



THE NATIONAL HEALTH COUNCIL

Value Assessment Get-Ready Checklist FOR PATIENT ORGANIZATIONS

Companion piece to the [Patient-Centered Value Assessment Rubric](#)

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Overview

What is Value Assessment and What do Patient Organizations Need to Know?

THE ISSUE

The U.S. health care system continues to undergo transformative changes in the way it delivers and pays for care. As the traditional fee-for-service payment system gives way to more value-based payment arrangements, **understanding and defining the value of health care treatments and interventions has become a national priority.**

Value assessment organizations have emerged to **help decision makers assess the value of new treatments.**

WHAT IS VALUE ASSESSMENT?

In a value assessment, the **health and economic outcomes of a new treatment are compared to an existing health care approach or treatment.** Some value assessments are **intended to support population-level decisions**, such as coverage and reimbursement decisions, for new healthcare treatments.

Some value assessments **include an economic model**, such as a cost-effectiveness analysis, to inform the efficiency of the resources needed with the new treatment. These models typically extrapolate short-term data (such as data from a randomized controlled trial) to a longer time horizon and compile multiple different evidence sources (e.g., clinical data, quality of life data, cost data) into one model. Economic models like these can be developed and/or used by payers and the biopharmaceutical industry to **help inform coverage and reimbursement decisions for the new treatment.** An example is the UK's [National Institute for Health and Care Excellence \(NICE\)](#).

WHAT HAS DRAWN ATTENTION TO VALUE ASSESSMENT FRAMEWORKS?

A variety of non-governmental organizations have released value assessment frameworks and supporting models. For example, by 2015, four organizations – the [American Society of Clinical Oncology \(ASCO\)](#), the [Institute for Clinical and Economic Review \(ICER\)](#), the [National Comprehensive Cancer Network \(NCCN\)](#), and [Memorial Sloan Kettering Cancer Center \(MSK\)](#) – released value frameworks. These were described as **intending to support physicians and/or payers in assessing treatment value.** Each organization can have different methods and different goals but are intended to **support decision contexts** at either the insurance plan level, benefit management level, or patient-provider shared decision-making level.

WHAT ARE THE DEBATES SURROUNDING VALUE ASSESSMENT?

Value assessment framework developers have taken different approaches to their assessments. Stakeholders—including the National Health Council (NHC)—voiced important concerns with the frameworks released in 2015 and beyond. At the time these concerns included: **lack of transparent patient engagement, methods or data issues, impact on patient access, sources of data on costs, and including only short-term costs.** The National Health Council was also interested in **how these tools would be used in shared-decision making** and **whether there was sufficient testing with users** when intended outputs were patient-provider shared-decision making tools. Disease specific patient organizations have also previously **questioned the utility/quality-of-life (QOL) evidence** leveraged in an assessment. For example, in a 2020 evidence report, the assessor used several citations to obtain information on patient quality of life and utility. All of those citations had been flagged as having major issues by the disease-related patient organization including that the assessor was using data that was not in line with other findings that noted that patients prioritized avoiding surgery for the condition.

VALUE ASSESSMENT FRAMEWORKS CAN BE USEFUL TOOLS, BUT ONLY WITH PATIENT INVOLVEMENT!

Value assessment frameworks and supporting models can help advance the national dialogue on value in health care, but only if they incorporate the patient voice throughout. Developers are working to improve how they gather and use patient inputs in their value frameworks.

Patient perspectives on value can differ significantly from that of physicians and payers, often integrating considerations beyond clinical outcomes and cost, such as a treatment's ability to help patients achieve personal goals.¹ To have true utility, value assessments and value assessment frameworks must incorporate these other value-influencing factors. The only way to achieve this is by having **robust processes in place to incorporate the patient voice.** Such action is particularly important if physicians and payers look to these tools to inform decisions that can affect the treatment options available to a patient.

The patient community must be involved in defining value as the end recipient of care. Patients, like other stakeholders, are eager to take part in the value discussion because the cost of and access to drugs have direct impact on their health and well-being. Historically patient organizations and patients have been involved in value assessment in a limited amount.

