NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Company evidence submission to the

**Commissioning Support Programme**

[Topic name and ID number]

Provided by [company sponsor/UK marketing authorisation holder]

 [Month year]

# Instructions for companies

This is the template for submission of evidence to the National Institute for Health and Care Excellence (NICE) Commissioning Support Programme (CSP). This document is used to inform the development of documents to support NHS England’s national clinical policy process for directly commissioned specialised services (for further details of the policy development programme, please consult NHS England’s specialised services [webpage](https://www.england.nhs.uk/commissioning/spec-services/)). The documents prepared by the CSP in support of this process include a clinical evidence review and an impact assessment; this submission will be used by the CSP as a source of evidence for these documents. Please refer to the CSP [standard operating procedure](https://www.nice.org.uk/about/what-we-do/our-programmes/commissioning-support-programme/how-we-support-policy-development) for further information.

The date for completion is as described in the letter sent with this submission template.

Please note the following important points about submitting clinical evidence:

Published evidence: It is not necessary to report the results of published evidence. These will be identified and reported by the CSP, via a systematic review of the literature.

Unpublished evidence: In line with NHS England’s requirement that the [clinical priorities advisory group](https://www.england.nhs.uk/commissioning/cpag/) (CPAG) should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 this 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 In exceptional circumstances, the CSP will consider accepting unpublished clinical evidence if it is from a draft version of the European public assessment report or where **all** of the following conditions are met:

* the evidence relates directly to an outcome listed in the scope
* there is no other published evidence for the outcome
* the evidence is written in manuscript form and can be provided to the CSP before the work on the clinical evidence review is due to begin (2 weeks following the submission deadline)
* the company confirms that it will publish the manuscript prior to the date that the evidence will be considered by CPAG (as an indication, manuscripts should be published within 4 months of the submission deadline, however this is only a guide and may vary).

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.

Where the CSP has agreed **in advance** to accept the manuscript for a study that is due to be published, the results of the study should be detailed within this submission (section 2.3).

The total submission should be no more than 50 pages, including the pages covered by this template. Appendices should be no more than 100 pages and should be clearly referenced in the main body of the submission. To reduce repetition, please refer to other parts of the submission rather than copying and pasting the same text into different sections.

### Confidential information

Commercial-in-confidence information cannot be accepted in this submission, except for the proposed list price (if not publically available) and expected marketing authorisation wording (table 2). Any commercial in confidence data included in this submission must be highlighted in turquoise and underlined. Unpublished academic-in-confidence data that have been accepted for publication within the timeframe of the evidence review and meet all of the criteria outlined above can be submitted only following prior agreement with NICE. Any academic in confidence data included in this submission must be highlighted in yellow and underlined. Information that has been put into the public domain, anywhere in the world, may not be marked as confidential. This submission must be accompanied by a completed confidential information checklist when returning to the CSP.

### Highlighting in the template (excluding the contents list)

Square brackets and grey highlighting are used in this template to indicate text that should be replaced with your own text.

To change the header and footer, double click over the header or footer text. Double click back in the main body text when you have finished.

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# Section 1 Preliminary information

1. Decision problem

A final scope is prepared by NICE and is sent to the company at the point of inviting a submission of evidence. Please use the table below to provide a description and explanation of any discrepancies between the scope and the evidence provided in this submission.

Table 1 Comparison of decision problem in scope and submission

|  |  |  |  |
| --- | --- | --- | --- |
|  | Final scope issued by NICE | Decision problem addressed in the submission | Rationale if different from the final NICE scope |
| Population | [Please state the population listed in the final scope issued by NICE] | [Please state the population considered in the submission] |  |
| Intervention | [Please state the intervention listed in the final scope issued by NICE] | [Please state the intervention considered in the submission] |  |
| Comparator(s) | [Please state the comparator(s) listed in the final scope issued by NICE] | [Please state the comparator(s) considered in the submission] |  |
| Outcomes | [Please state the outcomes listed in the final scope issued by NICE] | [Please state the outcomes considered in the submission] |  |
| Other issues | [Please cover any other issues here, for example subgroups] | [Please cover any other issues here, for example subgroups] |  |

