment in line with NHS England's integrated impact assessment template. This template asks for information on:

- patient numbers (current patient population, expected growth in patient numbers, current treatment options, patient pathway, treatment setting, coding and monitoring)

- service impact (implications for the existing clinical services that would be affected by the introduction of the new medicine) and
- financial implications of implementing the draft policy proposition (average cost per patient, overall cost to NHS England and to the NHS as a whole, funding implications and financial risks).

The CSP does not search for any evidence of, or comment on, the cost effectiveness of the medicine under consideration.

In order to complete the impact assessment report, a business analyst from NICE's Resource Impact Assessment team builds a costing template (in Microsoft Excel) to calculate the predicted financial impact of implementing the policy over a 5 year time period. The model contains a number of assumptions that are specific to the medicine or disease area under consideration, such as expected population growth or uptake of a new medicine. These assumptions are first discussed at the policy working group meeting and subsequently refined as the draft policy proposition develops. The NICE RIA business analyst directly contacts members of the policy working group in the 2 weeks following the policy working group meeting where clarification is required for any assumptions.

The acquisition cost of the medicine used in the financial model will be the publically available list price, or where this has not yet been agreed, a numerical value which is intended as a placeholder (that is, a dummy variable). The CSP does not accept any commercially sensitive information relating to the acquisition cost of a medicine.

The policy working group is asked to review both the impact assessment report and the costing template. Members of the policy working group are asked to check the validity of the assumptions and the accuracy of the calculations (or, where the acquisition cost of the medicine is not known, the policy working group is asked to comment on the remaining assumptions and the functionality of the model). The CSP also asks the company to comment on the accuracy of the data in the impact assessment report and costing template. This occurs at approximately 10 weeks following the policy working group meeting. The timeframe for responses to the CSP is 10 working days.

4.12 CPAG summary report

The CSP prepares part 1 the CPAG summary report; this report is similar to that prepared for the clinical panel (see section 4.9) and details the benefits of the technology and details of the proposition. There is no new information in this report that is not already contained in the draft policy proposition or clinical evidence review.

The NICE RIA team prepares part 2 of the CPAG summary report which summarises the activity and budget impact of implementing the draft policy proposition. The summary includes the number of patients affected in England, the total cost per patient over 5 years, the budget impact in years 1 to 5 (separate for each year), the total number of patients having treatment over 5 years and the net cost per patient having treatment over 5 years. There is no new information in this report that is not already contained within the impact assessment report and costing template. Beyond completing the templates, NICE has no role in presenting information to the CPAG.

4.13 Handover to NHS England

On completion of all key stages, NICE passes the commissioning support documents for the topic to the relevant NHS England national programme of care senior manager. The documents include the:

- scope
- clinical evidence review
- draft policy proposition
- CPAG summary for clinical panel
- Stakeholder engagement report
- comments table, including policy working group responses
- impact assessment report
- costing template
- CPAG summary report (parts 1 and 2).

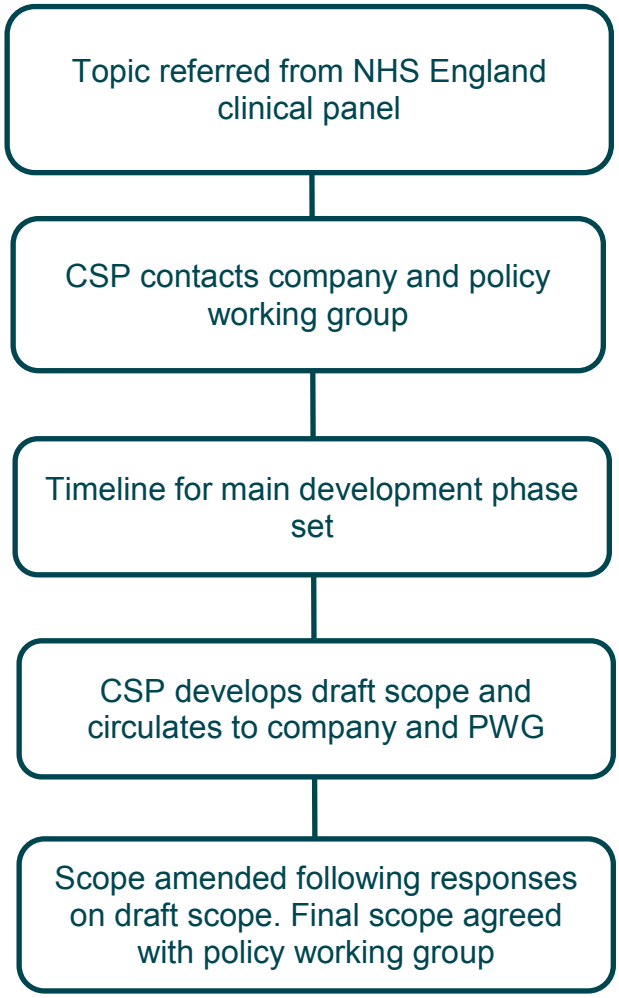
The programme of care senior manager submits the relevant documentation to the programme of care board, who will confirm the length of consultation. The programme of care senior manager will then run a public consultation on the documents (see Methods: National Clinical Policies). NICE reviews any comments received during consultation that challenge the evidence review, factual accuracy or completeness of the commissioning support documents, but otherwise has no further role in developing the NHS commissioning policy.