WHY THE GET-READY CHECKLIST?

The National Health Council has developed the **Value Assessment Get-Ready Checklist** to help guide patient organizations as they prepare to engage with other stakeholders in the development and implementation of value assessments and supporting models. This Get-Ready Checklist has been created as a **step-by-step guide for your organization on how to prepare to engage** in this important process.

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Instructions for Using This Checklist

The Get-Ready Checklist is intended to be used as a tool by patient organizations. It can assist an organization in actively planning, preparing for engagement, and collaborating in a value assessment. With this tool, patient organizations will be better able to prepare to help value assessors incorporate the patient perspective in a meaningful way in the development, dissemination, and use of value frameworks and assessments.

This tool can be used by your staff, or an organization's committee responsible for monitoring and engaging with value framework developers. To get the most from this Checklist, we recommend that you review the entire document and each section and questions in the checklist before beginning the specific tasks.

Understanding what needs to be done from the start will make your collaborations with all applicable members, partners, developers, stakeholders, and experts easier throughout the Checklist process.

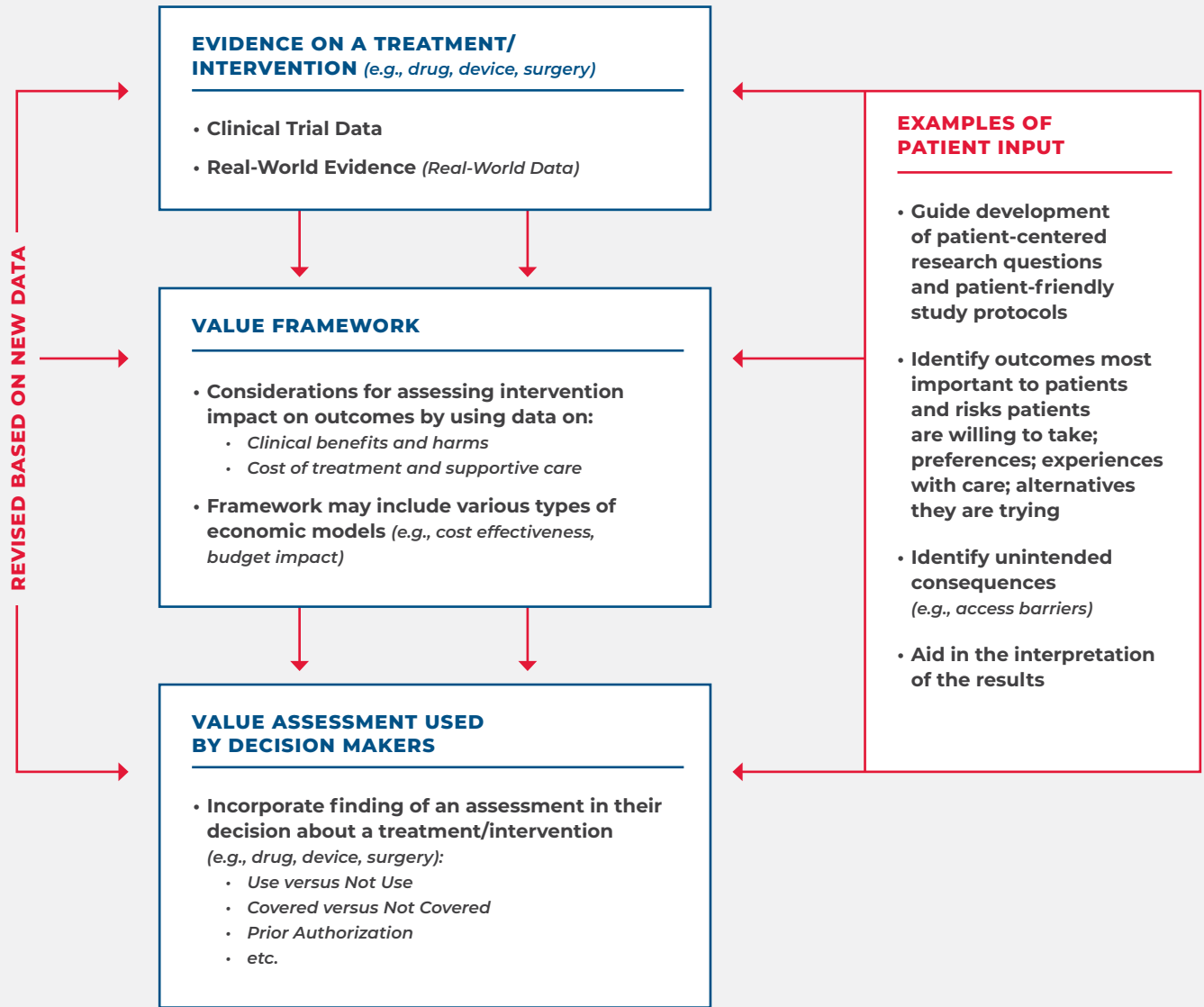
Suggestions Before You Begin

- **IT IS NEVER TOO EARLY TO START!**
- **TAKE NOTES IN A SEPARATE DOCUMENT.**
- **PLAN FOR THE TIME YOU WILL NEED TO DEDICATE TO EACH TASK.**
- **WHEN YOU HAVE COMPLETED THE TASK, CHECK THE CORRESPONDING BOX.**

Source: Fowler FJ Jr, Levin CA, Sepucha KR. Informing and involving patients to improve the quality of medical decisions. *Health Affairs (Millwood)*, 2011; 30: 699–706.

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Value Assessments: Incorporating the Patient Voice



The figure above depicts the process of incorporating data into a value assessment to produce recommendations that potentially feed into decision-making, and how patient-provided information can contribute. Evidence is gathered and included in the value assessment, which tries to capture what is known about the benefits, risks, and costs related to the treatment and care. The findings of that assessment can be incorporated by decision makers such as payers, providers, and patients. The assessment does not drive the decision but is part of the decision-making process.

Patients should have a role in contributing input throughout.

NHC Value Assessment Get Ready Checklist

1 Advance Preparation – As Early as Possible