1. Description of the technology being considered

Table 2 Description of the technology being considered

|  |  |
| --- | --- |
| UK approved name (or anticipated name) and brand name |  |
| Mechanism of action | [Please include a plain language description of the mechanism of action.]  |
| Marketing authorisation | [Indicate whether the technology has a UK marketing authorisation for the indication of interest. If so, give the date when this was granted. If not, state the current UK regulatory status, with relevant dates (for example, date of application and/or expected date of approval from the Committee for Human Medicinal Products). Give the (anticipated) indication(s) in the UK. If a submission is based on the company’s proposed or anticipated marketing authorisation, the company must advise NICE immediately of any difference between the anticipated and the final marketing authorisation approved by the regulatory authorities. This information may be marked as commercial in confidence if not yet publicly available – see notes for correct highlighting procedure on page 3.]  |
| Method of administration and dosage for the indication being reviewed | [State method of administration and dosage included in the marketing authorisation] |
| Duration of treatment  | [State duration of treatment, including starting and stopping or discontinuation rules as stated in the marketing authorisation] |
| Proposed or confirmed list price  | [This information may be marked as commercial in confidence if not yet publicly available]  |

1. Health condition and epidemiology

### Brief overview of the condition

[Provide a brief overview of the disease or condition for which the technology is licensed (or soon to be licensed) in no more than 250 words.]

### Epidemiology of the condition

[Provide a brief overview of the epidemiology of the disease or condition for which the technology is licensed (or soon to be licensed) in no more than 250 words; tables are acceptable).]

[Provide prevalence data for England specifically for the licensed or anticipated indication. If data are not available, provide prevalence data for the UK or another country comparable to England. Provide data sources and any assumptions used.]

1. Main benefits of the new technology

[Briefly explain (in no more than 250 words) the main benefits of the intervention.]

1. Position of the technology in the treatment pathway

### Current pathway of care in England

[Present a diagram and short description summarising the pathway of care for *current* NHS clinical practice in England (that is, excluding the technology of interest where it is not already in routine use). Please ensure the pathway is specifically for the health condition and population for which the technology is licensed (or soon to be licensed). Please also ensure that the diagram clearly illustrates the treatment(s) for which information is provided in the budget impact section of this submission.]

### Comparator treatments

Table 3 Comparator treatments in the current pathway of care

|  |  |  |
| --- | --- | --- |
| Name of comparator (in order of most common use in NHS clinical practice) | Percentage use of comparators in England | Summary information |
|  | [Please note: confidential information must not be included here.] | [Include a brief, plain language factual description of each intervention, for example, mode of action, administration] |
| [add more rows if needed] |  |  |

### Current treatment access criteria

[Please provide details of any clinical criteria (for example, patient characteristics or starting criteria) for accessing the comparator treatments listed in table 3.]

### Proposed pathway of care in England

[Present a diagram and a plain language short description summarising the proposed pathway of care in England that includes the technology under consideration.]

* 1. Related guidelines and NHS England policies

### Related NICE guidelines

[List any related NICE guidelines.]

### Related non-NICE guidelines

[List any related non-NICE guidelines.]

### Related NHS England clinical commissioning policies

[List any related NHS England clinical commissioning policies.]

* 1. Related NICE quality standards

[Specify whether any directly applicable NICE or equivalent quality standard needs to be monitored in association with the proposed technology. If yes, how will performance monitoring data be used for this purpose?]

1.9 Equality considerations

[NICE is committed to eliminating discrimination, advancing equality of opportunity, and fostering good relations, as required by the Equality Act 2010, and to complying with the Human Rights Act 1998. The Act prohibits discrimination, harassment, and victimisation in relation to people who share the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation. Briefly describe (in no more than 250 words) any equality issues, including whether commissioning the intervention is likely to improve equality and equity of access.]

1.10 Patient and carer organisations

[Please provide the details of the most relevant patient and carer organisations for the disease area in the table below. If possible, these should be national organisations.]

