

American Society of Clinical Oncology Criteria for High-Quality Clinical Pathways in Oncology

Heightened concern over rising healthcare costs and growing interest in assuring high quality value-based care have led to the increased use of clinical pathways as a mechanism to reduce variation in healthcare delivery and to control costs. Currently used by healthcare institutions, providers, commercial organizations and other health systems, pathways are increasingly being adopted by practices and insurance companies as a way to promote high-value care. An estimated 60 individual health insurance plans in the United States are currently implementing oncology specific pathways.¹ In 2010, approximately 15% of oncology “covered lives” were treated according to clinical pathways, which was expected to rise to 25% in 2015.²

Well-designed and effectively implemented clinical pathways can be an important tool for improving adherence to evidence-based medicine and reducing unwarranted variation in care.^{3,4} Clinical pathways also can enhance communication and patient education, serving as a way for oncology providers to share evidence-based information with patients about the complex details of treatment options.⁵ The recent proliferation of clinical pathways in oncology, however, has raised significant concerns about the variability and transparency in pathway development and implementation and the consequent impact on care delivery and patient outcomes.³

Under the leadership of the ASCO Board of Directors, the ASCO Task Force on Clinical Pathways conducted a review of the rapidly evolving landscape of oncology clinical pathways in the United States and identified a number of concerns about the way in which clinical pathway programs are currently developed and implemented in oncology practice. The Task Force found that standards defining high quality and transparent pathways do not exist. Therefore, developers of pathways and entities that implement pathways including payers, are at risk for wide variations in the quality, utility, functionality, and impact of pathway programs.⁶ Many pathways are often focused primarily on the selection of anticancer agents and are not inclusive of other critical aspects of cancer care, like supportive and palliative care services, diagnostic evaluation, surgery, radiation therapy, and laboratory testing, which are all central to quality patient care.⁷ The methods of pathway development, in many cases, are not transparent to patients and providers.⁸ As a result, there is no assurance that a given set of pathways has been developed without significant conflicts of interest, reflect the latest scientific evidence or explain the weighting of cost, efficacy and toxicity in the pathway recommendations.

The proliferation of oncology pathways has also introduced additional administrative burdens on physicians, who already report spending as much as one-sixth of their day on paperwork,⁹ limiting time with their patients. Some practices report using similar but different pathways from different payers for patients with the same type and stage of cancer, requiring them to sift through the requirements of each pathway program on a patient-by-patient basis, program Electronic Medical Records (EMRs), train staff, develop educational materials and processes to use different regimens for patients with the same clinical diagnoses. Because individual payers establish different pathways requirements, virtually identical patients may be treated with different drugs, different schedules, and different supportive care agents. Additionally, the amount of time spent seeking approval for off-pathway treatment can lead to harmful delays and erode the doctor-patient relationship and the overall quality of care, creating a shift from caring for the patient to caring for the pathway.

In January 2016, the American Society of Clinical Oncology (ASCO) released the *ASCO Policy Statement on Clinical Pathways in Oncology* to elevate awareness about clinical pathways in oncology and to convey a cautionary note that no current mechanism exists to ensure the integrity, efficient implementation and outcome assessments for these treatment management tools.¹⁰ The statement called for implementation of a **system to assess and improve the integrity and quality of pathways coming to market, and to ensure they support efficient, patient-centered, high-quality patient care**. Moreover, the statement called for the development of robust criteria to support certification of oncology pathway programs, recommending that pathway programs be required to meet specific criteria that clearly demonstrate integrity in their development, and that payers should accept all oncology pathway programs that achieve certification through such a process.

After releasing the ASCO policy statement on clinical pathways in oncology, the Task Force continued its efforts to ensure that pathways are consistently developed and transparent to all stakeholders, and that pathways are used in the way they are intended to guarantee quality care while helping to reduce unwanted variations in care and control costs. As a first step, the Task Force developed a set of draft criteria for the development and implementation of high-quality oncology pathway programs, and initiated a collaborative dialogue—through direct stakeholder meetings and interviews—with patient advocates, payers, vendors, and providers. This engagement was designed to thoughtfully elicit and consider all

stakeholder perspectives. The wide range of constructive feedback on the draft criteria led to consensus that the ultimate goal is to ensure that clinical pathways promote, and do not hinder, high-quality patient care. Moreover, ASCO was viewed by stakeholders as being able to play an important role—to serve as an “honest broker” that can guide the standard for pathway development and implementation, and to lead efforts to help oncologists, patients and payers navigate the current and evolving pathway environment.