5 Timelines

The CSP process links into NHS England's clinical commissioning policy development process. Various elements of the CSP process rely on meetings that are external to NICE (for example clinical panel meeting or programme of care board meeting) and on availability of individuals in the policy working group.

5.1 Preliminary development phase (up to 6 months before invitation to participate is sent to a company)

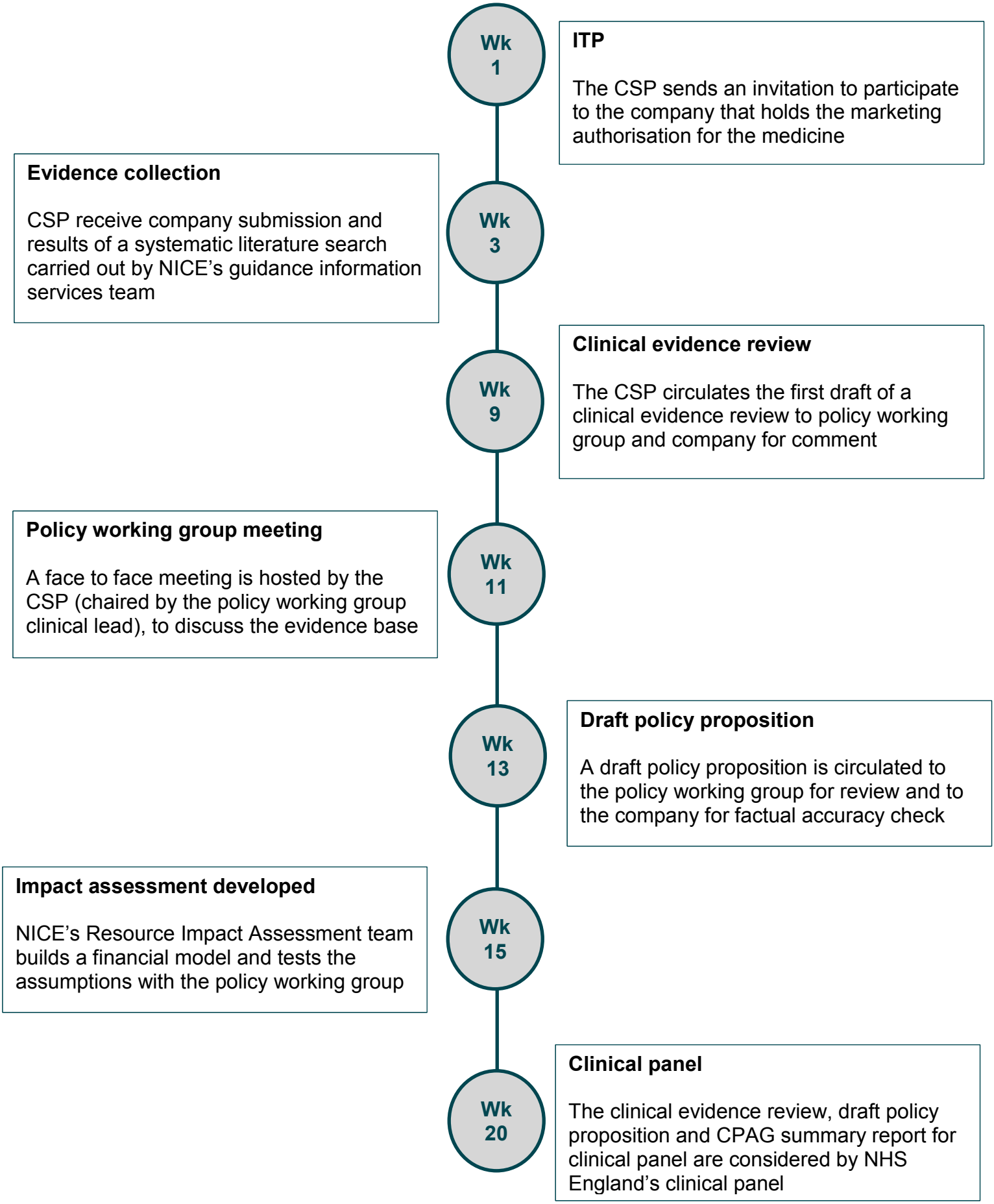
Before work on the topic can begin, the CSP will make initial contact with the policy working group and the company. This is known as the preliminary development phase and will occur up to 6 months before the main work begins (that is, the point at which NICE carries out a systematic search of the literature for a topic). During this timeframe, a scope will be developed with the policy working group in order to give the company as much notice as possible.