Know which organizations are developing an assessment for your disease of interest (or similar diseases); it will help you to be better prepared. Value assessment organizations should notify patient organizations in the disease of interest that they intend on conducting an assessment in that disease area. The timeframes of these announcements vary by organization so patient organizations should be ready to engage as needed.

These organizations should come to regard you as a partner in this process, but unfortunately some may need to be persuaded of the value of patient and patient organization input. Being prepared in advance will help you demonstrate the value that your data will bring. The steps below help you to begin to prepare.

A. SEARCH



Who are the value assessment organizations working in your area of interest?

Find the organizations known for developing value assessments. In the United States, those organizations include **ICER**, **ASCO**, **NCCN**, and **MSK**. They are the most well-known and talked about. However, ICER is the most common organization involved in coverage and reimbursement decision-making so that should be the first organization contacted/researched.



Network with other patient organizations and relevant health professional associations to learn from their past experiences with value assessors and to find out if new value assessment organizations are appearing on the scene.



Some payers (*i.e.*, health insurers) and biopharmaceutical companies also develop economic models. Find out about them in the published literature, in the press, or through conversations with other patient organizations or organizations representing providers who treat your condition of interest.



The NHC has a program for NHC member patient organizations looking to access peer-reviewed literature on value assessment. Please reach out to NHCprograms@nhcouncil.org to receive access.

Do your homework to identify and learn about these organizations; gather and share information among patient organizations as you learn more. Collaborations with other organizations are very useful during information scoping.

Look at value assessors' websites. Is your disease or a relevant treatment listed? Has the organization conducted a value assessment in the past that is relevant to your area of interest? Is it going to update that work? Is it planning to conduct a new assessment?

Sign up to receive alerts and newsletters so you know what work is planned for the future.

B. ASSESS



Understand the processes of each value assessment organization working in your area of interest.

Does this organization's existing process already seek patient input? Are there clear opportunities for engagement? Look for policies, calls for comment, and calls for nominations to advisory boards. You do not have to be limited to just those opportunities, but you should be aware of what they are.

