



THE NATIONAL HEALTH COUNCIL

Considerations Guide

FOR PATIENT ORGANIZATIONS DEVELOPING COMMENTS ON A VALUE ASSESSMENT

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

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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 organizations. It can assist in preparing actionable comments on a specific value assessment. With this tool, patient organizations 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 value assessment bodies. To get the most from this Guide, we recommend you review the entire document before beginning. It is organized around the following Considerations:

Considerations

- 3 **PICOTS FRAMEWORK**
- 6 **PATIENT-CENTERED DATA SOURCES**
- 8 **PATIENT PARTNERSHIP & TRANSPARENCY**
- 10 **COSTS**
- 12 **PREFERENCES & UTILITIES**

The objective of this tool is to help patient organizations 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 a value assessment, the PICOTS framework guides the evidence collected for the assessment. It also guides how evidence is further analyzed or incorporated into economic models.

→ **Population · Intervention · Comparator(s) · Outcome(s) · Timing · Setting**

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


INFORMATION MAY BE FOUND IN:


- The **scoping documents** of an assessment
- The section of the report that covers the **clinical 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)

Relevant NHC Modules or resources that can be helpful:

- **The Patient Voice in Value: Patient-Centered Value Assessment Rubric** — (see corresponding module)
- **Patient-Focused Medical Product Development Series**
- **Identifying PICOTS Elements (Population, Intervention, Comparator, Outcome, Time, and Setting)**

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CONSIDERATIONS		NOTES
<p>General</p> <ul style="list-style-type: none"> · Are all of the elements of the PICOTS framework described? Are they well-defined? Are references provided? Does it reflect current standard-of-care? · Are you able to understand the rationale for why each element of the PICOTS framework was defined the way it was? Do you agree? · Were members of the patient community encouraged to contribute to the PICOTS framework? 	<p><input type="radio"/></p> <p><input type="radio"/></p> <p><input type="radio"/></p>	
<p>Population</p> <ul style="list-style-type: none"> · Is the population(s) clearly defined? · Are epidemiologic estimates (e.g., incidence, prevalence) accurate? · Do inclusion/exclusion criteria seem overly rigid? · 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"> – Age – Comorbid conditions – Etiology – Ethnicity/Race – Gender – Genetics – Severity – Geographic location – Health literacy – Insurance coverage – Rural, suburban, urban location – Socioeconomic status · 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. 	<p><input type="radio"/></p> <p><input type="radio"/></p> <p><input type="radio"/></p> <p><input type="radio"/></p> <p><input type="radio"/></p>	
<p>Intervention</p> <ul style="list-style-type: none"> · Is the treatment regimen correct? · If there are multiple potential interventions, are all included? If not, is justification provided? Do you agree with the justification? · Is it used in the way it is expected to be used by patients in the real world? 	<p><input type="radio"/></p> <p><input type="radio"/></p> <p><input type="radio"/></p>	

CONSIDERATIONS		NOTES
<p>Comparators</p> <ul style="list-style-type: none"> · Does the choice of comparator(s) make sense? Does it reflect the treatments the population or subpopulations are receiving in the real-world? · If there are multiple comparators, are all included? If not, is justification provided? Do you agree with the justification? · Does it rely on clinical practice guidelines that are considered current or out-of-date? 	<input type="radio"/> <input type="radio"/> <input type="radio"/>	
<p>Outcomes</p> <ul style="list-style-type: none"> · Are the outcomes examined aligned with outcomes that patients have identified as important to them in terms of their goals, aspirations, and experiences? · Is a clear link described between the outcomes incorporated and their importance to patients? Specifically, with regard to: <ul style="list-style-type: none"> – <i>Functional status (mental/physical/societal)</i> – <i>Health-related quality of life</i> – <i>Well-being</i> – <i>Symptoms</i> – <i>Biomarkers/surrogate outcomes</i> – <i>Survival</i> – <i>Productivity</i> – <i>Goals, expectations</i> – <i>Financial impact/burden</i> · Does the way outcomes are measured/defined make sense? · Is there heterogeneity of treatment effect across subpopulations (<i>do different types of patients respond differently to the treatment</i>)? Do you believe it is sufficiently accounted for in sensitivity analyses (<i>analyses that test different assumptions to assess how those different assumptions change the conclusions</i>)? 	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>	
<p>Timing and Setting</p> <ul style="list-style-type: none"> · Does the follow-up time period selected make sense given what you know about how the treatment works? · Does the time horizon for the economic model make sense to capture all incremental costs and outcomes associated with the treatment? · Is the setting correct (<i>e.g., if it will be administered at home, are hospital costs unnecessarily included?</i>)? 	<input type="radio"/> <input type="radio"/> <input type="radio"/>	

Patient-Centered Data Sources

Why is this important?

