Accelerating the Development of Targeted Cancer Therapies

- Oral Oncolytics
- Oncology Medical Home
- Protocol Analyzer
Could you look him in the eye and tell him, “THIS IS OUR SURVIVAL PLAN.” Plan to treat for 1 year for an overall survival (OS) advantage as demonstrated in the VISTA trial.

IT’S THE MOMENT OF TRUTH. Will you tell your patients that in the VISTA trial: 1-year (50 weeks) median of VELCADE® (bortezomib) delivered a >1-year median OS advantage in combination with melphalan+prednisone (MP) vs MP alone for previously untreated multiple myeloma (median OS*: 56.4 vs 43.1 months, respectively)?

VISTA TRIAL: a randomized, open-label, international phase 3 trial (N=682) evaluating the efficacy and safety of VELCADE (bortezomib) administered intravenously in combination with MP vs MP in previously untreated multiple myeloma. After progressive disease was established, all patients were eligible to receive subsequent therapies. The primary endpoint was time to progression (TTP). Secondary endpoints were CR, ORR, PFS, and OS. At a prespecified interim analysis (median follow-up: 16.3 months), VELCADE+MP resulted in significantly superior results for TTP (median: 20.7 months with VELCADE+MP vs 15.0 months with MP \(p=0.000002\)), PFS, OS, and ORR. Further enrollment was halted, and patients receiving MP were offered VELCADE in addition. Updated analyses were performed.

INDICATION: VELCADE (bortezomib) is indicated for the treatment of patients with multiple myeloma.

CONTRAINDICATIONS: VELCADE is contraindicated in patients with hypersensitivity (not including local reactions) to bortezomib, boron, or mannitol, including anaphylactic reactions. VELCADE is contraindicated for intrathecal administration. Fatal events have occurred with intrathecal administration of VELCADE.

*HR=0.695 (95% CI, 0.57-0.85); \(p<0.05\).

**IMPORTANT SAFETY INFORMATION FOR VELCADE® (bortezomib)**

**WARNINGS, PRECAUTIONS, AND DRUG INTERACTIONS**

- Peripheral neuropathy: Manage with dose modification or discontinuation. Patients with preexisting severe neuropathy should be treated with VELCADE (bortezomib) only after careful risk-benefit assessment.
- Hypotension: Use caution when treating patients taking antihypertensives, with a history of syncope, or with dehydration.
- Cardiac toxicity: Worsening of and development of cardiac failure have occurred. Closely monitor patients with existing heart disease or risk factors for heart disease.
- Pulmonary toxicity: Acute respiratory syndromes have occurred. Monitor closely for new or worsening symptoms.
- Posterior reversible encephalopathy syndrome: Consider MRI imaging for onset of visual or neurological symptoms; discontinue VELCADE if suspected.
- Gastrointestinal toxicity: Nausea, diarrhea, constipation, and vomiting may require use of antiemetic and antidiarrheal medications or fluid replacement.
- Thrombocytopenia or Neutropenia: Monitor complete blood counts regularly throughout treatment.
- Tumor lysis syndrome: Closely monitor patients with high tumor burden.
- Embryo-fetal risk: Women should avoid becoming pregnant while being treated with VELCADE. Advise pregnant women of potential embryo-fetal harm.
- Cerebellar atrophy: Closely monitor patients receiving VELCADE in combination with strong CYP3A4 inhibitors. Avoid concomitant use of strong CYP3A4 inducers.

**ADVERSE REACTIONS**

Most commonly reported adverse reactions (incidence ≥20%) in clinical studies include nausea, diarrhea, thrombocytopenia, neutropenia, peripheral neuropathy, fatigue, neuralgia, anemia, leukopenia, constipation, vomiting, lymphopenia, rash, pyrexia, and anorexia.

