Patient-Centered Oncology Payment Model (PCOP): Response to the PRT's Questions 3-16-20*

Responses to Questions Received from the PTAC Preliminary Review Team on the "Patient-Centered Oncology Payment Model (PCOP)" PFPM Proposal Submitted by the American Society of Clinical Oncology (ASCO)

Participating Practice Qualifying Criteria

1. What kinds of clinical oncology practices would be able to be an oncology medical home and participate in the PCOP model? Would participation be limited to hematological oncology practices (as suggested on page 1 of the proposal)? Could a radiation and surgical oncology practice participate? Or is it only a multi-specialty oncology practice (i.e., a practice that has all three specialties required: hematology, radiation, and surgical) that would be allowed to participate in the model?

The model is intended for practices providing hematology and medical oncology services, specifically the prescription and management of chemotherapy and immunotherapies, as well as those in early survivorship or palliative care. Multi-specialty practices with hematology/oncology providers may participate.

2. Would all types of oncology practices be allowed to participate in the PCOP model? That is, can practices that are free-standing, owned/employed by a local hospital, or part of a national for-profit chain (e.g., US Oncology) all participate?

There are no limitations as to the type of practice (free-standing, hospital-based, etc.). As participants are clinically responsible for certain management and delivery of care requirements, some participants may need to partner with another entity in order to participate. For example, in an arrangement whereby a participating physician practice refers to a hospital outpatient department for chemotherapy, the physician practice should ensure that the hospital outpatient department is meeting all quality and safety standards for delivery of chemotherapy within the model.

^{*} This document has been modified to indicate the PRT questions in bold face to improve readability.



3. Will participants in the model be required to meet oncology medical home standards through a formal accreditation or recognition process (as discussed in the Abstract, and on pages 2 and 4)? If so, would they need to meet ASCO's medical home standards, and does ASCO have a formal accreditation or recognition process in place? Could another organization's oncology medical home standards and accreditation or recognition program be used (e.g., the National Committee for Quality Assurance [NCQA])? If not, would it be necessary to develop standards and an accreditation process in order for the PCOP model to be implemented? If practice participants must obtain oncology medical home accreditation, what is the estimated time/cost involved?

While practice participants are required to meet the care delivery requirements, it is not required that they do so through any specific formal accreditation; as an alternative, payer participants may conduct periodic audits to ensure compliance.

ASCO and the Community Oncology Alliance have begun working together to develop an Oncology Medical Home Certification program; one of the objectives in this program is to provide universal care delivery standards, measures, and recognition that may be relied upon for PCOP, as well as other payment models. While it may be practical for practices to obtain this certification to demonstrate compliance, it is not required under PCOP.

Participating Community Qualifying Criteria

4. The proposal states that the model is intended to be implemented by a community of payers, practices, and community stakeholders within a defined geography (pages 4 and 6). However, the proposal does not specify any qualifying criteria for participating communities, or minimum thresholds for provider participation or beneficiary alignment. What, if any, information can you provide about the qualifying criteria for Patient-Centered Oncology Payment (PCOP) communities, such as thresholds for payer and practice participation (page 6)?

In Section 7.7, we specified data management activities necessary for performance data governance and transparency. Data management activities include practice participation in regional health information exchange (RHIE) efforts and payer submission of oncology claims to an all-payer claims database (APCD). Practically, this limits participation to communities that already have in place or are committed to developing RHIE and APCD capabilities.

We have not specified a minimum threshold for provider or payer participation.

a. What are the estimated start-up costs associated with becoming a participating community?

We have not estimated the start-up costs for communities that do not already have a RHIE or APCD in place.



b. While the PCOP model aims to be fully multi-payer, the proposal states that it could be implemented as a single payer model with multiple providers (page 6). Can communities participate with just Medicare and perhaps Medicaid for duals without private plans? Is there a threshold of a minimum number or percentage of payers? Would Medicaid be required to participate for dually eligible beneficiaries?

It is possible to implement PCOP as a single payer model, such as Medicare and/or Medicaid. However, this introduces two limitations:

- i. Models in which a single, primary payer disrupts fee-for-service through a bundled payment means that providers must continue to bill fee-for-service in addition to the alternative billing mechanism. If we wish to advance alternative payment models while limiting administrative burden, a multipayer approach to bundled payments is most effective. That said, multiple Medicare models require fee-for-service billing to facilitate beneficiary costsharing.
- ii. While we have not established a required threshold for multi-payer support, we are concerned with the lack of private payer participation in OCM. To quote the Center for Medicare and Medicaid Innovation regarding the Comprehensive Primary Care Plus program, "Medicare alone cannot provide the adequate supports that practices need to make significant changes in the way they delivery care...." In oncology practices, Medicare is a major source of practice revenue; however, in regions with a high Medicare Part C penetration rate, Part B alone would not provide the necessary financial support for practice transformation.
- 5. The proposal states that "seed funding" is required in years 0-2 for the Care Management Payment (CMP) and Performance Incentive Payment (PIP) (page 12). Please provide additional information about the amount of seed funding needed, and any potential required role for payers and other potential sources in providing that seed funding. For example, would a certain amount of seed funding be needed in order to implement this model nationally? Is there a specific seed funding requirement for participating employers/plans and matching dollars requirement from other payers (Medicaid, Medicare Advantage [MA] plans, or other commercial payers)?

As with the Oncology Care Model's monthly enhanced oncology services payments, the care management payments associated with PCOP occur at the initiation of the model. As such, savings may not be achieved immediately. Payers considering participation must factor this into projections on the initial cost of the model (2-3% for care management payments, up to 2-3% for performance incentive payments), along with any administrative requirements not achievable with their current infrastructure.



6. Are you aware of any potential legal concerns, such as concerns relating to antitrust laws, which may arise and need to be addressed if multiple private payers in a community come together to discuss aspects of oncology care payment and cost-of-care metrics? If so, how might these legal concerns be addressed?

We have proposed that participating payers value care management payments at 2-3% of total cost of care; however, negotiation of specific rates for commercial plans should take place between individual payers and practices.

As successfully demonstrated in the Comprehensive Primary Care Plus model, we do not have legal concerns with adopting common metrics and methodologies.

Payment Methodology

7. What is the proposed level of monthly CMP funding (e.g., per-beneficiary-per-month [PBPM] or flat fee) in the PCOP model (page 11)? Would the monthly CMP payments be adjusted by case-mix or risk of attributed beneficiaries?

We have proposed that the monthly care management payment rates be modeled to average 2% of total cost of care for Track 1 participants and 3% of total cost of care for Track 2 participants. In table 4.2, we utilized Medicare data from the Maine All-Payer Claims Database to estimate the value for track 1 as \$450.00 for new patients' first month, \$225.00 during ongoing treatment, and \$75.00 for active monitoring; track 2 equals \$675.00, \$337.50, and \$112.50, respectively. Note that this differs from the Oncology Care Model, for which \$160.00 is paid per month, regardless of phase of care, typically guaranteed for the entire six-month episode.

We have not proposed case-mix or risk adjustment for care management payments. While we are not opposed to such adjustments, care should be taken to avoid undue complexity or administrative burden on the participants.

8. Page 5 states that "Practices that elect Track 1 are expected to advance into Track 2 within 2 years or else be subject to discontinuation of care management and performance incentive payments." Please clarify whether: 1) all Track 1 practices that do not advance into Track 2 within two years would lose their care management and performance incentive payments; and 2) what will happen to these practices after losing these payments (e.g., will they no longer be able to participate in the PCOP model)?

On page 5, we include language that practices who fail to advance to Track 2 will "be subject to discontinuation of care management and performance incentive payments." The choice of language "be subject to" was purposeful in order to give participating payers flexibility as to whether to discontinue payments as proposed or extend the deadline based on their own business interests.



Clinical Guidelines, Quality Measures, and Patient Preferences

9. The proposal states that PCOP Communities can select their own clinical pathways and quality measures (pages 1-3), but how would the appropriateness of these selections be assessed across communities under the proposed model, and how would comparisons be made across practices or between participating practices and the comparison group? Would any common sub-set of measures be required?

PCOP has limited the menu of available quality metrics to those in Appendix B. These measures were selected based on available benchmarks within ASCO's Quality Oncology Practice Initiative (QOPI) program and/or the Medicare Incentive Payment System (MIPS)that are electronically capturable (as demonstrated by ASCO's qualified clinical data registry) and were not determined to be "topped out" during our review. Having a limited menu of measures, which have available benchmarks, ensures appropriateness of selection.

With respect to clinical pathways, ASCO has published criteria for high quality pathways, available in Appendix C. These criteria include regular reporting and comparisons to performance of other providers.

10. The proposal suggests that practices would self-report adherence (page 16), quality (page 17), and cost-of-care (page 21) measures to the community-level Steering Committee. While the proposal also suggests an independent validator (page 24), how would performance be measured independently across practices and communities if the model was implemented nationally?

While performance will be measured regularly by PCOP participants for purposes of adjustment of performance incentive payments, retrospective independent evaluation will provide an assessment of whether the model itself made an impact on the cost, service use, and quality-of-care within the community—or whether observed changes would have occurred independent of model implementation. If implemented nationally—without comparator communities—then the evaluation must create an actuarial model that takes into account prior market trends and the most likely outcome if the model had not been implemented.

For Medicare's participation, such evaluation should comply with §1115A(b)(4) of the Social Security Act.



11. The proposal suggests that communities and practices could leverage Certified Electronic Health Record Technology (CEHRT), existing Health Information Exchanges (HIEs), and/or oncology specific All Payer Claims Database (APCD) capability, and ASCO's Quality Oncology Practice Initiative (QOPI) program to efficiently collect, integrate, and report quality and cost metrics (pages 10 and 25). Can you provide any further information on how many communities and practices currently have this capability and/or how burdensome it would be to collect the data suggested for measuring performance?

We believe that the 18 regions participating in the Comprehensive Primary Care Plus model are most appropriate for initial implementation of the PCOP model: Arkansas, Colorado, Hawaii, Greater Kansas City Region of Kansas and Missouri, Louisiana, Michigan, Montana, Nebraska, North Dakota, Greater Buffalo Region of New York, North Hudson-Capital Region of New York, New Jersey, Ohio and Northern Kentucky Region, Oklahoma, Oregon, Greater Philadelphia Region of Pennsylvania, Rhode Island, and Tennessee. The states of Maine, Maryland, and Washington may be added to this list, given their strong health information exchanges, all-payer claims databases, and regional healthcare improvement organizations. We have engaged with Maryland to discuss the inclusion of PCOP under their Episode Quality Improvement Program.

There may be other communities with these capabilities, or who are looking to develop such capabilities, of which we are unaware.

12. While the ASCO criteria for High-Quality Clinical Pathways require pathways to "include evidence-based options to account for differences in patient characteristics and/or preferences" (Appendix C), how are patient preferences taken into account when the expectation is to follow the clinical pathway for everyone?

It is not expected that a physician will adhere to the clinical pathway for 100% of patients they are treating. Section 6.1.3 of the performance methodology explains that scoring is based on provider adherence expressed as a percentile of adherence rates among providers participating in the same pathways program.

Depending on the pathway, average adherence may range from 70-90%, depending on the degree of flexibility or choice in a given pathway. The remaining 10-30% of patients may go off-pathway depending on a range of clinical or patient preferences. A pathway cannot fully account or anticipate every treatment or patient circumstance. Doing so would create a pathway too complex to maintain or use. We do require that providers justify off-pathway treatment and that the rationale for this decision be documented in the pathway decision-support system and/or medical record.



Attribution

13. Will there be prospective or retrospective assignment of beneficiaries to practices/Tax Identification Numbers (TINs) under the proposed model (page 21)? It appears as if attribution would have to be somewhat retrospective, as the starting point or trigger event is cancer diagnosis, but could longer term cancer patients be attributed prospectively?

The primary means of attribution is billing of the care management payment. The provider attests they are responsible for management of the patient's anti-cancer therapy, survivorship care, and/or palliative care. The secondary means of attribution, based on the billing of an antineoplastic or immunosuppressant agent, is intended to capture cases for which a provider fails to bill the appropriate care management payment. This would be retrospective.

14. The proposal states that "...If more than one provider bills one of the previously listed services, all shall be attributed the treatment month and associated measures" (page 19). Will providers be weighted equally, or will one provider be weighted more heavily based on volume? Are there any situations when it would be reasonable for more than one provider to bill the service, such as when both hematological and radiation oncologists are needed, a second opinion is sought, or a patient is in a trial?

Providers would be weighted equally. We would not expect that a second opinion would trigger a care management payment, unless that provider is assuming ongoing care of the patient. We do not expect that a radiation oncologist would bill for a care management payment under this model, which is intended for hematology and medical oncology providers.

15. Please clarify when the CMP payment (page 11) would begin and when it would stop. What is the trigger event for the start of CMP payment, and what trigger event stops the payment? How are beneficiaries that have already been diagnosed with cancer and had some treatment included in the payment model and Oncology Medical Home (OMH) care delivery program?

The new patient care management payment would be billed on the date that the patient begins treatment or is being actively managed, such as a patient receiving only palliative care management.

The cancer treatment care management payment would be billed once per month, for each month that the patient receives active drug or immunotherapy treatment, or for patients in hospice care managed by the billing physician, excluding the month in which the new patient care management payment is billed.

The active monitoring care management payment would be billed once per month, up to



twelve months, for each month that the patient is being managed by the oncology practice and does not otherwise qualify for the new patient or cancer treatment care management payment.

Possible Contributions of the Proposed PCOP Model

16. What aspects of ASCO's proposed PCOP model do you believe are most unique or different from current CMMI oncology models, such as the Oncology Care Model (OCM) or the proposed Oncology Care First (OCF) model which is under development? What aspects or features of the proposed PCOP model could potentially complement or strengthen existing models?

Unlike the Oncology Care Model (OCM), PCOP is first and foremost a care transformation model. Its aim is to improve quality of oncology patient care without increasing aggregate costs. As such, PCOP has a specific focus on clinical practice transformations required by its participants, defining 22 care delivery requirements. The payment and performance methodologies were determined based on how best to enable and measure the transformations.

PCOP differs from OCM and the proposed Oncology Care First (OCF) models in its performance methodology. In its establishment of the Center for Medicare and Medicaid Innovation, the Affordable Care Act (ACA) anticipated that innovative models would improve quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending. OCM and OCF fail to fully recognize improvements to quality of care contemplated by the ACA.

OCM is a cost-first model. Only after achieving a targeted reduction in cost is the quality of care and amount of savings factored into performance-based payments. For example, an OCM practice may achieve a 100% aggregate quality score and save Medicare 2% in total cost of care, yet will not receive a performance-based payment. PCOP has a balanced performance methodology, whereby performance in quality metrics, cost metrics, and pathway adherence – pathway adherence impacts both quality and cost – are weighted equally.

PCOP aims to disrupt fee-for-service for professional services using consolidated payments. This concept has since been added to the OCF concept in its Monthly Population Payment.

Finally, we have found that the risk model within OCM is untenable for most participants. The significant prediction error introduced in the OCM performance methodology places small practices at significant financial risk because of common cause variation. We do not feel it is appropriate to design a model in which funds from the Medicare program are spent by providers for reinsurance or employment of actuaries.

The PCOP model introduces financial risk through consolidation of professional service payments and then varying those payments based on the performance methodology. This differs from OCM in that it makes providers responsible for the services they are able to



control. PCOP adjusts those payments on a prospective basis, allowing providers to know their expected revenue for the next period without the risk of retrospective clawbacks.



Patient-Centered Oncology Payment Model (PCOP): Response to the PRT's Questions 4-28-20*

Responses to Questions Received from the PTAC Preliminary Review Team on the "Patient-Centered Oncology Payment Model (PCOP)" PFPM Proposal Submitted by the American Society of Clinical Oncology (ASCO)

Care Management Payments (CMPs) and Performance Improvement Payments (PIPs)

1. Table 4.2 on page 13 of the proposal lists the proposed values of the Medicare Care Management Payment (CMP) and Performance Incentive Payment (PIP) for Track 1 and Track 2 throughout a patient's course of treatment. The proposal states that ASCO utilized data from the Maine Health Data Organization to model the CMP and PIP amounts based on guidelines that are summarized in Table 4.1 regarding the relationship of the CMPs and PIPs to Total Cost of Care, and the relationship of the New Patient and Active Monitoring CMPs to the Cancer Treatment CMP. Please provide additional details regarding the financial modeling assumptions that were used to estimate that CMPS and PIPs in the PCOP model "shall total 2-4% for practices in Track 1 and 3-6% for practices in Track 2" (see page 12 and Appendix A).

To support PCOP modeling, we analyzed records of 2,865 patients treated in the state of Maine between October 2015 and December 2017, as provided by the Maine health Data organization. Analyzed data included patient covered by Medicare Parts A, B, and D; Medicare part C; Medicaid; and commercially offered insurance (including employer self-insurance).

In total, we included 16,408 months of care for Medicare patients, divided into three phases: (a) new patient months, within which the patient first received an evaluation and management service from a medical oncology provider; (b) cancer treatment months, within which patients had one or more identified anticancer drug treatments; and (c) active monitoring months, within which patients had one or more evaluation and management service from a medical oncology provider within a three-month period.

In responding to your question, we identified an error within table A.5, which is corrected below:

^{*} This document has been modified to indicate the PRT questions in bold face to improve readability.



Table 4.2

Care Management and Performance Incentive Payments – Medicare Rates

	New Patient	Cancer Treatment	Active Monitoring
Months of Care	1,560	6,616	7,872
Total Cost of Care	\$ 9,508	\$ 13,443	\$4,137
Care Management – Track 1	\$ 450	\$ 225	\$ 75
Performance Incentive – Track 1	up to 450	up to 225	up to 75
Blended Percentage			up to 4.0%
Care Management – Track 2	675	337.50	112.50
Performance Incentive – Track 2	up to 675	up to 337.50	up to 112.50
Blended Percentage			up to 6.0%

Under these assumptions:

- Care Management Track 1 payments have a weighted average of \$173.29, compared to a weighted average of \$8,495.63 total cost of care (2%).
- Performance Incentive Track 1 payments have a weighted average of up to \$173.29, compared to a weighted average of \$8,495.63 total cost of care (up to 2%).
- Care Management Track 2 payments have a weighted average of \$259.94, compared to a weighted average of \$8,495.63 total cost of care (3%).
- Performance Incentive Track 2 payments have a weighted average of up to \$259.94, compared to a weighted average of \$8,495.63 total cost of care (up to 3%).

Under the CMS Oncology Care Model (OCM), the Monthly Enhanced Oncology Payments (MEOS) were modeled at 4% of total cost of care. Given that MEOS payments were modeled from 2012-2015 data, they now represent less than 4% of current costs.

We felt that 2-3% was a more appropriate basis for Care Management Payments. We also felt that rather than a flat amount each month, the payments should be stratified based on the resources required for care management in each phase of care, for this reason, we increased the new patient amount and lowered the active monitoring amount, while maintaining a weighted average of 2% or 3%.

Performance Incentive Payments are proposed as an alternative to the Performance-Based Payments under OCM.



Savings Opportunities

2. Page 2 of the proposal indicates that "Financial modeling has shown savings opportunities up to 8% of total cost-of-care; a reasonable expectation is 4-6% reduction, totaling \$1.9 billion to \$2.8 billion in annual program savings," and Appendix A provides detailed information about how the financial model and saving projections were developed. Specifically, Appendix A states that the projections were developed from an analysis of records of 2,865 patients treated in the state of Maine between October 2015 and December 2017, as provided by the Maine Health Data Organization. Appendix A also cites several studies related to the impact of value-based clinical pathways and oncology medical home care management strategies on costs and utilization that were used in developing the savings projections

Recent trend data indicate that there has been a shift over time from inpatient to outpatient treatment modalities in oncology care, which has affected underlying inpatient hospitalization rates for oncology patients. However, some of the studies that were cited in Appendix A appear to rely on utilization data from more than a decade ago. For example, the 2011 study by Hoverman et. al. was based on an analysis of claims data from 2005-2007; the 2010 study by Neubauer et. al. was based on an analysis of claims data for 2006-2007; and the 2013 study by Kreys et. al. was based on an analysis of claims data for 2007-2009.

Please discuss the extent to which recent changes in practice patterns could potentially affect some of the assumptions that were used in the financial modeling, and how this might affect some of the savings estimates associated with this model. In particular, given recent trends or declines in inpatient admissions and emergency department (ED) visits, or current rates of ED visits, inpatient utilization, and spending on supportive/maintenance drugs, please comment on the feasibility of achieving sufficient reductions in these areas to offset the cost of the CMPs and PIPs.

Since the release of ondansetron in 1991, there has been a profound shift from inpatient to outpatient treatment modalities in the delivery of oncology drug treatments. A sizable portion of remaining admissions, as demonstrated by the cited studies, are due to symptoms resulting from the cancer or cancer treatments, rather than planned admissions for the administration of chemotherapy.

Along with the studies mentioned in your question, we also cited Mendenhall, et al., which demonstrated continued opportunities for admission reduction as recent as 2017. The consistency of studies findings spanning over 10 years show that opportunity to achieve savings through reduction of admissions and ED visits remains persistent in oncology.

We are concerned with the current lack of recent comparative data available from CMS regarding OCM, which would allow us to quantify the impact of OCM on current rates of ED visits, inpatient utilization, and drug spending and to estimate the further reduction opportunities for both OCM and non-OCM practices. In its latest evaluation report, CMS included no financial analysis of OCM performance. The last full evaluation report,



published in December of 2018, included only the first six-month performance period of July – December 2016. We do recognize that if more recent data had been published, it may have allowed for improved assumptions in future opportunities modeled within PCOP.

Payment Model

3. Question Page 13 states that "practices in Track 2 shall participate in Consolidated Payments for Oncology Care (CPOC)" that adjust and bundle a portion of fee-for-service reimbursements. Page 14 states that: at minimum, CPOC shall include: evaluation and management services by oncology providers; parenteral drug and biologic agent administration services; care management services by oncology providers (e.g., advance care planning, smoking cessation, transitional care management); and drug and biologics reimbursement above the purchase cost of such agents (e.g., for Medicare Part B drugs, the +6% amount would be included in consolidated payments, with the remaining average sales price reimbursed through fee-for-service billing).

Please clarify what other services will be included in the CPOC bundle under Track 2, specifically:

a. What other cancer (radiation and surgery) services are included or excluded?

CPOC payments, as modeled in the proposal, are limited to medical oncology services. This includes evaluation & management, care management, drug administration, drug and biologics reimbursements above the purchase cost of such agents.

b. What non-cancer services are included or excluded?

CPOC payments are limited to the medical oncology provider and do not include non-cancer services.

- c. When does the bundled/episode payment stop?
 - Aligned with the Active Monitoring CMP, consolidated payments end at twelve months after the completion of treatment, or when the patient is no longer actively managed by the oncology practice.
- d. When would certain services be "addressed by other alternative payment models," rather than being included in CPOC, as discussed at the bottom of page 14?

Radiation Oncology – in 2017, the American Society for Radiation Oncology published the Radiation Oncology Alternative Payment Model (RO-APM). RO-APM has since been adapted by the Center for Medicare and Medicaid Innovation as the proposed Radiation Oncology Model.

Surgical Oncology – The Center for Clinical Standards and Quality has developed a number of cost episodes for the Quality Payment Program (and previously, the Value-based Modifier), including one for Lumpectomy, Partial Mastectomy, and



Simple Mastectomy. Previously, an episode for prostatectomy was also used.

We did address the possibility that such specialties could be combined under a consolidated payment. However, to do so would require an additional component of an accountable care organization comprised of multiple specialties.

Category Care Delivery Requirements

4. Are the specific PCOP Care Delivery Requirements developed by ASCO and the Community Oncology Alliance-as referenced on page 10 (and outlined in Appendix D) of the proposal-available for public use? If they are proprietary, how are they accessed and at what associated costs, if any?

The following answer addresses the care delivery requirements that may be of concern regarding public use. If we have missed any, please let us know.

All patients are provided with education on their cancer diagnosis and an individualized treatment plan. The Institute of Medicine (IOM) 13-point treatment plan is copyrighted by the National Academy of Sciences (NAS) but is available for free download from The National Academies Press (NAP) and is for public use by healthcare providers.

The practice develops and implements a process to disseminate a treatment summary/survivorship care plan to patients within 90 days of the completion of treatment. Within, From Cancer Patient to Cancer Survivor, IOM includes a model for a proper survivorship care plan. This document is copyrighted by NAS but is available for free download from NAP and is for public use by healthcare providers.

Practice utilizes symptom management pathways/guidelines for triage and urgent care of patients experiencing symptoms from their cancer or cancer treatment. There are a number of proprietary symptom management pathways/guidelines. One such example is Telephone Triage for Oncology Nurses, available from the Oncology Nursing Society (ONS) for \$137.00 for nonmembers. It is not required that practices adopt any specific pathway/guideline and may develop their own for use.

All patients are provided navigation for support services and community resources specific to the practice patient population; on-site psychosocial distress screening is performed and referral for the provision of psychosocial care is provided, as needed. There are a number of distress screening tools available for personal use, free-of-charge, for use with patients: NCCN Distress Thermometer and Problem List, PROMIS-Cancer measures for anxiety and depression, Patient Health Questionnaire-4, and the Psychosocial Screen for Cancer.

The practice administers a patient satisfaction survey to cancer patients at least twice each calendar year or on an ongoing basis. The results of the survey are analyzed and used to guide quality improvement activities. There are a number of free and fee-based patient satisfaction tools and methods. The Community Oncology Alliance offers the OMH Patient Satisfaction Survey free-of-charge for oncology providers. This survey tool includes requirements by the Consumer Assessment of Healthcare Providers and Systems (CAHPS).



CAHPS also has a CAHPS Cancer Care Survey.

The practice follows QOPI safety standards for the administration of chemotherapy. The QOPI safety standards are based on the ASCO-ONS Chemotherapy Administration Safety Standards. These standards have been published on ascopubs.org and ons.org and are available via open access. We further specify that demonstration of accomplishing these standards may be demonstrated through, but is not required, ASCO's QOPI Certification Program, which does involve a fee based on the practice size.

The practice uses evidence-based treatment pathways; measures and reports on physician compliance with pathways; and requires documentation for off-pathway treatment. There are a number of proprietary, fee-based pathway programs available for use within PCOP. While it is possible for another, non-proprietary pathways be developed and used within a PCOP Community, it is likely that they would choose one of the current commercially available pathways. The practice would be responsible for all fees associated with such use as a requirement of receiving monthly care management pathways.

