

# The National Health Council

## Considerations Guide for Patient Organizations Developing Comments on a Value Assessment



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Companion piece to the [NHC's Patient-Centered Value Model Rubric](#)  
and the [NHC's Value Framework Get-Ready Checklist for Patient Organizations](#)

# Instructions for Using This Considerations Guide

The National Health Council’s (NHC’s) Considerations Guide for Patient Organizations Developing Comments on a Value Assessment is intended to be used as a tool by patient groups. It can assist in preparing actionable written comments on a specific value assessment. With this tool, patient groups will be better able to help value assessment bodies incorporate the patient perspective in a meaningful way when developing a value assessment.

This tool can be used by an organization’s staff or committee responsible for monitoring and engaging with framework developers. To get the most from this Guide, we recommend you review the entire document before beginning. It is organized around the following Considerations:

## Considerations

PICOTS Framework .....	3
Patient-Centered Data Sources .....	5
Patient Partnership and Transparency.....	6
Costs .....	7
Preferences and Utilities.....	8

The objective of this tool is to help patient groups think carefully about how a value assessment can be improved to better reflect patients’ experiences. Each consideration includes a series of related questions. Not all of them will apply to every value assessment.

For each Consideration:

- ┆ Plan for the time you will need to evaluate each section. You may wish to work with an expert in health economics and/or outcomes research to develop your responses.
- ┆ The considerations are simply a guide, do not feel obligated to comment on every consideration.
- ┆ Provide constructive criticism, but also give credit where credit is due. If a value assessment body did a good job at addressing a section, let them know that you appreciate what they did with specific examples of how patient experiences were accurately reflected.
- ┆ If you disagree with an approach taken by a value assessment body, try to suggest an alternative approach. This will help you develop a more balanced comment letter and build trust.
- ┆ Provide evidence or cite peer-reviewed literature to back-up your statements. This will help the value assessment body do a better job when revising their assessment.

# PICOTS Framework

## What is this?

The PICOTS Framework is a tool designed to assist researchers when developing a clinical research question. “PICOTS” is an acronym for the things to be included: patient population (P), intervention or issue of interest (I), the comparator(s) or comparison intervention(s) (C), the outcome of interest (O), time (T), and setting (S). In value assessment, the PICOTS framework guides the evidence collected for inputs into the assessment. It also guides how evidence is further analyzed or incorporated into economic models.

**Population, Intervention, Comparator(s), Outcome(s), Timing, and Setting (PICOTS)**

## Where is this information typically found in a value assessment report?

Information may be found in:

- The section of the report that covers the evidence base
- The value assessment report may not specifically describe a PICOTS framework, but should describe the individual elements (e.g., population, intervention, comparator(s), outcomes, time, and setting)
- If an “analytical framework” is presented in the report, it will likely include most PICOTS elements
- If you would like to go into greater detail, you may wish to look at the individual studies referenced in the report

## Relevant NHC Modules or Resources That Can be Helpful

- [The Patient Voice in Value: The Patient-Centered Value Model Rubric \(see corresponding module\)](#)
- [Heterogeneity of Treatment Effect module](#)
- [Patient-Focused Medical Product Development Series](#)
- [Identifying PICOTS Elements \(Population, Intervention, Comparator, Outcome, Time, and Setting\)](#)

Considerations	✓	Notes
<p><b>General</b></p> <ul style="list-style-type: none"> <li>• Are all of the elements of the PICOTS framework described? Are they well-defined? Are references provided? Does it reflect current standard-of-care?</li> <li>• Are you able to understand the rationale for why each element of the PICOTS framework was defined the way it was? Do you agree?</li> <li>• Were members of the patient community encouraged to contribute to the PICOTS framework?</li> </ul> <p><b>Population</b></p> <ul style="list-style-type: none"> <li>• Is the population(s) clearly defined?</li> <li>• Are epidemiologic estimates (e.g., incidence, prevalence) accurate?</li> <li>• Do inclusion/exclusion criteria seem overly rigid?</li> <li>• Are important subpopulations included? Are they analyzed separately as needed? Are they representative of real-world populations? Subpopulations may be defined by:               <ul style="list-style-type: none"> <li>○ Age</li> <li>○ Comorbid conditions</li> <li>○ Etiology</li> <li>○ Ethnicity</li> </ul> </li> </ul>		

