Summary of Information for Patients (SIP):

The pharmaceutical company perspective

# What is the SIP?

The Summary of Information for Patients (SIP) is written by the company who is seeking approval from NICE for their treatment to be sold to the NHS for use in England. It’s a plain English summary of their submission written for patients participating in the evaluation. It’s not independently checked, although members of the public involvement team at NICE will have read it to double-check for marketing and promotional content before it’s sent to you.

The Summary of Information for Patients template has been adapted for use at NICE from the [Health Technology Assessment International – Patient & Citizens Involvement Group](https://htai.org/interest-groups/pcig/) (HTAi PCIG). Information about the development is available in an open-access [IJTAHC journal article](https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/development-of-an-international-template-to-support-patient-submissions-in-health-technology-assessments/2A17586DB584E6A83EA29E3756C37A14).

**Notes for authors:** Please complete the template using plain language, taking time to explain all scientific terminology. As you draft your response, please do not delete the intro text included in each section. It might be a useful reference for patient reviewers.

However, any text preceded by the words ‘**Notes for authors**’ simply contains additional prompts for the company to advise them on the type of information that may be most relevant, and the level of detail they need to include. **You may delete this text where indicated.**

# Section 1: submission summary

## 1a) Name of the me**dicin**e

Both generic and brand name.

|  |
| --- |
| Response: (click or tap here to enter text) |

## 1b) Population this treatment will be used by

Please outline the main patient population that is being appraised by NICE:

|  |
| --- |
| Response: (click or tap here to enter text) |

## 1c) Authorisation

Please provide marketing authorisation information, date of approval and link to the regulatory agency approval. If the marketing authorisation is pending, please state this, and reference the section of the company submission with the anticipated dates for approval.

|  |
| --- |
| Response: (click or tap here to enter text) |

## 1d) Disclosures

Please be transparent about any existing collaborations (or broader conflicts of interest) between the pharmaceutical company and patient groups relevant to the medicine. Please outline the reason and purpose for the engagement/activity and any financial support provided:

|  |
| --- |
| Response: (click or tap here to enter text) |

# Section 2: current landscape

**Note to authors:** This SIP is intended to be drafted at a global level and typically contain global data. However, the submitting local organisation should include country-level information where needed to provide local country-level context.

Please focus this submission on the **main indication (condition and the population who would use the treatment)** being assessed by NICE rather than sub-groups, as this could distract from the focus of the SIP and the NICE review overall. However, if relevant to the submission please outline why certain sub-groups have been chosen. **You may delete this note text.**

## 2a) The condition – clinical presentation and impact

Please provide a few sentences to describe the condition that is being assessed by NICE and the number of people who are currently living with this condition in England.

Please outline in general terms how the condition affects the quality of life of patients and their families/caregivers. Please highlight any mortality/morbidity data relating to the condition if available. If the company is making a case for the impact of the treatment on carers this should be clearly stated and explained.

|  |
| --- |
| Response: (click or tap here to enter text) |

## 2b) Diagnosis of the condition (in relation to the medicine being evaluated)

Please briefly explain how the condition is currently diagnosed and how this impacts patients. Are there any additional diagnostic tests required with the new treatment?

|  |
| --- |
| Response: (click or tap here to enter text) |

## 2c) Current treatment options:

The purpose of this section is to set the scene on how the condition is currently managed:

* What is the treatment pathway for this condition and where in this pathway the medicine is likely to be used? Please use diagrams to accompany text where possible. Please give emphasis to the specific setting and condition being considered by NICE in this review. For example, by referencing current treatment guidelines. It may be relevant to show the treatments people may have before and after the treatment under consideration in this SIP.
* Please also consider:
	+ if there are multiple treatment options, and data suggest that some are more commonly used than others in the setting and condition being considered in this SIP, please report these data.
	+ are there any drug–drug interactions and/or contraindications that commonly cause challenges for patient populations? If so, please explain what these are.

|  |
| --- |
| Response: (click or tap here to enter text) |

## 2d) Patient-based evidence (PBE) about living with the condition

Context:

* **Patient-based evidence (PBE)** is when patients input into scientific research, specifically to provide experiences of their symptoms, needs, perceptions, quality of life issues or experiences of the medicine they are currently taking. PBE might also include carer burden and outputs from patient preference studies, when conducted in order to show what matters most to patients and carers and where their greatest needs are. Such research can inform the selection of patient-relevant endpoints in clinical trials.