Quality Oncology Practice Initiative (QOPI®) Certification Program

5. The QOPI® Certification Program (QCP) seems to be required for participating practices, since the required safety standards are a component of the broader certification program (see page 52 in Appendix E, where complete QCP standards are provided). The proposal notes that "Practices are not required to meet the QOPI chart abstraction/participation requirement but must meet all standards and measures in the QCP program."

Please clarify whether participation in the QOPI® Certification Program is required and how participation relates to the safety standards. If participation is required, what (if any) are the costs for practices to be certified and are there indirect costs that should be taken into consideration? Are there alternatives to the QOPI Certification Program?

Within our proposal, practices are required to demonstrate compliance with the safety standards. However, we have not proposed the QOPI® Certification Program as the sole method for demonstrating such compliance. PCOP communities are free to develop their own methods for ensuring compliance with all care delivery standards, including chemotherapy safety, so long as it does not violate ASCO's exclusive right to utilize the standards for a certification program. We are unaware of an equivalent certification program.

QOPI® Safety Standards

6. The QOPI® Safety Standards outlined in Appendix E are based on input from ASCO and the Oncology Nursing Society. Are these standards proprietary in nature or are they available for public use? If proprietary, do they require membership in ASCO and/or the Oncology Nursing Society in order to access the standards and their updates?

The safety standards outlined in Appendix E are based on the ASCO-ONS Chemotherapy Administration Safety Standards. These standards have been published on ascopubs.org



and ons.org and are available via open access. We have also published Appendix E in the full PCOP model at https://practice.asco.org/paymentreform.

High-Quality Clinical Pathways

7. ASCO responded to a previous question from the PRT (number 9, page 4) by indicating that: "ASCO has published criteria for high quality pathways, available in Appendix C."

How might pathways from other vendors be introduced and utilized? Please clarify--does the proposal require that a given pathway first be reviewed and approved for use by ASCO (against its criteria as highlighted in Appendix C), before the Steering Committee may select such a pathway?

New pathways may be developed by healthcare providers, payers, standard-setting organizations, or content management companies. A Steering Committee may evaluate and select any available pathway using ASCO's criteria. While PCOP does not require ASCO's evaluation of a pathway for use, a few agencies have questioned whether ASCO could play such a role within a federal payment program. We are open to discussion on how ASCO may best support evidence-based medicine in oncology.

If able, please provide an example of a High-Quality Clinical Pathway developer (and information on the pathway) that met the criteria and indicate whether their pathway is proprietary or publicly available. If proprietary, what are the requirements (e.g. permissions) and costs, if any, for the communities and/or practices who may wish to use them (e.g., are there any fees)?

In 2018, ASCO evaluated four pathway vendors: Anthem/AIM Cancer Care Quality Program (AIM), New Century Health, Value Pathways powered by the National Comprehensive Cancer Network (NCCN), and Via Oncology (now ClinicalPath). We have attached a copy of this published article.

Each of these pathways included proprietary content and were integrated into online decision-support tools. Each included fees for use, paid for by either the utilizing provider or by a payer for utilization management and/or quality measurement purposes. The practice would be responsible for all fees associated with such use as a requirement of receiving monthly care management pathways.

Quality Oncology Practice Initiative (QOPI®) Reporting Registry

8. Page 24 of the proposal (Section 7.6.4-Quality Registry) states that: "Clinical Data Registries are a data custodian for the collection, analysis, comparison against benchmarks, and distribution of quality metric performance. ASCO operates the QOPI Reporting Registry with medical and radiation oncology quality measures."

Would participating practices have to use the QOPI Reporting Registry? If so, what is the direct cost to a practice wanting to access and use the QOPI Reporting Registry (e.g., ASCO membership)? What indirect costs, if any, should be taken into consideration? Please briefly



describe whether other cancer clinical data registries could be used as alternatives. Will providers have free access to their own data?

We have not required that PCOP participants must use the QOPI Reporting Registry. Such a decision may be made by the implementing body (PCOP Community, CMS, or others). We offer the QOPI Reporting Registry as an option with current operational electronic measure capture to minimize practice administrative burden.

The current fee for participation in the QOPI Reporting Registry is \$495 per provider, per year for practices reporting via integration with their electronic health record. Other costs may include an interface or other license fee from the provider's electronic health record.

Other cancer clinical data registries have alternative measures that may be selected; it would be infeasible for a PCOP Community to utilize more than one registry.

Health Information Exchange (HIE) & Quality Data Pooling

9. As indicated above, our understanding is that practices would have to use ASCO's QOPI Reporting Registry or other clinical data registries as a data custodian for the collection, analysis, comparison against benchmarks, and distribution of quality metric performance. Are there membership requirements as well as costs associated with the practices or communities use of the HIE as the data custodian or in combination with another data custodian as referenced in the proposal (section 7.6.3 Data Custodian p. 23-24)?

The current fee for participation in the QOPI Reporting Registry is \$495 per provider, per year for practices reporting via integration with their electronic health record.

There are multiple regional health information exchanges operating with their own benefits, participation model, and fees. A few examples are included below (prices current as of the date of this letter):

- CliniSync in Ohio: access to a longitudinal community health record, clinical results and reports delivery, direct messaging, and electronic referrals costs \$300 per provider, per year, for the first 10 physicians in a practice, with a downward sliding scale for additional physicians.
- OneHealthPort in Washington State: annual subscription fees are based on the
 participating practices annual net operating revenue (\$600 for up to \$10 million,
 \$6,000 for up to \$100 million, \$12,000 for up to \$500 million, etc.). This gives access
 to ADT messages, medication history queries, clinical results and reports delivery,
 reporting to public health registries, secure messaging and other data exchange.
- CORHIO™ in Colorado: \$35 per month for full-time providers, \$10 per part-time provider for small and medium practice access to their Integrated HIE Package (EHR integration, PatientCare 360® Web portal, Clinical In-Box, and Secure Messaging), plus a one-time implementation fee of up to \$4,500.



Health Information Exchange (HIE), All-Payer Claims Database (APCDs) & Costof-Care Data Pooling

10. As with quality data, a data custodian would potentially be needed for the collection, analysis, comparison against benchmarks, and distribution of cost-of-care performance, particularly since ASCO's PCOP is intended to be a multi-payer model. See for example, Figure 7.2 Data Repository Model, on page 25 of the proposal. If the data custodian could be a HIE or APCD, are there membership requirements as well as costs associated with the participating practices' or communities' use of the HIE or APCD for purposes of cost-of-care performance data pooling and assessment? Are there any alternatives to using an HIE or APCD for these purposes, and if so, what are they?

There are multiple all-payer claims databases operating with their own benefits, participation model, and fees. A few examples are included below (prices current as of the date of this letter).

- Maine Health Data Organization: starting at \$4,750 for one year of medical and pharmacy claims data, starting at \$650 per year of inpatient hospital encounters and \$100 per year for hospital healthcare quality data.
- Center for Improving Value in Health Care in Colorado: standard reports start at \$500, custom reports at \$1,500, and data sets at \$10,000. In 2018, the average data access fee was \$18,500. Colorado also has scholarships available
- Utah All Payer Claims Database: the base price for a single year of Utah's standard limited use data set is \$8,000, with a 50% discount for data contributors.

A number of HIE and APCD have public reports available free-of-charge or operate a data co-op, by where data contributors have free or discounted access to aggregated data.

Regarding use of HIE and APCD

We included HIEs and APCDs within the implementation model in order to streamline the current environment of data interchange and quality measurement. Today, providers share data with multiple entities through a myriad of disjointed ways, a portion of which are included below:

- HIEs for access to and delivery of clinical results and reports.
- State registries for immunizations, syndromic surveillance, and cancer reporting; some HIEs support reporting to state registries.
- Qualified clinical data registries or other means for reporting to CMS's Quality Payment Program (e.g. QOPI Reporting Registry).
- Reporting to alternative payment model registries, such as with the CMS Oncology Care Model.
- Manual entry of data to clinical treatment pathway vendors and/or other utilization management tools for purposes of prior authorization of diagnostics and treatments.



This fractionated approach creates significant administrative burden on providers to interchange with multiple entities, as well as limits availability of complete data sets for measurement and analysis of quality and cost. Instead, we envision a model by which providers improve the quality and completeness of oncology data in their submission to HIEs, who shall then interchange with other entities, such as the QOPI Reporting Registry. ASCO and its nonprofit subsidiary, CancerLinQ LLC, and the MITRE Corporation are collaborating to develop and launch mCODE™: Minimal Common Oncology Data Elements in order to advance the quality and completeness of data interchanged for cancer patients.

While HIEs present a method to exchange clinical data, APCDs are a tool by which multiple payers and providers can aggregate encounter and claims data and make it available to each other and for public use. Within an alternative payment models, this includes claims-based measures that are aggregated across multiple payers using common definitions. In Washington State, an annual Community Cancer Care in Washington State Report uses claims and cancer registry data to produce a public report of 17 metrics, including inpatient stays during chemotherapy and chemotherapy in the last 14 days of life.



The full version of this paper may be viewed online at DOI: https://doi.org/10.1200/JOP.17.00033.

Oncology Clinical Pathways: Charting the Landscape of Pathway Providers

Bobby Daly, Robin T. Zon, Ray D. Page, Stephen B. Edge, Gary H. Lyman, Sybil R. Green, Dana S. Wollins, and Linda D. Bosserman

ASSOCIATED CONTENT



See accompanying editorials on pages 144 and 147



Data Supplement available online

INTRODUCTION

There has been a tremendous growth in the use of oncology clinical pathways (OCPs), spurred by the shift to value-based reimbursement. As the voice of cancer care providers and the patients they serve, the American Society of Clinical Oncology (ASCO) has takensteps to elevate awareness about clinical pathways among oncology providers, patients, and other stakeholders as well as collaborate with these stakeholders and the pathway vendors to ensure theintegrity of these products. 1,2 In March 2017, ASCO released its Criteria for High-Quality Clinical Pathways (hereafter referred to as the Criteria), creating a mechanism for evaluating pathways based on development, implementation and use, and analytics. As a next step, the ASCO Task Force sought to advance this effort by evaluating national pathway vendors against these Criteria to help stakeholders better navigate the current pathway environment.

METHODS

Identification of Prominent Pathway Vendors

This work assesses several national pathway vendors that have emerged as leaders in the oncology marketplace. Our methodology defined pathway vendors broadly as those that provide treatment management tools to standardize and promote evidence-based care and drive quality. The toolsvariedfromthosehighlightingasingle

best treatment option to those offering multipleguideline-concordantcarechoices. We included vendors targeting providers as well as payers, because both have an impact on our stakeholders. Vendors were identified through twomeans. First, survey results were analyzed from the ASCO State of Cancer Care in America 2016 report to determine the OCPs used by respondents.³ Second, we collaborated with the external consulting firm DK Pierce (Zionsville, IN) to identify national vendors.⁴

Six vendors were initially identified as meeting our criteria for evaluation. Upon additional review, the Task Force concluded that evitiand eviCoredonot provide what some might consider pathways. These two products are primarily decision support tools. For that reason, we placed eviCore and eviti in a separate category entitled decision support tool vendors. We still proceeded to compare their products against the Criteria. Given their prominent role in the oncology market, we determined this assessment would be of interest to readers.

Criteria Evaluation

After identifying vendors, the Task Force compared each product with the published Criteria. The Task Force primarily used publicly available information from company Websites, pressreleases, and academic and lay press articles to evaluate performance against the Criteria. Subsequently, the Task Force conducted follow-up

DOI: https://doi.org/10.1200/JOP. 17.00033; published online ahead of print at jop.ascopubs.org on February 7, 2018.

Table 1. Summary of Results

	Clinical Pathway Vendors			
Key Questions	Anthem/AIM	New Century Health	Value Pathways/ NCCN	Via Oncology
Expert driven Do practicing oncology providers with relevant disease and/or specialty expertise play a central role in pathway development?	Met	Met	Met	Met
Reflects stakeholder input Is there a mechanism in place for patients, payers, and other stakeholders to provide input during the development process?	Met	Partially met	Met	Met
Transparent Is there a clear process or methodology for pathway development that is transparent to all pathway users, stakeholders, and the general public? Is information disclosed on:				
The methodology used for development?	Met	Met	Met	Met
The strengths and types of evidence used to generate consensus?	Met	Met	Met	Met
The specific evidence used to support the pathway recommendation (including key literature citations, guidelines, or other evidence)?	Met	Partially met	Met	Met
The way in which efficacy, toxicity, and cost are assessed and balanced in determining the pathway recommendation?	Met	Met	Met	Met
Is therea 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:		Met	Met	Met
The nature of relationships required for disclosure?	Not met	Met	Met	Met
The manner in which disclosure information is made publicly available?		Met	Met	Met
The required steps for managing conflicts of interest?	Not met	Met	Met	Met
The required steps to managing commets of interest: The required steps to ensure policy adherence and enforcement?	Not met	Met	Partially met	Met
Evidence based			•	
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, FDA labeling indications, and/or dissemination vehicles?	Met	Met	Met	Met
Is a mechanism in place for considering high-quality evidence generated from validated real-world data (ie, rapid-learning health care systems)?	Partially met	Partially met	Partially met	Partially met
Patient focused Do the pathways include evidence-based options to account for differences in patient characteristics and/or preferences (ie, patient comorbidities, prior diagnoses and treatments, risk of treatment-	Met	Met	Met	Met
related toxicities, treatment schedule, and/or financial toxicity)? How is cost factored into pathway recommendations of therapeutically M	et	Met	Met	Met
similar or equivalent treatments? Are stakeholder assessment and pathway analysis used for pathway revision?	Met	Met	Met	Met
Up to date Are pathways updated in a timely way as relevant new information, including new FDA indication approvals, becomes available?	Met	Met	Met	Met
How rapidly are new, practice-changing data incorporated into pathway recommendations?	Met	Met	Met	Met
(continued on	following page)			

Table 1. Summary of Results (continued)

	Clinical Pathway Vendors			
Key Questions	Anthem/AIM	New Century Health	Value Pathways/ NCCN	Via Oncology
Comprehensive Do the pathways address the full spectrum of cancer care from diagnostic leavaluation through first course of therapy, supportive care, posttreatment 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? If the pathways are not comprehensive, do they clearly describe the phase and elements of care they are intended to address?		Data Supplement Da	ita Supplement Data	a Supplement Met
Promotes participation in clinical trials Are available clinical trial options incorporated into the pathway program? Is treatment provided to patients participating in phase I to III clinical trials always considered pathway-appropriate treatment?	· ·	Met Met	Met Met	Met Met
Clear and achievable expected outcom Is information provided on the specific cancer type, stage, and molecular N profile that the pathway is intended to cover?		Met	Met	Met
stakeholders on what constitutes treatment on pathway, treatment off pathway, and warranted variation from pathway recommendations?	Met	Met	Met	Met
,	Not met	Met Met	Not met	Met Not met
strength of evidence for the disease and stage? Do adherence rates incorporate precision medicine based on current FDA-approved indications as on pathway?	Met	Met	Met	Met
Do adherence rates allow for evidence- based variation and take into Paraccount individual patient differences and the resources avaithe particular health care system or setting to provide recommended care?		Partially met	Partially met	Partially met
Integrated, cost-effective technology and decision support Does the pathway program offer or plan to offer clinical decision support or other resources (ie, 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 offering to users and other stakeholders?	Met	Met	Met	Met
Efficient processes for communication and adjudicat Does the pathway program provide references or links to references that N		Partially met	Met	Met
may support pathway variation? Does the pathway program inform the provider in real time of pathway Me		Met	Met	Met
compliance? Is the mechanism for choosing an off- pathway recommendation and documenting the rationale for this choice easily imbedded in the pathway program?	Met	Met	Met	Met
(continued on	following page)			

Table 1. Summary of Results (continued)

	Clinical Pathway Vendors			
Key Questions	Anthem/AIM	New Century Health	Value Pathways/ NCCN	Via Oncology
Efficient and public reporting of performance metrics 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?	Met	Met	Met	Met
Will the performance reports provided include these reasons for nonconcordance?	Met	Partially met	Met	Met
Will public reporting of providers' pathway adherence be disclosed as a composite report only (ie, not an individual provider or provider group level)?	Not met	Met	Not met	Met
Do providers have an opportunity to review performance reports and revise any areas in need of adjustment?	Met	Met	Met	Partially met
Outcomes-driven results Does the pathway program have analytics in place to enable a movement over time from adherence-driven compliance to outcome-driven results?	Met	Met	Met	Met
Promotes research and continuous quality improvement Does the pathway program demonstrate a commitment to research aimed at assessing and improving the impact of pathways on patient and provider 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?	Met	Met	Met	Met
Are the analytics generated from pathway programs publically available to patients and/or participating providers for benchmarking and understanding of complex cancer outcomes?	Partially met	Met	Met	Met

Abbreviations: FDA, US Food and Drug Administration; EHR, electronic health record; NCCN, National Comprehensive Cancer Network.

telephone interviews from February through April 2017 with each vendor to clarify issues identified in the respective pathway evaluations. Each pathway was assessed as meeting, not meeting, or partially meeting each criterion. Each assessment required a unanimous vote by the members of the Task Force. Subsequently, the preliminary assessments were provided to the respective vendors for review; they were able to submit any queries or concerns to the Task Force. These comments were considered by the Task Force in making the final categorizations presented herein. This report reflects the review period through July 2017.

RESULTS

The pathway vendors included in this assessment are as follows: Anthem/AIM Cancer Care Quality Program, New Century Health, Value Pathways powered by the National

Comprehensive Cancer Network, and Via Oncology. As noted, decision support products from eviti and eviCore were also analyzed; results are provided in the online article and are summarized here in Table 1.

DISCUSSION

Several studies have demonstrated that use of OCPs is associated with lowering cost while maintaining or improving outcomes. ⁵⁻⁸ Given the demonstrated value proposition of OCPs, one national payer has urged ASCO to "recommend adoption of a pathway program by every oncology practice in the United States." ⁹(p¹⁴⁹) Separately, ASCO has stated that not all pathways are equal and has considered recommending a system to assess and improve the integrity and quality of pathways coming to market. To that end, ASCO developed the Criteria for pathways to help oncology providers and all stakeholders,

including pathway developers, to better evaluate clinical pathways and ensure that pathways are developed and implemented in a way that advances the delivery of high-value care.¹

The pathway vendors we identified in this process were collaborative in working with ASCO to better understand the current pathway landscape. Given the vendor-unique business models and objectives, it is not surprising that there are differences among the OCP programs. The vendors target different customers, including payers and providers. The target audiences inform their product development decisions, and this in turn may affect how they perform on the Criteria. In this evaluation, there was no expectation that any individual OCP programwouldmeetallthe Criteria. The Task Forceand ASCO make no judgment on the suitability of an OCP for a specific application or practice, and that was not the objective of this analysis. Rather, the Task Force hopes this work will highlight areas for the continuous evolution of OCP programs and invites other pathway programs, including single-institution OCPs, to report on their status vis-à-vis the Criteria. In sharing this assessment, the Task Force hopes this work illuminates how pathways can progress toward the shared goal of providing the best care for patients with cancerop

Acknowledgment

B.D. and R.T.Z. contributed equally to this work. Supported by an American Society of Clinical Oncology Health Policy fellowship (B.D.).

Authors' Disclosures of Potential Conflicts of Interest Disclosures provided by the authors are available with this article at jop.ascopubs.org.

Author Contributions

Collection and assembly of data: All authors Conception and design: All authors Data analysis and interpretation: All authors Administrative support: Sybil R. Green, Dana S. Wollins

Provision of study materials or patients: All authors

Manuscript writing: All authors

Final approval of manuscript: All authors

Accountable for all aspects of the work: All authors

Corresponding authors: Bobby Daly, MD, MBA, Thoracic Oncology Service, Memorial Sloan Kettering Cancer Center, 885 Second Ave, New York, NY 10017; e-mail: dalyr1@mskcc.org; Robin T. Zon, MD, FACP, FASCO, 5340 Holy Cross Parkway, Mishawaka, IN 46545; e-mail: docrzon@aol.com.

References

- 1. Zon RT, Edge SB, Page RD, et al: American Society of Clinical Oncology criteria for high-quality clinical pathways in oncology. J Oncol Pract 13:207-210, 2017
- $2.\ \ ZonRT, FrameJN, NeussMN, et al: American Society of Clinical Oncology policy statement on clinical pathways in oncology. J Oncol Pract 12:261-266, 2016$
- 3. American Society of Clinical Oncology: The state of cancer care in America, 2016: A report by the American Society of Clinical Oncology. J Oncol Pract 12:339-383, 2016
- 4. Schroeder A: Clinical pathways: A current snapshot, and the journey ahead. J Clin Pathways 3:33-40, 2017
- 5. Neubauer MA, Hoverman JR, Kolodziej M, et al: Cost effectiveness of evidence-based treatment guidelines for the treatment of non-small-cell lung cancer in the community setting. J Oncol Pract 6:12-18, 2010
- 6. Hoverman JR, Cartwright TH, Patt DA, et al: Pathways, outcomes, and costs in colon cancer: retrospective evaluations in two distinct databases. J Oncol Pract 7: 52s-59s, 2011 (suppl)
- 7. Kreys ED, Koeller JM: Documenting the benefits and cost savings of a large multistate cancer pathway program from a payer's perspective. J Oncol Pract 9: e241-e247, 2013
- 8. Jackman DM, Zhang Y, Dalby C, et al: Cost and survival analysis before and after implementation of Dana-Farber clinical pathways for patients with stage IV non-small-cell lung cancer. J Oncol Pract 13:e346-e352, 2017
- $9.\ NewcomerLN, MalinJL: Payer view of high-quality clinical pathways for cancer. \ J\ Oncol\ Pract\ 13:148-150, 2017$

Expert-Led, Evidence-Based Review Series from JCO

Curated by thought-leaders, recent high-impact topics include:

- Novel Therapeutic and Diagnostic Advances in Bone and Soft Tissue Sarcomas Associate Editors: Gary K. Schwartz, MD, and Robert G. Maki MD, PhD, FACP
- Emerging Concepts in the Management of Central Nervous System Malignancies Associate Editors: Ingo Mellinghoff, MD, and Richard Gilbertson, MD, PhD
- Genomics in Hematologic Malignancies
 Associate Editors: Jonathan W. Friedberg, MD, and Benjamin Ebert, MD, PhD

Get Unprecedented Access: Visit JCO.org



AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Oncology Clinical Pathways: Charting the Landscape of Pathway Providers

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to www.asco.org/rwc or ascopubs.org/jop/site/ifc/journal-policies.html.

Bobby Daly

Employment: Quadrant Holdings Leadership: Quadrant Holdings

Stock and Other Ownership Interests: Quadrant Holdings (I), CVS Health, Johnson & Johnson, McKesson, Walgreens Boots Alliance, Eli Lilly (I), Walgreens Boots Alliance (I)

Robin T. Zon

Consulting or Advisory Role: Medical Protective Malpractice Insurance

Research Funding: Agendia (Inst)

Other Relationship: Medical Protective Malpractice Insurance

Ray D. Page

Employment: Center for Cancer and Blood Disorders Honoraria: Astellas Medivation, Community Oncology Alliance,

AmerisourceBergen

Consulting or Advisory Role: Via Oncology

Research Funding: Sarah Cannon Research Institute

Stephen B. Edge

Research Funding: Pfizer (Inst)

Gary H. Lyman

Leadership: Generex Biotechnology

Consulting or Advisory Role: Halozyme, GI Therapeutics, Coherus

Biosciences

Research Funding: Amgen (Inst)

Dana S. Wollins

 $Honoraria: Abbott \ Laboratories\ (I),\ Abb Vie\ (I),\ Amgen\ (I),\ Johnson\ \&$

Johnson (I), Pfizer (I), Procter & Gamble (I)

Sybil R. Green

No relationship to disclose

Linda D. Bosserman

Employment: City of Hope Medical Foundation, Front Line Medical Communications, Anthem Blue Cross Wellpoint, Prime Care Inland Valley,

LA County Fair

Honoraria: Pfizer, Association of Managed Care Pharmacy, American Society of Breast Surgeons, Association of Nurse Navigators, Medscape,

Physicians Education Resource, JADPRO

Consulting or Advisory Role: Pfizer, Association of Community Cancer

Centers, Novartis, Sandoz-Novartis, Merck, UpToDate, Puma

Biotechnology, AstraZeneca, Roche/Genentech

Speakers' Bureau: Puma Biotechnology

Oncology Clinical Pathways: Charting the Landscape of Pathway Providers

Bobby Daly, Robin T. Zon, Ray D. Page, Stephen B. Edge, Gary H. Lyman, Sybil R. Green, Dana S. Wollins, and Linda D. Bosserman

Memorial Sloan Kettering Cancer Center, New York; Roswell Park Cancer Institute, Buffalo, NY; Michiana Hematology-Oncology, Mishawaka, IN; Center for Cancer and Blood Disorders, Fort Worth, TX; Fred Hutchinson Cancer Research Center and University of Washington, Seattle, WA; American Society of Clinical Oncology, Alexandria, VA; and City of Hope, Rancho Cucamonga, CA

ASSOCIATED CONTENT



See accompanying editorials on pages 144 and 147



Data Supplement available online

INTRODUCTION

There has been a tremendous growth in the use of oncology clinical pathways (OCPs) by providers and payers. The American Society of Clinical Oncology (ASCO) State of Cancer Care in America 2017 report documented a 42% increase from 2014 to 2016 in practices reporting compliance with a pathway program.^{1,2} An OCP is defined by ASCO as a detailed protocol for delivering cancer care, including but not limited to anticancer drug regimens for specific patient populations, including type, stage, and molecular subtype of disease. The forces promoting OCP growth for payers and providers are many, including: ensuring consistency of evidencebased care in an increasingly complex field, managing drug use, lessening the administrative burden associated with payer appeals, capturing stage and molecular data, putting pressure on drug prices, and promoting accrual to clinical trials.³

As the voice of cancer care providers and the patients they serve, ASCO has taken steps to elevate awareness about clinical pathways among oncology providers, patients, and other stakeholders and collaborate with the sestakeholders as well as with the pathway vendors to ensure the integrity of these products. ^{4,5} In 2016, ASCO established a Pathways Task Force to examine the role of pathways in oncology and subsequently to define the characteristics of a high-quality OCP. In March 2017, ASCO released its Criteria for High-Quality

Clinical Pathways (hereafter referred to as the Criteria), creating a mechanism for evaluating pathways based on development, implementation and use, and analytics. ⁴ As an ext step, the Task Force sought to advance this effort by evaluating national pathway vendors against these Criteria to help stakeholders better navigate the current pathway environment. The evaluation process and results of this effort are presented here.