Table 4 Patient and carer organisations

|  |
| --- |
| Organisation name |
|  |
| [add more rows if needed] |

# Section 2 Clinical effectiveness evidence

Section 2 should be used to notify the CSP of the relevant clinical effectiveness evidence for the indication under consideration. Please note the restrictions around submitting academic in confidence data as stated on pages 2 and 3 of this template.

* 1. Published clinical effectiveness evidence

[Please list the published studies that provide evidence of the clinical effectiveness and safety profile of the technology, in table 5. This may include evidence on quality of life. Please do not provide results as these will be extracted from the publication by the CSP.]

Table 5 Published evidence of clinical effectiveness and safety profile for the technology under consideration

|  |  |  |  |
| --- | --- | --- | --- |
| Study name | [add or delete columns as needed. If it is difficult to fit all columns onto the page, either present this table in landscape, or create multiple versions of this table and place below.] |  |  |
| Study design | [for example, randomised controlled trial, cohort study, systematic review] |  |  |
| Full publication reference  |  |  |  |
| Primary outcomes | [for example, 5-year survival] |  |  |
| Secondary outcomes |  |  |  |

* 1. Subgroups

[If there is evidence of a clinical benefit in a particular subgroup of people within the licensed indication, briefly describe the subgroup and why the technology may be more effective in this subgroup.

In table 5, include details of any published studies that provide evidence of the clinical benefit for the subgroup. Please do not include the results of the study as these will be extracted by the CSP.]

* 1. Unpublished clinical effectiveness evidence

[If there are any unpublished studies at the time of submission that are expected to be published before the evidence is reviewed by NHS England’s Clinical Priorities Advisory Group (CPAG), and which can be provided to the CSP in final manuscript form, these can be listed below (table 6). Please note that only studies that provide evidence that is not otherwise available from the published evidence base and which is directly relevant to an outcome from the scope can be accepted. The final manuscript must be provided to the CSP before the clinical evidence review is scheduled to begin (2 weeks after the submission deadline). See pages 2 and 3 of this template for further details relating to confidential information.]

Table 6 Unpublished evidence of clinical effectiveness and safety profile for the technology under consideration

|  |  |  |
| --- | --- | --- |
| Study title | [add or delete columns as needed.] |  |
| Study type |  |  |
| Aim of the study |  |  |
| Study dates |  |  |
| Setting  |  |  |
| Number of participants |  |  |
| Population | [state the disease characteristics of the population and if appropriate, provide a breakdown by disease characteristics (including numbers of participants)] |  |
| Inclusion criteria |  |  |
| Exclusion criteria |  |  |
| Intervention(s) |  |  |
| Comparator(s) |  |  |
| Methods |  |  |
| Length of follow-up |  |  |
| Primary outcome(s) and results |  |  |
| Secondary outcome(s) and results |  |  |
| Adverse events | [please provide details of any adverse events that are not reported as primary or secondary outcomes] |  |
| Interpretations and conclusions from the results |  |  |
| Source of funding | [please state who funded the study] |  |
| Submitted for publication? | [please note only studies that have been submitted for publication can be accepted] |  |
| Expected date and journal of publication |  |  |

* 1. Key strengths of the clinical effectiveness evidence base

[Summarise the key strengths of the overall clinical effectiveness evidence base, including the published and unpublished evidence. Provide details of applicability to NHS clinical practice in England.]

* 1. Key evidence gaps and limitations

[Present the key limitations of the clinical effectiveness evidence base, including the published and unpublished evidence. Provide details of any gaps in the evidence base.]

# Section 3 Budget and service impact

The information requested in section 3 will be used as a starting point for the assumptions in a costing template to be provided to NHS England. The costing template calculates the cost per patient over 5 years, and the total budget impact to the NHS of implementing the medicine.

The information in this section is also used to populate NHS England’s Integrated Impact Assessment form. This document includes a summary of the budget impact as well as information relating to the impact on the clinical service if the medicine were to be routinely commissioned.