In this section, please provide a summary of any PBE that has been collected or published to demonstrate what is understood about **patient needs and disease experiences**. Please include the methods used for collecting this evidence. Any such evidence included in the SIP should be formally referenced wherever possible and references included.

|  |
| --- |
| Response: (click or tap here to enter text) |

# Section 3: the treatment

**Note to authors:** Please complete each section with a concise overview of the key details and data, including plain language explanations of any scientific methods or terminology. Please provide all references at the end of the template. Graphs or images may be used to accompany text if they will help to convey information more clearly. **You may delete this note text.**

## 3a) How does the new treatment work? What are the important features of this treatment?

Please outline as clearly as possible important details that you consider relevant to patients relating to the mechanism of action and how the medicine interacts with the body

Where possible, please describe how you feel the medicine is innovative or novel, and how this might be important to patients and their communities.

If there are relevant documents which have been produced to support your regulatory submission such as a summary of product characteristics or patient information leaflet, please provide a link to these.

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3b) Combinations with other medicines

Is the medicine intended to be used in combination with any other medicines?

[ ] Yes

[ ] No

If yes, please explain why and how the medicines work together. Please outline the mechanism of action of those other medicines so it is clear to patients why they are used together.

If yes, please also provide information on the availability of the other medicine(s) as well as the main side effects.

**If this submission is for a combination treatment, please ensure the sections on efficacy (3e), quality of life (3f) and safety/side effects (3g) focus on data that relate to the combination, rather than the individual treatments.**

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3c) Administration and dosing

How and where is the treatment given or taken? Please include the dose, how often the treatment should be given/taken, and how long the treatment should be given/taken for.

How will this administration method or dosing potentially affect patients and caregivers? How does this differ to existing treatments?

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3d) Current clinical trials

Please provide a list of completed or ongoing clinical trials for the treatment. Please provide a brief top-level summary for each trial, such as title/name, location, population, patient group size, comparators, key inclusion and exclusion criteria and completion dates etc. Please provide references to further information about the trials or publications from the trials.

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3e) Efficacy

Efficacy is the measure of how well a treatment works in treating a specific condition.

In this section, please summarise all data that demonstrate how effective the treatment is compared with current treatments at treating the condition outlined in section 2a.

* Are any of the outcomes more important to patients than others and why?
* Are there any limitations to the data which may affect how to interpret the results?

Please do not include academic or commercial in confidence information but where necessary reference the section of the company submission where this can be found.

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3f) Quality of life impact of the medicine and patient preference information

What is the clinical evidence for a potential impact of this medicine on the quality of life of patients and their families/caregivers? What quality of life instrument was used? If the EuroQol-5D (EQ-5D) was used does it sufficiently capture quality of life for this condition? Are there other disease specific quality of life measures that should also be considered as supplementary information?

Please outline in plain language any quality of life related data such as patient reported outcomes (PROs).

Please include any patient preference information (PPI) relating to the drug profile, for instance research to understand willingness to accept the risk of side effects given the added benefit of treatment. Please include all references as required.

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3g) Safety of the medicine and side effects

When NICE appraises a treatment, it will pay close attention to the balance of the benefits of the treatment in relation to its potential risks and any side effects. Therefore, please outline the main side effects (as opposed to a complete list) of this treatment and include details of a benefit/risk assessment where possible. This will support patient reviewers to consider the potential overall benefits and side effects that the medicine can offer.

Based on available data, please outline the most common side effects, how frequently they happen compared with standard treatment, how they could potentially be managed and how many people had treatment adjustments or stopped treatment. Where it will add value or context for patient readers, please include references to the Summary of Product Characteristics from regulatory agencies etc.

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3h) Summary of key benefits of treatment for patients

Issues to consider in your response:

* Please outline what you feel are the key benefits of the treatment for patients, caregivers and their communities when compared with current treatments.
* Please include benefits related to the mode of action, effectiveness, safety and mode of administration

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3i) Summary of key disadvantages of treatment for patients

Issues to consider in your response:

* Please outline what you feel are the key disadvantages of the treatment for patients, caregivers and their communities when compared with current treatments. Which disadvantages are most important to patients and carers?
* Please include disadvantages related to the mode of action, effectiveness, side effects and mode of administration
* What is the impact of any disadvantages highlighted compared with current treatments

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3i) Value and economic considerations

**Introduction for patients:**

Health services want to get the most value from their budget and therefore need to decide whether a new treatment provides good value compared with other treatments. To do this they consider the costs of treating patients and how patients’ health will improve, from feeling better and/or living longer, compared with the treatments already in use. The drug manufacturer provides this information, often presented using a health economic model.