METHODS

Identification of Prominent Pathway Vendors

With the growth in pathway demand, there has been a proliferation of vendors, including OCP programs developed by payers, provider groups, and third parties. This work assesses several national pathway vendors that have emerged as leaders in the oncology marketplace. Our methodology defined pathway vendors broadly as those that provide treatment management tools to standardize and promote evidence-based care and drive quality. The toolsvariedfromthosehighlightingasingle best treatment option to those offering multipleguideline-concordantcarechoices. We included vendors targeting providers as well as payers, because both have an impact on our stakeholders. Single-institution OCPs were excluded because their effect on the landscapeismorelimited. Vendorswere identified through two means. First, survey

DOI: https://doi.org/10.1200/JOP. 17.00033; published online ahead of print at jop.ascopubs.org on February 7, 2018. results were analyzed from the ASCO State of Cancer Care in America 2016 report to determine the OCPs used by respondents. Second, we collaborated with the external consulting firm DK Pierce (Zionsville, IN) to identify national vendors.

Six vendors were initially identified (Data Supplement) as meetingour criteria for evaluation. Upon additional review, the Task Force concluded that eviti and eviCore do not provide what some might consider pathways. These two products are primarily decision support tools. For that reason, we placed eviCore and eviti in a separate category entitled decision support tool vendors. We still proceeded to compare their products against the Criteria. Given their prominent role in the oncology market, we determined this assessment would be of interest to readers. A seventh vendor, Cardinal Health P4 Pathways, was identified as meeting our inclusion criteria. However, Cardinal Healthhasretired itspathway programand was not included in the analysis.

Criteria Evaluation

After identifying vendors, the Task Force compared each product with the published Criteria. For the purposes of this study, on-pathway treatment was defined as treatment that is in concordance with the selections presented by the vendor's pathway tool. The Task Force primarily used publicly available information from company Web sites, press releases, and academic and lay press articles to evaluate performance against the Criteria. Subsequently, the Task Force conducted follow-up telephone interviews from February through April 2017 with each vendor to clarify issues identified in the respective pathway evaluations. Key questions in certain criteria were not explored if they were materially covered by other criteria. Each pathway was assessed as meeting, not meeting, or partially meeting each criterion. Each assessment required a unanimous vote by the members of the Task Force. Subsequently, the preliminary assessments were provided to the respective vendors for review; they were able to submit any queries or concerns to the Task Force. These comments were considered by the Task Force in making the final categorizations presented herein. This report reflects the review period through July 2017. This is notable because some vendors modified their processes during the review, potentially based on the Criteria and on interactions with the Task Force.

RESULTS

The pathway vendors included in this assessment are as follows: Anthem/AIMCancer Care Quality Program(AIM), New

Century Health, Value Pathways powered by the National Comprehensive Cancer Network (NCCN), and Via Oncology. AIM and New Century Health partner with payers to provide pathways for clinician decision support, quality tracking, and coverage determination. Value Pathways powered by NCCN and Via Oncology focus on the provider market, with pathway products for use by community and academic practices at the point of care. As noted, decision support products from eviti and eviCore were also analyzed.

Akey finding from each section of the Criteria—development, implementation and use, and analytics—is described in the following sections. A detailed report of performance according to each criterion is provided in the Data Supplement.

Pathway Development: Expert Driven

A key criterion for high-quality pathways is that they be developed by cancer clinicians. This ensures that pathways include the best available evidence, encompass the tumorspecific expertise of oncologists from specialty disciplines, and reflect clinicians' understanding of the nuances of the physician-patient relationship. In the ASCO guiding principles for the development of clinical pathways in oncology as well as in the ASCO Criteria, ASCO asserts that practicing oncologists should play a central role in developing and revising oncology pathways. 4,5

Provider-marketed pathway vendors

Value pathways powered by NCCN. In 2013, US Oncology and McKesson Specialty Health formed a collaborative relationship with NCCN for the development of clinical pathways. The Value Pathways use NCCN guidelines as a foundation. A clinical pathway committee exists for each disease with oncologists from the US Oncology network plus up to three physician members of the NCCN Guideline Panel. The NCCN Guideline Panel is composed of experts from all disciplines relevant to each disease. The Value Pathways are a formal subset of the NCCN Treatment Guidelines, and this subset is determined by the clinical pathway committee based firston efficacy. When efficacy is identical orthed ifferences are not clinically significant, the clinical pathway committee will take into account factors such as toxicity, cost, and patient convenience.

Via oncology. Via Oncology pathways are developed by physician disease committees. Each pathway committee is jointly chaired by an academic-based oncologist and community-based oncologist. Committee meetings are

open to all providers using Via Pathways who complete an annual conflict-of-interest form. The committees prioritize efficacy followed by toxicity and then cost. Cost is taken into account only when the efficacy and toxicity of two regimens are comparable.

Payer-marketed pathway vendors

AIM. AIM uses a panel of eight to 12 physicians representing community and academic settings to develop its pathways. AIM does not configure a panel of experts for each pathway; rather, the panel is complemented with subject matter experts who participate in the process depending on need. AIM reports that the panel applies the various oncology value frameworks, including those of ASCO and the European Society for Medical Oncology, to define a subset of optimal treatments in oncology. The panel evaluates clinical outcomes, toxicity, and cost with outcome or efficacy as the primary consideration. AIM is a wholly owned subsidiary of Anthem.

Newcenturyhealth. NewCenturyHealthhastwolevelsof pathways: Level 1 Pathways and Level 2 Pathways. Level 2 pathways are medical oncology compendia—listed regimens usedbythe Centers for Medicare and Medicaid Services. Level 1 Pathways are a subset derived from Level 2 by a team of four oncology pharmacists and eight medical oncologists based on a hierarchy starting with efficacy, then toxicity, and then, if equivalent, as a final step, cost. The pharmacists draft the initial Level 1 Pathways. These are then reviewed and revised by clinical consultants who are academic based and disease specific. Lastly, the pathways go to a national scientific advisory board that meets every 3 months for final revisions.

Decision support tool vendors

eviCore. eviCore uses the entirety of the NCCN guidelines as its primary reference. eviCore has taken the NCCN guidelines and converted them into a proprietary algorithm displayed to the provider as a decision tree. Providers answer a short series of leading questions, just as one would to navigate an NCCN guideline, to arrive at the point where the NCCN-recommended regimens are presented.

eviti. eviti has developed an evidence-based medical library (EBML) but not pathways. Clients of eviti can use the EBML to construct their payer- or enterprise-specific pathways. The minimum requirements for inclusion in the EBML are: the treatment must be recommended by one of the nationally or internationally recognized oncology consensus groups, data from the supporting clinical trial must be

available, and each individual drug within the regimen must be US Food and Drug Administration approved for marketing in the United States. The EBML is maintained and kept current by a team of oncology-certified nurses, a content information specialist, and the eviti chief medical officer. There is also an advisory board of oncology physicians who review the EBML and provide feedback. Eviti does not rank different regimens; rather, it empowers payers or providers with the information they need to designate their own preferred treatments.

Implementation and Use: Integrated Cost-Effective Technology and Decision Support

The ASCO State of Cancer Care in America 2017 report documents that more than half of oncology practices surveyed identified increasing administrative and overhead costs as a top pressure. The ASCO State Affiliate Council raised a concern about the potential for OCPs to increase administrative burden. This prompted the Task Force to consider the degree of integration of OCPs into electronic health records for decision support, seamless structured documentation and order entry, and automation of communication with payers to streamline payer authorizations.

Provider-marketed pathway vendors

Value pathways powered by NCCN. All Value Pathways are integrated into Clear Value Plus, a clinical decision support tool, which is integrated into several electronic health record platforms. The Value Pathways are integrated into order sets with the iKnowMed electronic health record and EPIC. Value Pathways is developing tools to support automated payer authorization and has accomplished it in certain cases.

Via oncology. The Via Portal can be interfaced with commonly used electronic health records. With several electronic health records, Via can automatically queue up order sets based on physician selection within the Via portal. Via has not automated priorauthorization.

Payer-marketed pathway vendors

AIM. The AIM Provider Portal is not integrated into electronic health records and does not trigger order sets. The portal requires separate data entry that provides simultaneous availability of prior authorization and delivery of S code for pathway prescribers that can be mastered by nonclinical staff. AIM reported that it is currently piloting electronic health record integration.

New century health. New Century Health is integrated withone electronic health record. It has data transfer capability for payers to allow automated payer authorization. New Century Health is implementing links to NCCN order templates.

Decision support tool vendors

eviCore. The eviCore pathway program is not fully integrated into the electronic health record today. However, eviCore reports it is heavily invested in electronic health record integration. On-pathway therapies receive coverage determination and prior authorization within 2 to 5 minutes via their platform.

eviti. The eviti program is integrated into the AllScripts Sunrise program for order entry. eviti also has the ability to generate in real time an eviti code to demonstrate that the selected treatment meets insurer claim language for that payer.

Analytics: Promotes Researchand Continuous Quality Improvement

There is substantial variation in oncology care that is attributed to the cancer clinician. ^{9,10} These variations in care quality can lead to differences in outcomes that may disproportionately affect certain segments of the population. ¹¹⁻¹³ The promise of pathways for patients is that OCPs will lead to care associated with the best outcome and least toxicity, at the lowest cost, and that OCPs can be a means to close this equality gap. The Criteria recommend that high-quality oncology pathway programs promote pathway adherence reporting and support research and continuous quality improvement.

Provider-marketed pathway vendors

Value pathways powered by NCCN. Value Pathways powered by NCCN provides pathway adherence performance reports in real time and may be compared with other collective groups using these pathways. Reports are available to providers or practices to determine how best to use the data, and reports include reasons for documented off-pathway exceptions.

Value Pathways has a research arm and reports a history of peer-reviewed publishing regarding pathways. 14-16 Value Pathways is examining using administrative claims data linked to pathway practice data to move beyond pathway adherence measures to outcome measures. Value Pathways is collaborating with academic centers around research projects related to pathways.

Via oncology. Via Oncology provides pathway adherence performance reports and capture rate (percentage of visits

where the patient situation was not documented by the provider). Reasons for nonconcordance are tracked and reported. Via Oncologyreportsmakingresearchapartof what it does in collaboration with practices. The Via publishing committee is reviewing the pathway data of certain institutions to better understand elements of care, and the data are being transformed into publishable projects. Via, in collaboration with selected customers, has published data on pathway use in peer-reviewed literature. 17,18

Payer-marketed pathway vendors

AIM. The Anthemcontractallowsforproviderstoretrieve their pathway adherence performance reports. The reports provide benchmarks locally (state level) and nationally. The reports provide detailed information on why a case was determined to be nonconcordant.

AIM reports a robust research pipeline and roadmap and is gathering data from multiple sources including pathways and claims to gain a comprehensive view of the impact of OCPs.

New Century Health. New Century Health provides reports on pathway adherence performance. Providers and practices are benchmarked to their region and nationally with blinded data from other practices. A report includes whether a regimen was a pathway choice and, if not, what the choice would have been in that clinical scenario.

New Century Health reports a robust analytic department. It collects data on response duration and duration of therapy data and is beginning to collect data on complications (eg, hospitalizations) to match to patient cohorts.

Decision support tool vendors

eviCore. Although it has the capability, eviCore is not currently producing reports on pathway adherence performance. eviCore has a research group that is active in analyzing pathway data and conducting research to determine how to improve pathways to create value. eviCore is focused on a variety of outcomes, including rates of emergency room visits and hospitalizations, overall survival, success of regimen adherence, and therapy intensity near the end of life. eviCore has published on adherence with its program in the peer-reviewed literature. ¹⁹

eviti. eviti is able to provide reports on pathway adherence performance to payers and network providers. eviti can also provide the data to clients to do the reporting themselves. As more network providers come onboard, eviti will be able to providebetterbenchmarking. eviti is able to providethereason for pathway nonconcordance.

eviti research has focused mainly on use rather than outcomes, but as its product is used by more networks, it will be able to access outcomedata. eviti has published data examining care patterns and has collaborated on these projects with a cademic institutions. ²⁰

DISCUSSION

Several studies have demonstrated that use of OCPs is associated with lowering cost while maintaining or improving outcomes. ^{15,16,21,22} Given the demonstrated value proposition of OCPs, one national payer has urged ASCO to "recommend adoption of a pathway program by every oncology practice in the United States." ^{23(p149)} Separately, ASCO has stated that not all pathways are equal and has considered recommending a system to assess and improve the integrity and quality of pathways coming to market. To that end, ASCO developed the Criteria for pathways to help oncology providers and all stakeholders, including pathway developers, to better evaluate clinical pathways and ensure that pathways are developed and implemented in a way that advances the delivery of high-value care.⁴

The pathway vendors we identified in this process were collaborative in working with ASCO to better understand the currentpathwaylandscape. Given the vendor-unique business models and objectives, it is not surprising that there are differences among the OCP programs. The vendors target different customers, including payers and providers. The target audiences inform their product development decisions, and this in turn may affect how they perform on the Criteria. In this evaluation, there was no expectation that any individual OCP program would meet all Criteria. The Task Force and ASCO make no judgment on the suitability of an OCP for a specific application or practice, and that was not the objective of this analysis. Rather, the Task Force hopes this work will highlight areas for the continuous evolution of OCP programs and invites other pathway programs, including single-institution OCPs, to report on their status vis-à-vis the Criteria. In sharing this assessment, the Task Force hopes this work illuminates how pathways can progress toward the shared goal of providing the best care for patients with cancer.

This initial project also challenges ASCO to further consider and refine these Criteria to ensure that they are of value to our stakeholders and provide a fair assessment of pathway vendors and developers. Furthermore, although these Criteria

allow evaluation of current OCPs, they do not remedy all of the concerns of our members regarding pathways. For example, some pathway programs have integrated automated payer authorization, whereas others have not. The administrative burden associated with certain use management policies, including requirements for practices to comply with multiple pathway programs, remains an ongoing concern. ASCO is addressing this through its collaboration with the American Medical Association and advocating for additional reforms.²⁴ Additionally, the Task Force turned to ASCO members to identify vendors. ASCO acknowledges that this is not an exhaustive list and intends to continue to monitor the pathway landscape. However, the companies reviewed all seek to improve cancer care quality by supporting use of standardized, evidence-based care and have different mechanisms for helping providers achieve that goal. In the future, a more specific definition of a pathway company and its goals for pathway use may be required.

The need to identify and promote use of high-quality clinical pathways in oncology is clear. In April, the California Assembly introduced AB 1107, the Oncology Clinical Pathways Act of 2017.²⁵ This bill requires health plans and health insurers that develop and implement clinical pathways to comply with specified requirements. Many of these requirements were drawn from the Criteria for high-quality clinical pathways in oncology. The bill has been met with support from ASCO as a critical first step in ensuring consistency and transparency in pathway development.²⁶ A similar bill has been proposed in Connecticut. ASCO will continue to advocate for additional steps to ensure that the promise of pathways is achieved for patients and providers. Further study is needed to determine whether these Criteria alone or a formal certification program for high-quality clinical pathways is required. Payer and regulator support and recognition of high-quality clinical pathway programs could have many potential benefits, including: freeing practices from the burden of compliance with multiple pathways by reassuring payers of their quality and laying the foundation for value-based reimbursement models by driving optimal resource use. Additionally, pathway program analytics can provide important insights into patient outcomes, the impact of use management strategies, and the financial implications of treatment choices for patients and families. Vendors are currently exploring pathway program data to understand factors affecting treatment choice and how this information can be used to identify patients at high risk for costly events

such as hospitalization, along with the best means to help avoid such events when possible, including identifying the need for symptom triage pathways, supportive care, care coordination, and other services. These data may also be used to evaluate and compare therapeutic regimens and their impact on specific patient populations. Continued academic and community collaboration with high-quality clinical pathways should be promoted to optimize data analyses, promote innovation, and improve the value of cancer care

Acknowledgment

B.D. and R.T.Z. contributed equally to this work. Supported by an American Society of Clinical Oncology Health Policy fellowship (R.M.D.).

Authors' Disclosures of Potential Conflicts of Interest Disclosures provided by the authors are available with this article at jop.ascopubs.org.

Author Contributions
Collection and assembly of data: All authors
Conception and design: All authors
Data analysis and interpretation: All authors
Administrative support: Sybil R. Green, Dana S. Wollins
Provision of study materials or patients: All authors
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

Corresponding authors: Bobby Daly, MD, MBA, Thoracic Oncology Service, Memorial Sloan Kettering Cancer Center, 885 Second Ave, New York, NY 10017; e-mail: dalyr1@mskcc.org; Robin T. Zon, MD, FACP, FASCO, 5340 Holy Cross Parkway, Mishawaka, IN 46545; e-mail: docrzon@aol.com.

References

- 1. American Society of Clinical Oncology: The state of cancer care in America, 2016: A report by the American Society of Clinical Oncology. J Oncol Pract 12:339-383, 2016
- 2. American Society of Clinical Oncology: The state of cancer care in America, 2017: A report by the American Society of Clinical Oncology. J Oncol Pract 13:e353-e394, 2017
- 3. Polite B, Ward JC, Cox JV, et al: A pathway through the bundle jungle. J Oncol Pract 12:504-509, 2016
- 4. Zon RT, Edge SB, Page RD, et al: American Society of Clinical Oncology criteria for high-quality clinical pathways in oncology. J Oncol Pract 13:207-210, 2017
- 5. 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
- 6. Schroeder A: Clinical pathways: A current snapshot, and the journey ahead. Journal of Clinical Pathways 3:33-40, 2017

- 7. eviti: Comprehensive, non-biased evidence-based medical library. http://www.eviti.com/cancer_care/products-2/#EBML
- 8. eviti: Medical advisory board. http://www.eviti.com/cancer_care/staff/medical-advisory-board/
- 9. Hollingsworth JM, Zhang Y, Krein SL, et al: Understanding the variation in treatment intensity among patients with early stage bladder cancer. Cancer 116: 3587-3594, 2010
- 10. Clough JD, Patel K, Riley GF, et al: Wide variation in payments for Medicare beneficiary oncology services suggests room for practice-level improvement. Health Aff (Millwood) 34:601-608, 2015
- 11. Daly B, Olopade OI, Hou N, et al: Evaluation of the quality of adjuvant endocrine therapy delivery for breast cancer care in the United States. JAMA Oncol 3:928-935, 2017
- 12. Daly B, Olopade OI: A perfect storm: How tumor biology, genomics, and health care delivery patterns collide to create a racial survival disparity in breast cancer and proposed interventions for change. CA Cancer J Clin 65:221-238, 2015
- 13. Daly B, Olopade OI: Race, ethnicity, and the diagnosis of breast cancer. JAMA 313:141-142, 2015
- 14. Hoverman JR, Klein I, Harrison DW, et al: Opening the black box: The impact of an oncology management program consisting of level I pathways and an outbound nurse call system. J Oncol Pract 10:63-67, 2014
- 15. Neubauer MA, Hoverman JR, Kolodziej M, et al: Cost effectiveness of evidencebased treatment guidelines for the treatment of non-small-cell lung cancer in the community setting. J Oncol Pract 6:12-18, 2010
- 16. Hoverman JR, Cartwright TH, Patt DA, et al: Pathways, outcomes, and costs in colon cancer: Retrospective evaluations in two distinct databases. J Oncol Pract 7: 52s-59s, 2011 (suppl)
- 17. Ellis PG, Brufsky AM, Beriwal S, et al: Pathways clinical decision support for appropriate use of key biomarkers. J Oncol Pract 12:e681-e687, 2016
- 18. Ellis PG, O'Neil BH, Earle MF, et al: The usefulness of clinical pathways (CP) in managing quality and cost in oncology networks. J Oncol Pract 13:e522-e529, 2017
- 19. Newcomer LN, Weininger R, Carlson RW: Transforming prior authorization to decision support. J Oncol Pract 13:e57-e61, 2017
- 20. Kelly RJ, Forde PM, Elnahal SM, et al: Patients and physicians can discuss costs of cancer treatment in the clinic. J Oncol Pract 11:308-312, 2015
- 21. Kreys ED, Koeller JM: Documenting the benefits and cost savings of a large multistate cancer pathway program from a payer's perspective. J Oncol Pract 9: e241-e247, 2013
- 22. Jackman DM, Zhang Y, Dalby C, et al: Cost and survival analysis before and after implementation of Dana-Farber clinical pathways for patients with stage IV non-small-cell lung cancer. J Oncol Pract 13:e346-e352, 2017
- 23. Newcomer LN, Malin JL: Payer view of high-quality clinical pathways for cancer. J Oncol Pract 13:148-150, 2017
- 24. American Society of Clinical Oncology: Coalition calls for prior authorization reform, releases principles to improve access to care and reduce administrative burdens. https://www.asco.org/advocacy-policy/asco-in-action/coalition-calls-prior-authorization-reform-releases-principles
- 25. Oncology Clinical Pathways Act of 2017, AB1107, California Assembly Committee on Health, April 2017
- 26. Hayes DF: Letter to Assemblymember Nazarian, 2017, http://image.broadcastemail.asco.org/lib/fe551570776d037a7c13/m/2/ASCO+Support+for+AB+1107+4+24+17.pdf?et_cid=39179669&et_rid=575246769&linkid=here

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Oncology Clinical Pathways: Charting the Landscape of Pathway Providers

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to www.asco.org/rwc or ascopubs.org/jop/site/ifc/journal-policies.html.

Bobby Daly

Employment: Quadrant Holdings Leadership: Quadrant Holdings

Stock and Other Ownership Interests: Quadrant Holdings (I), CVS Health, Johnson & Johnson, McKesson, Walgreens Boots Alliance, Eli Lilly (I), Walgreens Boots Alliance (I)

Robin T. Zon

Consulting or Advisory Role: Medical Protective Malpractice Insurance

Research Funding: Agendia (Inst)

Other Relationship: Medical Protective Malpractice Insurance

Ray D. Page

Employment: Center for Cancer and Blood Disorders Honoraria: Astellas Medivation, Community Oncology Alliance,

AmerisourceBergen

Consulting or Advisory Role: Via Oncology

Research Funding: Sarah Cannon Research Institute

Stephen B. Edge

Research Funding: Pfizer (Inst)

Gary H. Lyman

Leadership: Generex Biotechnology

Consulting or Advisory Role: Halozyme, GI Therapeutics, Coherus

Biosciences

Research Funding: Amgen (Inst)

Sybil R. Green

No relationship to disclose

Dana S. Wollins

Honoraria: Abbott Laboratories (I), AbbVie (I), Amgen (I), Johnson & Johnson (I), Pfizer (I), Procter & Gamble (I)

Linda D. Bosserman

Employment: City of Hope Medical Foundation, Front Line Medical Communications, Anthem Blue Cross Wellpoint, Prime Care Inland Valley, LA County Fair

Honoraria: Pfizer, Association of Managed Care Pharmacy, American Society of Breast Surgeons, Association of Nurse Navigators, Medscape, Physicians Education Resource, JADPRO

Consulting or Advisory Role: Pfizer, Association of Community Cancer Centers, Novartis, Sandoz-Novartis, Merck, UpToDate, Puma Biotechnology, AstraZeneca, Roche/Genentech

Speakers' Bureau: Puma Biotechnology

APPENDIX

Anthem Cancer Care Ouality Program analysis:

Criterion	Key Questions	Response
Expert driven Reflects stakeholder input	Do practicing oncology providers with relevant disease and/or specialty expertise play a central role in pathway development? Is there a mechanism in place for patients, payers, and other stakeholders	 Criterion met: AIM has a panel with 8-12 members representing community and academic settings who develop the pathways. These oncologists have roles in ASCO and the cooperative groups and are familiar with how to evaluate evidence and think about oncology practice. The panel is complemented with subject matter experts who participate in the process depending on need. These experts are familiar with the nuances of the data or clinical trial design. These experts do not interact directly with the panelists but rather provide input to the process. AIM does not configure a panel of experts for each pathway. AIM believes it is important to have a broader view and not just a subspecialty view. Criterion met: The way input is collected can vary by
	to provide input during the development process?	 health plan. AIM gets input from practicing physicians – occurs when pathway is first implemented and AIM regularly engages physicians with provider reports. AIM takes input via email, via a website, through physicians, and through the health plans. AIM also gets input from public forums and through conversations with patient advocacy groups. The forums are used to discuss specific treatments as well as the pathway development process. AIM also considers caregivers and the lay public as stakeholders. Caregivers are dealing with treatment toxicities and the lay public is addressing premium payments.
Transparent	Is there a clear process and methodology for pathway development	

that is transparent to all pathway users, stakeholders, and the general public? Is information disclosed on:	
The methodology used for development?	The panel is configured to bring tolife the ASCO value framework and other relevant value frameworks to define a subset of optimal treatments in oncology. The panel evaluates the clinical results, toxicity, and cost. Theclinical results trump other considerations. AIM doesn't post evidence summaries publicly but they are available upon request.
The strengths and types of evidence used to generate consensus?	Criterion met: The scope of evidence includes NCCN guidelines, ASCO guidelines, other available guidelines, abstracts, and peer reviewed literature. AIM employs medical librarianswho do formal searches and systematic reviews. Limits the scope to what is publicly available. Want to have transparent discussions with providers and patients so don't take unpublished data into account. Abstract data is considered a lower standard of evidence as many abstracts don't get published orhave different conclusions at time of publication.
The specific evidence used to support the pathway recommendation (including key literature citations, guidelines, or other evidence)?	Evidence summaries available upon request.
The way in which efficacy, toxicity, and cost are assessed and balanced in determining the pathway recommendation?	 Criterion met: It is not formalized how value frameworks are operationalized. The panel is trying to realize it the best it can. Hard to be black and white so have practicing physicians who can take into account elements like the schedule of regimens, transportation costs, etc. The panel does its best to make judgments in the face of these frameworks.
Is there a policy in place and adhered to that requires public disclosure of all potential conflicts of interest by oncology pathway panel members and any other individuals or entities that contribute to the development of pathway content? Does this policy describe:	AIM is preparing to publicly display panelists' conflict of interest and a broad description of the qualifications included among the panelists, and its policy for disclosure, management of conflicts of interest, and steps to ensure adherence and

Evidence-based	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? 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 dissemination vehicles? Is a mechanism in place for considering high quality evidence generated from validated real world data (i.e., rapid learning healthcare systems)?	enforcement. AIM does not publicly display panel names because it wants the panel to function without being shadowed and harassed by pharma and other interests. Criterion not met. Criterion not met. Criterion met: Yes. Criterion met: AIM is tracking real-time data from the learning health system. AIM will study specific questions like how does the management of growth factor affect rates of febrile neutropenia and hospitalizations (ASCO 2017 Quality Symposium poster). AIM also incorporates in reports to practices not only their adherence to pathways but rates of hospitalization and use of hospice and other claimbased metrics. AIM expects to be able to more systematically and consistently pipe these data back into the panel process in a learning health system. It is too early to have the piping squared away across each scenario.
Patient-focused	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, risk of treatment-related toxicities, treatment schedule and/or financial toxicity)?	Criterion met: For AIM, a pathway is an optimal subset of treatments for a given clinical scenario. Clinical scenarios are detailed and account for many differences in patient characteristics such as key biomarkers (like HER2 or NRAS, PD-L1 expression, etc.) and clinical factors (such as performance status). AIM's pathways include many evidence based options that are also based on patient differences. AIM does not categorically limit its pathways to a single choice.