<ul style="list-style-type: none"> <li>• Gender</li> <li>• Genetics</li> <li>• Geographic location</li> <li>• Health literacy</li> <li>• Insurance coverage</li> <li>• Rural, suburban, urban location</li> <li>• Race</li> <li>• Socioeconomic status <ul style="list-style-type: none"> <li>○ Severity</li> </ul> </li> <li>• Does the VA report consider variety of disease trajectories (as needed)?</li> <li>• Does it account for different stages of a patient's life?</li> <li>• Is there alignment between the FDA indication (or expected indication) and the population being analyzed? Note: whether a treatment is “on-label” or “off-label” may have implications for level of evidence available</li> </ul>		
<p><b>Intervention</b></p> <ul style="list-style-type: none"> <li>• Is the dose correct?</li> <li>• Is it used in the way it is expected to be used by patients in the real world?</li> </ul>		
<p><b>Comparators</b></p> <ul style="list-style-type: none"> <li>• Does the choice of comparators make sense? Does it reflect the treatments the population or subpopulations are receiving in the real-world?</li> <li>• If there are multiple possible comparators, are all included? If not, is justification provided? Do you agree with the justification?</li> <li>• Does it rely on clinical practice guidelines that are considered current or out-of-date?</li> </ul>		
<p><b>Outcomes</b></p> <ul style="list-style-type: none"> <li>• Are the outcomes examined aligned with outcomes that patients have identified as important to them in terms of their goals, aspirations, and experiences?</li> <li>• Is a clear link described between the outcomes incorporated into the model and their importance to patients? Specifically, with regard to: <ul style="list-style-type: none"> <li>▪ Functional status (mental/physical/societal)</li> <li>▪ Health-related quality of life</li> <li>▪ Well-being</li> <li>▪ Symptoms</li> <li>▪ Biomarkers/surrogate outcomes</li> <li>▪ Survival</li> <li>▪ Productivity</li> <li>▪ Goals, expectations</li> <li>▪ Financial impact/burden</li> </ul> </li> <li>• Does the way outcomes are measures/defined make sense?</li> </ul>		

<ul style="list-style-type: none"> <li>Is there heterogeneity of treatment effect across subpopulations (do different types of patients respond differently to the treatment)? Do you believe it is sufficiently accounted for in sensitivity analyses (analyses that test different assumptions to assess how those different assumptions change the conclusions)?</li> </ul>		
<b>Timing and Setting</b> <ul style="list-style-type: none"> <li>Does the follow-up time period selected make sense given what you know about how the treatment works?</li> <li>Does the time horizon for any economic models make sense for the type of treatment being evaluated?</li> <li>Is the setting correct (e.g., if it will be administered at home, are hospital costs unnecessarily included?)</li> </ul>		

