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ALSO IN THIS ISSUE



SP219

ZANUBRUTINIB STUDIES. Data for zanubrutinib (Brukinsa) were reported at the European Hematology Association, including results from ALPINE showing the Bruton tyrosine kinase inhibitor compares favorably with ibrutinib in relapsed and refractory (R/R) chronic lymphocytic leukemia/ small lymphocytic lymphoma. Updated phase 2 results from MAGNOLIA show effectiveness for adults with R/R marginal zone lymphoma treated with at least 1 prior line of therapy, [SP219-SP222](#).

ONCOLOGY VALUE COALITION.

Two online meetings of the Oncology Value Coalition, featuring faculty from City of Hope, Highmark Blue Cross Blue Shield, and Cardinal Health, convened discussions of the value of genomic testing for payers and employers and the rise of real-world evidence in the FDA regulatory process, [SP206-SP209](#).



ALVARNAS FEINBERG

GUIDELINES UPDATE.

Updated guidelines from the National Comprehensive Cancer Network for Waldenström macroglobulinemia have added zanubrutinib (Brukinsa) as a preferred regimen, [SP210](#).

**BIOSIMILARS UPDATES.**

The FDA cautions Amgen about an advertisement of its Neulasta Onpro device for delivery of pegfilgrastim, and a report highlights the discounts that come with biosimilar use, [SP227-SP228](#).



Make plans for our 10th anniversary meeting, September 23-24, 2021, in Nashville, Tennessee! See [SP211](#), [SP234](#), [SP244](#).



POLICY

Health Insurance, Blood Cancer Care, and Outcomes: A Literature Review

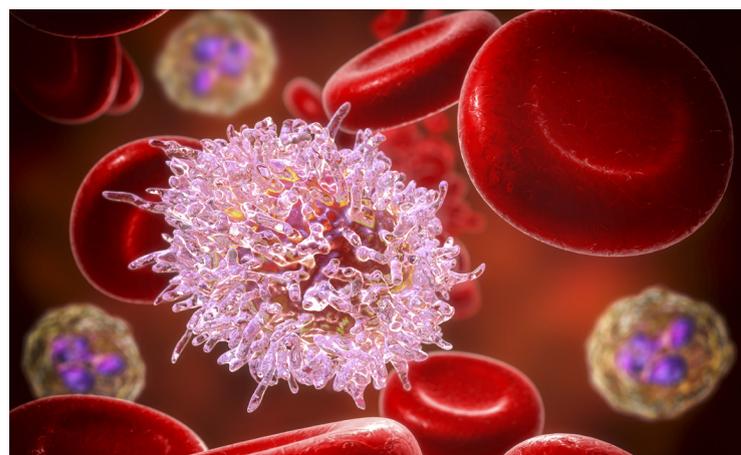
Karen Crotty, PhD, MPH; Marialanna Lee, MSc; Katherine Treiman, PhD; Maria Sae-Hau, PhD; Candi Wines, MPH; Catherine Viator, MS; and Elisa Weiss, PhD

INTRODUCTION

The Patient Protection and Affordable Care Act (ACA) established several health insurance reforms important to cancer care in the United States,¹ including prohibiting insurers from denying coverage or setting higher premiums on the basis of preexisting health conditions, expanding Medicaid eligibility to adults with incomes up to 138% of the federal poverty level, eliminating the Medicare Part D coverage gap or “donut hole,” and requiring commercial insurers to cover the cost of routine care that a patient receives while enrolled in a clinical trial. Yet despite these reforms, many patients with cancer continue to experience significant financial burden² and distress associated with their care, referred to as the “financial toxicity” of cancer.^{3,4}

Financial toxicity is particularly prevalent among patients with blood cancer, who are increasingly treated with expensive, orally administered anticancer drugs. A rapid rise in the cost of these drugs has offset the savings patients should have seen from the closing of the donut hole.⁵ Consequently, many of the more than 1.3 million people in the United States who are either living with, or are in remission from, blood cancer⁶ face higher out-of-pocket costs than patients with other cancers.⁷ Additionally, patients with blood cancer report a myriad of other access barriers, ranging from lack of insurance and inadequate provider networks to coverage denials. With recent growth in the availability of health plans that do not comply with the ACA's market reforms, these barriers are likely to grow.⁸

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An illustration of hairy cell leukemia, a form of chronic lymphocytic leukemia, showing an accumulation of abnormal B lymphocytes.