		 AIM offers as many choices in its optimal subset (pathways) as the data would support as it operationalizes the relative clinical value framework. The optimal subset of regimens defined by its program do not constitute the full scope of acceptable regimens that would be approved automatically in its web-based portal. The AIM program simultaneously authorizes medical necessity for evidence-based (acceptable) regimens and identifies when an optimal subset (pathway) regimen has been chosen so that additional treatment planning and care coordination can be billed by participating providers.
	How is cost factored into pathway recommendations of therapeutically similar or equivalent treatments?	 Criterion met: Costs are a complex question - out-of-pocket costs vary by the patient, and downstream costs are hard to know (hospitalizations, ED visits, etc.), over time AIM will be able to use its program to feedback data regarding downstream costs. Currently put data in front of panel regarding direct costs, such as ASP, for a set clinical duration (typically 12 weeks). This is used to facilitate a discussion for panel around how to weigh cost against other considerations.
Up-to-Date	Are stakeholder assessment and pathway analysis used for pathway revision? Are pathways updated in a timely way as relevant new information, including	Yes. Anthem has a systematic approach to collecting information/feedback, analyzing that feedback and collecting additional research, and sharing that with the panel for more formalized discussions. Criterion met: Yes. Panel meets quarterly.
	new FDA indication approvals, become available? How rapidly are new, practice-changing data incorporated into pathway recommendations?	Criterion met: Ad hoc calls depending on clinical scenarios. AIM notes that it doesn't mean patients are not getting the therapy if the pathway committee has not met. Importance not as acute as only defining optimal pathways that require enhanced reimbursement not access to a particular drug.

Comprehensive	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?	TABLE SELF REPORT Diagnostic Evaluation First Course of Therapy Supportive Care Post-treatment surveillance Treatment of recurrent cancer Survivorship End-of-life care Surgical Oncology Radiation Oncology Imaging Laboratory Testing Molecular Diagnostics/ Precision Medicine Comments:
	If the pathways are not comprehensive,	Criterion met:
	do they clearly describe the phase and elements of care they are intended to address?	• Yes.
Promotes participation in clinical trials	Are available clinical trial options	Criterion partially met:
	incorporated into the pathway program?	 AIM and Anthem explicitly endorse clinical trials as good care. Anthem considers the National Cancer Institute's Molecular Analysis for Therapy Choice (NCI – MATCH) trial enrollments to be on pathway. In this case, special emphasis is placed on this national, high impact NCI trial. When there is a randomized trial that includes a pathway backbone, the backbone is still considered on pathway. For example, with a trial comparing cisplatin/etoposide to cisplatin/etoposide/atezolizuma b in small cell lung cancer, the regimen is considered on pathway (since the cisplatin/etoposide is a pathway backbone). The adherence metric reflects the proportion of on pathway regimens prescribed/total regimens. When a patient is treated in the context of a clinical trial, the trial-based regimens are only included in

	Is treatment provided to patients participating in Phase I-III clinical trials always considered pathwayappropriate treatment?	the adherence metric if they are on pathway (ie in the numerator when applicable), otherwise they are removed from the denominator. • The adherence metric does not trigger any specific consequences (ie additional payments or rewards). It is information used for quality improvement. Criterion not met: • See above.
Clear and achievable expected outcomes	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	Criterion met: • Yes. Criterion met: • Yes.
	recommendations? Does the pathway program report and communicate to all stakeholders the goal adherence rates? Are expected adherence rates established in a way that reflects the strength of	Criterion met: As a rule of thumb 80% of patients should be reasonably treated with onpathway regimens. Criterion not met: Expected adherence rates vary in
	evidence for the disease and stage?	relation to the strength of evidence for any given clinical scenario (i.e. the details regarding staging, biomarkers, and key clinical characteristics) in the AIM program. • The expected adherence rates, per scenario, are not calculated formally or voted upon by the panelists. • There is no formal consequence based on adherence rates in AIM program. As currently configured by AIM's clients, the S-code payments available for optimal prescribing (i.e. choosing pathways) are made on a transactional basis. • Overall, adherence expectations are typically set by the practices themselves as they decide what the reporting data mean to them in their quest to continuously improve care.
	Do adherence rates incorporate precision medicine based on current FDA approved indications as on-pathway?	Criterion met: • Yes.

	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?	An AIM pathway does not mean a provider cannot use something else, there is no penalty. The provider receives enhanced reimbursement for an optimal subset of on-pathway therapies.
Integrated, cost-effective technology and decision support	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 offering to users and other stakeholders?	 Criterion met: The program is designed to allow for ease of implementation and simultaneous availability of prior authorization and delivery of S-code for pathway prescribing through an electronic portal that can be mastered easily by trained non-clinical staff. Physicians and mid-level providers and nurses involved in oncology care and prescribing access online pathways and the clinical worksheets (to help guide the collection of the key clinical data for portal entry). The program does not currently integrate with the EMR's. AIM is currently piloting such an integration and working towards multiple integrations over time.
Efficient processes for communication and adjudication	Does the pathway program provide references or links to references that may support pathway variation?	Criterion not met: No.
	Does the pathway program inform the provider in real time of pathway compliance?	Criterion met: • Yes.
	Is the mechanism for choosing an off- pathway recommendation and documenting the rationale for this choice easily imbedded in the pathway program?	Criterion met: • Yes.
Efficient and public reporting of performance metrics	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? Will the performance reports provided include these reasons for nonconcordance?	Criterion met: Anthem contract allows for providers to log-in and retrieve their practice reports, at aggregate level, and practices can see their performance across various metrics. The report also provides benchmarks locally (state level) and nationally. Criterion met: AIM reports give detailed information regarding each request with specific reasons why a case was determined to be non-concordant based on AIM definitions of pathway regimens and the matching clinical scenarios. The AIM program does not insist on collecting provider-level details for their choices that are based on their own assessments and shared decision-making.

	Will public reporting of providers'	Criterion not met:
	pathway adherence be disclosed as a composite report only (i.e., not an individual provider or provider group level)?	By design, public reporting, is not a feature of the program.
	Do providers have an opportunity to review performance reports and revise any areas in need of adjustment?	Providers can provide feedback on the reports and corrections of reporting errors for the practices are made when appropriate.
Outcomes-driven results	Does the pathway program have analytics in place to enable a movement over time from adherence-driven compliance to outcome driven results?	Yes, incorporating data on hospitalizations, use of hospice, and other claim-based metrics.
Promotes research and continuous quality improvement	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?	Anthem has a robust research pipeline. Its research group has presented abstracts at ASCO meetings.
	Are the analytics generated from pathway programs publically available to patients and/or participating providers for benchmarking and understanding of complex cancer outcomes?	 Criterion partially met: Anthem has a robust roadmap to look at data points that are informing pathways. Want to have comprehensive view from multiple sources (pathways, claims data, and other sources) to examine clinical, resource use, and economic outcomes. Kicked off this year to inform Anthem moving forward. Have needed time to gather data from multiple sources. These analytics are not publically available.
Additional Features	Are there any incoming features for 2017?	 AIM will be providing its customized reporting through the portal for real time analysis by appropriate practice personnel. As a part of an on-going need to help prioritize work flow efficiency and practice eduction, Anthem and Aim have implemented field based teams to provide hands-on training and guidance for all practice constituents. These practice engagement teams make regular site visits to improve understanding and overall pathway adherence. As mentioned above, AIM has active agreements in place and ongoing work on integrating our pathways with EMR data in order to transfer key clinical data into the AIM portal and to show providers at the point of regimen ordering which regimens are on pathway. We do not expect this

	functionality to be fully available in 2017, but the work is ongoing.

eviCore analysis:

Key Questions	Response
Do practicing oncology providers with relevant disease and/or specialty expertise play a central role in pathway development? Is there a mechanism in place for patients, payers, and other stakeholders to provide input during the development process?	 The eviCore solution utilizes the entirety of the NCCN guidelines as its primary reference. The NCCN panels are made up of multiple practicing oncologists of every discipline (medical, surgical, radiation, pathology, etc.), who create the guideline documents. The eviCore solution is best thought of as a clinical decision support (CDS) program rather than a pathway program. All NCCN guideline recommended treatments are supported. eviCore has no additional layers of pathway restriction beyond NCCN recommendations, eviCore is capable of working with individual provider groups and payers to promote a locally preferred subset of NCCN treatment recommendations based on institutional experience, but has no immediate plans to generate its own more restrictive pathways to push out to a national audience. The fundamental goal of eviCore's Medical Oncology solution is to ensure that each patient is provided with the most appropriate treatment. The program is not designed to deny care, but rather to redirect the provider (when appropriate) to the best treatment options for each individual patient, based on his/her medical history, pathology, genetics, line of therapy, functional status, and disease severity. eviCore develops all of its CDS algorithms in collaboration with NCCN. eviCore does have a process to incorporate provider and payer input
Is there a clear process and methodology for pathway development that is transparent to all pathway users, stakeholders, and the general public? Is information disclosed on:	regarding improved platform efficiency and local treatment preferences.
	Is there a mechanism in place for patients, payers, and other stakeholders to provide input during the development process? Is there a clear process and methodology for pathway development that is transparent to all pathway users,

	The methodology used for development?	The NCCN's process for guideline and compendium development is available on its website. eviCore has taken NCCN guidelines and converted them into proprietary algorithms that display to the provider as a decision tree. Providers answer a short series of leading questions (just as one would navigate an NCCN guideline) to arrive at the point where the NCCN recommended regimens are presented.
	The strengths and types of evidence used to generate consensus?	eviCore uses the NCCN categories of evidence and can limit individual cancer type regimens to category 1, 2A, or 2B.
	The specific evidence used to support the pathway recommendation (including key literature citations, guidelines, or other evidence)?	eviCore CDS treatment choices are linked to NCCN treatment recommendations, which include robust primary literature references.
	The way in which efficacy, toxicity, and cost are assessed and balanced in determining the pathway recommendation?	eviCore CDS algorithms are inclusive of all NCCN guideline recommended regimens, which are based on efficacy and toxicity. Relative cost information on the drug regimen can be added. Future development will provide overall health care cost impact.
	Is there a policy in place and adhered to that requires public disclosure of all potential conflicts of interest by oncology pathway panel members and any other individuals or entities that contribute to the development of pathway content? Does this policy describe:	 eviCore does not develop proprietary pathways. eviCore's CDS algorithms represent consensus NCCN treatment recommendations. NCCN does publish an annual conflict of interest statement for all its panel members.
	The nature of relationships required for disclosure?	See above.
	The manner in which disclosure information is made publicly available? The required steps for managing conflicts of interest?	See above.See above.
	The required steps to ensure policy adherence and enforcement?	See above.
Evidence-based	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 dissemination vehicles?	The eviCore Medical Oncology solution treatment recommendations are based on NCCN guidelines and FDA indications.

	Is a mechanism in place for considering high quality evidence generated from validated real world data (i.e., rapid learning healthcare systems)?	•	High quality evidence from validated sources is considered in those situations where the NCCN guidelines do not provide reasonable treatment options for an individual patient. eviCore is starting to gather information about real-world therapeutic selections using its platform. Based on its experience with over 25 million insured lives under management, eviCore is dedicated to providing emerging knowledge and serving as a partner to the nation's health care system. eviCore plans to offer providers information about the treatment choices that physicians make for patients with identical profiles. In the future, eviCore will be able to provide users with data on ER visits and hospitalization rates for competing regimens, as well as outcome data, such as survival rates.
Patient-focused	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, risk of treatment-related toxicities, treatment schedule and/or financial toxicity)?	•	eviCore's Medical Oncology solution treats each patient as an individual. In order to determine the best treatment options, eviCore collects significant details regarding the individual patient's key disease characteristics, comorbidities and past treatments, and uses that information to establish the NCCN- recommended treatment regimens for that unique patient. eviCore also recognizes that some patients will not fit neatly into the NCCN guideline recommendations, and all requests for custom treatment regimens are reviewed by one of eviCore's board certified medical oncologists against peer- reviewed published literature in consultation with the prescriber.
	How is cost factored into pathway recommendations of therapeutically similar or equivalent treatments? Are stakeholder assessment and pathway analysis used for pathway revision?	•	The cost of prescribed drugs is not currently factored into the decision support tool, but could be added if a client were to request that it be included. While eviCore does not restrict pathway options beyond NCCN recommendations, narrowing can be done in collaboration with a specific provider or payer stakeholder for use in their own patient population to support their internal quality measures.

Up-to-Date	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?	 eviCore updates every guideline at least annually, and often more frequently based upon new medical evidence in the literature, off-cycle NCCN guideline updates, emerging treatment options, or new or expanded FDA indications Physician reviewers are notified immediately about any changes to the algorithms and incorporate the changes into their clinical reviews as soon as they are informed of the change New or expanded FDA indications are live in eviCore's system within 2 business days. NCCN Flash Updates are incorporated into the CDS algorithms within 30 business
Comprehensive	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?	days. TABLE SELF REPORT Diagnostic Evaluation First Course of Therapy Supportive Care Post-treatment surveillance Treatment of recurrent cancer Survivorship End-of-life care Surgical Oncology Radiation Oncology Imaging Laboratory Testing Molecular Diagnostics/ Precision Medicine Comments: All of the elements of cancer care listed above are either directly or indirectly influenced by one or more of eviCore's specialty solutions. Surgical Oncology management is currently restricted to the circumstances in which surgical care influences decision making in medical oncology, radiation therapy, and/or radiology.
Promotes participation in clinical trials	If the pathways are not comprehensive, do they clearly describe the phase and elements of care they are intended to address? Are available clinical trial options incorporated into the pathway program?	Currently, payers retain control of clinical trial adjudication. eviCore plans to incorporate available clinical trials into pathways alongside NCCN standard of care regimens to support improved rates of clinical trial enrollment.

		Multiple partners have shown an
		interest in eviCore managing this process directly.
	Is treatment provided to patients participating in Phase I-III clinical trials always considered pathwayappropriate treatment?	eviCore believes that the best first option for most cancer patients is clinical trial enrollment.
Clear and achievable expected outcomes	Is information provided on the specific cancer type, stage and molecular profile (if applicable) that the pathway is intended to cover?	 Pathways apply to those malignancies covered by the NCCN guidelines. NCCN covers 97% of cancer patients. Information on cancer stage, type, and molecular profile included.
	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?	 To the oncologist, eviCore's Medical Oncology solution displays all NCCN-recommended treatment options for the individual patient as "on-pathway" options. For cases that do not seem to fit within the NCCN recommendations, eviCore's solution also enables the provider the option to create a custom treatment regimen and attach the clinical rationale and any relevant peer-reviewed published evidence supporting the custom regimen. All requests for custom regimens are reviewed by one of eviCore's board-certified medical oncologists in consultation with the prescriber within 2 business days
	Does the pathway program report and communicate to all stakeholders the goal adherence rates?	eviCore encourages an appropriate level of variation. The overall rate of pathway adherence in eviCore's solution is 85-90%, with 10-15% of approvals pertaining to custom regimens.
	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	Because the eviCore solution includes all NCCN regimens with category 1, 2A, or 2B as recommended options, our expected adherence rate is high based on the strength of these national consensus recommendations. Within specific cancer types, adherence rates for a particular cohort of like patients may be higher or lower based on the overall strength of the NCCN recommended options for that unique subgroup. Yes.
	indications as on-pathway?	

Integrated, cost-effective technology and decision support	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? 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	 eviCore establishes adherence rates using ranges by design, to allow for this kind of variability. All NCCN guideline recommended treatments are on pathway, and the provider has the flexibility to incorporate patient differences into treatment plan within the NCCN recommended options. As eviCore's adherence rates represent national data, local healthcare system differences are not included in this calculation. On pathway therapies receive coverage determination/payer authorization within 2-5 minutes. While not fully integrated today, aviCore is heavily invested in EHP.
	integrated into commonly used EHRs? How does it communicate these offering to users and other stakeholders?	eviCore is heavily invested in EHR integration. The goal is to eliminate duplicate entry, allow for download of information from electronic health records and push information back to the practice including the authorization letter, case number, and prior authorization. • Currently eviCore can capture individual patient dosing/administration information in a way that the standard regimen data are pre-populated for the physician based on NCCN templates and primary references. However, this information is modifiable by the prescribing physician to accommodate individual patient needs. • eviCore is amassing a large dosing/administration database to connect to electronic prescribing capabilities once electronic health record authorization is in place.
Efficient processes for communication and adjudication	Does the pathway program provide references or links to references that may support pathway variation?	• No.
	Does the pathway program inform the provider in real time of pathway compliance?	 If the provider selects an NCCN regimen, the provider will receive immediate approval notification, with an average end user time of 2-5 minutes. Providers requesting a custom treatment are notified immediately that they will be informed of the status of their request within 48 hours.

Efficient and public reporting of	Is the mechanism for choosing an off- pathway recommendation and documenting the rationale for this choice easily imbedded in the pathway program? Are regular reports provided to	The Custom Regimen option is listed on every treatment selection screen to allow seamless custom requests without requiring the resubmission of clinical data that have already been entered. eviCore has the capability to
performance metrics	participating providers that demonstrate the level of current pathway performance and performance over time with comparisons to the performance of other groups of providers?	 produce those reports. Providers do have access to their own personal order history for all of their patients. eviCore is not currently delegated by any of its clients to provide that information directly to individual providers.
	Will the performance reports provided include these reasons for non-concordance? Will public reporting of providers' pathway adherence be disclosed as a	 eviCore has the capability to produce those reports. eviCore has the capability to produce those reports.
	composite report only (i.e., not an individual provider or provider group level)? Do providers have an opportunity to	eviCore has the capability to
	review performance reports and revise any areas in need of adjustment?	 evicore has the capability to produce those reports. Providers do have access to their own personal order history for all of their patients.
Outcomes-driven results	Does the pathway program have analytics in place to enable a movement over time from adherence-driven compliance to outcome driven results?	eviCore is focused on a variety of important outcomes related to the longitudinal cancer patient experience. Examples include rates of emergency room visits and hospitalizations, overal survival, success of regimen adherence and therapeutic intensity near end of life.
Promotes research and continuous quality improvement	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?	 eviCore maintains a research group that is active in analyzing program data and creating abstracts, posters, and publications to determine how to improve pathways and createvalue. eviCore is interested in tracking patient reported outcomes, but it is early in the life span of some of its solutions. Currently, eviCore implements patient engagement around care management for the Radiology and Post-Acute Care solutions, so that capability can be leveraged in the future for Medical Oncology.
	Are the analytics generated from pathway programs publically available to patients and/or participating providers for benchmarking and understanding of complex cancer outcomes?	Analytics are not currently publicly available.

Additional Features	Are there any incoming features for	eviCore's 2017 features include:
	2017?	Capability to simultaneously review
		injectable, oral, or combined drug
		regimens allowing providers a single
		encounter focused on the entire
		treatment plan.
		• Review of patient-specific chemotherapy
		dosing and administration at the time of
		treatment selection.
		 Expansion of supportive medication
		management to include proactive
		prompting to add specific supportive
		drugs that are NCCN-recommended
		based on the particular treatment
		regimen approved.

eviti analysis:

Criterion	Key Questions	Response
Expert driven Reflects stakeholder input	Key Questions Do practicing oncology providers with relevant disease and/or specialty expertise play a central role in pathway development? Is there a mechanism in place for patients, payers, and other stakeholders to provide input during the development process?	 eviti develops an evidence-based medical library (EBML) but not pathways. eviti's clients can usethe EBML to construct their pathways. For its EBML, eviti has an in-house team of certified oncology nurses that through a combination of electronic data feeds and manual review keep up to date with major cancer affiliated peer groups or consensus groups in close to real time. eviti also keeps abreast of publications by major cancer journals that might change the standard of care. The certified oncology nurses are coordinated by a director of clinical informatics. The team then reports to the eviti Chief Medical Officer. A medical advisory board does a high level review of the EBML by disease to ensure it contains the most relevant and recent data. There is a mechanism for physicians to reach out to eviti if something is missing from the library that needs to be added. eviti will look at anything
		pointed out as being standard of care and see if it fits with the criteria eviti has specified in its white paper on development. No current mechanism for patients.
Transparent	Is there a clear process and methodology for pathway development that is transparent to all pathway users, stakeholders, and the general public? Is information disclosed on:	
	The methodology used for development?	 Yes, eviti has outlined the methodology used for development of its EBML in its white paper. The regimen has to be endorsed by a national or international clinical group as standard of care, the regimen has to have data (abstract/peer review) to support its use, and the drugs used in the regimen must be approved by the FDA.

The strengths and types of evidence used to generate consensus?	Each regimen has an evidence based score, included in the score are elements such as design of study, endpoint of study, etc. The evidence based score is a modification of the National Cancer Institute's Physician Data Query (PDQ) evidence-based score.
The specific evidence used to support the pathway recommendation (including key literature citations, guidelines, or other evidence)?	• For each regimen, there is a link to the reference, a link to the abstract (not to the paper), it defines the patient group where it is endorsed, appropriate molecular subtypes if warranted, probable performance status of patients. eviti advisor also provides a summary of clinical outcomes, major toxicities in terms of severity and frequency, evidence-based approach to giving therapy (dose, frequency), and supportive drugs that go with the regimens based on supportive drug guidelines.
The way in which efficacy, toxicity, and cost are assessed and balanced in determining the pathway recommendation?	eviti not weighing different regimens. eviti empowers payers or providers with the information they need. The EBML sorts by level of evidence, outcomes, cost.
Is there a policy in place and adhered to that requires public disclosure of all potential conflicts of interest by oncology pathway panel members and any other individuals or entities that contribute to the development of pathway content? Does this policy describe:	 Conflict of interest policy for evitiis based on ASCO conflict of interest policy and is public. eviti does not make disclosures public.
The nature of relationships required for disclosure?	Yes, conflicts of interest policy outlines relationships required for disclosure.
The manner in which disclosure information is made publicly available?	Disclosure information is not made publicly available.
The required steps for managing conflicts of interest?	Yes, limits participation in EBML based on conflicts of interest.
The required steps to ensure policy adherence and enforcement?	Yes, this is outlined in the conflict of interest policy. Every covered person shall sign a statement that affirms that he or she has received a copy of this policy, has read and understands it, and has agreed to comply with it.

Evidence-based	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 dissemination vehicles? Is a mechanism in place for considering high quality evidence generated from validated real world data (i.e., rapid learning healthcare systems)?	EBML compiles treatment from peer-reviewed literature, oncology associations, and government agencies, among other sources. As stated prior, eviti does not rank treatment regimens. At present, real-world data not fed back into the medical library. As eviti becomes embedded within more provider networks where it is able to obtain outcome data than that becomes possible.
Patient-focused	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, risk of treatment-related toxicities, treatment schedule and/or financial toxicity)? How is cost factored into pathway	 No single best option. Evidence-based medical library comprises multiple options. eviti estimates cost using ASP+6%.
	recommendations of therapeutically similar or equivalent treatments? Are stakeholder assessment and pathway analysis used for pathway revision?	 There is a mechanism for physicians to reach out to eviti if they think something is missing from the library. The medical office works closely with the eviti content team, if a regimen comes up that should be in the library, it is added.
Up-to-Date	Are pathways updated in a timely way as relevant new information, including new FDA indication approvals, become available?	The EBML is updated continuously as there is an ongoing review of definitive trials presented in peer-reviewed literature, major oncology meetings throughout the year, and updates to guidelines produced by national government agencies, national and international oncology professional societies, and consensus groups. Medical advisory board reviews whenever questions come up and on an annual basis.
	How rapidly are new, practice-changing data incorporated into pathway recommendations?	Novel changes in care can beturned around in approximately 1 week.

Comprehensive	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?	TABLE SELF REPORT Diagnostic Evaluation First Course of Theraby Supportive Care Post-treatment surveillance Treatment of recurrent cancer Survivorship End-of-life care Surgical Oncology Radiation Oncology Radiation Oncology Laboratory Testing Molecular Diagnostics/ Precision Medicine Comments:
	If the pathways are not comprehensive, do they clearly describe the phase and elements of care they are intended to address?	• Yes.
Promotes participation in clinical trials	Are available clinical trial options incorporated into the pathway program?	 If provider network using evitiadvisor enterprise, it can be set up to prioritize trials that are available at its own site or network. eviti also has TrialCheck – a clinical trial database incorporated into its platform.
	Is treatment provided to patients participating in Phase I-III clinical trials always considered pathwayappropriate treatment?	Again, eviti does not rank treatment regimens.
Clear and achievable expected outcomes	Is information provided on the specific cancer type, stage and molecular profile (if applicable) that the pathway is intended to cover?	• Yes.
	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?	eviti doesn't control or mandate how its clients interpret the data, rather eviti provides them the data for their use.
	Does the pathway program report and communicate to all stakeholders the goal adherence rates?	See above.
	Are expected adherence rates established in a way that reflects the strength of evidence for the disease and stage?	See above.
	Do adherence rates incorporate precision medicine based on current FDA approved indications as on-pathway?	See above.
	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?	See above.