## Patient-Centered Data Sources

<b>Why is this important?</b>		
The value assessment should rely on a variety of credible data sources that allow for timely incorporation of new information and account for the diversity of patient populations and patient-centered outcomes. Examples include clinical trials, patient and other stakeholder input, and real-world evidence.		
<b>Where is this information typically found in a value assessment report?</b>		
Information may be found in: <ul style="list-style-type: none"> <li>The methods section of the value assessment report or a separate methodology document (e.g., data sources)</li> <li>The section of the report that covers the evidence base</li> </ul>		
<b>Relevant NHC Modules That Can be Helpful</b>		
<ul style="list-style-type: none"> <li><a href="#">The Patient Voice in Value: The NHC Patient-Centered Value Model Rubric</a> (see corresponding module)</li> </ul>		
<b>Considerations</b>	<b>✓</b>	<b>Notes</b>
<ul style="list-style-type: none"> <li>Are important data missing?</li> </ul>		
<ul style="list-style-type: none"> <li>Is sufficient evidence available to complete an assessment? If the assessment relies on limited evidence, is this communicated as a limitation throughout the report and in other, corresponding communications?</li> </ul>		
<ul style="list-style-type: none"> <li>Are data that you submitted incorporated (e.g., patient survey)? If not, is justification for why it was not incorporated provided?</li> </ul>		
<ul style="list-style-type: none"> <li>If high-quality real-world evidence studies are available, were they incorporated?</li> </ul>		
<ul style="list-style-type: none"> <li>If high-quality patient-reported outcome data are available, were the data incorporated?</li> </ul>		
<ul style="list-style-type: none"> <li>Are the populations studied in the data sources reflective of the diversity of patients with the condition?</li> </ul>		

## Patient Partnership and Transparency

### Why is this important?

- When evaluating a VA report, it is important to consider how patient input contributed to the assessment.
- The assumptions and inputs into the value assessment itself — and each step in the process — should be disclosed to patients in both an understandable way and timely fashion. If information is not communicated transparently, it is difficult for the patient community to meaningfully contribute to the value assessment process or discussion.

### Where is this information typically found in a value assessment report?

Evidence of partnership and transparency (or lack thereof) will be found throughout an assessment, including within upfront material, methods, related announcements, and appendices.

Considerations	✓	Notes
<ul style="list-style-type: none"> <li>• Does the assessment clearly describe the role patients played in developing the assessment?</li> </ul>		
<ul style="list-style-type: none"> <li>• Did the value assessment body make responses to public comments publicly available to allow the patient community to understand how its input has or has not been used?</li> </ul>		
<ul style="list-style-type: none"> <li>• Are the purposes, goals, and intended audience of the assessment made clear to patients?</li> </ul>		
<ul style="list-style-type: none"> <li>• How transparent is the value assessment regarding the amount and quality of evidence available, and are better data on the horizon?</li> </ul>		
<ul style="list-style-type: none"> <li>• Are all assumptions and inputs articulated in an understandable and patient-centered way?</li> </ul>		
<ul style="list-style-type: none"> <li>• Is the methodology clearly described and made available to patients in a timely manner (e.g., inputs, assumptions, etc.)?</li> </ul>		
<ul style="list-style-type: none"> <li>• Are mechanisms for updating the assessment clear? For example, if key evidence to inform decision-making (e.g., data on an important subpopulation) is not yet available, is a process for updating the assessment outlined?</li> </ul>		
<ul style="list-style-type: none"> <li>• Were all funding sources publicly disclosed? Were all potential conflicts of interest disclosed, including those of patient partners?</li> </ul>		

## Costs

### Why is this important?

A value assessment often includes health economic analyses. Different decision-makers are concerned about different types of costs. For example, an assessment intended to inform a health insurer's decision may only include costs that the insurer is responsible for, such as hospital costs. But other costs, such as lost wages, caregivers, and other out-of-pocket expenses, are extremely important from a patient and societal perspective. Factoring in these additional costs may result in different conclusions about whether a treatment is cost-effective.

### Where is this information typically found in a value assessment report?

Within the methods section, look for headers or tables such as "Economic Inputs." You may find additional costs listed within sections on "Sensitivity Analysis" and/or "Scenario Analysis."