What does their announced or typical timeline look like? Are your opportunities to engage clearly outlined? Track those dates and prepare for them. If no dates are published, use the schedule of released frameworks to help you develop a work plan for meeting deadlines. Contact the value assessment organization directly to ask that the comment process be transparently listed.

Who is the target audience for their assessment? Payers? Physicians? This is often stated outright and knowing this can help you understand and, if necessary, refute approaches used or assumptions made.

How can you help the value assessors make their work more patient centered? What can you provide? Make a clear list of what you have to offer. See [Appendix II](#) for suggestions.

Find a point of contact at the organization for future communications. The value assessment organization may have a dedicated patient engagement or alliance staff member. Reach out as soon as you can to voice your eagerness for involvement. Do not reach out to that person until you are adequately prepared for the conversation and know what the objective is for your outreach.

C. LEARN



Familiarize yourself with the value assessors' website, materials, and past value-related work.

Look for recent publications, press releases, and commentaries.



Review other organizations' publicly available comments submitted to the value assessor. You can learn from the organization's perspectives and may find them a good resource for information and partners. Organizations like ICER publicly post all comments they received during the draft report comment period which may be useful as a historical reference tool. You can find an example of these comments from a review [here](#).



Make preparation calls to value assessment organizations to inquire about their processes, opportunities to engage, and to gain other pertinent information.



Research external perceptions of the value assessor through various publicly available resources (e.g. news publications, blog posts, Facebook, X, LinkedIn, etc.)



D. INVESTIGATE



What is the Food and Drug Administration (FDA) review timeline for products in your disease area, and how will it impact the timeline for value assessment development?

Is a new treatment for your disease of interest under FDA review? Some value assessment organizations focus on new products and time their assessment around potential FDA approval.



When is the new treatment(s) expected to be approved? These dates can be critical to the economic model within a value assessment as the price of the product, which will be incorporated, may not be available until the product is launched. The product launch will be predicated on the FDA review timeline. Some economic models are developed prior to approval, but many use product pricing at launch.



E. ALIGN



Does the value assessors' work align with the National Health Council Value Model Rubric?

Familiarize yourself with the [NHC Patient-Centered Value Assessment Rubric](#).

Ensure that the value assessors' processes are patient centered. The NHC defines patient centered as broadly meaning any process, program, or decision that is focused on patients, in which patients play an active role as participants, and with a central focus on optimizing the use of patient-provided information. Where does their work align or differ with the NHC Patient-Centered Value Assessment Rubric.

Developers may state they are taking a patient-centered approach, but that does not necessarily mean they are. You need to make your own assessment.

How can you help the value assessor improve patient centeredness?



NHC Value Assessment Get Ready Checklist

2 Decide Whether to Engage

Engaging in a value assessment can be resource intensive and time consuming. Your organization should carefully make a decision about whether to engage and to what extent, guided by need, urgency, resources, and capacity. If you choose not to engage, the consequences should be carefully considered.

A. ARTICULATE



Everyone involved should understand the issues.

Create a short paragraph on why this value assessment is important to your organization. Why should you engage? An example of value assessment and its importance to a specific condition can be found on the Arthritis Foundation website [here](#). You can find more examples in the appendices of this document.



Vet this paragraph with colleagues, your organization’s Board of Directors, medical board, external research and clinical experts, and others who have relevant experience. As applicable, gain their feedback.



Define the resources your organization will commit to this activity and how frequently you will revisit this commitment.



Communicate to your whole organization—staff, leadership and constituents—that you are taking this process seriously and want patients to be involved. Use various communication channels to state this such as your website, patient support groups, blog, e-news, print publication and social media. These channels can announce specific ways patients can participate.



B. EVALUATE



Internally evaluate your organization's appetite for engagement.

What are the overall goals of your organization? How do your organization's goals align with value assessment?

What resources do you have? What resources do you need to engage?

Do you have the capacity to take this on? Do you need outside help such as external research, economic, and clinical experts? Who else will be on the team? What does it take to get them up to speed?