Integrated, cost-effective technology and decision support	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 offering to users and other stakeholders?	 eviti has several EMR integration efforts underway. The eviti platform is integrated into the AllScripts Sunrise program. With the AllScripts integration, providers stage the patient, can bring up eviti to identify treatments loaded in the EBML that fit the clinical data, after choosing a regimen it feeds back into AllScripts to trigger downstream processes, like order entry. eviti also has the ability to generate in real-time an eviti code to show that the selected treatment meets insurer claims language for that payer.
Efficient processes for communication and adjudication	Does the pathway program provide references or links to references that may support pathway variation?	 If eviti is the IT and the medical office, then eviti medical office will get additional clinical information from the physician's office. If initial review by APN shows clear reason why patient should not get standard of care, eviti directs the approval. It the APN can't make a determination, there will be a peer-to-peer review. If eviti is not the medical office, then the payer handles that interaction directly.
	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?	 Yes. eviti is not constructing the pathways but simply providing the EBML as a foundation.
Efficient and public reporting of performance metrics	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?	 Payers able to obtain this data from a web-based platform. eviti can do the reporting or provide the data to the clients to do the reporting themselves. eviti is able to generate the reports for network providers using eviti advisor enterprise. As more and more medical networks come on board, eviti will be able to provide better benchmarking
	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 an individual provider or provider group level)?	 eviti is able to provide this data. eviti not planning to report publicly. There are contractual issues around public reporting.
	Do providers have an opportunity to review performance reports and revise any areas in need of adjustment?	 eviti has not been asked on a large scale by practice or network to review data being given to a payer, but eviti has had conference calls to discuss data with practice and payer in certain circumstances. Practices can review data with eviti.

Outcomes-driven results	Does the pathway program have analytics in place to enable a movement over time from adherence-driven compliance to outcome driven results?	 eviti research has focused mainly on utilization rather than outcomes. As eviti becomes more tied into networks providing access to outcome data, the ability to look at outcomes will be done more easily. As more and more providers are using eviti's decision support tool, and as eviti becomes more integrated into the EMR, it will have the ability to look at outcome, toxicity, total cost at a scalable level.
Promotes research and continuous quality improvement	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?	 eviti has published in abstract form data examining patterns of care for a number of sites; for example, in breast cancer how radiation oncologists are adhering to a Choosing Wisely campaign for single fraction radiation for bone metastases. Colleagues at John Hopkins are looking at de-identified data forhead and neck cancer regimens. As eviti integrates and collaborates with provider networks and EMR vendors, could use patient portals to incorporate patient reportedoutcomes. NantHealth has also developed a patient version of eviti, CancerConnect. Patient could use iphone or tablet to query the EBML around their cancer. This product is available for a limited number of cancers. These tools will have the potential ability to collect patient outcomes and add patient input to the library. eviti has the technology and future goals to incorporate into the library in the future.
	Are the analytics generated from pathway programs publically available to patients and/or participating providers for benchmarking and understanding of complex cancer outcomes?	 Multiple layers of contracts. Collecting data from provider networks and payers have contractual requirements around making database uniformly open to the world. Most of the contracts allow for use of data in de-identified fashion.
Additional Features	Are there any incoming features for 2017?	

New Century Health analysis

Criterion	Key Questions	Response
Expert driven	Do practicing oncology providers with	Criterion met:
	relevant disease and/or specialty	NCH has two levels of pathways—
	expertise play a central role in pathway	Level 1 pathways and Level 2
	development?	pathways.
	_	Level 2 pathways are medical
		oncology compendia listed regimens.
		Compendia support includes NCCN
		Drugs and Biologics Compendium and
		the additional 4 compendia that
		support Medicare coverage
		determinations.
		For Level 1 pathways, NCH has a team
		of four oncology pharmacists and eight
		medical oncologists. The pharmacists
		do the initial pathway draft based on
		patterns of utilization, compendia
		review, critical assessment of primary
		literature (i.e. are the endpoints
		meaningful, what are the toxicities and
		hospitalization rates, etc.). Pathways
		are then sent to clinical consultants
		who are academic based, disease
		specific and the pathways are revised
		based on this review. NCH will also
		survey community oncologists as to
		the regimens they are employing.
		Lastly, the pathway goes to a national
		scientific advisory board that meets
		every 3 months for final revisions.
		Level 2 pathways have a real-time
		update when there is a new compendia
		listing. Since bulk of business is
		Medicare Advantage plans, NCH
		adheres to Medicare guidelines, which
		are compendia based.
Reflects stakeholder input	Is there a mechanism in place for	Criterion partially met:
1	patients, payers, and other stakeholders	Input is solicited from payer clients
	to provide input during the	and pharma. However, payer and
	development process?	pharma representatives are not
		members of NCH's Scientific
		Advisory Board (SAB), which is the
		final independent arbitrator.
		NCH is currently interviewing
		patient candidates for its SAB.
		SAB members who provide
		oncology sub-specialty expertise are
		from academic and community
		settings.
		25things.

Transparent	Is there a clear process and methodology for pathway development that is transparent to all pathway users, stakeholders, and the general public? Is information disclosed on: The methodology used for development?	 Criterion met: NCH uses a hierarchy: efficacy, then toxicity, then, if equivalent, as a final step, NCH considers cost. Fundamentally, pathways are a quality tool; if you deliver better quality care then savings will fall naturally out of preventing hospitalizations and inappropriate use of chemotherapy regimens. Cost is the final consideration.
	The strengths and types of evidence used to generate consensus?	S major compendia are used, as well as primary literature and utilization data. Almost all Level 1 pathways are consistent with NCCN Categories 1 or 2a.
	The specific evidence used to support the pathway recommendation (including key literature citations, guidelines, or other evidence)?	 Criterion partially met: NCH currently provides access to NCCN guidelines on its provider portal. NCH is in process of providing links to abstracts and articles that can be accessed without copyright infringement.
	The way in which efficacy, toxicity, and cost are assessed and balanced in determining the pathway recommendation?	 Criterion met: As above, NCH uses a hierarchy: efficacy, then toxicity, then, if equivalent, as a final step, cost. Convincing survival data generally trumps other outcomes measures such as time to progression, non-inferiority, etc. NCH uses the following paper as a reference resource in determining clinically meaningful outcomes: <i>Journal of Clinical Oncology</i> 32, no. 12 (April 2014) 1277-1280.
	Is there a policy in place and adhered to that requires public disclosure of all potential conflicts of interest by oncology pathway panel members and any other individuals or entities that contribute to the development of pathway content? Does this policy describe:	 Yes: per NCH Conflict of Interest Policy all employees, non employees (contractors, consultants) and Board members (BOD, Scientific Advisory Board members) complete a Conflict of Interest Disclosure (COI) form upon hire or start and annually thereafter. Advisory board members can't be a direct employee of pharma, a payer, or NCH. The advisory board members' names are not publicly disclosed; board

	members have expressed concerns about being lobbied by pharma and other interests. Only a de-identified list is available.
The nature of relationships required for disclosure?	 Yes: Per COI policy disclosure include: Any relationship or affiliation on the part of NCH of a Consultant (as defined below) that could compromise the independence or objectivity of the independent health utilization management review process. Conflict of interest includes but is not limited to:
The manner in which disclosure information is made publicly available?	specific case under review Criterion met: De-identified information can be provided upon request.
The required steps for managing conflicts of interest?	An agenda item for each SAB meeting "Review of COI disclosures of all SAB members" prior to start of meeting. If there a conflict, the member may be asked to recues him/herself from further input on the topic.
The required steps to ensure policy adherence and enforcement?	Review of COI disclosures, recusal by members, COI disclosure forms are reviewed by a sub-committee including the Compliance Officer, Head of Human Resources, Chief Medical Officer, and Legal Counsel. Each disclosure by an individual will be addressed on a case-by-case basis to determine if an actual or potential conflict exists that may compromise the professional integrity or decision-making of the staff or otherwise

		violate NCH policies and procedures.
Evidence-based	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 dissemination vehicles?	Criterion met: • Yes.
	Is a mechanism in place for considering high quality evidence generated from validated real world data (i.e., rapid learning healthcare systems)?	 Real world experience reported in peer reviewed journals is utilized to update NCH pathways. For example, FOLFIRINOX and TC (docetaxel and cyclophosphamide) are considered High Risk (for febrile neutropenia) regimens based on real world data. Each pathway decision is essentially assigning a patient to a cohort. NCH has detail on 250,000 treatment regimens from across the country (stage, treatment intent, molecular profile, line of therapy, and in many cases response to therapy) and can combine it with claims data (how many months on therapy, what percentage of patients ended up in a hospital for a particular regimen) to get real-world experience beyond clinical trials. The claims data and the pathway data are combined in the NCH data warehouse to be reviewed by NCH data analysts. NCH plans to use this data in several ways – feedback to pathway development (e.g. identify regimens associated with high hospitalization rates or poor response) as well as identification of patients at risk for complications (e.g. a patient specific hospitalization rate for a particular regimen) to flag the patient back to the practice for interventions.

Patient-focused	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, risk of treatment-related toxicities, treatment schedule and/or financial toxicity)?	NCH does not believe in a single best treatment, some pathways have 10 regimens on Level 1 (generally 3-4 regimens). NCH tries to make the tool as flexible and as easy to use as possible and tries to minimize clicks. If you have only one on-pathway option, then the provider is going to have decline and describe why they are declining. It will take more time working with the portal than simply clicking on the regimen they want. Level 2 pathways include all compendia listed regimens thus there is optionality to address patient-specific characteristics.
	How is cost factored into pathway recommendations of therapeutically similar or equivalent treatments?	 Criterion met: Look at cost of drug and model it out as ASP. We will add in supportive drugs (e.g. high emetic riskregimens, growth factor). NCH generally presents a 3-month cost of the regimen. Hospitalization cost is challenging. NCH will flag regimens with high risk of hospitalization or acute care but don't tag a cost estimate to it.
Up-to-Date	Are stakeholder assessment and pathway analysis used for pathway revision? 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?	Criterion met: Yes, already described. Criterion met: For Level 1 pathways, independent Scientific Advisory Board reviews pathways quarterly. Criterion met: The CMO has the ability to make an immediate "provisional update," which then needs to be confirmed at the next scientific advisory board meeting. Level 2 pathways, which correspond to the 5 major clinical compendia for oncology utilized by CMS, are made available for selection within one week of compendia changes.

Comprehensive	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?	TABLE SELF REPORT Diagnostic Evaluation First Course of Therapy Supportive Care Post-treatment surveillance Treatment of recurrent cancer Survivorship End-of-life care Surgical Oncology Radiation Oncology Imaging Laboratory Testing Molecular Diagnostics/ Precision Medicine
		Comments: Imaging and diagnostic evaluation pathways are in development.
	If the pathways are not comprehensive, do they clearly describe the phase and elements of care they are intended to address?	Criterion met: • Yes.
Promotes participation in clinical trials	Are available clinical trial options incorporated into the pathway program?	 Criterion met: Links to Cooperative Group trials as well as Targeted Agent and Profiling Utilization Registry (TAPUR) and Molecular Analysis for Therapy Choice (MATCH) are built into pathways. NCH also provides a hyperlink, imbedded in its electronic portal and available to physicians, to imbed into any software or desktop. The link provides access to the major resources for trials, and displays NCH pathways within 2 clicks. Providers can also select a regimen or custom build a regimen and then click a button indicating it is a clinical trial. The NCH system gives the provider pathway credit and automatically approves the regimen.
	Is treatment provided to patients participating in Phase I-III clinical trials always considered pathwayappropriate treatment?	 Criterion met: As above, registered trials are always on pathway. Pharma demonstration projects are not on pathway. NCH works with 8,000 oncologists so NCH can't pre-populate all practice specific trials into the pathway.
Clear and achievable expected outcomes	Is information provided on the specific cancer type, stage and molecular profile (if applicable) that the pathway is intended to cover?	Criterion met: • Yes.

	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?	Yes. NCH expects warranted variation about 25% of the time from Level 1 pathways. Pathway adherence goals are clearly communicated to all stakeholders. If on Level 1 pathway, there is an incentive (national payers will look at pathway adherence on a tiered system), or adherence is used as a quality metric for shared savings (greater shared saving if higher adherence rate to Level 1 pathways).
	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 in disease as an archysty?	Criterion met: • Yes, all pathways have NCCN Category 1 or 2A evidence. Criterion met: • Yes.
	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?	 Criterion partially met: Yes: 4 examples in which evidence based variation is taken into account include: 1. If the patient is a bone marrow candidate transplant candidate; 2. Time to relapse; 3. Patient performance status; 4. If there is a leucovorin shortage, then levoleucovorin is considered on pathway. NCH expects up to 25% deviation from Level 1 Pathways which should account for individual variation as well as variation in available resources in different geographic regions. Additionally, there are generally multiple pathway choices for each clinical situation (NCH doesn't believe in one best option). This allows the additional room for individual patient differences.
Integrated, cost-effective technology and decision support	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 offering to users and other stakeholders?	Yes: a) NCH has successfully integrated with an EMR via EMR Interface Technology; b) NCH has 270/271 data transfer capability to payers to allow automated payer authorization; c) NCH implementing links to NCCN order templates; d) NCH capabilities and tools are communicated to users via direct education to practice staff and periodic electronic newsletter.

		 By selecting on-pathway option, regimen is approved in real-time and claims payment is expedited. NCH's ultimate goal: once a provider picks a regimen it can immediately prior approve and then fire back to the EMR to load the chemotherapy. Not easy to do and some resistance from EMR companies.
Efficient processes for communication and adjudication	Does the pathway program provide references or links to references that may support pathway variation?	 Criterion partially met: NCH is in the process of providing such reference links into its system. Currently, NCH provides access to NCCN guidelines on provider portal.
	Does the pathway program inform the provider in real time of pathway compliance?	Criterion met:Yes – either on-pathway or not.
	Is the mechanism for choosing an off- pathway recommendation and documenting the rationale for this choice easily imbedded in the pathway program?	 Yes. If off Level 1 and Level 2 the regimen is evaluated by one of thirty-five oncology nurses. About 15% of the time, requested regimens are off compendia. If nurse can't find reason to approve it, then it is kicked up to medical oncologist. The medical oncologist will call the provider to get clarification. Approximately 2% of time, the requested regimen doesn't seem like good quality care. NCH will then forward to payer with a recommendation for adverse determination. The payer makes the final determination for approval or denial.
Efficient and public reporting of performance metrics	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?	 Criterion met: Yes. Physicians don't like to be outliers and that is as much a motivator as payment plans. Providers and practices are benchmarked to their region and nationally with blinded data from other practices.
	Will the performance reports provided include these reasons for non-concordance?	Detail reports include all the clinical data entered into the pathway portal for each individual patient, the regimen selected, whether the regimen was a pathway choice or not, and if not a pathway choice, what the pathway choice would have been in that clinical situation.

	Will public reporting of providers' pathway adherence be disclosed as a composite report only (i.e., not an	Yes, provider de-identified composite reporting has been
	individual provider or provider group level)?	disclosed in presentations and published peer-reviewed abstracts.
	Do providers have an opportunity to review performance reports and revise any areas in need of adjustment?	Criterion met: • Yes.
Outcomes-driven results	Does the pathway program have analytics in place to enable a movement over time from adherence-driven compliance to outcome driven results?	Yes, NCH now collecting some outcome data, as discussed.
Promotes research and continuous quality improvement	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? Are the analytics generated from pathway programs publically available to patients and/or participating providers for benchmarking and	 Yes, NCH has a robust analytics department. NCH is collecting response data, duration of therapy data, and is beginning to collect complication of therapy data (hospitalizations, etc.). NCH is attempting to match this topatient cohorts as determined by pathway choices. NCH regularly reviews this data and uses it to make suggestions to its advisory board for modifications to the pathways. NCH is not collecting patient reported outcomes but would hope to in the future. NCH would like to answer questions like – what did patient think of the outcome, did they return to work, what was their quality of life. NCH is beginning to ask if practices would upload imaging results, to evaluate responses, and marry with patient reported outcomes. NCH doesn't currently have a mechanism for collecting the patient data. Criterion met: Yes, provider de-identified pathway data has been disclosed in presentations and published peer-
	understanding of complex cancer outcomes?	reviewed abstracts.
Additional Features	Are there any incoming features for 2017?	 Incorporating next generation gene sequencing into pathways. Physician dashboards with realtime pathway adherence reporting. Selected QOPI and consensus quality metrics reporting.

Value Pathways Powered by NCCN analysis:

Criterion	Key Questions	Response
Expert driven	Do practicing oncology providers with relevant disease and/or specialty expertise play a central role in pathway development?	Criterion met: All contributing members are practicing oncologists at independent community-based clinics or academic centers. In 2013, US Oncology formed a relationship with NCCN. NCCN appoints up to 3 physician members for each clinical pathway committee as voting members. NCCN clinical pathway physicians are existing members of NCCN Guideline panels.
Reflects stakeholder input	Is there a mechanism in place for patients, payers, and other stakeholders to provide input during the development process?	 Criterion met: All recommendations are sent out in advance to a network of ~1,000 oncology providers for feedback, including disease-specific researchers. Outside parties can submit pharmacoeconomic data for consideration. Anyone can use this submission process, but it is mostly used by pharmaceutical manufacturers. Payers have not developed content for pathways but rather are interested in adherence to pathways. Patients don't sit on pathway committees and don't vote oncontent. Patients could use external feed.
Transparent	Is there a clear process and methodology for pathway development that is transparent to all pathway users, stakeholders, and the general public? Is information disclosed on:	
	The methodology used for development?	 Value Pathways use NCCN guidelines as foundation. Rarely therapy recommendations come up that aren't on NCCN guidelines and this prompts a discussion with NCCN. NCCN has revised guidelines based on these discussions. Value Pathways don't regurgitate all therapies on NCCN guidelines. Value Pathways evaluate efficacy, first and foremost, but also take into account

	other factors such as toxicity, cost, and patient convenience issues (route of administration, length of therapy). • Efficacy is always first because it is the science. If the therapy is superior, it is on pathway even if expensive. When efficacy is similar or differences are not clinically significant, then will factor in toxicity and cost. Criterion met:
The strengths and types of evidence used to generate consensus?	 Value Pathways powered by NCCN are a formal subset of the NCCN Treatment Guidelines using the clinical standards as developed by The NCCN. NCCN levels of evidence are included for all Value Pathway regimens.
The specific evidence used to support the pathway recommendation (including key literature citations, guidelines, or other evidence)? The way in which efficacy, toxicity, and	Start with NCCN as foundation. Value Pathways completes own independent evidence review. A team of PharmD's creates an evidence table that has outcomes, toxicities, and other relevant findings. Uses phase III randomized trials when available, will sometimes use an abstract but typically wait for peerreview. Committees also look at utilization patterns from pathway data. Criterion met:
cost are assessed and balanced in determining the pathway recommendation?	Efficacy is primary then toxicitythen cost.
Is there a policy in place and adhered to that requires public disclosure of all potential conflicts of interest by oncology pathway panel members and any other individuals or entities that contribute to the development of pathway content? Does this policy describe: The nature of relationships required for disclosure?	Criterion met: Conflict of interest policy not publicly available for Value Pathways. Conflict of interest relationships are publicly available for clinical pathway committee voting members. NCCN has its own publicly available conflict of interest policy. Criterion met: The following categories are available: clinical research support; advisory boards, speakers bureau, expert witness, or consultant; patent, equity, or royalty; other; date completed.
The manner in which disclosure information is made publicly available?	The above disclosures are publicly available on the Value Pathways website.

Evidence-based	The required steps for managing conflicts of interest? The required steps to ensure policy adherence and enforcement? Are the pathways based on the best	Criterion met: Other than disclosures, Value Pathways require task force members to have no more than \$10,000 in general payments from pharmaceutical manufacturers. Criterion partially met. Available for NCCN voting members. Criterion met:
Evidence-based	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 dissemination vehicles?	• Yes.
	Is a mechanism in place for considering high quality evidence generated from validated real world data (i.e., rapid learning healthcare systems)?	 Value Pathways uses its own rapid learning health system with pathways data and utilization patterns since 2005. Value Pathways is working with a partner to do predictive modeling, plan to incorporate into decision support tool not only the evidence but predictive modeling for particular patients.
Patient-focused	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, risk of treatment-related toxicities, treatment schedule and/or financial toxicity)?	 Criterion met: When patient characteristics and preferences are anticipated as a result of the disease process, considerations are given to these issues and incorporated. Individual patient preferences are left to the discretion of the treating provider. Does not employ specific nodes for each patient characteristic as becomes too prescriptive. Oncologists should use judgment and not have to click through every clinical scenario. Value Pathways has some of the patient characteristics but not everything – and that is deliberate. Performance status is captured in certain clinical scenarios.
	How is cost factored into pathway recommendations of therapeutically similar or equivalent treatments?	Criterion met: • Medicare-ASP based reimbursement.

	Are stakeholder assessment and pathway analysis used for pathway revision?	 Criterion met: Yes, committees consider utilization data. Regular annual evaluations for each pathway are performed to review clinical data, the cost/value of options, and provider adherence as well as off- pathway treatments. The impact of the pathway for patients is not included as thiselement is expected to be part of the provider-patient relationship.
Up-to-Date	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?	Criterion met: Evidence to be considered for pathways reviewed during monthly calls. Criterion met: Committees can meet and make decisions on breaking news. Caution is used for presented data prior to peer-review process.
Comprehensive	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?	TABLE SELF REPORT Diagnostic Evaluation First Course of Therapy Supportive Care Post-treatment surveillance Treatment of recurrent cancer Survivorship End-of-life care Surgical Oncology Radiation Oncology Radiation Oncology Laboratory Testing Molecular Diagnostics/ Precision Medicine Comments:
	If the pathways are not comprehensive, do they clearly describe the phase and elements of care they are intended to address?	Criterion met: • Yes.
Promotes participation in clinical trials	Are available clinical trial options incorporated into the pathway program?	Some new tools can present clinical trials available at participating practice's institution based on clinical scenario. This is an add-on feature.

	Is treatment provided to patients	Criterion met:
	participating in Phase I-III clinical	Clinical trials are always on pathway.
	trials always considered pathway- appropriate treatment?	
	appropriate treatment.	
Clear and achievable expected outcomes	Is information provided on the specific	Criterion met:
	cancer type, stage and molecular profile	Each Value Pathway includes specific
	(if applicable) that the pathway is intended to cover?	disease characteristics. When a scenario is not included in the
	intended to cover:	Pathway's intent, the provider is
		alerted.
		Value Pathways are not intended to
		address every scenario.
	Is there clear information provided to	Criterion met:
	pathway users and other stakeholders on what constitutes treatment on	Treatment on and off pathway are clear.
	pathway, treatment off-pathway, and	Cicur.
	warranted variation from pathway	
	recommendations?	
	Does the pathway program report and	Criterion not met:
	communicate to all stakeholders the goal adherence rates?	While guidelines exist foradherence recommendations, each practice is
	goal author circo rates.	encouraged to develop an internal
		process, review their own data, and
		determine which specific adherence
		guidelines their practice should follow.
		 Value Pathways are not directly
		associated with any coverage
		guidelines.
	Are expected adherence rates established	Criterion not met:
	in a way that reflects the strength of evidence for the disease and stage?	See above.
	Do adherence rates incorporate precision	Criterion met:
	medicine based on current FDA approved	Precision-based medicine is included
	indications as on-pathway?	in the pathways.
	Do adherence rates allow for evidence-	Criterion partially met:
	based variation and take into account individual patient differences and the	Value does not create its pathways around certain
	resources available in the particular	practices/groups/hospitals with
	healthcare system or setting to provide	resource constraints.
	recommended care?	With its decision support tool, Clear
		Value Plus, clients can customize
		pathways to account for resource constraints.
Integrated, cost-effective technology and	Does the pathway program offer - or	Criterion met:
decision support	plan to offer - clinical decision support	Pathways integrated into order sets
	or other resources (i.e. automated payer	with iKnowMed EMR and EPIC.
	authorization, links to order sets, data	Working on automated payer
	collection tools) in a way that is integrated into commonly used EHRs?	authorization. Have been able to accomplish in some cases but not
	How does it communicate these offering	others.
	to users and other stakeholders?	

Efficient processes for communication and adjudication	Does the pathway program provide references or links to references that may support pathway variation?	 Criterion met: Clear Value Plus, as the decision support tool, provides not only Value Pathway choices, but the NCCN Treatment Guideline options. Off-Pathway treatment options are available and documented with exception rationale at the time of ordering. NCCN levels of evidence are included for all NCCN and Value Pathways regimens and antiemetic and neutropenic fever risk is included per the NCCN Treatment Guidelines.
	Does the pathway program inform the provider in real time of pathway compliance?	Criterion met: • Yes.
	Is the mechanism for choosing an off- pathway recommendation and documenting the rationale for this choice easily imbedded in the pathway program?	Yes. Process includes structured data or free text collection for non-concordant decisions.
Efficient and public reporting of performance metrics	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?	Reporting is available in real-time and may be compared to other collective groups using Value Pathways. Reports are available to providers/practices to determine how best to utilize data and reports include documented off — pathway exceptions.
	Will the performance reports provided include these reasons for non-concordance?	Criterion met: Reports include off-pathway exception documentation.
	Will public reporting of providers' pathway adherence be disclosed as a composite report only (i.e., not an individual provider or provider group level)?	Criterion not met: No plan for public reporting.
	Do providers have an opportunity to review performance reports and revise any areas in need of adjustment?	Providers can comment on pathway reports and revise them.
Outcomes-driven results	Does the pathway program have analytics in place to enable a movement over time from adherence-driven compliance to outcome driven results?	Criterion met: Yes, Value Pathways is starting to examine claims data(hospitalizations, ED use, hospice use) to link pathways to outcomes. Value pathways is striving to do better, move beyond pathway adherence measures to outcome measures. Analytics may be performed on a pathway by pathway basis to assess outcomes and are periodically used to assess treatment options.

Promotes research and continuous quality improvement	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? Are the analytics generated from pathway programs publically available to patients and/or participating providers for benchmarking and understanding of complex cancer outcomes?	 Value Pathways has a research arm. Have done a fair amount of publishing regarding pathways and have more projects in preparation. Just now starting to incorporate patient reported outcomes; oncology care model is driving this push. Patient reported outcomes are new to Value Pathways and relatively new as far as collecting that information for the EMR. Criterion met: Analytics are given to providers for benchmarking and understanding outcomes. Value Pathways is in the early phase of collaborating with academic centers on research projects related to pathways.
Additional Features	Are there any incoming features for 2017?	1

Via Pathways analysis:

Criterion	Key Questions	Response
Expert driven	Do practicing oncology providers with relevant disease and/or specialty expertise play a central role in pathway development?	Via Pathways are developed by physician disease committees. Committees are jointly chaired by academic-based and community-based oncologists. Committee meetings are open to all providers using Via Pathways who complete an annual conflict of interest form.
Reflects stakeholder input	Is there a mechanism in place for patients, payers, and other stakeholders to provide input during the development process?	 Criterion met: Committee meetings open to all providers using Via Pathways and Via physicians are able to submitinquiries regarding pathways. On a national level, Via has given access to the Via Pathways to the National Patient Advocacy Foundation (NPAF) as well as other patient advocacy groups. Have stopped short of having patients on pathway committees. Individual physicians are welcome to share the Via Pathways with their patients. Via happy to open up to payers access to pathways to support individual practices in their payer relationships. However, payers are not involved in pathway content.
Transparent	Is there a clear process and methodology for pathway development that is transparent to all pathway users, stakeholders, and the general public? Is information disclosed on:	
	The methodology used for development?	 Criterion met: Prioritize efficacy > toxicity > cost. Evidence reviews and committee meeting minutes are available to physicians who use the portal. Certain patient advocacy groups or payers would have access at an individual provider's request and if signed non-disclosure agreement.
	The strengths and types of evidence used to generate consensus?	 Criterion met: Never draw a line in the sandover type of evidence that can be used. Not working for payers but for practices so not set up to restrainuse.