N.B. The timeframe between the final scope being agreed by the policy working group and the start date for the main work of the CSP will vary depending on regulatory timeframes, availability of policy working group members and any notifications from NHS England's clinical panel regarding the priority for development of a policy.

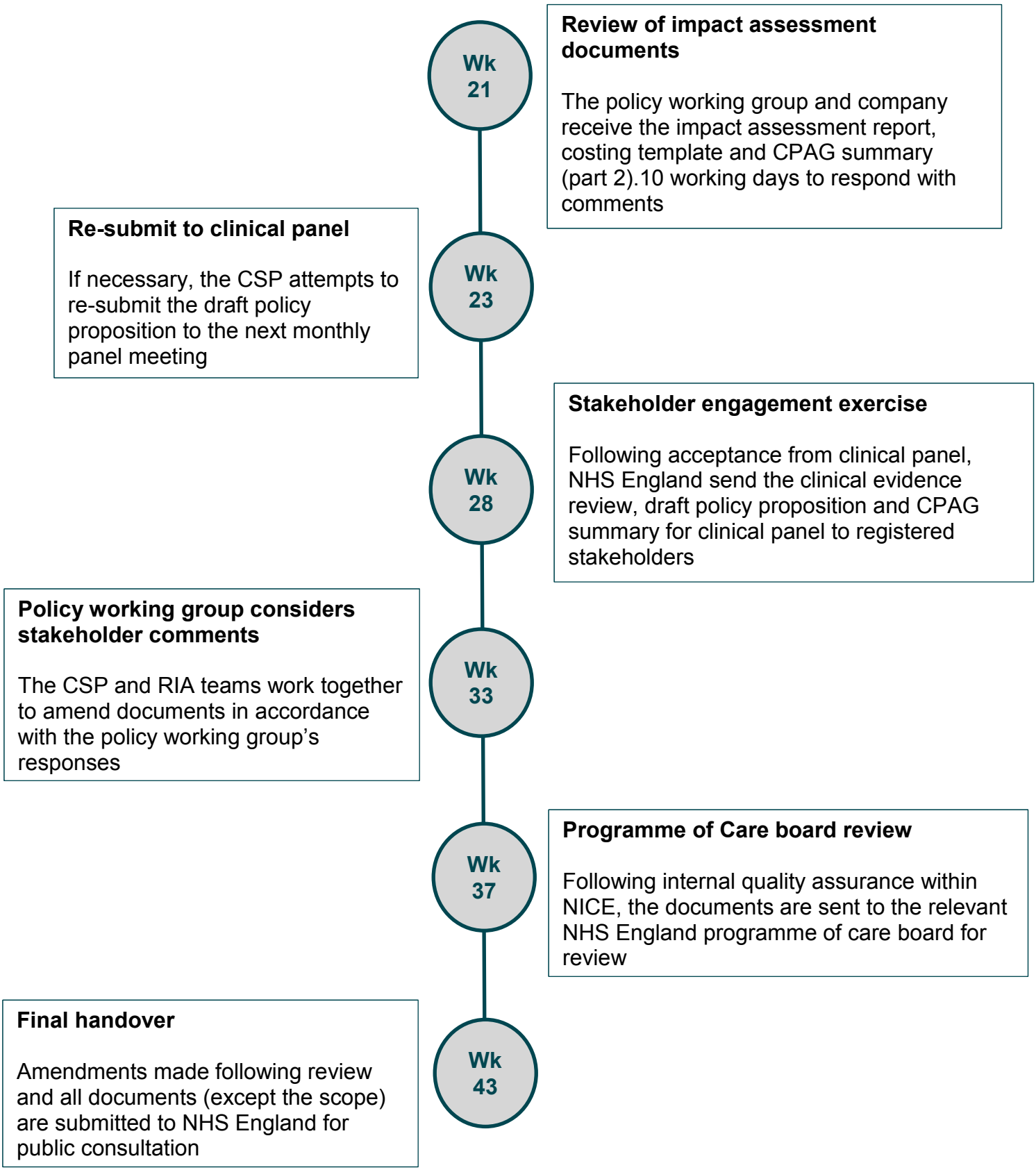
5.2 Main development phase (week 1 to week 20)