The ASCO criteria for a high-quality oncology pathway program, provided below, focus on three key areas: development, implementation and use, and analytics. The criteria have been developed for use by multiple stakeholders to evaluate clinical pathways and guide their future development. Each of the 15 individual criteria is presented as a series of concrete, practical questions that provide an overarching framework for assessing individual pathway programs. It is hoped these criteria will help guide the development, implementation and assessment of pathway programs, as well as help oncology providers and other stakeholders better evaluate clinical pathways and ensure that pathways are developed and implemented in the way they are intended and promote the desired outcomes.

Clinical pathways are likely to continue to expand their role as a central component of oncology practice and may serve as a cornerstone of future payment methodologies and quality of care efforts. ASCO, as the voice of cancer care providers and the patients they serve, will continue to work to ensure that pathway programs meet high standards of quality. The Society will continue to lead efforts to help stakeholders navigate the current pathway environment, assure their optimal implementation, encourage analytics to understand the outcomes of pathway use, and maximize their value to patients.

ASCO Criteria for High-Quality Oncology Pathway Programs

I. Pathway Development

Criterion	Key Questions
Expert Driven	<ul style="list-style-type: none"> ➤ Do practicing oncology providers with relevant disease and/or specialty expertise play a central role in the pathway development?
Reflects Stakeholder Input	<ul style="list-style-type: none"> ➤ Is there a mechanism in place for patients, payers, and other stakeholders to provide input during the development process?
Transparent	<ul style="list-style-type: none"> ➤ Is there a clear, consistent process and methodology for pathway development that is transparent to all pathway users, stakeholders and the general public? Is information disclosed on: <ul style="list-style-type: none"> ○ The methodology used for development? ○ The <i>strength</i> and <i>types</i> of evidence used to generate consensus? ○ The specific evidence used to support the pathway recommendation (including key literature citations, guidelines or other evidence)? ○ The way in which efficacy, toxicity and cost are assessed and balanced in determining the pathway recommendation? ➤ Is there a policy in place and adhered to that requires public disclosure of all potential conflicts of interest by oncology pathway panel members any other individuals or entities that contribute to the development of pathway content? Does this policy describe: <ul style="list-style-type: none"> ○ The nature of relationships required for disclosure? ○ The manner in which disclosure information is made publicly available? ○ The required steps for managing conflicts of interest? ○ The required steps to ensure policy adherence and enforcement?

Evidence-Based	<ul style="list-style-type: none"> ➤ Are the pathways based on the best available scientific evidence as documented or disseminated in clinical practice guidelines, peer-reviewed journals, scientific meetings, Medicare compendia, Food and Drug Administration (FDA) labeling indications, and/or other dissemination vehicles? ➤ Is a mechanism in place for considering high quality evidence generated from validated real world data (i.e., rapid learning healthcare systems)?
Patient-Focused	<ul style="list-style-type: none"> ➤ Do the pathways include evidence-based options to account for differences in patient characteristics and/or preferences (i.e., patient co-morbidities, prior diagnoses and treatments, risks of treatment-related toxicities, treatment schedule and/or financial toxicity)?
Clinically-Driven	<ul style="list-style-type: none"> ➤ Is there an established methodology for prioritizing efficacy, safety and cost? ➤ How is cost factored into pathway recommendations of therapeutically similar or equivalent treatments? ➤ Are stakeholder assessment and pathway analysis used for pathway revision?
Up-to-Date	<ul style="list-style-type: none"> ➤ Are pathways updated in a timely way as relevant new information, including new FDA indication approvals, become available? ➤ How rapidly are new, practice-changing data incorporated into pathway recommendations? ➤ What is the process used to ensure timely updates are made? ➤ Is a full review of the entire pathway performed and documented at least annually, and does a mechanism exist for ongoing rapid evaluation?
Comprehensive	<ul style="list-style-type: none"> ➤ Do the pathways address the full spectrum of cancer care from diagnostic evaluation through first course of therapy; supportive care; post-treatment surveillance; treatment of recurrent cancer (lines of therapy); survivorship; and end-of-life care? Do they include medical, surgical, and radiation treatments; imaging and laboratory testing; and molecular diagnostics/precision medicine? ➤ If the pathways are not comprehensive, do they clearly describe the phase and elements of care they are intended to address?
Promotes Participation in Clinical Trials	<ul style="list-style-type: none"> ➤ Are available clinical trials options incorporated into the pathway program? ➤ Is treatment provided to patients participating in Phase I - III clinical trials always considered pathway-appropriate treatment?