The specific evidence used to support the	There are also many places in pathways where there is not published evidence/data to support superiority of one treatment over another; in these cases, Via believes that expert consensus is still preferable to unexplained variability. Via does ask committees to only use evidence that is available in the public domain (peer reviewed journal or abstract accepted at a peer meeting). Criterion met:
pathway recommendation (including key literature citations, guidelines, or other evidence)?	Each decision has a link to the evidence supporting it: 1) treatment itself has a citation, 2) able to link to evidence review (how did the committee get to this decision.)
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	Efficacy>toxicity>cost. Cost only taken into account when efficacyand toxicity are comparable. Criterion met: Via has a written conflict of
potential conflicts of interest by oncology pathway panel members and any other individuals or entities that contribute to the development of pathway content? Does this policy describe:	 Via does require chairs and physicians participating in the committees to disclose conflicts of interest and those disclosures are reviewed at each committee call. Voting members and their conflicts
	of interest are published on the www.viaoncology.com website as of July 2017.
The nature of relationships required for disclosure?	The following categories are disclosed: grant/research; all other funding types; date completed.
 The manner in which disclosure information is made publicly available?	Criterion met:Publicly available on website.
The required steps for managing conflicts of interest?	Criterion met: Detailed in publicly available conflict of interest policy.
The required steps to ensure policy adherence and enforcement?	Criterion met: Detailed in publicly available conflict of interest policy.

Evidence-based	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 dissemination vehicles?	Disease committees are charged with weighing the best available scientific evidence. Staff supports them to ensure literature search is done. The committees come together to review the evidence – usually peer-reviewed journals, abstracts if in public domain. The committee does not look at other guidelines. Primary source is peer-reviewed journal articles.
	Is a mechanism in place for considering high quality evidence generated from validated real world data (i.e., rapid learning healthcare systems)?	 Criterion partially met: To the extent that real-world data is published in peer reviewed journals, it can be considered by the disease committees. The committees will not examine real-world data that has not been published. Pathways are learning pathways so committees do look at the on-pathway detail from the prior quarter and look at any pathway that is performing at less than a 70% adherence rate.
Patient-focused	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, risk of treatment-related toxicities, treatment schedule and/or financial toxicity)?	 Criterion met: Committees can include as many "Other Patient Scenarios" (OPS) as they deem warranted. Each OPS must delineate the specific patient scenario (e.g. "neuropathy" or "oral drugs not an option"). Committees can add OPS that relate to financial toxicities and patient convenience elements (e.g. oral versus IV regimens). The committees are incorporating the OPS that they see in clinical practice. Quarterly review of poorly performing pathways branches helps to inform the disease committees of the potential need for additional OPS.
	How is cost factored into pathway recommendations of therapeutically similar or equivalent treatments?	Medicare allowables per billableunit. Wedicare allowables per billableunit. Via has now also built a publicly available cost analyzer tool. The tool calculates combination of cost to Medicare and to the patient. Uses 24 weeks for "treat to progression" regimens to normalize regimens with different dosing intervals.

	Are stakeholder assessment and pathway analysis used for pathway revision?	Via captures the reason for off-pathway, examines pathways performing at less than 70%, and also accepts submissions regarding pathways from users. Via has an electronic submission process within the Via Portal for physicians to submit their concerns and suggestions. Such submissions are reviewed with Co-Chairs when developing agendas for next meeting.
Up-to-Date	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?	 Criterion met: Pathways are reviewedquarterly and can be updated more frequently as determined by the Co-Chairs. Criterion met: Ad-hoc meetings can be called as necessary by committee chairs. Time from ad-hoc meeting until change incorporated into pathway is usually 30-45 days. Process involves 4 layers of quality review.
Comprehensive	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?	TABLE SELF REPORT
Promotes participation in clinical trials	If the pathways are not comprehensive, do they clearly describe the phase and elements of care they are intended to address? Are available clinical trial options incorporated into the pathway	Criterion met: • Yes. Criterion met: • Yes. Pathways show trials that are
110motes paracepation in chinesis is an	incorporated into the pathway program?	

	Is treatment provided to patients	Criterion met:
	participating in Phase I-III clinical	Phase I-III clinical trials arealways
	trials always considered pathway-	considered pathway appropriate
	appropriate treatment?	treatment and counted as on
	appropriate treatment:	pathway.
		÷ *
		• Step further – if don't accrue to trial,
		Via requires input as to why provider
		didn't accrue patient to the trial.
Clear and achievable expected outcomes	Is information provided on the specific	Criterion met:
	cancer type, stage and molecular profile	Specific cancer type, stage, and
	(if applicable) that the pathway is	molecular profile are included.
	intended to cover?	
	Is there clear information provided to	Criterion met:
	pathway users and other stakeholders	Yes. Providers know if on or off
	on what constitutes treatment on	pathway at the time of use of the Via
	pathway, treatment off-pathway, and	Pathway.
	warranted variation from pathway	Overall high level adherence
	recommendations?	goal is 80%, but it is not a bright
		line.
	Does the pathway program report and	Criterion met:
	communicate to all stakeholders the	Via does not set expected
	goal adherence rates?	adherence rates but states in all
		collateral material that 80% is a
		high-level goal. Nothing is tied to
		physician compensation or prior
		authorization.
		Hard to set a goal for eachindividual
		disease due to changes in data over
		time and the strength of the evidence
		within each disease.
	Are expected adherence rates established	Criterion not met:
	in a way that reflects the strength of	See above.
	evidence for the disease and stage?	
	Do adherence rates incorporate precision	Criterion met:
	medicine based on current FDA approved	Yes – precision medicine is included
	indications as on-pathway?	on-pathway.
	Do adherence rates allow for evidence-	Criterion partially met:
	based variation and take into account	Via does not have a resource
	individual patient differences and the	constrained pathway per se. Cost is
	resources available in the particular	factored into the Disease Committee
	healthcare system or setting to provide	recommendations when efficacy and
	recommended care?	toxicity are comparable. Via presents
		cost information for each regimen
		even when the deciding factor was
		NOT cost. Finally, when a Disease
		Committee feels that a treatment with
		better outcomes may be financially
		unaffordable for a number of patients,
		they may add an additional treatment
		option (still considered on pathway)
		for patients with significant resource
		constraints.

Integrated, cost-effective technology and decision support	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 offering to users and other stakeholders?	 Via Portal can be interfaced with the commonly used EHR's for demographics, physician schedule, and notes back into the patient's record. Single sign-on and patient context are also available. Via has not automated prior authorization, would need payers to be willing to allow electronic submission out of Via portal into their tools. Via does send payers data files routinely, however, getting payers to be willing to automate payer authorization has been elusive. With several EMR's, Via can automatically queue up order sets based on physician selection within the Via Portal. For practices without an EMR, Via provides printable order sets.
Efficient processes for communication and adjudication	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?	Criterion met: Resources available to identify alternative regimens. Criterion met: Yes.
	Is the mechanism for choosing an off- pathway recommendation and documenting the rationale for this choice easily imbedded in the pathway program?	Yes. Provider enters a reason but continues with order. Data istracked for quarterly discussion by pathway committees.
Efficient and public reporting of performance metrics	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?	Yes – on pathway rate and capture rate reported. Capture rate is what percentage of visits did provider document the patient situation, an indication of data completeness. These reports go to the physician and leadership.
	Will the performance reports provided include these reasons for non-concordance?	Reasons for non-concordance are tracked and reported.
	Will public reporting of providers' pathway adherence be disclosed as a composite report only (i.e., not an individual provider or provider group level)?	Via publishes 12 Month On Pathway Rates for its aggregate customer base at https://www.viaoncology.com/what/#p athways under "Disease Coverage."
	Do providers have an opportunity to review performance reports and revise any areas in need of adjustment?	Providers receive their individual reports monthly for review but can't adjust/revise them. The reports are based on what the physicians actually charted within the Via Portal and, if they selected the off pathway option, includes the reason they cited for going off pathway.

Outcomes-driven results	Does the pathway program have analytics in place to enable a movement over time from adherence-driven compliance to outcome driven results?	Publishing committee is reviewing the pathway data to better understand elements of care (e.g. molecular marker testing rates). The data is being transformed into abstracts, posters, manuscripts, as well as quality improvement projects. Have hired dedicated staffincluding medical writer and biostatistician to move in this direction of outcome driven results.
Promotes research and continuous quality improvement	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?	Criterion met: Via supports each customer's clinical research activities by placing their locally available trials within the Via Portal (ahead of the standard of care treatment). Accrual to trial is always counted on pathway and the provider must indicate a reason for non-accrual to each trial within that state/stage of disease. Via is making research a part of what they do in collaboration with the practices. Not currently looking at patient reported outcomes. Practices could intersect Via pathway data with patient reported outcome data but Via doesn't get patient reported outcome data.
	Are the analytics generated from pathway programs publically available to patients and/or participating providers for benchmarking and understanding of complex cancer outcomes?	Criterion met: Routinely submitting abstracts and had second manuscript accepted to JOP. Nothing yet rises to the level of complex cancer outcomes but moving in that direction.
Additional Features	Are there any incoming features for 2017?	In 2017, Via launched the Triage Pathways as well as Via Cost Analyzer (regimen costing tool). Via is also starting a Precision Medicine pathway that will support treatment and clinical trial matching for precision medicine that is not specific to a cancer type.



CHAIR OF THE BOARD

Howard A. Burris, III, MD, FACP, FASCO

PRESIDENT

Lori J. Pierce, MD, FASTRO, FASCO

PRESIDENT-ELECT

Everett E. Vokes, MD, FASCO

PAST PRESIDENT

Monica M. Bertagnolli, MD, FACS, FASCO

TREASURER

Laurie E. Gaspar, MD, MBA, FASTRO, FACR, FASCO

DIRECTORS

Ethan M. Basch, MD, MSc, FASCO

A. William Blackstock, MD, FASCO

Lisa A. Carey, MD, FASCO

Lee M. Ellis, MD, FACS, FASCO

Tara O. Henderson, MD, MPH, FASCO

Reshma Jagsi, MD, DPhil, FASTRO, FASCO

> Michael P. Kosty, MD, FACP, FASCO

Elizabeth A. Mittendorf, MD, PhD

Tony S. K. Mok, BMSc, MD, FRCP(C), FRCP (Edin.), FHKCP, FHKAM (Medicine), FASCO

Elizabeth R. Plimack, MD, MS

Eric J. Small, MD, FASCO

Enrique Soto Pérez de Celis, MD, MSc

Michael A. Thompson, MD, PhD, FASCO

Tracey F. Weisberg, MD, FASCO

EX-OFFICIO MEMBERS

CHAIR, CONQUER CANCER
BOARD
Thomas G. Roberts, Jr., MD,
FASCO

CHIEF EXECUTIVE OFFICER Clifford A. Hudis, MD, FACP, FASCO

2318 Mill Road, Suite 800 Alexandria, VA 22314 T: 571-483-1300 F: 571-366-9530 www.asco.org

Via Electronic Submission

July 24, 2020

Preliminary Review Team
Physician-Focused Payment Model Technical Advisory Committee
C/o US DHHS Assistant Secretary for Planning and Evaluation, Office of
Health Policy
200 Independence Avenue, SW
Washington, DC 20201

Re: Response to second set of questions received from the PTAC Preliminary Review Team regarding the ASCO Patient-Centered Oncology Payment Model

Dear Members of the PCOP Preliminary Review Team and ASPE Staff:

Thank you for the opportunity to discuss ASCO's Patient-Center Oncology Payment Model on Tuesday, July 21. As promised, attached are written responses to the questions asked during the meeting. We hope that this information will assist the team in your review.

Respectfully,

Stephen S. Grubbs, MD

Vice President - Clinical Affairs

- 1. **Total-Cost-of-Care** (**TCOC**): Please confirm how the term Total Cost of Care is defined and used in the proposed payment methodology. As described on page 12 of the proposal, TCOC is defined as: "total cost-of-care, in aggregate costs included physician services, inpatient stays, diagnostics, provided drugs, *and other claims received by Medicare*."
 - a. Does TCOC include all Part A and B claims, as well as all Part D claims (as suggested by Table A.1 and Table A.2)? Are these the same assumptions that were included in TCOC in Table A.6, which models PCOP's impact on Total Cost of Care?

Yes, Parts A, B, and D were included in TCOC calculations. In our analysis, 47% of traditional Medicare and 97% of all other payer months included oral drug coverage. We adjusted our figures in Appendix A to reflect 100% oral drug coverage.

b. Does TCOC include the costs for hematology/oncology related services as well as any other cancer-related services (e.g., radiation, surgery) and non-cancer related services (e.g., cardiac, etc.) associated with the services (i.e., physician, inpatient stays, diagnostics, provided drugs, and other claims) provided to beneficiaries attributed to PCOP model provider participants?

TCOC included all services and items provided during the new patient, cancer treatment, and active monitoring months.

c. Page 12 of the proposal states that the Track 1 monthly Care Management Payments (CMPs) are 2% of TCOC and Track 1 Performance Improvement Payments (PIPs) can be up to 2% of the TCOC, while Track 2 monthly CMPs are 3% of TCOC and Track 2 PIP payments can be up to 3% of the TCOC. How is TCOC defined in this context? What claims are included (i.e., Part A, B, and D claims?) and what services are included (i.e., hematology/oncology, any other cancer-related services, and non-cancer related services?)

All services were included in TCOC and our analysis of the 2% and 3% amounts. This approach is similar to the OCM methodology, where the MEOS amounts were calculated using 4% of TCOC. Where PCOP differs from OCM is that, rather than a flat amount, we have built risk and reward into the Care Management Payments such that they increase or decrease based on performance (see Performance Incentive Payment).

2. **Cost-of-Care (COC) Performance:** Please confirm how the term "Cost of Care (COC) Performance" is defined and used in the proposed payment methodology. Page 18 indicates that the performance methodology includes accountability for cost-of-care metrics, including unplanned acute care hospital admissions, emergency department (ED) and observation care visits, and supportive and maintenance care drug costs. Page 20 indicates that the rates for the "cost-of-care metrics" will be calculated relative to a comparison population and adjusted for differences in case mix.

a. Please confirm whether the proposed "cost-of-care metrics" related to ED visits/observation stays and unplanned hospitalizations—would be for any condition (e.g., cancer or non-cancer, all Part A and B claims) or whether they would be restricted to some subset of conditions determined to be related to hematology/oncology services (e.g., avoidable oncology ED and observation visits or hospitalizations).

All unplanned admissions and ED visits are included, regardless of condition. Unplanned excludes planned surgeries, transplants, and admits for chemotherapy. We took this approach because condition-based inclusion criteria subjects performance rates to differing coding practices among hospitals.

This is similar to OCM-1 and OCM-2, except that it transitions from an every 6-month measure to a monthly measure which may be reported with greater frequency. ASCO may further develop these measures, at which time adjustments may be made, such as limited exclusion criteria: MVA, GSW, and other trauma or accident.

b. Although the example shown suggests an equal weighting between the three cost-of-care metrics, page 21 of the proposal states that "the calculation of the overall cost-of-care category performance will be determined by weights established by each PCOP Community's Oncology Steering Committee." Will there be any guidelines regarding the relative weighting that the Oncology Steering Committees can use for the various cost-of-care metrics?

For purposes of implementation within the Medicare program, we recommend equal weighting. Outside of the Medicare program, we have purposefully built in flexibility, such that stakeholders may adjust as necessary to meet their collective goals.

- 3. Calculation of the Aggregate Performance Score (APS): Page 14 states that the APS will be used to determine the performance adjustment for both the monthly PIP payments (for Tracks 1 and 2) and the Track 2 CPOC payments. Although the example shown suggests an equal weighting between the three performance metrics and ASCO's 3-16-20 response to the PRT's questions also indicated that these performance metrics would be weighted equally, page 21 states that "the Oncology Steering Committee will be responsible for weighting performance categories for calculation of an aggregate performance score."
 - a. Please confirm whether the cost-of-care performance metrics would be equally weighted (e.g., one-third each) with the clinical treatment pathway score and quality metrics category score to calculate the APS, in the PCOP model, or whether each PCOP community's Oncology Steering Committee would have discretion to determine the relative weighting of these metrics.

For purposes of implementation within the Medicare program, we recommend equal weighting. Outside of the Medicare program, we have purposefully built in flexibility, such that stakeholders may adjust as necessary to meet their collective goals.

b. Please explain how the APS will be calculated, and how the APS will be used to determine the PIP amounts and the CPOC amounts. It is not clear based on the example in Table 5.1 on page 15 how the qualitative descriptions of the three sample practices' performance were used to calculate the APS scores. Additionally, it is not clear how the APS scores were used to determine the sample practices' CPOC amounts in Table 1, or what the sample practices' corresponding PIP amounts would be.

The aggregate performance score is calculated on a scale of 0 to 100 points and is multiplied by the available performance incentive payment and portion of the consolidated payment placed at risk. The examples of high cost, low quality, etc. are illustrative.

4. **Drug Costs Included in Different Model Implementation Years:** Are financial incentives related to both maintenance/supportive drug costs and chemotherapy drug costs included in all years of the PCOP model (year 0 and years 1-5), or are financial incentives related to some drug costs included in years 0-2 and others added in later years?

Measurement of maintenance/supportive drug costs as a metric is included in years 1-5. Year 0 exists to reflect some of the infrastructure activities necessary to stand up the model.

- 5. **Application of the CMP and PIP:** Please clarify the timeframes and process for applying the CMP and the PIP, as well as the relationship between the CMP and PIP. On page 22, the proposal states that PCOP is proposing a five-year model, and identifies some Year 0 activities related to building the infrastructure necessary for successful implementation of the model.
 - a. On page 12, the proposal states that "a portion of the CMP fees will be allocated to a Performance Incentive Payment (PIP). Providers who are successful in quality metrics, adherence to clinical treatment pathways, and reduction in cost-of-care, as compared to national trends, will receive positively adjusted PIP amounts, whereas those who fail to achieve target rates will have their PIP amounts reduced." Please confirm how the payment of the PIP amounts will work in practice (e.g., will a portion of the PIP be withheld from the CMP to form a PIP pool that would not be allocated until the Aggregate Performance Scores are available for the period's performance metrics?)

The care management payments begin immediately in the model. The performance incentive payments are not made until year 2 and are based on the practices performance in year 1.

b. Page 22 states that the application of the CMP amounts will begin in Year 0 and the application of the PIP amounts will begin in Year 2, but the introduction of the Total Cost of Care metric will not begin until Year 3. Please confirm how the initial CMP and PIP amounts will be calculated before the TCOC metric is available (since page 12 states that the Track 1 and Track 2 CMP and PIP amounts are supposed to be calculated as a percentage of TCOC).

The reference to a TCOC metric on page 22 is in error, as such a metric no longer exists in the performance methodology and has been replaced with three metrics: ED visits, admissions, and maintenance/supportive care drug costs. All three begin with performance period 1.

The initial CMP amounts are based on historical TCOC and may be adjusted annually based on trends. We note that we did not make that clear in the proposal.

- 6. **Further Clarification on CMP Payments:** Please clarify the following additional questions.
 - a. Please confirm that the evaluation and management (E/M) and other services needed to work-up and make a cancer diagnosis are not included in the New Patient CMP (thus, prior to making a diagnosis and determining that chemotherapy is needed). In other words, what are the E/M services that would be included in New Patient costs?

As a medical oncology model, the new patient CMP may include E/M services necessary to confirm diagnosis after referral to medical oncology. This is common in blood cancers. Workup by other physicians in a month prior to referral to medical oncology is not included.

b. Please clarify how subsequent rounds of chemotherapy would be handled within the PCOP model. Would a patient potentially move from Active Monitoring into Cancer Treatment, bypassing the New Patient stage of care?

Correct. For patients with advancement of cancer, new lines of therapy, or relapse would bypass new patient stage of care. A new primary tumor may trigger a new patient stage of care.

- 7. **Basis for Cancer Groupings and Case Mix Adjustment:** Page 20 states that the PCOP cost of care metrics would be adjusted for differences in case mix, including cancer type.
 - a. What is the proposed approach for adjusting for case-mix in the PCOP model?

At minimum, we recommend the following factors for case mix adjustment in the PCOP model: cancer type, secondary malignancy, transplant, and trial participation. b. Please describe the rationale for the proposed grouping of the major cancers into cohorts A-D. For example, is the grouping related to average costs and/or other factors? How would these cohorts and/or other information be used for case-mix adjustment?

We grouped major cancers based on similar costs and for purposes of administrative simplification.

c. Pages 20-21 suggest that PCOP communities would be required to adjust the cost of care metrics by certain factors (such as cancer type, presence of a secondary malignancy, bone marrow or stem cell transplant, clinical trial participation, and adjustments for missing cost data e.g., prescription drug data), but adjustment for other factors such as age and sex of the patient would not be required. What, if any impact is this expected to have on the performance data?

In experience, complexity in risk adjustments models are correlated to the overall risk that a model poses to its participants. OCM's goal was to measure ALL aspects of cost and apply that calculation to a two-sided risk model, whereby a physician must write a check to Medicare if their costs are above the predicted amount. Despite a highly complex model and multiple revisions, there are still flaws in the methodology that have a great impact on results.

In contrast, PCOP measures specific costs – ED, admissions, and maintenance/supportive drug costs, and including those as a third of our methodology. This poses less risk to the provider and allows for a more selective use of risk factors to only those that are meaningful to our specific measures.

8. **Care Delivery Requirements:** Why are some of the proposed care delivery requirements included in both Tracks 1 and 2 of the PCOP model, while others are restricted to Track 2? Is it primarily related to cost, or were other factors considered in making this determination?

PCOP's two tracks, and associated care delivery requirements, were designed to meet practices where they are at in their journey towards value-based care. Practices who have not participated in OCM or private payer pilots may gravitate towards track 1, giving them time to implement new practice transformations throughout the model. Those who have participated in OCM or applied an oncology medical home model may choose track 2.

9. Clinical Pathways and Adherence to Clinical Treatment Pathways Performance Measure: Page 2 of the proposal states that "Clinical pathways play a key role in the success of PCOP. Communities are encouraged to adopt a single pathway for all payers and providers in the model. Studies have shown that application of value-based clinical pathways . . . result in lower anti-cancer and supportive care drug costs." Since clinical pathway adherence is one of the central mechanisms through which the PCOP model proposes to

improve quality and reduce cost, and is a key component of the performance methodology, we'd like to understand more about aspects of the proposed clinical pathways, the proposed guideline management process, and the proposed clinical pathway adherence measure. Please address the questions below.

a. Do the proposed clinical pathways go beyond hematology/oncology to include, multiple cancer specialties or do they primarily focus on the chemotherapy related portion of treatment?

There are well-developed radiation pathways and symptom management pathways available. In our care delivery requirement and adherence measure, we have focused on use of chemotherapy/biologic therapy pathways due to the high cost of these agents and the importance of measuring appropriate utilization.

- b. Please provide more detail regarding how clinical preferences related to patient preferences are included in the clinical pathways (e.g., whether to have surgery or radiation or chemotherapy or watchful waiting, or palliation vs. active treatment).
 - O Some of the pathways have various options, allowing for clinician discretion. How are patient-centered preferences reflected in the pathways and flexibilities vs. flexibilities applied as a result of and based solely on physician judgement resulting from clinically-based impressions only? Further, how might such flexibilities influence improvements in quality and reduced spending?

In 2018, ASCO published a study of four major pathway vendors against ASCO's criteria for high-quality pathways. All four met the requirement to account for differences in patient characteristics and/or preferences.

o In light of the PCOP model's emphasis on adherence to clinical guidelines with appropriate accommodation for patient preference, how would the proposed model use clinical outcomes – including those driven by patient preferences – to improve the clinical guidelines?

PCOP includes measurement and transparency. Measurement of quality, cost, and use of evidence-based medicine. Transparency is sharing results of each of these areas with all stakeholders. Through measurement, we may find that practices following certain pathways have improved quality or cost metrics. This allows for continuous feedback to improve.

c. Please describe in more detail how Adherence to Clinical Treatment Pathways would be measured. For example with regard to determining the treatment decisions determined to be on-pathway (p 16), would all treatment decisions be considered equal in this formula without weighting or other factors such as relative importance?

Adherence is based on each treatment regimen given – initial therapy and subsequent lines of therapy. A provider choosing a non-pathway regimen will not receive partial credit based on overlap of specific ingredients. For example, if the recommended regimen is FOLFOX6, a provider will not receive partial credit for selecting FOLFOX6+bevacizumab.

d. Additionally, page 16 states that pathway adherence should be "adjusted by weighting a provider's individual disease adherence against the overall proportion of treatments by disease within the pathway program's aggregate." In Table 6.1 in the proposal (p 17), "Example Adjustment of Overall Pathways Adherence by Disease," please clarify what the third column, "Aggregate Proportion of Treatment Decisions" represents and explain how it would be possible for overall adherence rates to be as low as 72% in the examples in Practice A and B, if the clinicians would largely be defining the pathways they will be held accountable against.

Pathways are defined by expert panels, either institution-specific or national collaborations.

Because it is impossible for pathways or guidelines to account for every treatment scenario, patient characteristic, or preference, as well as drug shortages, payer requirements, etc., expected adherence is 80-90%. It is our experience that certain treatment pathways have better or worse adherence rates for certain diseases. This may be due to complexity of the disease or that a pathway did not account for as many patient characteristics or preferences in their design.

Adjustment by disease accounts for a situation where one provider may happen to see a greater proportion of patients for a disease in which the pathways fails to equally perform.

e. Please provide more information regarding why ASCO believes that the proposed adherence to clinical treatment pathways measure is a well-validated measure of quality and, as constructed, is likely to lead to reductions in costs without negative consequences (e.g., stinting)?

