

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

A guide for patient organisations

Completing an organisation submission



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Introduction

About this guide

This guide is for organisations that represent people (and their carers and families) with the condition for which the treatment is being appraised. It has been designed to help them prepare their submissions for technology appraisals to NICE. For simplicity, NICE calls these organisations 'patient organisations'.

Understanding the experiences of people living with a condition, and their carers and families, helps NICE technology appraisals committees to make their decisions. We need your help to collect and present important information about what it is like for a person to live with a condition, and to have specific medicines or treatments. You can also provide us with information on what it is like to have care for a specific condition in the NHS in England. Your input is essential to help us consider the experiences and views of people directly affected by the recommendations we make. We very much appreciate the time and effort you put into completing a submission.

Help and support

Members of the NICE public involvement team are available to guide you through the submission process. We are able to read through your draft submission and highlight any areas that could be strengthened. If you have any questions, we are happy to support you. **Please contact PIP@nice.org.uk.**

Resources available elsewhere are given on the back page of this document.

What is involved in a submission?

To submit information from your patient organisation for a technology appraisal, you need to complete a patient organisation submission form. This document helps patient organisations provide us with suitable information from people living with the condition (and their families and carers) for the appraisal of a particular treatment. Strong submissions contain facts, information and summaries of experiences, and give a concise, accurate and balanced overview of patients' and carers' perspectives.

Your submission will be published on the NICE website, as are all documents providing evidence for a technology appraisal.

Why provide a submission?

People living with a condition have knowledge, perspectives and experiences that are unique, and can provide essential evidence for the appraisal process. They can provide insight into what it is like to live with that condition, and the advantages and disadvantages of treatments. Your submission could identify important aspects of the treatment or condition that may not be:

- represented in research published in peer reviewed journals

- well captured in quality-of-life measures or other outcome measures used in clinical trials and other research studies
- immediately understood by the NICE committee.

The submission is also an opportunity to identify the priorities and preferences of patients, and what the added value of a particular treatment might be to them.

How your submission is used in the appraisal

The input of people with the condition, and their families and carers, may be used in many different ways during an appraisal, including to:

- identify outcomes that are important to patients
- represent patient expectations and direct experience with the treatment being appraised
- help in the critical appraisal of evidence, by assessing its relevance to patients
- help interpret other evidence, such as that provided by the company selling the treatment
- provide new evidence.

Planning and completing a submission

When planning your submission, you should decide whether you need to gather new information from people with the condition, and their family and carers, or whether you already have the necessary information to complete the submission form.

If you need to gather new information, we suggest you start doing so as soon as you hear from us that an appraisal has been referred by the Department of Health and when it is due start. When the appraisal starts, you will be sent an invitation to participate. This will contain a link to [NICEdocs](#) (our online document-sharing platform), which will include the patient organisation submission form. You have 8 weeks to complete a submission.

What to include in your submission

We want to understand the experiences of people living with the health condition for which the treatment being appraised is used, and of people caring for them. It is important to report on the experiences of many people living with the condition, rather than only people with exceptional experiences. It is also important to focus on how the condition affects the quality-of-life of people with the condition, and their families and carers, rather than clinical or cost effectiveness because these latter issues are comprehensively covered by other stakeholders.

Please remember to be clear and concise. Your submission will have the most impact if it covers a range of experiences, is balanced and acknowledges both advantages and disadvantages of the new treatment.

Try to include both quantitative (numbers from surveys) and qualitative (quotes about the experiences of people with the condition, and their families and carers) data throughout your submission.

Completing the form

Not all questions or suggestions in the form will be relevant to every submission. It is OK to leave a section blank.