Do you want to engage with this value assessor at this time and on this topic?



NHC Value Assessment Get Ready Checklist

3 Consider Coalitions and Partnerships

When possible, engaging with key organizations and stakeholders can make this process easier and more impactful.

A. MOBILIZE



Bring together relevant organizations and stakeholders.

Reach out to provider groups, patient organizations, and other stakeholders in your field as well as groups in similar disease areas for their input.

Explore comment letters, press releases, media quotes, and any articles from organizations you could collaborate with.

A united voice of like-minded individuals and groups is more powerful than a lone voice. You can also work in a collaborative fashion to stress different things in a complementary approach.

Develop strategies for how you might work together.

NHC Value Assessment Get Ready Checklist

4 Refine Your Strategy

Your organization's strategy(s), objective(s), and rationale should be established before you reach out to value assessors. They should be clear to all involved.

A. ASSEMBLE



Your strategy is best substantiated with data and facts.

What do you have in-house that can inform an assessment? Gather and organize the facts and figures you already have at your organization; keep them up-to-date and accessible. Data may not always be scientifically rigorous, and results should not be misrepresented or exaggerated, simply factual.



Sources of data should be inclusive of patient experiences, narratives and backgrounds. This may include patient stories and experiences as well as survey or registry data, both published and unpublished.



B. GATHER



Information from your community is a key asset.

For data you do not yet have on hand, gather insights and information from your patient community.



Do you know your community's opinions, preferences, experiences, and views?



Conduct interviews, focus groups, and surveys to gather the data that can inform the framework. You can find a patient-centered value assessment survey template [here](#).



C. SEARCH

Fill gaps in data where you are able.

Your patient registry may have valuable data that can inform a framework or model. Tap that resource.

Use external sources such as literature and web searches for other useful data (*i.e., landscape assessment or literature review*).

An FDA patient-focused drug development meeting and “Voice of the Patient” report may provide valuable data. Check the [FDA website](#) for those resources.

Note any limitations of the data that your organization or other organizations have. For example, many organizations struggle to collect truly diverse data that is representative of the entire patient population they serve. Indicate whether this is a limitation in any comments to the value assessor.

D. CONSULT

Experts can help you organize and understand the data.

Tap your organization’s scientific committee early so they are alerted and ready when you need them.

Consult with outside economic experts who may be familiar with your disease of interest. Several universities also have centers for value assessment and have health economists on staff/faculty. You can reach out to staff at the National Health Council for a list of recommended patient-centered health economics experts or universities.

If you do not fully understand something, ask for help or obtain training. Utilize the National Health Council’s [Value Classroom](#) for a basic understanding of patient-centered value assessment.

E. ARTICULATE



State your intentions clearly.

Document your strategy(s), objective(s), and rationale with any data you can cite.



Be concise and clear.



Vet with appropriate parties (e.g., members, Board of Directors, partners, consultants, health economists, etc.).



Be prepared to update your strategy as you gather new information. This will be an iterative process.



F. RE-EVALUATE



Assess your strategy(s) and objective(s) as more information is gathered.



G. MESSAGE



Have your message ready to deliver.

Prepare consistent messaging. Tailor messages appropriately for various audiences such as your scientific committee, patient and families, and value assessors.



Decide whether or not you want to engage with the media/press; what role you want the press to play; and what you will put on your website or a blog about the topic.



H. PREPARE



Be prepared for some negativity toward patient organizations.

Some value assessors are concerned about patient organization bias. They may state that patient organizations are:



- Too vested in finding treatments and vulnerable to accepting treatments that do not work or are not cost effective;
- Too personally connected to assess the evidence in an unbiased way; or
- Being used or influenced by the biopharmaceutical industry to serve as their advocate.

Be prepared for these views. Be able to clearly explain your organization’s funding model and the policies you have in place to avoid conflicts of interest, including certification through the NHC **Standards of Excellence Program®**.



There is no need to defend being pro-patient and pro-treatments for your constituency. However, be armed with data and present your expertise. Rely on more than your general advocacy for your constituency.