In our criteria for high-quality pathways, we require that pathways balance efficacy, toxicity and cost in their recommendations, commonly in that order. Efficacy ensures that the best treatment is on pathways, regardless of cost; whereas clinically equivalent treatments may be filtered by which is higher

or lower cost. This approach drives value-based decision-making, while guarding against stinting of care.

10. **Radiation and Surgical Oncology Services:** Page 14 of the proposal indicated that the scope of CPOC in a given PCOP community may also include radiation and surgical oncology services. However, ASCO indicated in its 4-28-2020 response to the PRT's questions that while radiation and surgical oncology services were listed as potential optional services for Track 2, these services were not included in the CPOC payments as modeled in the proposal. Why were these services excluded from the calculations of potential savings associated with the proposed PCOP model?

PCOP is designed to address the services and phase of care managed by the medical oncologist. We would like to see a community apply multiple models for cancer patients, including surgical episodes, radiation, and PCOP.

11. **Potential Contributions of the PCOP Model:** ASCO provided some information about how the proposed PCOP model differs from current Center for Medicare & Medicaid Innovation (CMMI) oncology models in its 3-16-20 response to the PRT's questions. In that response, ASCO emphasized the PCOP model's focus on clinical practice transformation, the PCOP model's "balanced performance methodology," and the PCOP model's method of introducing financial risk through the use of consolidated professional service payments for oncology care that are adjusted for performance on a prospective basis. Are there any additional features that ASCO would like to highlight regarding how the PCOP model differs from other oncology models?

As you mentioned in your question, PCOP is a clinical transformation model. ASCO believes that improvements in clinical care delivery is required and achievable in an oncology medical home. The associated care delivery requirements, performance methodology, and financial incentives are designed to support clinical transformation.

The use of clinical treatment pathways to address drug utilization is a core component of PCOP and has demonstrated control of drug expenses while maintaining appropriate care.

Finally, we designed PCOP with multiple payer participation in mind. Through use of a common care delivery model, shared measures and performance improvement methodology, and collaboration in data sharing, PCOP offers practices opportunity to apply the PCOP model to all patients, regardless of payment source.

12. **Basis For Achieving Savings Through Reduction of Admissions and ED Visits in Oncology:** ASCO indicated in its 4-28-2020 response to the PRT's questions that "there has been a profound shift from inpatient to outpatient treatment modalities in the delivery of oncology drug treatments," and "a sizable portion of remaining admissions . . . are due to symptoms resulting from the cancer or cancer treatments, rather than planned admissions for

the administration of chemotherapy." ASCO also indicated that studies show that "an opportunity to achieve savings through reduction of admissions and ED visits remains persistent in oncology." Please identify any studies which provide evidence indicating that the use of oncology medical home-like care delivery requirements by hematology/oncology providers can result in savings through the reduction of unplanned hospital inpatient admissions and ED visits.

Mendenhall MA, Dyehouse K, Hays J, et al: Practice transformation: early impact of the Oncology Care Model on hospital admissions. J Oncol Pract, 14(12), e739-e745, 2018.

Handley NR, Schuchter LM, Bekelman JE: Best practices for reducing unplanned acute care for patients with cancer. J Oncol Pract, 14(5), 306-313, 2018.

Daly B, Balwin-Medsker A, Perchick W: Using remote monitoring to reduce hospital visits for cancer patients. Harvard Business Review, November 1, 2019.



CHAIR OF THE BOARD

Howard A. Burris, III, MD, FACP, FASCO

PRESIDENT

Lori J. Pierce, MD, FASTRO, FASCO

PRESIDENT-ELECT

Everett E. Vokes, MD, FASCO

PAST PRESIDENT

Monica M. Bertagnolli, MD, FACS, FASCO

TREASURER

Laurie E. Gaspar, MD, MBA, FASTRO, FACR, FASCO

DIRECTORS

Ethan M. Basch, MD, MSc, FASCO

A. William Blackstock, MD, FASCO

Lisa A. Carey, MD, FASCO

Lee M. Ellis, MD, FACS, FASCO

Tara O. Henderson, MD, MPH, FASCO

Reshma Jagsi, MD, DPhil, FASTRO, FASCO

> Michael P. Kosty, MD, FACP, FASCO

Elizabeth A. Mittendorf, MD,

Tony S. K. Mok, BMSc, MD, FRCP(C), FRCP (Edin.), FHKCP, FHKAM (Medicine), FASCO

Elizabeth R. Plimack, MD, MS

Eric J. Small, MD, FASCO

Enrique Soto Pérez de Celis, MD, MSc

Michael A. Thompson, MD, PhD, FASCO

Tracey F. Weisberg, MD, FASCO

EX-OFFICIO MEMBERS

CHAIR, CONQUER CANCER BOARD Thomas G. Roberts, Jr., MD, FASCO

CHIEF EXECUTIVE OFFICER Clifford A. Hudis, MD, FACP, FASCO

2318 Mill Road, Suite 800 Alexandria, VA 22314 T: 571-483-1300 F: 571-366-9530 www.asco.org

Via Electronic Submission

August 31, 2020

Physician-Focused Payment Model Technical Advisory Committee C/o US DHHS Assistant Secretary for Planning and Evaluation, Office of Health Policy

200 Independence Avenue, SW Washington, DC 20201

Re: Response to the Preliminary Review Team Report on the Patient-Centered Oncology Payment Model

Dear Dr. Bailet and Members of the Committee:

Thank you for the opportunity to discuss ASCO's Patient-Center Oncology Payment Model (PCOP) at the September 15, 2020 Public Meeting. We have had an opportunity to review the Preliminary Review Team (PRT) Report and share the following comments for consideration by the Committee.

We appreciate the thorough review undertaken by the PRT in reviewing our proposal and for providing thoughtful feedback. We are encouraged that many of the PRT's findings agreed that PCOP places value over volume and ensures patient safety and choice while encouraging improved care coordination. The PRT's characterization of PCOP as a model that "emphasizes quality improvement through practice transformation and a community-wide, multi-payer, hematology/oncology care provider and stakeholder approach" is entirely consistent with ASCO's vision for this framework.

Our comments below pertain to areas where we differ with the PRT's findings regarding PCOP's alignment with criteria for physician-focused payment models. This letter addresses the PRT's qualitative ratings for criteria 1-3. We ask that the Committee consider these comments before making its final determinations.

Scope: PCOP expands upon the Centers for Medicare & Medicaid Services (CMS) portfolio of alternative payment models

The PRT concluded PCOP does not meet criteria 1 (scope), noting that CMS has an existing alternative payment model for oncology. Given that the current Oncology Care Model (OCM) concludes at the end of 2021 and CMS has yet to finalize a new model, we ask that the Committee rate PCOP as "Meets Criterion" or "Meets Criterion and Deserves Priority Consideration." This would be consistent with prior Committee determinations supporting positive recommendations for the *Oncology Bundled Payment Program Using CNA*-

Guided Care¹ and Making Accountable Sustainable Oncology Networks (MASON)² proposals.

The PRT rightfully notes that OCM is limited in scope, with 139 practices participating as of February 2020 (now 138³), representing approximately 5% of all hematology/oncology practices. OCM has experienced a decrease of 52 participating practices in the past 3 years, with much of the decrease corresponding with a December 2019 deadline of practices having to accept two-sided risk if they have not previously achieved a performance-based payment. ASCO's work with a diverse group of practices suggests they are willing to assume financial risk. The practices' reluctance to assume risk in the context of OCM relates to their lack of confidence in the prediction model and retrospective calculation of performance in its two-sided risk methodology.

We do not believe that extension of the current OCM model—beyond what is necessary for stability during the public health emergency or to bridge a gap prior to a new model—will achieve the desired value based care delivery for Medicare beneficiaries. In 2019, CMS released an informal request for information on a potential Oncology Care First (OCF) model.⁴ The proposed OCF model made several changes to OCM, many of which are features of PCOP. However, OCF retained the prediction model and retrospective calculation of financial risk that resulted in reduced participation within OCM. Given that OCF has not yet been proposed in administrative rulemaking, we recommend that the Committee continue to explore other oncology models to replace OCM at its conclusion.

Quality and Cost: PCOP's care delivery model reduces the total cost of care for cancer patients

The PRT expressed concerns regarding PCOP's ability to reduce total cost of cancer care. The PRT cited results from a recent evaluation of OCM, which showed that participating practices, in aggregate, failed to achieve target cost savings. ASCO interprets the evaluation of OCM differently than the PRT. First, OCM's estimated reduction in cost prior to model payments of \$23 million in period 1 and \$46 million in period 2 demonstrates the potential for reductions in the total cost of cancer care. Further, the \$32 million in performance-based payments over the first two periods is evidence that several practices in the model achieved savings that surpassed model payments and OCM's 4% discount factor.⁵ The report does not address possible reasons

¹ In its Report to the Secretary of Health and Human Services: Comments and Recommendation on Oncology Bundled Payment Program Using CNA-Guided Care, the Committee included a rating of "Meets Criterion" for Criterion 1.

https://aspe.hhs.gov/system/files/pdf/255906/HMHCotaReportSecretary.pdf

² In its Report to the Secretary of Health and Human Services: Comments and Recommendation on Making Accountable Sustainable Oncology Networks, the Committee included a rating of "Meets and Deserves Priority Consideration" for Criterion 1.

https://aspe.hhs.gov/system/files/pdf/255731/PTACReportIOBS.pdf

³ CMS reports 138 participating practices at https://innovation.cms.gov/innovation-models/oncology-care, as of August 31, 2020.

⁴ Oncology Care First Model: Informal Request for Information. https://innovation.cms.gov/files/x/ocf-informalrfi.pdf

⁵ Oncology Care Model – Third Annual Evaluation Report: Performance Periods 1-3. https://innovation.cms.gov/data-and-reports/2020/ocm-evaluation-annual-report-2

that some practices achieved success while others did not. It is clear, however, that participating practices did not consistently employ recommended care management services.⁶

In this update of PCOP, ASCO identified and addressed a number of flaws within OCM, including its lack of a consistent care model rooted in proven strategies to reduce the total cost of care. In our proposal, we cited numerous studies showing that use of clinical pathways and deployment of the oncology medical home model of care significantly reduce cost of drug treatments and hospitalizations. It is for this reason that PCOP includes clear and comprehensive care delivery requirements for participating practices.

Further, it should be noted that PCOP's care management and performance incentive payments are intentionally designed to reward practices that demonstrate improvement in cost and quality, while reducing payments to practices failing to perform within the model. OCM's monthly enhanced oncology services payments were modeled to equal 4% of total cost of care, providing practices the necessary resources to transform their care delivery. However, OCM lacks the ability to adjust such payments based on performance. ASCO likewise modeled PCOP's care management payments based on total cost of care; however, we set such payments at 2% of total cost of care for track 1 participants. The remaining 2% is varies based on practice performance. This structure, plus the requirement that practices move to track 2 and consolidated payments by year 3, prevents practices from collecting 4% care management payments for years without demonstrated improvements to quality and/or cost savings.

Quality and Cost: PCOP's care delivery model mitigates the risk of stinting of care through use of clinical pathways

The PRT has noted on several occasions that the PCOP risk framework creates potential for stinting of necessary care. We agree that, regardless of the payment model, every patient should receive evidence-based, high quality cancer care. PCOP mitigates this risk through a comprehensive suite of care delivery requirements and the requirement to demonstrate compliance with high quality clinical pathways. Both elements are enforced in the performance methodology.

In its Policy Statement on Clinical Pathways in Oncology,⁷ ASCO recommended that pathways "should promote the best possible evidence-based care in a manner that is updated continuously to reflect the rapid development of new scientific knowledge." ASCO continued its work on clinical pathways with the development of "ASCO Criteria for High-Quality Oncology Pathway Programs," included in our proposal. In 2018, ASCO published an evaluation of four commercially available pathway providers and found that all four met criteria that pathways are "based on the best available scientific evidence" and "account for differences in patient characteristics and/or preferences."

PCOP not only requires that practices follow clinical pathways in patient care, but also that practices must track and report adherence to such pathways and includes pathway adherence in its performance methodology. Use of and adherence with clinical pathways within PCOP

⁶ Included in OCM's Third Annual Evaluation Report is a tabulation of 177 participating practices' OCM Practice Transformation Plans and results from 13 site visits in year two. Results include that only 64% of practices used protocol-driven nurse triage lines for support between clinic visits and/or after hours and only 4 of 13 visited sites offered same-day urgent care visits.

⁷ https://ascopubs.org/doi/full/10.1200/jop.2015.009134

⁸ https://ascopubs.org/doi/full/10.1200/JOP.2016.019836

⁹ https://ascopubs.org/doi/full/10.1200/JOP.17.00033

ensures that patients receive the most appropriate care, addressing cost as well as preventing stinting of necessary care.

Payment Methodology: PCOP addresses in detail how its payment methodology achieves the goals of the PFPM criteria

We believe PCOP meets criterion 3 requirements. As noted by the PRT, PCOP's payment methodology provides financial support for clinical practice transformation and incentives practices to improve quality and cost of care. Along with two participation tracks with corresponding care delivery requirements and financial incentives, PCOP introduces financial risk through partially consolidated payments adjusted based on practice performance. As the PRT states in their report, this component does not exist in the current OCM. Based on these statements, we believe PCOP clearly meets criterion 3's requirement that practices are paid in a method to achieve the goals of the PFPM criteria and differs from current payment methodologies.

The PRT does mention in their summary of the rating that they are concerned with certain flexibilities provided to non-Medicare payers, including the ability to extend the deadline for track 2 and consolidated payments based on their own business interests. Providing some accommodation or flexibility in payment methodology for non-Medicare payers is both appropriate and necessary to encourage participation in multi-payer models. Despite our desire that non-Medicare payers adopt the full payment methodology, private payers must comply with state laws governing which health plans may offer capitated or risk-based payments and purchaser requirements for self-insured plans or other business requirements. ¹⁰ To achieve necessary payer alignment, PCOP calls for payers to adopt the care delivery requirements and performance methodology according to the model but must provide flexibility in use of alternative payments. Similar flexibilities exist within other CMS models and does not preclude a model from meeting the PFPM criteria.

Thank you again for the opportunity to further discuss PCOP on September 15, 2020. We hope that this letter assists in your evaluation and recommendation of the model and hope that we can continue to work with the Administration to achieve the value-based care delivery system to benefit our patients.

Respectfully,

Stephen S. Grubbs, MD Vice President, Clinical Affairs American Society of Clinical Oncology

Jeffrey C. Ward, MD Medical Oncologist Swedish Cancer Institute

Blasé Polite, MD, MPP Professor of Medicine University of Chicago Medicine Brian Bourbeau, MBA
Division Director, Clinical Affairs
American Society of Clinical Oncology

¹⁰ CMS makes similar accommodations within Comprehensive Primary Care Plus. See pages 5-6 of Payer Solicitation FAQs. https://innovation.cms.gov/files/x/cpcplus-payersolicitationfaq.pdf.

PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

+ + + + +

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL WITH THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) SUBMITTERS

+ + + + +

TUESDAY, JULY 21, 2020

5:30 p.m.

PRESENT:

JENNIFER WILER, MD, MBA, PTAC Committee Member PAUL CASALE, MD, MPH, PTAC Committee Member CHARLES DESHAZER, MD, PTAC Committee Member

STELLA (STACE) MANDL, Office of the Assistant Secretary for Planning and Evaluation (ASPE) AUDREY MCDOWELL, ASPE

BRIAN BOURBEAU, AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO)
STEPHEN GRUBBS, MD, ASCO

JIM CORDES, Neal R. Gross & Co. (NRGCO)
Transcription

1	P-R-O-C-E-E-D-I-N-G-S
2	5:31 p.m.
3	MS. MANDL: Good evening. This is
4	Stace Mandl. So, we're all here. So, I'll go
5	ahead and just kick things off.
6	First of all, thank you very much for
7	joining this call, to everybody. We're going to
8	be just doing very, very brief introductions.
9	And Jennifer, is it okay with you if I
10	just go ahead and start all of that?
11	DR. WILER: Please do.
12	MS. MANDL: Okay. Great. So, as we -
13	- someone just joined. Hello?
14	MR. MOIDUDDIN: Hi Stace, this is Adil
15	Moiduddin from NORC.
16	MS. MANDL: Okay. Great. We're going
17	to go ahead and get started, Adil. So as we
18	know, the American Society of Clinical Oncology,
19	ASCO, has submitted to us a proposal for the
20	Physician-Focused Payment Model Technical

Advisory Committee, also known as PTAC, regarding

the Patient-Centered Oncology Payment Model,

1 PCOP.

And this is a meeting that has been called by the Preliminary Review Team, also known as the PRT, that is reviewing this proposal, in order to ask some questions, or some follow-up questions with ASCO regarding the proposal.

So, what we're going to start off now, is just to do some very brief introductions. I'll start with myself.

And just as a reminder that -- to identify yourselves for the transcriptionist, and that the call is being recorded.

So, I am -- so, I'm with the Department of Health and Human Services. I am the PTAC Staff Lead here at ASPE. And we support the Preliminary Review Team.

And we have online here other folks from ASPE as well as our contracting staff from NORC including, as I said, a transcriptionist.

So we just want to remind everyone that this is recorded, as I said. And that the - - so where possible, as you have discussion and

1 chime in, just go ahead and just say your name. 2 So again, this is Stace Mandl. I'm going to hand it over to Audrey to introduce 3 4 herself. And then quickly through the NORC team so that the transcriptionist has a -- has a list 5 6 of who attended on our end. Thank you, Stace. 7 MS. MCDOWELL: My name is Audrey McDowell. And I also work in 8 ASPE. And I'm also part of the team within ASPE 9 10 that's supporting the PRT. I'm now going to ask the members of 11 12 our contracting staff to introduce yourselves and indicate your affiliation. 13 Thank you, Audrey. 14 DR. DEVERS: This 15 is Kelly Devers, NORC. I'm the ASCO PRT staff 16 support to ASPE and the PRT. 17 MS. COLLIGAN: This is Erin Colligan and I'm supporting Kelly with this work. I'm a 18 19 senior research scientist at NORC. MS. AMERSON: Hi, this is Amy Amerson, 20 I'm the PTAC logistics lead. 21

MOIDUDDIN: And this is

MR.

Adil

1	Moiduddin. I'm the NORC Project Director for the
2	project.
3	MR. WALDO: My name is Dan Waldo, I
4	work for Actuarial Research Corporation. We're
5	subcontractors to NORC.
6	MS. MCDOWELL: Well, thank you to the
7	NORC team. Now we will turn it over to Dr.
8	Jennifer Wiler and the PRT.
9	DR. WILER: Thanks Audrey. Hi, I'm
10	Dr. Jennifer Wiler. I'm an emergency physician
11	by training.
12	I'm a professor of medicine and
13	business and serve as the Chief Quality Officer
14	of UC Health Denver. And I'm a co-founder of our
15	health system's CARE Innovation Center.
16	And I have the pleasure of being the
17	chair of this PRT. And I'd love to have our
18	members introduce themselves.
19	Paul, would you like to go first?
20	DR. CASALE: Sure. So, Paul Casale.
21	I'm a cardiologist by training and lead
22	population health for New York-Presbyterian,

Weill Cornell, and Columbia. 1 2 DR. WILER: And Charles? DR. DESHAZER: Hi, Charles DeShazer. 3 4 Internist by training, and the Chief Medical Officer for Highmark Health. And SVP of Clinical 5 6 Informatics and Medical Policy for the Highmark, 7 Inc. organization in Pittsburgh. DR. WILER: Great, thanks. Everyone 8 who's on the phone, since we have so many folks 9 10 that are joining I'll ask that those who aren't speaking, if they will mute themselves since 11 we're hearing a lot of feedback. 12 13 So, thanks to our ASCO representatives for being here today. I'll ask you both to 14 15 introduce yourselves. And then we'll talk a 16 little bit about how we'll spend our hour. 17 Brian, would you like to go first? DR. GRUBBS: Yeah, thanks. Hi, Steve 18 19 Grubbs. I'm -- and thank you again for allowing us to have this conversation with you today. 20

We really appreciate the time you've

already put into this. It's clear from your

21

1 questions that you've really delved into this 2 proposal. I'm medical oncologist. 3 а I've 4 practiced for 31 years in the Newark/Wilmington, Delaware area. And I've been at ASCO five years 5 as the Vice President of our Clinical Affairs 6 7 Department. And we oversee ASCO's activities in 8 payment reform. And Brian, will you introduce 9 10 yourself, please? 11 Yes. This is Brain MR. BOURBEAU: I am the Division Director of Practice 12 Bourbeau. 13 Health Initiatives and Payment Reform here at the 14 American Society of Clinical Oncology. 15 DR. WILER: Wonderful. Well, thank 16 you both for making time. Here in Denver it's 17 not yet evening. 18 So, thanks for working into the 19 evening to accommodate also our schedules. It's 20 tough to get everyone on the phone.

As I believe everyone on the phone

knows, but just to make sure that we have said it

21

explicitly, our purpose today is to hear answers to the questions that we've posed. And I know that those were provided to you in writing before.

But the PRT is unable to provide any technical assistance. Nor are the PRT members able to provide any feedback that might be perceived as deliberation.

So, if that were to occur, I would have to call that as out of order. And staff are here also to hold us accountable for that.

The next is, even though we have an hour, I assume it's going to go quite quickly.

And we have posed to you 12 questions.

And so really, I will leave it up to our ASCO colleagues to see how you'd like us to work through this list.

I can leave the floor open to you to have you describe the work. But you really do, you know, I need to call the meeting at the time certain when it arrives.

So, you know, we will get through what

we can. My first question before we decide how you want to go through these questions is, will you be anticipating providing us with also written responses?

Or is your expectation that during this call we'll cover all of the topics?

(Simultaneous speaking.)

DR. GRUBBS: Yeah, go ahead Brian.

MR. BOURBEAU: Yeah. Yeah, I think we can provide written responses afterwards and you know, focus today, we'll give kind of the brief answer today, and see if there is any follow-up questions that we can then either answer or put in writing.

DR. WILER: Okay, great. Maybe we'll revisit that at the end of our conversation today. The process is one that's also very onerous on you all, so we want to be respectful also of your time. But to make sure that, you know, we fully understand the proposal so that when we are asked to deliberate and evaluate, we have all of the information.

So with that, you gentlemen have the floor.

MR. BOURBEAU: Great. Thank you. So, this is Brian Bourbeau with ASCO. And the first question that you had was regarding total cost-of-care.

And whether total cost-of-care included Parts A, B, and D. Whether it included all services. And then how we utilize total cost-of-care to calculate our care management payments and performance improvement payments.

And so, the first answer is, we did utilize Parts A, B, and D in our total cost-of-care calculations. This total cost of care was calculated on a monthly basis and then spread out between what stage of care a patient was at.

Were they a new patient, were they a patient on active treatment, or were they a patient who had been monitored, whether in palliative or survivorship mode there.

And so it did include all three parts. Not everyone in the data set had Part B, and we

accounted for that. So, we treated all patients as if they had Part B enrollment there. And so, when you look at the Part B numbers that's assuming coverage.

We did include all services, but they were all services that were given while the patient was receiving -- you know, in one of these parts of care. So, either a new patient, receiving chemotherapy or biologic therapy, or in an active monitoring phase.

And so, that would not include diagnostic work-up or biopsies or surgeries that would happen prior to the referral to medical oncology.

As we calculated our amount, we took a similar approach to the OCM's¹ methodology and how they calculated their Monthly Enhanced Oncology Services.

So when OCM calculated MEOS, they took the total cost-of-care. They then divided that up by the number of months and calculated 4%. And approximately 4% ended up being \$160 per

¹ Oncology Care Model

patient per month for that.

Now, they applied that in OCM regardless of what phase of care someone's in, regardless of whether or not that month happens to be more expensive than other months, you know, based upon where the patient's in the care. So they did flat amount across all months.

We took a couple of different approaches to that. One is we did adjust for what month of care a patient's in.

Certainly a new patient or a patient receiving active therapy IV^2 is more intense in services then a patient receiving hormonal maintenance therapy. And so, we adjusted for that depending upon what phase of care a patient was in.

Second, we did not want to just have a flat amount to where a practice, regardless of performance, receives the same monthly payment.

And so we established two different payments that happen each month.

First is a care management portion, a

² Intravenous Treatments

1	flat amount that you receive for the enhanced
2	services. And that's 2% for Track 1 and 3% for
3	Track 2.
4	The second is a performance incentive
5	payment. So, you're putting part of your monthly
6	payment at risk. And so that is up to 2% in
7	Track 1 and up to 3% in Track 2.
8	And so if your performance slips,
9	you're going to receive less total each month.
10	And if your performance increases, you'll receive
11	more. And so that differs from the flat 4%
12	within OCM.
13	So, I first want to see if there's any
14	follow-up questions to question one?
15	DR. WILER: Members of the PRT?
16	Charles or Paul?
17	DR. DESHAZER: No questions from my
18	perspective.
19	DR. CASALE: No, I'm okay. I don't
20	have any questions. Thank you.
21	DR. WILER: Thank you. Staff, any

questions?

1	MS. MANDL: This is Stace. None from
2	myself. But I defer to Audrey and Kelly on the
3	NORC side.
4	MS. MCDOWELL: No.
5	DR. DEVERS: None. This is Kelly from
6	NORC.
7	DR. WILER: Thank you. Okay, Brian, do
8	you want to proceed?
9	MR. BOURBEAU: Okay. Thank you.
10	Brian Bourbeau again here from ASCO. And the
11	next question was regarding cost-of-care
12	performance.
13	So, I'll give a little history here in
14	that the purpose of the model is to improve the
15	quality of care and reduce down the total cost.
16	And so when we look at cost-of-care,
17	we look first at the total cost of all services
18	that a patient receives. And we utilized data
19	from an all-payer claims database in Maine to
20	look at both Medicare and non-Medicare patients
21	and those costs.

22 And then we identified areas of high

cost, so what makes up that total cost-of-care.

And areas where the research has shown that practices can make a considerable difference in total cost-of-care. And those focused on unplanned admissions and ED visits and on drug utilization.

And so as we developed a performance methodology, rather than measuring total cost as a large number of some things that you can assess and some things you can't, we drilled down into those areas where we know that a practice can make a difference.

And so the first was unplanned admissions and ED visits. And those are two different measures in our cost-of-care performance.

The question that the group asked was whether or not they were for any condition, whether that was cancer or non-cancer.

And so our answer on that is, it is very difficult from coding to determine whether or not an admission is from cancer or non-cancer.