1. Epidemiology of the health condition

[Provide details in the table below of the incidence and prevalence of the health condition.]

Table 7 Disease incidence and prevalence

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Current year | 1 year | 2 years | 5 years | 10 years | Reference/ source |
| INCIDENCE(number or rate)[England only. If not available, provide for UK or other country comparable to England] |  |  |  |  |  |  |
| PREVALENCE IN CURRENT YEAR (number or rate)[England only. If not available, provide for UK or other country comparable to England] |  | Not applicable – prevalence for these years will be calculated using current year prevalence and incidence predictions thereafter |  |

### Factors likely to affect the size of the patient population

[Provide details of factors likely to affect the number of people with the disease for which this technology is (or is expected to be) indicated, for example increased survival rates, improved diagnosis.]

### Geographical distribution of the health condition

[Provide details of how the population is currently geographically distributed in England in the table below. Provide a rationale for any expected changes in the geographical distribution of the health condition in the future.]

Table 8 Estimated regional distribution of patients

|  |  |  |
| --- | --- | --- |
|  | Current  | Future (5 to 10 years) |
| North | [Insert % estimates and source]  | [Insert “Unknown”, “No difference anticipated”, or insert % estimates and source if an estimate can be made. Add additional columns if data are available for multiple years] |
| Midlands & East |  |  |
| London |  |  |
| South |  |  |

### Age distribution of people with the health condition

[Please provide details of the age distribution of the population for which the treatment is indicated.]

1. Number of eligible people in England

### Characteristics of the population defined by the marketing authorisation

[Please provide details of any age restrictions in the marketing authorisation.]

[In the table below, provide a breakdown of the estimated number of people in England with the health condition as per the marketing authorisation.]

Table 9 Estimated number of eligible people

|  |  |  |  |
| --- | --- | --- | --- |
|  | Percentage | Number | Reference/Source |
| Population of England |  |  |  |
| [Add rows as necessary – for example if MA states ‘refractory to treatment’ include this as a separate row to demonstrate how the total number eligible for treatment (below) has been calculated. Do not include uptake.] |  |  |  |
| TOTAL number of people eligible for treatment [Do not include uptake figures here] | N/A |  | N/A |

[In the table below, provide details of the projected change in number of eligible patients. Please note, this table is not requesting information regarding uptake of the technology. This is the predicted total number of people in England with the condition as per the marketing authorisation.]

Table 10 Projected change in number of eligible people

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Current year | 1 year | 2 years | 3 years | 4 years | 5 years | 10 years | Reference source |
| [The current year should be the total number of eligible people from table 9] |  |  |  |  |  |  |  |

### Availability of new technology

[Please state whether the new treatment is already in use in NHS clinical practice in England. If so, provide the number of people currently accessing the treatment as per the licensed indication.]

1. Estimated uptake of treatment

[Provide details in the table below for uptake of technologies in the different treatment pathways.]

Table 11 Uptake of treatments in the proposed and current pathways

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Proposed pathway (that is, if the technology was routinely commissioned) | Comparator pathway (that is, current treatment pathway without the new technology) | 2nd comparator pathway (if no consensus on most commonly used treatment in the NHS) | Reference sources |
| Eligible population  | [This is 100% of the eligible population, that is the total number of eligible people from table 9] |  |
| Percentage of eligible population clinically assessed for treatment |  |  |  |  |
| Percentage of eligible population considered to meet an exclusion criterion following assessment  |  |  |  |  |
| Percentage of eligible population choosing to start treatment  |  |  |  |  |
| Percentage of eligible population who are expected to comply with treatment  |  |  |  |  |
| Percentage of eligible population completing treatment  |  |  |  |  |

1. Discontinuation and mortality rates

[Please provide details of the discontinuation rate and state the reference or source of this information.]

[Please provide details of the mortality rate for people with the health condition and state the reference or source of this information.]

1. Costs and resource use

[Provide details of resource use and costs for the new technology and comparator(s) using the table below.]