The main work of the CSP is between the point that the invitation to participate is sent to the company (week 1) and the date of the clinical panel (week 20). During this timeframe, the timelines are relatively fixed.


Wk 1
ITP
The CSP sends an invitation to participate to the company that holds the marketing authorisation for the medicine
Wk 3
Evidence collection
CSP receive company submission and results of a systematic literature search carried out by NICE's guidance information services team
Wk 9
Clinical evidence review
The CSP circulates the first draft of a clinical evidence review to policy working group and company for comment
Wk 11
Policy working group meeting
A face to face meeting is hosted by the CSP (chaired by the policy working group clinical lead), to discuss the evidence base
Wk 13
Draft policy proposition
A draft policy proposition is circulated to the policy working group for review and to the company for factual accuracy check
Wk 15
Impact assessment developed
NICE's Resource Impact Assessment team builds a financial model and tests the assumptions with the policy working group
Wk 20
Clinical panel
The clinical evidence review, draft policy proposition and CPAG summary report for clinical panel are considered by NHS England's clinical panel

5.3 Review and final handover phase

From the point at which the CSP receives confirmation from NHS England's clinical panel that the topic can proceed to the next stage of development, the timelines are subject to external meetings outside of NICE's responsibility and may therefore vary. However, the process following clinical panel approval, with approximate weeks, is given below:



N.B In this part of the process, the week numbers are approximate and should only be taken as a guide.

Delays to the process

The standard CSP timelines may be extended if there are delays outside NICE's control. These may include, but are not limited to:

- The timing of the clinical panel meeting relative to the completion of papers to be submitted to the panel (papers must be submitted no less than 3 weeks before the clinical panel meeting).
- The clinical panel's decision to overturn a recommendation made by the policy working group and request the documents to be resubmitted following amendment.
- Availability of the policy working group to work with the CSP throughout development and to attend or contribute to the policy working group meeting.
- The effect of national holidays, such as Christmas, on the scheduling of the stakeholder engagement exercise.
- Delays to the expected publication of clinical evidence.

6 Who is involved in the work of the Commissioning Support Programme?

The CSP is responsible for the overall delivery of the work programme. During the process, the team works with a number of internal specialist NICE teams:

6.1 Public involvement programme

NICE's Public Involvement Programme supports and develops public involvement across NICE's work programmes. During the development of a topic it assists patient and carer organisations, for example to explain the format and purpose of the policy working group meeting.

6.2 Guidance information services

NICE's guidance information services team does systematic literature searches for clinical evidence on behalf of internal teams. The team is responsible for doing systematic literature searches for evidence about the clinical effectiveness and safety of medicines being considered by the CSP. Database search strategies are based on the population, intervention, comparator and outcome elements that are

detailed in the scope. The team provides a high level sift of the studies found through this search. Reasons for excluding studies at this stage include:

- Articles are outside the scope of the topic.
- Trial reports are limited to a discussion on outcomes that are not considered clinically relevant (for example pharmacokinetics, pharmacodynamics and some biomarker studies, regardless of whether they are based on randomised controlled trial data).
- They are only available as conference abstracts.
- They are non-English language articles.
- They are study protocols (without results).
- They are studies involving people without the condition.
- References have an irrelevant title and no abstract is available.

6.3 Medicines and prescribing team

NICE's medicines and prescribing team produces guidance, advice and support for delivering quality, safety and efficiency in the use of medicines. The team's medicines advisers support the development of commissioning support topics.