Please see Brief Summary for VELCADE adjacent to this advertisement.
VELCADE® (bortezomib) for Injection is indicated for the treatment of patients with multiple myeloma. VELCADE for Injection is contraindicated in patients with hypersensitivity (not including local reactions) to bortezomib or to any of its ingredients. VELCADE is also contraindicated in patients with severe renal insufficiency (i.e., creatinine clearance ≤35 mL/min) and in patients with severe hepatic impairment (i.e., Child-Pugh class C). VELCADE is also contraindicated in patients with moderate to severe heart failure (New York Heart Association (NYHA) class III or IV). VELCADE may decrease cardiac output and may cause hypotension, or even cardiogenic shock. VELCADE is not recommended in patients with moderate to severe liver disease. VELCADE is not recommended in patients with moderate to severe pulmonary edema.

INDICATIONS:

VELCADE is approved for the following indications:

- Multiple Myeloma: In combination with dexamethasone, VELCADE is indicated for the treatment of patients with multiple myeloma who have received at least two prior lines of therapy and failure of one of these treatments included melphalan/prednisone.
- Relapsed Multiple Myeloma: In combination with dexamethasone, VELCADE is indicated for the treatment of patients with multiple myeloma who have received at least two prior lines of therapy and failure of one of these treatments included melphalan/prednisone.

ADVERSE REACTIONS:

The most common adverse reactions (incidence ≥10%) associated with VELCADE treatment are nausea, asthenia, thrombocytopenia, peripheral neuropathy, and pyrexia. The most common adverse reactions leading to dose reduction or interruption are neutropenia, peripheral neuropathy, thrombocytopenia, and nausea. The most common adverse reactions leading to dose delay were neutropenia, peripheral neuropathy, and nausea. The most common adverse reaction leading to discontinuation was neutropenia. Other adverse reactions occurring in >5% of patients and leading to discontinuation were fatigue, peripheral neuropathy, anemia, and infection.

Gastrointestinal Toxicity:

Patients may develop nausea, vomiting, diarrhea, constipation, stomatitis, and dry mouth. Patients may experience taste alteration. The frequency and severity of gastrointestinal toxicity have been reduced by the addition of dexamethasone. Patients should be monitored for symptoms of gastrointestinal toxicity, such as nausea, vomiting, diarrhea, and constipation. In the event of severe or worsening gastrointestinal toxicity, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

Neurotoxicity:

Peripheral neuropathy may occur with VELCADE treatment. Peripheral neuropathy is characterized by paresthesias, numbness, weakness, tingling, burning sensations, and/or difficulty with coordination. The frequency and severity of peripheral neuropathy have been reduced by the addition of dexamethasone. Patients should be monitored for symptoms of peripheral neuropathy, such as paraesthesia, paresthesia, numbness, weakness, tingling, burning sensations, and/or difficulty with coordination. In the event of severe or worsening peripheral neuropathy, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

Hematologic Toxicity:

The most common hematologic adverse reaction is neutropenia. Patients may experience neutropenia, thrombocytopenia, and anemia. Patients should be monitored for symptoms of hematologic toxicity, such as fever, infection, bruising, or bleeding. In the event of severe or worsening hematologic toxicity, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

Cardiac Toxicity:

Cardiac dysfunction, including reduced ejection fraction and cardiomyopathy, is a known complication of VELCADE treatment. Patients should be monitored for signs and symptoms of cardiac dysfunction, such as dyspnea, edema, chest pain, and syncope. If worsening cardiac function occurs, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

Pulmonary Toxicity:

Acute Respiratory Distress Syndrome (ARDS) and acute or subacute progressive pulmonary edema have been reported. Pulmonary edema may be associated with neutropenia, and patients may experience respiratory distress, hypoxemia, or respiratory failure. Patients should be monitored for signs and symptoms of pulmonary toxicity, such as dyspnea, cough, wheezing, or decreased oxygen saturation. In the event of severe or worsening pulmonary toxicity, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

Renal Toxicity:

Acute renal failure and acute renal insufficiency have been reported. Patients should be monitored for signs and symptoms of renal toxicity, such as oliguria, anuria, or worsening renal function. In the event of severe or worsening renal toxicity, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

Proteinuria:

Proteinuria has been reported in patients treated with VELCADE. Proteinuria may occur with or without symptoms of renal insufficiency. Patients should be monitored for signs and symptoms of proteinuria. In the event of severe or worsening proteinuria, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

Bacterial and fungal infections have been reported with VELCADE treatment. Patients should be monitored for signs and symptoms of infections, such as fever, chills, or malaise. In the event of severe or worsening bacterial or fungal infections, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

Tumor Lysis Syndrome:

Tumor lysis syndrome has been reported with VELCADE treatment. Tumor lysis syndrome is a potential complication that may occur in patients with rapidly proliferating tumors. Patients should be monitored for signs and symptoms of tumor lysis syndrome, such as fever, hypocalcemia, hyperuricemia, or hyperkalemia. In the event of severe or worsening tumor lysis syndrome, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

QTc Interval Prolongation:

QT interval prolongation has been reported with VELCADE treatment. Patients should be monitored for signs and symptoms of QT interval prolongation, such as palpitations, dizziness, or syncope. In the event of severe or worsening QT interval prolongation, appropriate measures, including a reduction in the dose of VELCADE, should be considered.

Other Adverse Reactions:

Other adverse reactions occurring in ≥1% of patients treated with VELCADE include peripheral sensory neuropathy, paresthesia, hypesthesia, asthenia, fever, headache, diarrhea, anorexia, agitation, insomnia, nausea, vomiting, fatigue, cough, and dyspepsia.

We Support the Health of your Practice

With the Same Dedication that You Support Us

Your number one priority is the health of your patients. With the changing healthcare landscape, our number one priority is the business health of your practice.

Dedicated exclusively to the viability of community oncology, ION Solutions provides contracting, technology, education and advocacy support that ensures you have the tools to run your practice both efficiently and effectively. With the support of ION Solutions, you can navigate this changing environment and focus on providing quality care for your patients.

To learn how ION Solutions enables community oncology practices to improve operational efficiency, financial performance and quality of care, contact your Strategic Account Manager or visit IONOnline.com.

To experience ION Solutions advocacy support, visit ouroncommunitycouns.org.
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What's News at ION

In this issue, we introduce you to Foundation Medicine, a molecular information company. Because of their ability to identify unique genomic alterations in a patient’s tumor and match them to a targeted therapy, Foundation Medicine’s clinical products may help oncologists identify treatment options that may not have been considered. See page six to learn more.

It is possible that the targeted therapy identified for a patient today will be an oral agent. Oral oncolytics represent 10 to 25 percent of all anticancer treatments prescribed. Managing these therapies poses unique challenges for oncology practices. In this issue’s Reimbursement Watch, we examine patient identification for and adherence to oral therapy and a CMS proposal that would pay for Chronic Care Management.

Launched in May 2012, the Michigan Oncology Medical Home Demonstration Project is a multipractice oncology medical home model supported by payment reform. Read what the four participating practices learned during the first year of the project about enhancing patient care and eliminating operational inefficiencies on page 18.

ION Solutions is your partner in the way forward for community oncology. We have been successful in educating payers and Congress about the community oncology value proposition, and in partnership with you, we will thrive. Thank you for your continued support of ION Solutions.

Sincerely,
Mark Santos
President
ION Solutions GPO

Editorial & Design staff:

· Chris Vorce
  Director, Marketing & Communications, ION Solutions

· Melissa Bradbury
  Manager, Marketing & Communications, ION Solutions

· Tricia Musslewhite
  Manager, Marketing & Communications, ION Solutions

· Amy Gonsuron
  Coordinator, Marketing & Communications, ION Solutions

· Peter Kemp
  Graphic Designer, PKDesign

ION Solutions article and advertising submissions:

Article submissions and suggestions, as well as advertising inquiries, may be sent to:

Chris Vorce
Managing Editor, Oncologistics
c/o ION Solutions
3101 Gaylord Parkway
Frisco, TX 75034

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All archived issues of Oncologistics are available online at www.iononline.com.
Foundation Medicine is a molecular information company dedicated to a transformation in cancer care where treatment is informed by a deep understanding of the genomic changes that contribute to each patient’s unique cancer.