Table 12 Costs and resource use

|  |  |  |  |
| --- | --- | --- | --- |
|  | New technology | Comparator | 2nd comparator (if applicable) |
| Publically available list price (acquisition cost) [see notes on providing in confidence information on page 3] |  |  |  |
| Is the technology VAT exempt?  |  |  |  |
| Is the medicine delivered or administered at home or in hospital/primary care? |  |  |  |
| Acquisition costs for any treatments given in combination as per the licensed indication |  |  |  |
| Dosage details |  |  |  |
| Frequency of administration |  |  |  |
| Average duration of treatment (include reference) |  |  |  |
| Monitoring costs |  |  |  |
| Outpatient appointments required |  |  |  |
| Diagnostic tests required (describe and state costs) |  |  |  |
| [Please add rows as required, for example if there are inpatient admission costs or transportation costs for lab samples] |  |  |  |

1. Existing tariff and pricing mechanisms

[Provide details of tariffs and pricing in the table below.]

Table 13 Tariff and pricing

|  |  |  |  |
| --- | --- | --- | --- |
|  | New technology | Comparator | 2nd comparator (if applicable) |
| National prices | [Specify whether the technology is within the national tariff, and if so, specify Healthcare Resource Group and tariff] [Specify whether the technology is excluded from national prices] |  |  |
| Patient access schemes | [Specify whether there is a patient access scheme for the technology. Do **not** provide details of the patient access scheme here unless they are within the public domain] |  |  |
| Local price arrangement  | [State whether the technology is covered under a local price arrangement. If so, if the information is within the public domain, state range, mid-point, and level of certainty that activity is not attributable to other clinical services. Note: if subject to commercial confidentiality, please do not provide details here] |  |  |
| Prior approval mechanism  | [Are there any prior approval mechanisms required either during implementation or permanently, to support the implementation of the new policy?] |  |  |

1. Budget impact of implementing the new technology

### Net cost per patient over 5 years

[Specify the estimated net cost per patient to NHS England in years 1, 2, 3, 4, and 5 in the table below. This should take into account the impact of the new care pathway compared with the most commonly used comparator treatment(s), and should include acquisition costs of any drugs, monitoring or follow-up costs, and other consumables. State which costs include VAT and at what rate. To aid clarity, please add additional rows to illustrate how the net cost for each treatment has been calculated.]

Table 14 Net cost per patient to NHS England of the new technology compared with current practice

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Reference source |
| Cost per patient – new technology |  |  |  |  |  |  |
| Cost per patient – comparator [add additional rows if more than one comparator] |  |  |  |  |  |  |
| Net cost per patient to NHS England  |  |  |  |  |  |  |

### Budget impact

[Specify the overall cost impact to the NHS and others in the table below. State which costs include VAT and at what rate.]

Table 15 Overall cost impact to the NHS and others

|  |  |
| --- | --- |
| Budget impact on other parts of the NHS | [Specify the budget impact of the proposal on other parts of the NHS, for example cost saving, neutral or cost pressure for other providers, clinical commissioning groups etc.] |
| Budget impact on NHS as a whole  | [Specify the budget impact to the NHS as a whole. Include any potential savings to NHS England or CCGs (resources released, costs avoided, disinvestment opportunities. Are there any non-cash benefits?] |
| Costs for non-NHS commissioners or public sector funders  | [Specify whether there are likely to be any costs for non-NHS commissioners or public sector funders, and what these are] |
| Saving for non-NHS commissioners or public sector funders  | [Specify whether there are likely to be any savings for non-NHS commissioners or public sector funders, and what these are] |

### Expected acquisition cost changes

[Please detail any expected changes to the acquisition costs for the new technology and the comparator technologies, including changes to patents, within the next 10 years.)]

1. Uncertainty of budget and service impact evidence

[State what issues or risks are associated with any answers provided in part 3 of this submission, for example, quality or availability of evidence such as uncertainty about number of eligible patients, uncertainty about estimates of uptake, uncertainty about future drug prices, uncertainty around potential off-set costs, uncertainty around standard of care. Please state how these can be mitigated.]