6.4 Resource impact assessment

NICE's resource impact assessment team evaluates the resource impact of implementing a change in treatment options. The team is responsible for building the costing template, testing the assumptions with members of the policy working group, producing the integrated impact assessment report and completing part 2 of the CPAG summary report. RIA works closely with the CSP and with members of the policy working group to ensure consistency across the full suite of documents before submission to NHS England.

7 Publication

NICE's publications executive considers the CSP's outputs before signing them off for publication on the NICE website. Publication happens after the end of NHS England's public consultation on the topic. The documents we publish are:

- scope
- clinical evidence review

- draft policy proposition (NHS England template)
- integrated impact assessment (NHS England template)
- stakeholder engagement report (NHS England template)
- Clinical Priorities Advisory Group (CPAG) summary of benefits for Clinical Panel consideration (NHS England template)
- CPAG summary report parts 1 and 2 (NHS England template)

8 About this standard operating procedure

This standard operating procedure will be reviewed at 6 months from the date of publication.

Glossary

Clinical panel

A group chaired by NHS England's medical director for specialised services. It agrees the routing for topics. It also considers whether a policy proposition is built on the available clinical evidence and whether the policy can proceed to the stakeholder engagement exercise and impact analysis phase as either a 'routine' or 'not for routine' commissioning proposal.

Clinical priorities advisory group (CPAG)

The group that makes recommendations to NHS England about commissioning services, treatments and technologies, and considers which of these should be prioritised for investment. Its scope includes all specialised services of NHS England.

Clinical reference group (CRG)

There are 42 clinical reference groups providing clinical advice to NHS England's national programme of care boards. Each group comprises clinicians, commissioners, pharmacists, public health experts, patients and carers. CRG members are notified of the stakeholder engagement exercise to provide the opportunity for comments on the clinical evidence review and draft policy proposition.

Company

The company that manufactures or sponsors the medicine being reviewed.

Comparator

The intervention that would be replaced if the new medicine were to be adopted in NHS clinical practice. If an active treatment is not available, the comparator may be best supportive care.

Draft policy proposition

A document that contains the considerations of the policy working group to NHS England. It covers a short summary of the evidence, epidemiology and treatment pathway as well as a draft commissioning recommendation and starting or stopping criteria for the medicine. This document is discussed by the clinical panel and CPAG. NICE drafts this document on behalf of the policy working group.

Integrated impact assessment

This document captures the predicted impact of implementing a policy on the treatment pathway, the clinical service and on the NHS budget.

National programmes of care

NHS England has 6 national programmes of care that commission specialist services (internal medicine, cancer, mental health, trauma, women and children, blood and infection). The CSP works with the relevant national programme of care senior manager to hand over the finished documents.

Outcome

A measure of the possible results of a treatment with a preventive or therapeutic intervention. Outcome measures can be either intermediate or final end points.

Policy working group

A group of clinicians, commissioners, pharmacists, public health experts, patients and carers that advise NICE on elements of the clinical evidence and resource impact of technologies considered by the CSP. The policy working group is responsible for agreeing the content of the draft policy proposition.

Appendix 1 – Evidence selection

Searching

The search strategy is developed based on the scope of the topic, and the following sources are searched:

- Medline (including Medline in process, early online and daily update records)
- Embase
- Cochrane Library (incorporating Cochrane Database of Systematic Reviews (CDSR); DARE; CENTRAL; HTA database; NHS EED).
- Clinicaltrials.gov
- Clinicaltrialsregister.eu

Limits on searches, such as dates and study types, are based on the scope of the topic.

All references are imported into EPPI reviewer and electronically de-duplicated.

Sifting

A first sift at title and abstract stage is done in EPPI reviewer by NICE guidance information services to exclude any further duplicates and all studies clearly not fitting the scope of the topic.

A second sift at title and abstract stage is done in EPPI reviewer by the NICE Commissioning Support Programme and medicines and prescribing teams to exclude any remaining studies that do not fully fit the scope of the topic, before ordering full text papers.

Study selection

Full inclusion and exclusion criteria specific to the scope of the topic are applied to all full text articles which were included at sifting. All studies not meeting the criteria for inclusion are listed, with reasons for exclusion given.

Company submission

The company submission is used to check that all relevant studies have been identified by the search. If there is a lack of published evidence in the area, the company may also be asked to provide unpublished data for inclusion in the

evidence review. However, that evidence will need to have been published before the policy proposition can be finalised.

Data extraction

All studies selected for inclusion in the evidence review are extracted into standard data extraction tables.