NHC Value Assessment Get Ready Checklist

5 Engage with Value Assessors

Strive for partnership. Expect to be treated like a partner and behave like a partner. This can take time.

A. APPROACHING VALUE ASSESSOR



Have a game plan mapped out.

Reach out to the contact you have identified at the value assessment organization(s) with a letter of introduction describing your organization and its mission. Send the letter by email, or, reach out to a contact person you may have met or have already contacted for information.

Explain that you would like to introduce yourself and state your objective(s) (e.g., you want to become more engaged in their assessment work).

Briefly outline your expertise and what you have to offer (e.g., knowledgeable individuals in your membership about the disease of interest, a list of the leading clinicians in the country with expertise about the disease, or a disease registry of patient-reported outcome data).

Stress the uniqueness of the disease or issues the value assessors might not be familiar with that you want them to know about as they begin their review. Emphasize things like heterogeneity of the disease (that all patients do not experience the disease the same way/do not respond the same way to treatments) and any patient-level outcomes (e.g., productivity, caregiver time) that are impacted by the treatment. Stress that medical literature cannot tell them everything they need to know about your community, its needs, and treatment hopes. Identify specific gaps or limitations in common literature if you know it. For example, a commonly cited study that does not use a diverse patient population.

Follow up to arrange a meeting to speak. You may need to call several times to schedule this meeting or receive a response.

Take every opportunity possible to introduce yourself and your organization to the staff at the development organization. Introduce yourself at public meetings and express your desire to partner.

B. OBJECTIVE(S)

Define your objectives for the conversation.

What are your objectives for the conversation? What do you want to achieve? These should be written down to help you maintain focus. Over time, you will have different objectives for different conversations. For example, on telephone call #1: Introduction, establish your organization's credibility, share your expertise, encourage interaction with your medical experts, or offer to arrange discussions with patients. Get them to understand why they need to engage with you. On telephone call #2: Discuss scientific challenges with the review they plan to do; get them to understand the value in talking with patients directly; share data and scientific information about your community that they might not have access to. If a health economist is assisting your organization, they should be involved with these calls



Be conservative and reasonable in your expectations. Possible objectives could be:

- Introductions
- Express interest in engagement
- Gather information on how to engage
- Offer data you have
- Establish points of contact
- Set up future calls and interactions
- Nominate yourself or a member to be on an advisory committee (i.e., such as [ICER's Patient Council](#))
- Ask how these councils are formed and how representatives are chosen
- Suggest changes to the research question
- Suggest changes to the data or assumptions
- Point out areas of controversy for the project
- Describe challenges they may encounter
- Propose solutions to those challenges
- Suggest patient-centered approaches



Do not expect to get everything you ask for right away. Let the value assessor know you are committed to a true partnership and are in it for the long haul.



C. COMMUNICATION WITH VALUE ASSESSORS



Establish clear avenues of communication and a good working relationship with the contact person you identify to help you gain entry. They need to know who your lead is and who you have access to; you should request the same on their end.



Avoid negativity. Do not be on the attack even if there are negative assumptions made about patient involvement.



Stress your mission and willingness to engage.



Rehearse what you will say to keep yourself on track and raise your comfort level. Be concise and direct. Lack of preparation might convey lack of expertise or commitment and could undermine trust.



Document conversations to ensure transparency.



NHC Value Assessment Get Ready Checklist

6 Follow Through

Build on your initial outreach. Keep the line of communications open.

A. FOLLOW UP



Demonstrate your continued commitment.

Send a note of thanks that includes important points from the conversation and the next steps committed to by both parties.



Continue to send letters or emails to the organization with information, encouragement when appropriate, and to repeat your asks as needed.



Prepare well-thought-out comments when there are public comment periods. You can find an example of these letters in [Appendix IV](#).



B. VISIBILITY



Use every opportunity to be viewed as an important stakeholder.

Make note of every publicly available comment period and opportunities for engagement within a value assessment.



Plan your schedule accordingly and plan to attend virtual meetings with your camera on. Be engaged during these meetings; ask questions and provide comments.