About you	
1. Your name	If you are submitting on behalf of an organisation, your name will be removed from the submission.
2. Name of organisation	Please give the name of the organisation that is making the submission. If you wish to make a joint submission with 1 or more other organisations, please put all the names in this box.
3. Job title or position	If you are an employee or volunteer of the organisation, please give details.
4a. Brief description of the organisation	<p>If you get funding from pharmaceutical companies, please list all of them, and state how much they give.</p> <p>Briefly describe how you interact with people with the condition, and their carers and families, for example, through: newsletters, a website, social media, local events, helplines or support groups.</p> <p>Please describe the organisational aims and objectives (or vision and mission).</p>
4b. Do you have any direct or indirect links with, or funding from, the tobacco industry?	Please state if you have any links with the tobacco industry and, if so, explain what these are.
5. How did you gather information about the experiences of patients and carers to include in your submission?	<p>Please give an overview of the sources you used, for example, information may have been gathered from: one-to-one discussions with colleagues, people with the condition and those caring for them; telephone helplines; focus groups; online forums; published or unpublished research; user-perspective literature; or an organisational survey.</p> <p>We recognise that there may sometimes be reasons why you may not have been able to consult directly with patients on this treatment.</p>

Living with the condition

6. Describe:

- what it is like to live with the condition (1 or 2 sentences)
- what the likely outcome of the condition is
- what carers experience when caring for someone with the condition.

Please include the experiences of a range of people living with the condition, not just those with exceptional experiences, because this will strengthen your submission.

If experiences vary between different groups of people living with the condition, please explain this in section 10 ('patient populations').

Consider the 5 aspects that are often considered for EQ-5D, NICE's preferred measurement to assess health-related quality of life:

- mobility – this might be overall, or of particular parts of the body
- self-care – such as the ability to get dressed, wash, eat and live independently
- usual activities – work, education, family and social life
- pain and discomfort – explore what this means in real terms about the ability to do things
- anxiety and depression – describe what the impact of the condition is on mental health.

However, these 5 aspects may not cover everything particular to people with this condition (or may not cover everything adequately). So, please also consider other physical symptoms. Examples might include:

- tiredness and fatigue, such as the severity and the effects
- diarrhoea incontinence, such as the severity and the effects
- difficulty breathing, eating, drinking or sleeping.

Consider what affects the condition has on quality of life such as:

- ability to work or gain an education
- emotional health and well-being
- diet
- exercise
- travel.

Consider what aspects of the condition are the most important to control, for example, symptoms that limit social interaction or ability work.

Consider whether caring for somebody with this condition affect the carer's own health to the extent that they need to seek NHS treatment themselves.

Current practice in treating the condition

7. What do patients and carers think of the current treatments and care available on the NHS in England?

This section includes your experience of current practice in the NHS, outcomes important to people living with the condition, unmet needs, and risks and benefits of current treatments. (Some of these may be used as comparators for the new treatment and they will be listed in the scope for this appraisal).

- General questions about the current treatments:
 - What do people living with the health condition, and the people caring for them, most want from any treatment?
 - What is most important to them and why?
 - How far do the current treatments meet those needs?
 - Do the treatments improve the conditions and symptoms and do they have any side effects?
 - Are there any treatments being used currently that people living with the condition would like to replace with the new treatment? If so, please tell us what they are and why? For example, is this individual choice about treatment benefits and side effects, or does it depend on a particular group of people with different characteristics? (See also later question 10 about patient populations and equalities.)
 - If you know of any differences in opinion between patients about the benefits of the treatment being appraised, please tell us about them.

Below is a list of aspects that you may want to consider.

- Advantages of current treatments on:
 - the course or outcome of the condition
 - physical symptoms
 - pain
 - level of disability
 - mental health
 - quality of life (such as lifestyle or work)
 - other people (for example, family, friends and employers)
 - ease of use (for example, tablets rather than injection)
 - where the treatment has to be used (for example, at home or in hospital)
 - any other issues not listed above
 - the most important benefits of the current treatment.

- Disadvantages of current treatments:
 - aspects of the condition that current treatments cannot help with, or might make worse
 - any difficulties in taking or using current treatments (for example, injection rather than tablets)
 - any side effects (for example, type or number of problems, how often they occur, how long they last, how severe they are); please describe which side effects people living with the condition might be willing to accept or tolerate and which would be difficult to accept or tolerate
 - any concerns about where current treatments have to be used (for example, in hospital rather than at home, stigma, frequency of treatments, frequency of testing or the nature of tests and number of check-ups)
 - any burden of therapy on daily life (for example, family, friends and employers)
 - any financial impact on the people living with the condition or their family (for example, the cost of travel to hospital or paying a carer)
 - concerns about long-term use of any of the current treatments
 - any other issues not listed above.