1. Evidence sources and rationale

[State which evidence sources for budget and service impact were used and why. Describe where the main evidence gaps lie.]

1. Current treatment and service details

[Provide details of current treatment and service details in the table below.]

Table 16 Current treatment and service details

|  |  |
| --- | --- |
| Current organisation of the service  | [for example tertiary centres, networked provision] |
| How the treatment is delivered to the patient  | [for example acute trust, mental health provider, inpatient, outpatient, homecare] |
| Current treatment access | [Provide details of current treatment access] |
| Current providers  | [Provide details of the current number of providers contracted to care for the eligible population by region – North, Midlands and East, London, South. State the current number of providers required in each region.]  |
| Current sources of referral  | [for example patient self-referral, GP, secondary care, tertiary care] |

1. Proposed treatment with the new technology and service details

[Provide details of proposed treatment with the new technology and service details in the table below.]

Table 17 Proposed treatment and service details

|  |  |
| --- | --- |
| Sources of referral  | [State what impact commissioning the new technology would have on referral. For example no impact, increase, decrease. Provide a source for this information.]  |
| Commissioning or provider action required for implementation of new technology  | [State whether commissioning or provider action is required for implementation of the new technology. Provide a source for this information.] |
| Changes in provider physical infrastructure required  | [State whether a change in provider physical infrastructure is required. Provide a source for this information.] |
| Changes in provider staffing required  | [State whether a change in provider staffing is required] |
| Lead-in time for implementation of new technology  | [State whether a lead-in time is required for implementation of the new technology, and if so, whether an interim plan for implementation will be required (if yes, outline the plan)] |
| Changes in clinical dependency or adjacency requirements | [State whether new clinical dependency or adjacency requirements would be needed] |
| Changes to support services | [State whether changes to support services would be needed] |
| Changes to provider or inter-provider governance | [State whether a change in provider or inter-provider governance is required for example operational delivery network arrangements or prime contractor] |
| Changes in the number of commissioned providers | [Specify whether there is likely to be either an increase or decrease in the number of commissioned providers, and if so, specify the estimated number of providers needed in each region] |
| Changes in delivery setting | [Provide details of whether commissioning the new technology would require a change of delivery setting] |
| Changes in capacity requirements | [Provide details of whether commissioning the new technology would require a change in capacity requirements] |
| Changes in organisation of commissioned services | [State whether commissioning the new technology will change the way the commissioned service is organised] |

1. Recording and monitoring impact

[Provide details of recording and monitoring of proposed treatment with the new technology in the table below.]

Table 18 Recording and monitoring of proposed treatment

|  |  |
| --- | --- |
| Datasets to record the new patient pathway activity  | [Specify the datasets used to record the new patient pathway activity] |
| Identification of activity related to the new patient pathway  | [Specify how the activity related to the new patient pathway will be identified] |
| New or revised requirements needed for inclusion in the NHS standard contract information schedule  | [Specify any new or revised requirements needed for inclusion in the NHS standard contract information schedule]  |
| Analytical information, monitoring or reporting requirements  | [Provide details of any analytical information or monitoring or reporting requirements, including validation requirements, to ensure activity is not double charged through existing routes] |
| Contract monitoring by supplier managers  | [Specify contract monitoring to be done by supplier managers and any changes from current arrangements] |
| Business intelligence | [Is there potential for duplicate reporting? If so, please specify, along with any mitigation] |
| Dashboard for technology being considered  | [Specify whether a dashboard exists for the proposed intervention. If so, specify how routine performance monitoring data will be used for dashboard reporting. If not, is a dashboard expected to be developed?] |
| Changes to the approach to the organisation of care  | [State whether the new technology requires a new approach to the organisation of care, for example implementation of a lead provider model, implementation of a new model of care, implementation of a network model to support appropriate selection of treatment] |
| Pharmacy monitoring required (for tariff excluded drugs)  | [For treatments that are tariff excluded drugs, specify the pharmacy monitoring required, for example, reporting or use of prior approval systems] |

END