PAYMENT MODELS

Clinicians and Payers Expect to Wait and See Before Embracing CMS' MIPS Value Pathways

Erin Crum, MPH

QUALITY MEASUREMENT in federal health care programs has been around since at least 2007, when CMS introduced the Physician Quality Reporting System (PQRS) for providers caring for Medicare beneficiaries. The program continued to evolve, and it eventually became part of CMS' Merit-Based Incentive System (MIPS), CMS' first attempt to integrate several different incentive-based programs under one umbrella, including PQRS and meaningful use.¹ The goal of MIPS is to optimize patient care by utilizing financial incentives to encourage providers to deliver high-quality, cost-efficient care.

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PRACTICE TRANSFORMATION

ASCO, COA Release Updated Standards for Oncology Medical Home

Mary Caffrey

ON JULY 13, the American Society of Clinical Oncology (ASCO) and the Community Oncology Alliance (COA) released updated standards for the Oncology Medical Home (OMH), putting renewed emphasis on the importance of palliative care and ASCO's Quality Oncology Practice Initiative (QOPI), which seeks to promote safety and best practices in the administration of chemotherapy.¹ Details on the new standards were published in *JCO Oncology Practice*.²

A joint statement from the 2 groups stated that the new standards offers a roadmap for delivering “equitable, high-quality cancer care.”³

“In releasing the new standards, ASCO and COA seek to achieve a broad consensus among all stakeholders—including patients, clinicians, payers, purchasers, and employers—on what patients with cancer should expect and receive from their cancer care teams,” the groups said.

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Clinicians and Payers Expect to Wait and See Before Embracing CMS' MIPS Value Pathways

ERIN CRUM, MPH

CONTINUED FROM SP245

Although the program's intentions are good, stakeholders have shared criticism of potential structural flaws in MIPS; these flaws may serve to prevent widespread adoption and discourage commercial payers from fully embracing the program and similar risk arrangements structured around value-based care. CMS is attempting to rectify many of these critiques about MIPS by introducing MIPS Value Pathways (MVPs).² MVPs are disease state- or specialty-specific subsets of measures and activities that consolidate core concepts across the 4 separate performance areas in MIPS.

A closer look at what CMS is attempting to do with these specialty-specific MVPs, as well as ways they can be made more successful than MIPS, may provide some useful insight for clinicians and payers.

MVPs Strive to Eliminate Cherry-Picking of Quality Measures and Improvement Activities

One concern with the MIPS program is that it provides clinicians with full autonomy to select the quality measures and improvement activities that they want to report. The 4 performance areas—quality, improvement activities, promoting interoperability, and cost—are very siloed, rather than integrated. In its current format, clinicians can select quality measures where their performance is high, even if the measures are not relevant to the core activities of their area of specialty. Furthermore, clinicians can select from a full list of improvement activities for their 90-day attestation, even if the activity has been fully adopted at the practice for several years. In such cases, CMS is not achieving the intent of the program by stretching clinicians to adopt new, innovative solutions to drive improved patient care.

The new MVPs attempt to eliminate these silos and target the issue of cherry-picking, along with some other fundamental flaws in the MIPS program. To achieve this, CMS has indicated that the new MVPs promote targeted concepts across the 4 MIPS categories, making the program more meaningful and valuable by having clinicians report on measures and activities specific to their areas of practice. Different specialties will have a core set of measures relating to their areas of care that clinicians will be obligated to choose from, rather than selecting their top-performing measures from the full menu of quality measures and improvement activities. CMS' vision is to create a core set of measures and activities that are complementary and drive improvements in patient care, targeting specific disease areas or specialty care.