In completing your input to the NICE appraisal process for the medicine, you may wish to reflect on:

* The extent to which you agree/disagree with the value arguments presented below (e.g., whether you feel these are the relevant health outcomes, addressing the unmet needs and issues faced by patients; were any improvements that would be important to you missed out, not tested or not proven?)
* If you feel the benefits or side effects of the medicine, including how and when it is given or taken, would have positive or negative financial implications for patients or their families (e.g., travel costs, time-off work)?
* How the condition, taking the new treatment compared with current treatments affects your quality of life.

**Note to authors:**

Response:

The bullets below give a suggestion of structure, subheadings and key points to give the context of how the cost effectiveness of the treatment has been modelled. Addressing each of the bulleted points below should be kept to a few sentences.

**How the model reflects the condition**

What is the structure of the model? Explain how the model reflects the experience of having the condition over time.

**Modelling how much a treatment extends life**

Does the treatment extend life? If so, please explain how (for example. by delaying disease progression, reducing disease severity or complications, reducing disease relapses or life-limiting side effects).

Describe briefly which trial outcomes feed into the economic model. If trial data used for a certain length of time followed by extrapolation, please note how long the trial data was used for and briefly how the data has been extrapolated.

**Modelling how much a treatment improves quality of life**

How is the treatment modelled to change a person’s quality of life compared with the treatments already in use? This should include after stopping treatment if relevant. For example, say if the treatment improves quality of life because of improving symptoms or decreases quality of life because of side effects.

Which quality of life measure(s) did you use to estimate a person’s quality of life over time and on treatments? Are there any aspects of the condition or its treatments affecting quality of life which may not have been fully captured by the methods used to estimate quality of life?

**Modelling how the costs of treatment differ with the new treatment**

Does the medicine lead to any cost implications (positive or negative) for the health service (e.g., drug costs, number of days in hospital)?

Are there any important differences in the way the medicine is given compared with those already in use that will affect the experience of the patient or costs to the health service or patients (e.g., where it is given or the monitoring that is needed)?

**Uncertainty**

Are there any key assumptions you have made in your model about the medicine’s benefits or costs because of lack of data?

Did you test using alternative assumptions or data in your model? Which had the largest effect on your cost effectiveness estimates?

Are there any data you have presented to support your modelled outcomes being plausible?

**Cost effectiveness results**

What is the modelled benefit in overall survival, quality adjusted life years and the incremental cost effectiveness ratio? Please do not include statements giving your conclusions on whether the medicine is cost effective, this I s because the appraisal committee will make this decision.

**Additional factors**

Have you made a case for a severity modifier being relevant for this condition? If so, please summarise the data presented

Are there any benefits or disadvantages of the treatment not captured in the modelling?

**You may delete this note text.**

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3j) Innovation

NICE considers how innovative a new treatment is when making its recommendations.

If the company considers the new treatment to be innovative please explain how it represents a ‘step change’ in treatment and/ or effectiveness compared with current treatments. Are there any QALY benefits that have not been captured in the economic model that also need to be considered (see section 3f)

|  |
| --- |
| Response: (click or tap here to enter text) |

## 3k) Equalities

Are there any potential equality issues that should be taken into account when considering this condition and this treatment? Please explain if you think any groups of people with this condition are particularly disadvantaged.

Equality legislation includes people of a particular age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation or people with any other shared characteristics

More information on how NICE deals with equalities issues can be found in the NICE equality scheme

Find more general information about the Equality Act and equalities issues here

|  |
| --- |
| Response: (click or tap here to enter text) |

#

# SECTION 4: Further information, glossary and references

## 4a) Further information

Feedback suggests that patients would appreciate links to other information sources and tools that can help them easily locate relevant background information and facilitate their effective contribution to the NICE assessment process. Please provide links to any relevant online information that would be useful, for example, published clinical trial data, factual web content, educational materials etc. Where possible, please provide open access materials or provide copies that patients can access.

|  |
| --- |
| Response: (click or tap here to enter text) |

Further information on NICE and the role of patients**:**

* [Public Involvement at NICE](https://www.nice.org.uk/about/nice-communities/nice-and-the-public/public-involvement)
* [NICE’s guides and templates for patient involvement in HTAs](https://www.nice.org.uk/about/nice-communities/nice-and-the-public/public-involvement/support-for-vcs-organisations/help-us-develop-guidance/guides-to-developing-our-guidance)
* [EFPIA – Working together with patient groups](https://www.efpia.eu/media/288492/working-together-with-patient-groups-23102017.pdf) (PDF)
* [National Health Council Value Initiative](https://nationalhealthcouncil.org/issue/value/)

## 4b) Glossary of terms

|  |
| --- |
| Response: (click or tap here to enter text) |

## 4c) References

Please provide a list of all references in the Vancouver style, numbered and ordered strictly in accordance with their numbering in the text:

|  |
| --- |
| Response: (click or tap here to enter text) |