Speak to the media to convey your message. But do this as planned and on your terms. An example of an op-ed to the media is in [Appendix IV](#).



Advocate when and where needed.



C. COMMUNICATION



Keep your constituents informed.

Keep your members, stakeholders, and other constituents informed along the way.



Inform and activate your patient community as needed, especially when you need volunteers.



D. RELIABILITY



Commit for the long haul.

Dedicate the time and resources to fulfilling any commitments you have made to the value assessor (e.g., serving on a committee, writing a review, providing data, etc.).



Should you have any questions about using this guide, please do not hesitate to contact the National Health Council at NHCPrograms@nhcouncil.org.

Appendix I  **ACRONYMS**

ASCO

American Society of Clinical Oncology
asco.org

FDA

Food and Drug Administration
fda.gov

ICER

Institute for Clinical and Economic Review
icer-review.org

MSK

Memorial Sloan Kettering
mskcc.org

NCCN

National Comprehensive Cancer Network
nccn.org

NHC

National Health Council
nationalhealthcouncil.org

Appendix II INFORMATION TO SHARE WITH VALUE ASSESSORS

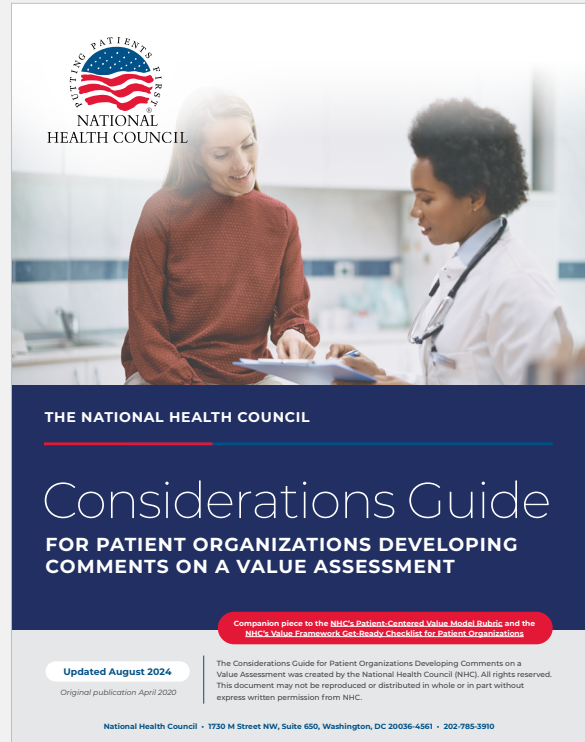
- Your mission statement and biographies of leadership team
- Any relevant policy letters that your organization has submitted in the past
- Descriptions of patient-centered programs and research your organization has developed
- Progress and financial reports highlighting trends in the past several years
- Facts regarding treatments of the specific disease/condition relevant to your organization
- Patient data (surveys, registries, and any qualitative data)
- How you are able to introduce them to patients directly
- Contact information and recommendations of national experts on the disease and their key publications
- Upcoming events and fundraisers, and why these are important to your community
- Partners your organization works with
- Public education and awareness outreach (including social media and publications)

Appendix III HELPFUL RESOURCES



NHC Patient-Centered Value Assessment Rubric

[Download](#)



NHC Considerations Guide for Patient Organizations

[Download](#)

Appendix IV **EXAMPLES OF PATIENT ORGANIZATION RESPONSES TO ASSESSORS**

- [Responses to ICER Review of Atopic Dermatitis – 2016](#)
- [Response to Public Comments Submitted to ICER Draft Report on Targeted Immune Modulators for Rheumatoid Arthritis – 2017](#)
- [Responses to ICER Ulcerative Colitis Draft Evidence Report – 2020](#)
- Blog Post Example:
[Asthma and Allergy Foundation of America Responds to Premature ICER Review of New Peanut Allergy Treatments – 2019](#)
- Blog Post Example:
[MHA Statement on the Institute for Clinical and Economic Review’s Final Report on Tardive Dyskinesia – 2018](#)

Value Assessment
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FOR PATIENT ORGANIZATIONS