8. Is there an unmet need for patients with this condition?

How much do the current treatments control or reduce the most challenging aspects of the condition?

Are there any important aspects of the condition that current treatments do not control at all?

Advantages of the new treatment

9. What do patients or carers think are the advantages of the technology?

If you have been unable to find anybody who has had the treatment, please tell us because we understand how difficult it can be to answer this question without their input.

- Please list the benefits that people living with the health condition, and those caring for them, expect to gain from using **this** treatment.
- Please explain any advantages that people living with the health condition, and those caring for them, think **this** treatment has over other NHS treatments in England.
- Consider:
 - the course or outcome of the condition
 - physical symptoms
 - pain
 - level of disability
 - mental health
 - quality of life (such as lifestyle or work)
 - other people (for example, family, friends, and employers)
 - ease of use (for example, tablets rather than injection)
 - where the treatment has to be used (for example, at home or in hospital)
 - any other issues not listed above.
- If you know of any differences in opinion between patients or carers about the benefits of the treatment being appraised, please tell us about them.
- If you are familiar with [EQ-5D](#), are there benefits from this treatment that are not adequately captured using the EQ-5D tool? Please explain what these are and why they are important to patients.

Disadvantages of the new treatment

10. What do patients or carers think are the disadvantages of the technology?

If you have been unable to find anybody who has taken the treatment, please tell us because we understand how difficult it can be to answer this question without their input.

Please list any concerns people living with the health condition, and those caring for them, have about this treatment.

- Consider:
 - aspects of the condition that this treatment cannot help with, or might make worse
 - any difficulties in taking or using this treatment (for example, injection rather than tablets)
 - any side effects (for example, type or number of problems, how often they occur, how long they last, how severe they are). Please describe which side effects people living with the condition might be willing to accept or tolerate and which would be difficult to accept or tolerate and why
 - any concerns about where this treatment has to be used (for example, in hospital rather than at home)
 - any negative effect on others (for example, family, friends and employers)
 - any financial impact on the people living with the condition or their family (for example, the cost of travel to hospital or paying a carer)
 - any other issues not listed above.
- If you know of any differences in opinion between people living with the health condition, and those caring for them, about the disadvantages of this treatment, please tell us about them.

Patient population

11. Are there any groups of patients who might benefit more or less from the technology than others? If so, please describe them and explain why.

- Are there challenges in managing this condition when people with the condition also have other medical conditions? Please give examples of those that you think are the most important.
- Are there any groups of people with the condition who might benefit more from this treatment than others? If so, please describe them and explain why.
- Are there any groups of people with the condition who might benefit less from this treatment than others? If so, please describe them and explain why.

- If you know, consider whether people treated in the NHS for this condition are different from those in the trial or trials and, if so, why.

(We note that this might link with the equality section below.)

Equality

12. Are there any potential [equality issues](#) that should be taken into account when considering this condition and treatment?

- Are there groups of people with the condition who would have difficulties using the new treatment?
- Are there any groups of people with the condition who have difficulties using the currently available treatments? (Would they therefore benefit particularly from the new treatment?)
- Consider practical issues such as mobility, manual dexterity if self-injecting, cognitive ability, other health conditions, acceptability of side effects, and religious or cultural reasons.
- Consider whether the equalities issues are different from the comparator treatment and why.
- What evidence do you think would help the committee to identify and consider such effects on people with the condition?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Protected characteristics are:

- age
- being or becoming a transsexual person
- being married or in a civil partnership
- being pregnant or having a child
- disability
- race including colour
- nationality
- ethnic or national origin
- religion
- belief or lack of religion or belief
- sex and sexual orientation.

Other issues

13. Are there any other issues that you would like the committee to consider?

These might include:

Innovation

What makes this treatment significantly different from other treatments for this condition?

Many treatments considered by NICE are 'new'. This does not necessarily mean that they are 'innovative' in the NICE sense. By 'innovative' we mean, for example, that they are: the first treatment of their type; they have a significant different mechanism of working; they are taken in a different way; or they have a significantly different side effect profile. They are considered to be 'a step change' treatment.

Is this an 'end of life' treatment?