II. Implementation and Use

Criterion	Key Questions
Clear and Achievable Expected Outcomes	<ul style="list-style-type: none"> ➤ Is information provided on the specific cancer type, stage and molecular profile (if applicable) that the pathway is intended to cover? ➤ Is there clear information provided to pathway users and other stakeholders on what constitutes treatment on pathway, treatment off-pathway, and warranted variation from pathway recommendations? ➤ Does the pathway program report and communicate to all stakeholders the goal adherence rates?

	<ul style="list-style-type: none"> ○ Are expected adherence rates established in a way that reflects the strength of evidence for the disease and stage? ○ Do adherence rates incorporate precision medicine based on current FDA approved indications as on-pathway? ○ Do adherence rates allow for evidence-based variation and take into account individual patient differences and the resources available in the particular healthcare system or setting to provide recommended care?
Integrated, Cost-Effective Technology and Decision Support	<ul style="list-style-type: none"> ➤ Does the pathway program comply with current federal mandates for meaningful use of electronic health record (EHR) technology or other requirements? ➤ Does the pathway program offer—or plan to offer—clinical decision support or other resources (i.e., automated payer authorization, links to order sets, data collection tools) in a way that is integrated into commonly used EHRs? How does it communicate these offerings to users and other stakeholders?
Efficient Processes for Communication and Adjudication	<ul style="list-style-type: none"> ➤ Does the pathway program provide references or links to references that may support pathway variation? ➤ Does the pathway program inform the provider in real time of pathway compliance? ➤ Is the mechanism for choosing an off-pathway recommendation and documenting the rationale for this choice easily imbedded in the pathway program?

III. Analytics

Criterion	Description
Efficient and Public Reporting of Performance Metrics	<ul style="list-style-type: none"> ➤ Are regular reports provided to participating providers that demonstrate the level of current pathway performance and performance over time with comparisons to the performance of other groups of providers? ➤ Is there a mechanism in place for the provider to record reasons for going off-pathway? Will the performance reports provided include these reasons for non-concordance? ➤ Will public reporting of providers' pathway adherence be disclosed as a composite report only (i.e., not at an individual provider or provider group level)? ➤ Do providers have an opportunity to review performance reports and revise any areas in need of adjustment?
Outcomes-Driven Results	<ul style="list-style-type: none"> ➤ Does the pathway program have analytics in place to enable a movement over time from adherence-driven compliance to outcome-driven results?
Promotes Research and Continuous Quality Improvement	<ul style="list-style-type: none"> ➤ Does the pathway program demonstrate a commitment to research aimed at assessing and improving the impact of pathways on patient and provider patient experience, clinical outcomes and value? For example, do data generated from the pathway program incorporate patient and treatment variables to allow and foster discovery of important unanticipated knowledge? ➤ Is patient assessment and pathway analysis used for pathway revision? For example, are reasons for off-pathway treatment captured, tracked and reviewed for consideration in modifying pathways?

- Are the analytics generated from pathway programs publically available to patients and/or participating providers for benchmarking and understanding of complex cancer outcomes?

¹ DKP Critical Insights®—Clinical Pathways Overview and Provider Perspectives, 2015.

² McKinsey & Company. “Strategies in Oncology: Spotlight on Clinical Pathways.” January 2012.

³ National Patient Advocate Foundation. Clinical pathways: barrier or benefit to patient access and personalized medicine?

<http://www.cfoundaion.org/sites/default/files/content/NPAF%20Clinical%20Pathways%20White%20Paper%20July%202015.pdf>.

⁴ Avalere. Clinical pathways: overview of current practices and potential implications for patients, payers, and providers. July 2015.

⁵Ibid.

⁶ DeMartino JK, Larsen JK: Equity in cancer care: Pathways, protocols, and guidelines. J Natl Compr Canc Netw 10:S1-S9, 2012 (suppl 1)

⁷ National Patient Advocate Foundation: Clinical pathways: Barrier or benefit to patient access and personalized medicine?

<http://www.cfoundaion.org/sites/default/files/content/NPAF%20Clinical%20Pathways%20White%20Paper%20July%202015.pdf>

⁸ Greenfield S, Steinberg EP, Auerbach A, et al: Clinical practice guidelines we can trust. Institute of Medicine, Washington, 2011

⁹ Casalino LP, et al: What does it cost physician practices to interact with health insurance plans? Health Affairs. 28 (4), w533-w543. 2009.

¹⁰ Zon RT, Frame JN, Neuss MN, et al: American Society of Clinical Oncology policy statement on clinical pathways in oncology. J Oncol Pract 12:261-266, 2016