Factors That May Inhibit MVPs' Success

While creating a framework for more specialty-specific and meaningful participation in the MIPS program through MVPs is positive movement in the right direction, many issues will apparently still need to be addressed before widespread adoption is likely to occur and for the program to become successful and viable for the long term. These include the following:

NEED FOR CLARITY ON SCORING METHODOLOGY FOR MVP VS. TRADITIONAL MIPS PARTICIPANTS. CMS recently published the 2022 Proposed Rule containing additional criteria for MVPs. Contained in the Proposed Rule, CMS further described the potential scoring methodology. CMS has proposed to reduce

the reporting burden for MVP participants by requiring 4 quality measures from a MVP-specific measure set instead of the 6 required by traditional MIPS that can be selected across an inventory of approximately 200 measures. This will certainly help reduce “cherry picking” of measures where clinicians select measures based on performance, rather than relevance to the area of medicine for that specialty clinician. However, there is no timeline for when the transition to MVPs will be required and not optional. It seems that there should be scoring considerations to incentivize specialty clinicians to adopt MVPs to even the playing field with those who choose to continue participating in traditional MIPS.⁷

Additionally, for some specialties, no measures are applicable in certain categories. For example, no specific episode-based cost measures are appropriate for medical oncology. There is a single, broad total per capita cost measure, which is more relevant to primary care services provided to Medicare patients. If CMS determines that this cost measure is not appropriate, how would CMS reweight the points for the cost category to make sure it is still fair across the board? Simply put, many questions around how scoring will occur are still open.

OPTIONAL PARTICIPATION WILL PERPETUATE ADOPTION LAG.

CMS is currently planning a gentle, phased-in rollout for MVPs, which ultimately may make it optional for many clinicians. This may slow adoption of the program and create difficulties for the incentives and penalties associated with the MVP. With low participation, the necessary funds will be lacking to pay incentives, since funding for the incentives is supposed to come from penalties paid by poor performers. But with low participation, very few practices will be penalized, providing very limited funds for incentives. This is the same situation as exists in MIPS, where the incentive payment has been hovering around 1%. Performers in the top 80% to 90% are earning an adjustment of only 0.9% to 1.2%. These practices have invested significant dollars to implement MIPS, so many feel it has not been worth the investment.

DELAYED INFORMATION FROM CMS DOES NOT PROVIDE ACTIONABLE DATA FOR PARTICIPANTS. One of the biggest issues practices have articulated regarding MIPS—which will likely also be an issue with MVPs—is that the program is retrospective and provides no actionable data. Practices are just now seeing their MIPS positive or negative adjustments from their participation in 2019, representing a 2-year delay. Additionally, CMS does not provide actionable feedback throughout the year that would enable clinicians or practices to better understand areas for improvement. Consequently, no ongoing feedback or identification of patients is included in the practice's MIPS scoring (specifically, their cost measure and patients who will be attributed to them), so they are unable to effectively manage their patients' overall cost of care nor to implement processes during the performance year that would lead to effective improvements in quality care and cost efficiencies.

Without some kind of timely data sharing that provides meaningful information—meaningful enough for practices to adjust the care they provide—MIPS Value Pathways will most likely struggle the same way MIPS has. »



Erin Crum, MPH, is the director, quality management strategy, McKesson.

Making MVPs More Successful Than MIPS

Since the new MVPs are still in the developmental stage, CMS has opportunities to address issues that could help ensure long-term success. First and foremost, CMS must provide better access to data for clinicians, technology vendors, and measure developers.

Clinicians need timely data to make positive, effective change throughout the performance year, so information is meaningful, actionable, and current. Technology vendors need CMS to supply data and funding, as they are currently burdened to develop solutions and incorporate data sets to provide feedback to clinicians. However, there is no money in MIPS submissions due to low participation. Measure developers face similar problems, with no access to Medicare data that would enable them to better develop measures that leverage information from multiple sources. A positive approach would be for CMS to make available claims data and other data sources that developers could then incorporate into more meaningful quality measures.

Over the years, CMS has outsourced certain responsibilities for measure and registry development and support to third parties, including registries, state societies, specialty societies, and organizations like McKesson. However, these endeavors are costly, and there is no incentive to develop or support these measures when there is no revenue in the program for these activities. By incentivizing—ie, funding measure development or providing resources to support the measures once they are established—CMS could ensure that experts stay involved and perhaps even encourage more collaboration across key stakeholders to develop meaningful measures.

The new MVPs should also align with other programs, such as the Oncology Care Model (OCM),³ the Radiation Oncology (RO) Model,⁴ and Primary Care First.⁵ By ensuring that the MVPs are developed such that they align with other regulatory programs and initiatives, the same core messages can be used across the practice to support quality care. For example, the measures in the OCM could align with the measures CMS selects for the oncology MVP core set of measures. Having this alignment would likely drive incorporation of these core measures and activities as part of managed care payer arrangements.