There are obvious ones like a motor vehicle accident or a gunshot wound.

But many, you know, conditions, the way that they're coded in hospital, and one hospital may code it in different orders than another. It relies upon appropriate documentation on inpatient of whether or not it's coded.

Present on admission indicators are not always reliable. And so for us, it was not reliable to attempt an avoidable oncology hospitalization or ED visit based upon coding.

And so instead, we landed on unplanned admissions. And unplanned excludes any planned surgeries, transplants, or admissions for chemotherapy that were planned, but includes all conditions that a patient may be admitted for. And then the same for ED visits, it includes all conditions.

And so that is very similar to the OCM-1 and OCM-2 measures that OCM initially -- they pulled back their admission one, but initially developed. The only difference being

that we moved from a six-month measure to a monthly measure.

The other question was on weighting of the total cost-of-care. And then there was also another question about weighting of metrics and the aggregate performance score.

So, for purposes of Medicare, we recommend weighting equally. However, outside of Medicare programs we purposefully built in flexibility to where a payer, practices and so on have some flexibility to adjust the weighting to meet their particular needs.

And so we would not lock them into equal weighting in the measures. But for Medicare we recommend equal weighting on cost-of-care measures as well as the aggregate performance score with the three categories of cost-of-care, quality, and pathway adherence.

So, I'll see if there's any questions regarding that answer. And I think that kind of covers questions two and three here.

DR. WILER: Any questions from the

PRT? Charles or Paul?

DR. CASALE: This is Paul. No, I'm good. Thank you. It was helpful, thank you.

DR. DESHAZER: Yeah. Good on my end as well. Thank you.

DR. WILER: All right, I'll ask a quick question. It's a little off-script, but can you describe how you would collect data on pathway adherence?

MR. BOURBEAU: Sure. So, we require that a practice utilize a decision support tool. And one of ASCO's criteria for a high quality treatment pathway is that that decision support tool track and report on pathway adherence and have the ability for the provider to document reasons why they were off pathway. We want them to, you know, review that as part of quality improvement activities to determine how to improve pathway adherence.

DR. DESHAZER: Hi, this is Charles. Quick questions, or follow-up questions. So, you guys -- are you guys thinking about embedding

into EHRs?

Or do you have specific systems in mind? And how are you thinking about the process to look at that, those results and provide that feedback?

And I would assume you'd want to adjust guidelines based on the outcomes.

DR. BOURBEAU: So, from a standpoint of integration into EHRs, there are a number of commercial pathway vendors that have mature decision support tools.

And the -- we reviewed four of them in a publication that we have cited in our proposal.

And they include American Imaging Management, they include Value Pathways by McKesson.

They include what's called ClinicalPath now by Elsevier. And they include New Century Health pathways.

And in each of them, they had decision support tools and they had begun to integrate some of them with EHRs. And each one, depending upon the pathway vendor and the EHRs, is at a

different place.

But for example, one that both Dr. Grubbs and I have experience with is fully integrated into the EHR, where all clinical information passes between the two. And then all four of them have the reporting capabilities that we ask for in the PCOP model.

And so there may be others today. And certainly, you know, we hear those. But those were the four that we evaluated and would say would be appropriate for use in PCOP.

DR. DESHAZER: Okay. Got it.

DR. GRUBBS: I think the other point to make here is, there is a differentiation between a pathway program and general guidelines.

A pathway program is much more specific that's been built for a combination of efficacy, toxicity, and then eventually cost if the other two find equivalent treatments.

And again, that's been one of the complaints by folks of large, broad guideline programs. It's not specific enough to achieve

1	the goal that we've just tried to do.
2	DR. DESHAZER: Okay.
3	MR. BOURBEAU: Yeah. And there were a
4	couple of other questions regarding pathways.
5	And we can go there next if there are no other
6	questions regarding the weighting.
7	And we can skip ahead to pathways and
8	then bounce back if you like.
9	DR. WILER: However you'd like to
10	proceed. Maybe question four?
11	MR. BOURBEAU: Okay, we'll go ahead to
12	question four. We'll hit pathways later in
13	conversation.
14	So question four is, how drug costs
15	are included in the model. And you know, when
16	are they added and so on.
17	And so, what we have is a performance
18	metric that's part of our total cost-of-care
19	category. And that is measurement of
20	maintenance/supportive care drug costs.
21	And so that begins in year 1. And
22	that measure would continue all five years of the

1 model.

Now, there was a couple of questions as to what we're referring to when we say year 0. And the year 0 is an opportunity to stand up all the infrastructure and allow a practice to put in place what's necessary, like if they don't have a pathway program, right, they need to put that in place in year 0.

And of course, you know, payers or government programs have a lot of activities that have to happen before you start your first performance year.

So, year 0 was that infrastructure year. But the first performance period starts in year 1. And that measurement of maintenance supportive care drug cost continues from year 1 to 5.

DR. WILER: Brian? Hello? Dr. Grubbs?

DR. GRUBBS: Yeah. I'm still here. Did we lose Brian?

DR. WILER: It sounds like we did. Do

1	you want to contact him and let him know he
2	dropped off?
3	DR. GRUBBS: Yeah. He's
4	MR. BOURBEAU: Hello. Are you able to
5	hear me?
6	DR. GRUBBS: There you go. We dropped
7	you.
8	DR. WILER: Okay. Now we now we
9	can hear you.
10	MR. BOURBEAU: I don't know. I heard
11	like a, I'm muted sound or something. And then I
12	was unmuted. So maybe that I don't know what
13	happened.
14	DR. WILER: Okay. I think we only
15	missed a couple of seconds. So, if you want to
16	proceed.
17	MR. BOURBEAU: Yes. So, the next
18	question, question five, was our application of
19	the care management and performance improvement
20	payment.
21	So as I mentioned, rather than paying
22	a, for example, flat 4% amount that OCM does for

the MEOS, we broke it out to a guaranteed portion and then a performance-based portion.

And so we expect that the care management payments, 2% for Track 1 and 3% for Track 2, would begin immediately in the model.

And then the performance incentive payments would not begin until year 2. And they're based upon performance in year 1.

The other question was that page 22 of the proposal states that there is a total cost-of-care metric that would not begin until year 3.

That reference in that graphic was an error.

So, I mentioned before, we had started looking at total cost-of-care. And then we refined the model by really looking at targeted cost-of-care opportunities with ED visits, admissions, and maintenance/supportive care drug costs.

And so ultimately, in the final draft of the proposal, we removed a total cost-of-care metric. And so that reference on page 22 is an error there.

1	Now, there is also a question
2	regarding how do you calculate the initial CMP
3	amounts. And they would be calculated based upon
4	historical numbers, very similar again to how in
5	OCM they had calculated their MEOS and historical
6	numbers first.
7	DR. WILER: Thank you. Any questions
8	from our PRT?
9	DR. CASALE: I think I'm good. Thank
10	you.
11	DR. DESHAZER: No questions.
12	DR. WILER: Questions from staff?
13	MS. MANDL: This is Stace. I don't
14	have any. Do how about others on the team?
15	DR. DEVERS: None from me, Kelly,
16	thank you. NORC.
17	DR. WILER: Okay. Thanks Brian.
18	You're on a roll. Next item.
19	MR. BOURBEAU: Thank you. So, Brian
20	again from ASCO for the transcriptionist there.
21	So, question number six is regarding some of the
22	phases of care, and going from new patient to

cancer treatment to active monitoring and so on.

And so the first question of 6a asks, what about the work up that's used as -- to make a cancer diagnosis? And whether or not that's included in the model, whether it be in the care management payment or in any consolidated payments or bundling of services there.

And so the answer is that, as a medical oncology model, anything that happens after that referral to the medical oncologist would be included.

And that's common in some cancers. I mean, there are referrals that are believed to be cancer and after further work-up by the medical oncologist, it's confirmed not to be cancerous.

There are other cases, especially in blood cancers, where there is not a confirmed diagnosis yet, and that further work-up is done by the hematologist or medical oncologist to reach a final diagnosis.

And so all of that work after it reaches the medical oncologist is included in

that new patient month. And so it was included in our analysis in various tables, considered for that care management payment, and considered in calculation of any consolidated payments.

Now, there are situations where a patient does flow back and forth from these different categories. And so, if you are a new patient and move to cancer treatments and then move to active monitoring, but after a subsequent scan there's a recurrence or an advancement of cancer, you would go back to cancer treatment. The only time where you would go into a new, new patient stage of care, is if you have a new primary tumor.

And so you've been through all the phases. You may even be out of active monitoring and be considered a survivor. But if there is a new primary tumor with a, you know, a new primary site, we'd switch you over again.

DR. WILER: Any questions from the PRT or from staff? Or NORC?

DR. CASALE: I'm good. This is Paul.

1	DR. WILER: All right. Hearing none -
2	- thanks Paul.
3	DR. DEVERS: None from NORC.
4	DR. WILER: Thank you.
5	MS. MANDL: And this is Stace. None
6	for myself.
7	DR. WILER: Okay. Great. We'll
8	proceed.
9	MR. BOURBEAU: Okay. Thank you. So,
10	Brian Bourbeau again here from ASCO. The next
11	set of questions under number seven was regarding
12	case mix adjustment in cancer groupings.
13	And so for PCOP, we wanted to simplify
14	some of the case mix adjustment that is done in
15	other models.
16	One of the reasons why a case mix
17	adjustment is so complex with certain models in
18	that they're trying to predict a total cost of
19	care prospectively, and do so in the most
20	accurate way.
21	Unfortunately, that was OCM's goal as
22	well. And despite a highly complex model and now

multiple revisions, there are still identified flaws in the methodology.

And so, what we're trying to do in PCOP is balance maybe some simplicity in the model. But also reducing the inherent risk of the model.

And so the PCOP methodology is not to attempt to predict total cost of care and then make a decision of who writes a check to whom. Whether it be from the practice to Medicare or from Medicare to a practice.

But of course, we've reduced that risk to putting a portion of your care management payments or a portion of fee-for-service revenue at risk, not attempting to reconcile a total cost-of-care at the end.

And so we've said at minimum, case mix adjustment needed to include cancer type, whether the patient has a secondary malignancy, so not a new primary, but bone metastasis, brain metastasis, liver, lung and so on.

Whether the patient was a transplant

patient. And you really kind of set those aside and calculate them differently. And whether or not the patient was on a clinical trial.

So that was the minimum. Now, if there are other categories which can improve that case mix adjustment, great.

But unfortunately, sometimes these complex case adjustments actually make the prediction less accurate.

So, for example, within OCM, we found that multiple myeloma patients with Part B coverage are grossly under-predicted. It's really because the formula is so complex that it actually, the introduction of that Part B case mix adjustment threw off the numbers more than improved them for multiple myeloma.

And so you know, we are very careful in the number of case mix factors we put into there.

The second question on rationale for proposed groupings, we had grouped into four categories. There are other models, for example,

Medicare's notice of proposed rulemaking for radiation oncology had 17 categories.

In looking at that, pancreatic, liver, bladder and upper GI, four different categories of those 17 have average amounts within 4% of each other.

And so for administrative simplification, do you create 17 different codes when at least for those four, one code could get you within 4% of everyone else.

And so, we had grouped into, you know, four categories based upon similar costs and kind of duration of the phases.

The third question, and I talked about some of it, the risk adjustment there. And I think I kind of fully answered that one in talking about the risk adjustment and why we included certain factors and not others.

DR. WILER: Thank you. Any questions from the PRT or from staff or NORC?

DR. CASALE: I don't have any. This is Paul.

1	DR. WILER: Stace or Kelly? Others?
2	MS. MANDL: Yeah. None from yeah,
3	this is Stace. None from myself.
4	DR. DEVERS: None from NORC. Thank
5	you.
6	DR. WILER: Okay. Great. You can go
7	ahead, Brian, proceed.
8	MR. BOURBEAU: Thank you. Brian
9	Bourbeau from ASCO. So, the next question I
10	I'll go ahead and answer questions eight and nine
11	here for interest of time, and then see if there
12	is any follow-up questions.
13	So, question eight was care delivery
14	requirements. And why we had Track 1 and 2, and
15	why some requirements were in Track 1 and others
16	were added into 2.
17	And really, this is about meeting
18	practices where they are in their journey towards
19	value-based care. And so, we're coming to the
20	end of the Oncology Care Model.
21	We have practices that have
22	participated in OCM and have invested, whether it

be their MEOS payments or Shared Savings into care delivery reform in their practice, and are ready to look at a model where you put in consolidated payments and additional requirements, innovations, and so on.

And so we would expect those practices to go into Track 2. And we expect more from them in their care delivery requirements.

We give a higher potential reward and higher care management and performance incentive payments to pay for that more advanced care. But -- and then we have more risk for them in the consolidated payments for oncology care portion.

But there are other practices that were not in OCM or may not be in private payer pilots.

And so to meet them where they are, we have Track 1, an opportunity to begin to innovate in care delivery and to receive moderate reimbursement and incentives for that. And so that's where Track 1 came from.

On question nine, we talked some here

about clinical pathways and adherence to clinical treatment pathways performance measures.

We mentioned already in this call there are a number of well-developed vendors both in content of the pathways and in decision support tools, reporting tools, and so on, on the IT side.

There -- question 9a is whether or not clinical pathways do go beyond hematology and oncology. And the answer is, they do.

We are measuring clinical treatment pathways because our focus and reason for doing so is based upon the high cost of drugs.

And so, it is ASCO's position that oncologists are not responsible for the list price of drugs. So, when you go into an antineoplastic drug cost discussion, the oncologist does not set that price.

What they do set is utilization. In clinical treatment pathways about the use of chemotherapy and biologics, measures unfold to make oncologists accountable for that utilization

1 question.

If you're adhering to a pathway that prioritizes efficacy, toxicity, and cost, and in lower cost, then we're going to, you know, hold you accountable for that. And you're ultimately going to have good outcomes both on the quality and cost side.

So, that's why we focused on those. There are radiation pathways that radiation oncologists may use.

There are symptom management pathways that a practice may use to help them with lowering their ED and admission costs. But that particular performance measure is on the drug treatment pathways.

There is also a question --

DR. GRUBBS: Brian. Brian --

MR. BOURBEAU: Yes?

DR. GRUBBS: This is Steve Grubbs.

One more thing I want to add to that I think is very, very important here.

A path -- a well-designed pathway

compliance program adds extra benefits. First of all, it makes sure that there's no stinting of care, meaning you're going to pick lower cost drugs to make your financial look better.

If they're inappropriate and they're not on the pathway, you're going to get dinged on that. The other thing is it standardizes care and begins to attack perhaps some of the difficulties we've had with healthcare disparities.

So, I think there's secondary gain to this other than, you know, the financial part of how we're using this.

MR. BOURBEAU: Thank you, Steve. So this is Brian Bourbeau with ASCO. There are also questions regarding pathways and options that they have.

Now, some pathways are more narrow than others in their number of options. But in general, they're certainly more restrictive than what you would consider to be a guideline.

And so I could pull a guideline for a

disease and a certain patient cohort, and maybe have 12 treatments that are listed in that quideline.

Some of them FDA-approved, and then some of them off medical lists. But some of those treatments are older. Some of them are now less efficacious. And yet they remain on the quideline because they have an FDA indication.

Pathways are more restrictive. They're looking at the most effective treatment. They're looking at toxicity then. If there are two treatments that have similar efficacy. And then after that, they're looking at costs. And so if there are two therapeutic equivalents and one is lower cost than the other, the pathway is going to limit.

Now, there are certainly, and part of our criteria, we require that pathways consider differences in patient characteristics and/or preferences.

And so there are some parts of, you know, patient characteristics, perhaps

performance status, that may change what regimen you select. There's also the fact that we are not expecting 100% compliance with pathways.

And here's why. If you attempt to build a pathway that is expected to be 100%, essentially what you end up with is that guideline with 12 options.

And so you're putting in all, you know, all types of options to account for every single scenario. And then you're unable to, you know, really determine performance there.

So, pathways have been narrowed down. But typically expect 80% to 90% adherence. And in my experience kind of the average adherence is 85%, because they understand that there will be situations where you go off a pathway.

Perhaps it's a patient characteristic that wasn't accounted for in the pathway. Perhaps there is a drug shortage, perhaps a specific payer requires in their medical policy that you use a different product than the one that's included in the pathway.

And so what we require is that you document the reason why. And then of course we're expecting overall good adherence.

So, there will be situations where you go off the pathway for the reasons that I mentioned.

Now, there was another question regarding adjustment of the pathways and why we would, you know, adjust based upon your case mix and really your disease mix.

And that's because in our experience, certain treatment pathways have better or worse adherence for certain diseases. So, they all perform at slightly different rates.

Perhaps they do well for lung cancer, but do poorly for multiple myeloma. And so a disease adjustment accounts for that based upon if you're the practice that has more multiple myeloma and your -- that your pathway vendor performs poorly on that one, we would adjust by disease.

Finally, I think that is it for

1	pathways. So, there are quite a few sub-
2	questions on that. Hopefully we covered them
3	all.
4	But if there are any follow-up
5	questions, we'd be happy to answer.
6	DR. WILER: Any questions from the
7	PRT?
8	DR. CASALE: No, I don't have any
9	questions, thank you.
10	DR. DESHAZER: None for me.
11	DR. WILER: So Brian, I do have a
12	question, you know, I think actually the PRT
13	members are pretty familiar with pathways in our
14	day jobs and understand and appreciate what
15	you've described in terms of utilization.
16	But and that you know, you'll never
17	have 100% compliance because it's not appropriate
18	to have 100% of patients, as you've described.
19	But I'm curious about, you know,
20	pathways clearly usually describe multiple steps
21	in a process, i.e., a bundle. And so, what will

the methodology be for bundle compliance for one

pathway of care, i.e., will you give credit if one element of the bundle is used, or there's an attestation that the pathway was used? Or is the expectation 100% compliance when it's deemed the pathway is appropriate in terms of bundle compliance?

MR. BOURBEAU: Okay, thank you, yeah, for the question. So, Brian Bourbeau here again from ASCO.

And so we have pathways that are built into regimens. And we would expect that the exact regimen is recorded.

And you would either be on pathway or off pathway. And so, if a regimen, if a pathway recommends FOLFOX plus Bevacizumab, we would expect FOLFOX plus Bevacizumab.

We would not accept FOLFOX alone as an alternative to what that pathway says. And the same if the pathway says FOLFOX-6 and you add Bevacizumab to it in a certain adjuvant setting, that would not pass.

And so we really do expect it at a

1 regimen level. Now, most of these pathways, you 2 know, you still make dose adjustments down if a patient is not tolerating treatment and so on. 3 4 It's really at the regimen selection 5 that the drug pathways for oncology are measured 6 upon. 7 DR. WILER: Thank you. Any other questions regarding question nine or pathways? 8 Hearing none, since we have 9 Okay. 10 about 13 minutes left, and a couple more items, 11 please proceed. MR. BOURBEAU: Okay thank you. 12 13 Bourbeau from ASCO. So, question number ten was regarding 14 regarding radiation and surgical 15 oncology and so on. 16 And we said, you know, these are 17 things that could be combined into PCOP, especially for those looking at bundled payments 18 19 and pay scale and so on.

So, PCOP is designed as a medical oncology model. We believe medical oncology is not only a distinct set of services, but a

20

21

22

certain phase of care for a patient that is not just acute phase of care, but more chronic management of condition. This is becoming, you know, more and more a part of medical oncology and cancer care here.

And so there are other models for radiation. There are episodes being designed by Medicare programs, Medicaid programs and others around different surgical oncology episodes like mastectomies and lumpectomies.

And so we like to see, you know, a group of practices and payers look at all three.

But PCOP itself is a medical oncology model.

And what we had mentioned in that section of the proposal is, we would like to see these different models come together and be implemented in the same number of stakeholders.

And then you know, final questions, question twelve was a question about citations and reduction of admissions and ED visits.

And I did include in the proposal and I will include in the follow-up letter a number

of citations.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

One of them that I'm a coauthor on, showing that the medical oncology home model, which is built into the care delivery reduction requirements, have shown of hospitalization and ΕD visits at multiple institutions.

And that's why we adopted them into the model. And then finally question eleven just, you know, potential contributions as a PCOP model.

And you know, we noted a number of differences in this model compared to others. But I would say the number one, if I have to do an elevator speech, is that we emphasize the clinical care delivery model first in what we want to see in advancement of quality and value in oncology. And then after that, we've aligned the measures, the payment incentives, performance methodology, and so on to support that innovation and improvement in the clinical care delivery model.

1	Steve, anything to add there?
2	DR. GRUBBS: Yeah, Brian. You've done
3	a wonderful job. I think you've answered the
4	question of how we see this entire program
5	working. Thank you.
6	DR. WILER: Any questions from the
7	PRT?
8	DR. DESHAZER: No questions.
9	DR. CASALE: Yeah. Yeah, no questions
10	from me.
11	DR. WILER: Any additional questions
12	from staff or NORC?
13	MS. MANDL: Jennifer I this is
14	Stace from ASPE. I do have one quick question if
15	that's if we have time. Or we can
16	DR. WILER: Please. We have nine
17	minutes.
18	MS. MANDL: Okay. If you could if
19	you guys could briefly go back over the
20	protections in place for for protections for
21	stinting.
22	That was something that sort of stood

out as you were discussing. And there was a little bit of static on the line.

So, I thought that would be very helpful if you could just walk through that a little bit more as far as protection from stinting. Thanks.

MR. BOURBEAU: Sure.

DR. GRUBBS: Yeah. I think I was the one that -- this is Steve Grubbs. I was the one that mentioned that.

If one is following a well-designed pathway program and care of your patients, and you're receiving that high level of compliance, what that means is you're providing the patient population you care for the appropriate care that's been designed into that compliance program.

It will protect you. You're off pathway if you give a lesser effective treatment that's not on that pathway.

So, it protects on the downside risk of patients getting less care than they should

for reasons that should not be considered. It also protects on the upside of patients getting too much care for their condition.

So, patients are protected both on the upside and the downside. And I'm going to add another point here. We certainly in medical oncology are very much in favor of patients with informed decisions joining clinical trials.

And all the pathway programs I know of, on a clinical trial you are considered on pathway. So, this also encourages what we feel is very important in the medical oncology space, clinical trial participation.

So, I think there's a lot of patient protection on the upside and downside of over treatment, under treatment, standardization of treatment, and also participation in clinical trial activity.

Brian, any comments to that?

MR. BOURBEAU: Yeah. I would just refer the group in our supplementary information, we included ASCO's criteria for high quality

1	clinical pathways.
2	And we expect that a pathway
3	establishes the methodology for prioritizing
4	efficacy, safety, and cost. And so typically
5	it's in that order where efficacy is first.
6	And so you would not be on pathway if
7	you are a less effective treatment than the
8	standard. And that prevents stinting.
9	DR. WILER: All right. Stace, does
10	that answer your question?
11	MS. MANDL: Yes.
12	DR. WILER: Or other questions for the
13	group?
14	MS. MANDL: Yeah. No, that answers my
15	question. Thank you.
16	DR. DEVERS: This is Kelly Devers from
17	NORC. I just had one question related to the
18	planned admissions.
19	Do they include scheduled, you know,
20	hip replacements or other non-cancer related
21	treatments?
22	MR. BOURBEAU: Yeah. So, the

unplanned admission measure would exclude any planned surgeries, whether that's cancer or otherwise.

So, if there is a planned surgery, it would be excluded as -- from the numerator.

DR. DEVERS: Thank you very much.

DR. WILER: Any other questions from folks on the phone of our presenters? So, Brian and --

MS. MANDL: Yeah, this is Stace.

DR. WILER: Yeah. Go ahead.

MS. MANDL: No, I'm sorry, Jennifer. I was just saying none for myself, I was also just checking in with my colleague Audrey here at ASPE.

MS. MCDOWELL: Yes, this is Audrey. There was a lot of static on the line. But, I just wanted to confirm in the context of question number five, whether in terms of the way that the performance improvement payment worked, is a portion of performance improvement payment withheld from CMP³ that then is paid out of, you

³ Care Management Payment

1	know, in year 2, or how does that work?
2	MR. BOURBEAU: Yes. This is Brian
3	from ASCO. And there's a little static on the
4	line. So, I didn't catch every word.
5	But, there was a question regarding
6	how those performance incentive payments were
7	applied. So, we had yeah, what we expect there
8	is that a practice in Track 1 would receive a
9	care management payment equal to 2% in year one.
LO	In year 2, it would continue that 2%
L1	payment, but now be eligible for up to an
L2	additional 2% that would be paid out in year 2.
L3	And so there's no withhold from year 1
L 4	to pay that out, it's simply added in year 2. So
L5	a practice with average quality and average costs
L6	and average adherence would expect, you know, the
L7	2% care management payment.
L8	And then they may get 1% in
L9	performance incentives. But we're not carrying
20	it forward or writing bulk amounts.
21	DR. WILER: Thanks Audrey. Any other

questions?

1	All right. Hearing none, Stephen and
2	Brian, we want to thank you so much for taking
3	the time to answer our questions, and not only
4	participate in the call today, but in such a
5	thoughtful way to get through so much
6	information.
7	We know it took a lot of preparation.
8	And you covered a lot of ground in a lot of
9	detail. And so we appreciate the time and effort
10	that you put into the questions we had and with
11	the responses given.
12	If there aren't any additional
13	questions, then I think we'll wrap up today.
14	I'll offer one more opportunity for folks on the

phone to ask any questions.

15

16

17

18

19

20

21

22

Paul or Charles, any other comments? DR. DESHAZER: Nothing from me.

DR. CASALE: No. I'm good thank you. No other comments. Thank you.

DR. GRUBBS: Well, this is Steve. want to thank you all for spending time with us today. And we did get this done in 58 minutes.

1	So, I think that was just where we
2	wanted to be. And Brian, I think we will send
3	back the responses we gave in writing so they can
4	so everyone can read that in addition to the
5	verbal responses we gave today.
6	DR. CASALE: Yeah. This is Paul. I'd
7	appreciate that. I think that would be very
8	helpful.
9	Thank you. And thanks for your time
10	this evening, everyone on the call. You've been
11	helpful. Thank you.
12	DR. WILER: Great. With that, thank
13	you very much. We appreciate it. Take care.
14	(Whereupon, the above-entitled matter
15	went off the record at 6:29 p.m.)
16	
17	
18	
19	

<u>C E R T I F I C A T E</u>

This is to certify that the foregoing transcript

In the matter of: Conference Call with the American

Society of Clinical Oncology

Before: PTAC

Date: 07-21-20

Place: teleconference

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Court Reporter

near Nous &