By this we mean would somebody who might take this treatment be expected to live less than 2 years without it? If they were to take the treatment, would they expect to live an extra 3 months (longer than expected)? What evidence can you point the committee to, to support this?

Research evidence on patient or carer views of the treatment

- Is your organisation familiar with the published research literature for the treatment?
 - Please comment on whether people with the condition's experiences of using the treatment as part of their routine NHS care reflects the experiences of patients in the clinical trials.
 - Do you think the clinical trials have captured outcomes that are important to people living with the condition? Are you aware of any limitations in how the treatment has been assessed in clinical trials?
 - If the treatment being appraised is already available in the NHS, are there any side effects that were not apparent in the clinical trials but have emerged during routine NHS care?
- If you are aware of any relevant research on patient or carer views of the condition or existing treatments (for example, qualitative studies, surveys and polls), please provide references to the relevant studies.

Are there any other issues that you would like the appraisal committee to consider?

Topic specific questions

Sometimes there will be additional questions specific to this condition or treatment that is being appraised.

If there are any questions in this section and you would like help, please contact the Public Involvement Programme (PIP) team at PIP@nice.org.uk

Key messages

14. In no more than 5 bullet points, please summarise the key messages of your submission.

- When somebody reads your submission, which are the most important messages you would like them to remember?
- If you had to choose up to 5 things from your submission to be presented to the committee, what would you want them to be?
- You may have fewer than 5 key messages.
- For each bullet point, summarise your message into a short sentence or phrase.
- The aim is to highlight and reinforce something that you explained more fully earlier in your submission.
- The more succinct your summarised key message, the more impact it is likely to have.

What not to include in your submission

Not necessary	Reason
Clinical or scientific evidence	<p>As part of the process for assessing the treatment, the scientific evidence will be provided either by the company whose treatment this is or by the academic review group.</p> <p>When all the evidence has been presented to the committee any gaps in the evidence will be highlighted during the consultation on the evidence. Please signpost us to it then.</p>
Summarised or reworded information from sources other than patients or caregivers (for example, clinicians, other healthcare professionals, pharma companies or other stakeholders).	<p>The purpose of a patient group submission is to collect input from people living with the condition and their carers. The patients' views, opinions and experiences are unique. Please spend your time and effort on this perspective. Input from clinicians, pharmaceutical companies and other stakeholders is sought separately.</p>
The same message repeated under different template headings	<p>Sometimes it may be difficult to limit information to only 1 section of the template. Please ensure that you are answering the specific question under each section and not repeating information. We want to ensure that we get only the most relevant information so that the committee has the best evidence and information possible to make their decision. If you would like advice about completing the template, please contact the PIP team at NICE.</p>
Emotive language	<p>This detracts from your key points and may be undermine your submission.</p>
An unbalanced submission	<p>This could be not including the experiences of a range of people living with the condition, or both positives and negatives of the new treatment; either of these are likely to weaken your submission because it may be seen as incomplete or potentially biased.</p>

Information available elsewhere

- [Patient involvement](#) (apart from submissions) in the rest of the technology appraisal process – this is available on the NICE website.
- The [methods and processes](#) for NICE technology appraisals – this is available on the website.
- How to do qualitative research and write it up – this is available in the HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)¹ *Guidance for patient organisations to complete a patient group submission template: For health technology assessment and appraisal of medicines*. Available as a [PDF](#) or [Word Doc](#).
- Supplementary information for patient and carer groups on taking part in Health Technology Assessments – provided by HTAi PCIG and including:
 - an introduction to Health Technology Assessments and the role of patients (a webinar)
 - help conducting surveys
 - other videos and guides.

See: [For patients and patient groups](#)

We would like to thank the HTAi Interest Group on Patient and Citizen Involvement on HTA (PCIG), the Scottish Medicines Consortium, David Chandler (lay member and Chief Executive of Psoriasis and Psoriatic Arthritis Alliance [PAPAA]), and patient organisations and technology appraisal committee members who have given us feedback on the previous patient organisations submission template, for their help in producing this guide.

¹ Health Technology Assessment International (HTAi) Patient and Citizen Involvement in HTA Interest Group (PCIG) - <http://www.htai.org/interest-groups/patient-and-citizen-involvement/>