By aligning under some core values or initiatives from these programs, practices can take certain activities across the entire patient population and monitor their success for all patients. This encourages measuring things that matter, enabling clinicians to “buy in” on a core set of services or activities that are applicable for all of their patients, regardless of a patient’s participation in a particular program. This alignment facilitates development of processes and procedures across the care team that focus on the core areas. These activities—including advance care planning, depression screening, and pain management, to name just a few—are essentially the services the practice will provide for every patient, as they are part of the right clinical approach and are also critical components of high-quality, comprehensive cancer care.

Not only should the new MVPs align across programs, they should also align components

within the quality measure sets that drive improved patient-centered care and emphasize initiatives known to be associated with reduced health care costs and improved outcomes in oncology. To be successful, the MVPs should be outcomes-focused, and not just broad-based process measures.

McKesson and The US Oncology Network Collaborate on a Patient-Centric MVP

McKesson, a leader in advancing value-based cancer care, has collaborated with The US Oncology Network (The Network), a network of independent, physician-owned community practices, to develop an oncology-specific MVP; it has been submitted to CMS for consideration to be included in the future MIPS framework. The Network represents more than 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, and the organization was instrumental in gathering input for the proposal.

This MVP addresses legitimate ways to improve specialty care and the patient experience, while reducing costs, when possible, through a more integrated approach than the current MIPS framework. It offers opportunities to improve the quality of care and value for cancer patients, as well as measures and activities that foster care coordination across care teams. This ensures patient-centric, personalized care that aligns with patients’ goals and wishes.

Unlike the existing MIPS program, the quality measures and improvement activities in McKesson’s MVP are meaningful to oncology. They measure items that matter to the oncology clinician, rather than holding them accountable for management of health care concerns better managed by other specialists, such as diabetes or other chronic conditions. The quality measures focus on components of care that prioritize patient involvement and the patient’s voice, which are critical to optimizing patient-centered oncology care. Many of the improvement activities stress shared decision-making in treatment choices, a core tenet of value-based care. Patient involvement is emphasized in such activities as development of a care plan and advance care planning initiatives; this fosters meaningful discussions with patients about their values and goals for treatment and end-of-life care.

With a strong emphasis on incorporating the patient voice to drive improvements in oncology care, McKesson’s MVP includes 2 patient-reported outcome measures: one to measure improvement in pain management, and a second that utilizes a comprehensive, oncology-specific patient survey to assess various aspects of cancer care and the patient experience. Gauging patients’ attitudes about their care and experiences paves the way to employ an exciting new area of research called mindsets—core assumptions about the nature and workings of things that can influence the mental and physical health of patients with cancer, potentially improving their outcomes.⁶ The MVP provides a strong framework for implementing targeted psychological interventions from the care team that aim to instill more positive mindsets in patients to drive better outcomes.

Through similar measure selection, care plan development, and integration of the patient

experience survey—all components of care that help improve quality and cost—McKesson’s MVP aligns with existing and proposed programs in the Center for Medicare and Medicaid Innovation (CMMI), such as the OCM, Oncology Care First, and the RO Model. By providing a similar framework and areas of focus as existing CMMI programs, the MVP serves as a vehicle to incrementally phase clinicians into alternative payment models and to create a sense of alignment to reinforce key areas critical to oncology care. Focusing on the core areas of care enables the care team to provide an enhanced suite of services under the value-based care umbrella, treating all patients equally without thinking about whether a patient is participating in a particular program.

Managed care will find many positives in McKesson’s patient-centric MVP, as it is designed to drive and support the delicate balance of improved quality with lower costs that value-based care requires, all while ensuring that the patient’s voice is strongly heard.

Wait-and-See Approach

Commercial payers will be keeping a close eye on what happens with the new oncology-specific MVPs. Because many questions still exist around whether quality measures actually have a meaningful impact on patient outcomes and reducing costs, payers have been slower to truly integrate quality measurements into value-based care arrangements. All stakeholders, including payers, are anxiously waiting to see how these programs perform and whether they meet hoped-for expectations. Payers tend to follow the government’s lead, but until many of the details are clearly defined within the regulatory programs and they are running smoothly, payers will most likely take a wait-and-see approach. They will also be looking for clear-cut evidence that these programs are effective in supporting value-based care before confidently moving forward. ♦

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