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.

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

INFORMATION MAY BE FOUND IN:

- Standalone **methodology document** (e.g., *protocol, model analysis plan*)
- The section of the report that covers the **clinical evidence base**
- The section of the report that covers the **economic model**

Relevant NHC Modules that can be helpful:

- **[The Patient Voice in Value: Patient-Centered Value Assessment Rubric](#)** — (see corresponding module)

PATIENT-CENTERED DATA SOURCES

CONSIDERATIONS	<input checked="" type="checkbox"/>	NOTES
Are important data missing?	<input type="checkbox"/>	
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?	<input type="checkbox"/>	
Are data that you submitted incorporated (e.g., patient survey)? If not, is justification for why it was not incorporated provided?	<input type="checkbox"/>	
If high-quality patient-reported outcome data are available, were the data incorporated?	<input type="checkbox"/>	
Are the populations studied in the data sources reflective of the diversity of patients with the condition?	<input type="checkbox"/>	



Patient Partnership & Transparency

Why is this important?


- When evaluating a value assessment 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 reports, and appendices.



CONSIDERATIONS		NOTES
Does the assessment clearly describe the role patients played in developing the assessment?	<input type="radio"/>	
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?	<input type="radio"/>	
Are the purposes, goals, and intended audience of the assessment made clear to patients?	<input type="radio"/>	
How transparent is the value assessment regarding the amount and quality of evidence available, and are better data on the horizon?	<input type="radio"/>	
Are all assumptions and inputs articulated in an understandable and patient-centered way?	<input type="radio"/>	
Is the methodology clearly described and made available to patients in a timely manner (e.g., inputs, assumptions, etc.)?	<input type="radio"/>	
Are mechanisms for updating the assessment clear? For example, if key evidence to inform decision-making (e.g., <i>data on an important subpopulation</i>) is not yet available, is a process for updating the assessment outlined?	<input type="radio"/>	
Were all funding sources publicly disclosed? Were all potential conflicts of interest disclosed, including those of patient partners?	<input type="radio"/>	

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?

INFORMATION MAY BE FOUND IN:

- Standalone **methodology document** (e.g., *model analysis plan*)
- The section of the report that covers the **economic model** (look for headers or tables such as "Model Inputs")

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

DIRECT COST: A cost that can be directly associated to something, such as a 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., *transportation costs*).


INDIRECT COST: Costs incurred by society as a result of the impact of disease, illness, and treatments, excluding direct costs. They include things like the 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 included in the evaluation. Traditional perspectives evaluated include the health care system and 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*) and patient health outcomes. The societal perspective is broader and also includes things like a patients' loss of productivity due to the inability to work.

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](#)

COSTS

CONSIDERATIONS		NOTES
Does the model include the costs that might be relevant to patients and their families, but not health insurers (e.g., <i>out-of-pocket costs, transportation</i>)? Is an assessment using a “societal perspective” presented?	<input type="radio"/>	
Does the report describe uncertainty in the inputs used in an economic model?	<input type="radio"/>	
When estimating the total treatment cost, does the report take into consideration the treatment duration?	<input type="radio"/>	
Does the report make any mention of hospitalization costs, drug administration costs, outpatient visit costs, if relevant?	<input type="radio"/>	
Does the report clearly state the source of the different cost estimates, and appropriately describe any key assumptions made in determining the cost estimates?	<input type="radio"/>	
Were all funding sources publicly disclosed? Were all potential conflicts of interest disclosed, including those of patient partners?	<input type="radio"/>	

Preferences & 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 MAY BE FOUND IN:

- Model Inputs
- Model Assumptions
- Utility Inputs
- References

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

UTILITY: Utility values are intended to **represent how patients value different states of health** (e.g., perfect health, having fatigue, being in pain, being unable to walk). States of health can be assigned a number — 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 that typically involve a questionnaire. Utility values are also known as **“health state preference values”** and are used when assessing quality of life.

PATIENT PREFERENCE: When faced with different choices, patients have personal views of how desirable or undesirable those choices are. In health care, 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 NHC Modules that can be helpful:

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

CONSIDERATIONS	<input checked="" type="checkbox"/>	NOTES
Is the source(s) of the utilities clear? Are you able to access background information/methods on how they were derived?	<input type="checkbox"/>	
Do the utility estimates stem from the relevant patient population (e.g., population or subpopulations included in the assessment)?	<input type="checkbox"/>	
Has the standard of care changed significantly since the utilities were calculated?	<input type="checkbox"/>	



Helpful Resources



NHC Patient-Centered Value Assessment Rubric

[Download](#)



NHC Value-Assessment Get-Ready Checklist for Patient Organizations

[Download](#)

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