### Relevant Definitions (also see [NHC Value Assessment Glossary](#))

- **Direct Cost:** The cost to an organization for providing the test, treatment, procedure, or service. The costs can be either "direct medical costs" (e.g., cost of medication) or "direct non-medical costs" (e.g., paid caregiver time).
- **Indirect Cost:** Costs incurred by society as a result of the impact of disease, illness, and treatments, excluding those that are for medical care. They include loss of ability to engage in normal daily activities, work, domestic responsibilities, volunteering, and social and recreational/leisure engagements.
- **Perspective:** The perspective or point-of-view in an economic analysis determines which types of costs and health benefits are relevant and should be included in the evaluation. Perspectives include: patient, hospital or clinic, health care system, or societal. An analysis based on a health care system perspective might only include costs incurred by the health system (e.g., costs for medicine, administration, and monitoring). The broadest is the societal perspective which includes things like a patient's loss of productivity due to the inability to work. Many types of costs exist--but not all costs are included in all perspectives.

### Relevant NHC Modules That Can be helpful

- [Getting to Know the Lingo](#)
- [Unlocking the Mysteries of the Quality-Adjusted Life Year \(QALY\)](#)
- [Tools for Dealing with Uncertainty in Economic Analysis](#)

Considerations	✓	Notes
<ul style="list-style-type: none"> <li>• Does the report address the costs and effects that might be relevant to patients and their families, but not health insurers (e.g., out-of-pocket costs, transportation)? Is an assessment using a "societal perspective" presented?<sup>1</sup></li> </ul>		
<ul style="list-style-type: none"> <li>• Does the report describe uncertainty in the inputs used in an economic model?</li> </ul>		
<ul style="list-style-type: none"> <li>• When estimating the total treatment cost, does the report take into consideration the treatment duration?</li> </ul>		
<ul style="list-style-type: none"> <li>• Does the report make any mention of hospitalization costs, drug administration costs, outpatient visit costs?</li> </ul>		
<ul style="list-style-type: none"> <li>• Does the report clearly state the source of the different cost estimates, and appropriately describe any key assumptions made in determining the cost estimates?</li> </ul>		

## Preferences and Utilities

### Why is this important?

Preferences and utilities play a critical role in value assessment and health care decision making as they represent the strength of an individual's preference for desired health outcomes. Both of these elements can impact the cost-effectiveness ratios for treatments, and when this occurs, input from patients can be leveraged to identify alternative assumptions that can be used for scenario analyses. In addition to this, involvement from patients can help to examine whether utilities included in the report are relevant and appropriate.

### Where is this information typically found in a value assessment report?

Information related to preferences and utilities may be found in the following sections of a value assessment report:

- Model Inputs
- Model Assumptions
- Utility Inputs
- Model Health States
- References

### Relevant Definitions (also see [NHC Value Assessment Glossary](#))

- **Utility:** Utility values are intended to represent how society values different health states (e.g., perfect health, having fatigue, being in pain, being unable to walk are all health states). All health states are assigned a numerical value – usually between 0 and 1, where perfect health is equal to 1 and death is equal to 0. To assign where the other health states (e.g., fatigue or pain) lie between 0 and 1, researchers ask patients and members of the general public to rate the desirability of these health states using methods such as a questionnaire. Utility values are also known as “health state preference values” and represent quality of life in a QALY calculation.
- **Patient preference:** When faced with different choices, patients have a personal view of how desirable or undesirable those choices are. In healthcare, patient preference is a measure of that level of desirability of the alternatives or choice among health outcomes or treatments (e.g., different drugs). There are various techniques used in research to measure patient preferences.

### Relevant Modules That Can Be Useful

- [Getting to Know the Lingo](#)
- [Unlocking the Mysteries of the Quality-Adjusted Life Year \(QALY\)](#)

Considerations	✓	Notes
<ul style="list-style-type: none"> <li>• Is the source(s) of the utilities clear? Are you able to access background information/methods on how they were derived?</li> </ul>		
<ul style="list-style-type: none"> <li>• Do the utility estimates stem from the relevant patient population (e.g., population or subpopulations included in the assessment) or are they from the general public?</li> </ul>		
<ul style="list-style-type: none"> <li>• Has the standard of care changed significantly since the utilities were calculated?</li> </ul>		



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