ION Solutions recently spoke with Dr. Kevin Krenitsky, Foundation Medicine’s chief commercial officer and senior vice president of international strategy, about how genomic profiling and targeted cancer therapies are enhancing patient care.

How is Foundation Medicine enhancing care for cancer patients?

Foundation Medicine makes precision medicine a reality for patients by offering comprehensive genomic profiling to oncologists. Our clinical products, FoundationOne and FoundationOne Heme, identify the genomic alterations unique to each patient’s tumor and match them to targeted therapy or clinical trial options to support oncologists in identifying treatment options for their patients that may not have otherwise been considered. The results of our tests are provided in an easy-to-read interpretive report with the relevant alterations in a patient’s tumor and the latest medical and scientific findings to support physician treatment recommendations. Foundation Medicine also collaborates with leading drug developers and cancer researchers to identify novel targets and redesign clinical trials to accelerate the development of targeted cancer therapies and continue to push the field of cancer care forward, bringing new therapies to patients faster.

Foundation Medicine markets two clinical products: FoundationOne® and FoundationOne® Heme. Please explain these tests.

FoundationOne and FoundationOne Heme are comprehensive and fully informative genomic profiles that complement traditional cancer treatment decision tools and often expand treatment options by matching each patient with targeted therapies and clinical trials that are relevant to the molecular changes in their tumor. Our clinical products have undergone robust analytic validation and can be performed on routine cancer specimens, such as FFPE samples, and in the case of FoundationOne Heme, peripheral blood or bone marrow samples. The test results are provided in easy-to-read reports with the most clinically relevant information to help inform patient treatment.
FoundationOne, Foundation Medicine’s product for solid tumors, utilizes next-generation sequencing (NGS) to interrogate the entire coding sequence of 315 cancer-related genes plus select introns from 28 genes often rearranged or altered in solid tumor cancers. These genes are sequenced to identify all classes of clinically relevant somatic alterations, including single base pair changes, insertions, deletions, copy number alterations, and selected rearrangements.

**Foundation Medicine** also offers educational programming by way of monthly webinars, molecular tumor boards, and speaker programs to educate practices on how to utilize comprehensive genomic profiling.

For FFPE specimens, Foundation Medicine will procure the specimen from pathology and return an easy-to-read interpretive report within 14 days of sample receipt for FoundationOne and 28 days for FoundationOne Heme. For blood and bone marrow aspirates, the physician can send the specimen with the test requisition and we begin processing as soon as the sample arrives at our laboratory.

**What programs does Foundation Medicine have in place to provide value to the community oncology setting?**

Both FoundationOne and FoundationOne Heme were designed to bring clinically relevant developments in cancer biology to patients everywhere, including in the community oncology setting. Both tests can be performed on routine cancer specimens and easy-to-read interpretive reports are delivered to oncologists within 14 days for FoundationOne and within 28 days for FoundationOne Heme.

Our Client Services and Medical Affairs team help provide information and guidance on interpretation of results and a seasoned team of account executives can provide clinical and logistical support. Foundation Medicine also offers educational programming by way of monthly webinars, molecular tumor boards, and speaker programs to educate practices on how to utilize comprehensive genomic profiling. If a physician has a promising patient case they would like to share with a broader audience, we are happy to assist in reviewing and potentially publishing compelling clinical narratives that demonstrate the impact of precision medicine in oncology.

To support patient-centric care, Foundation Medicine offers educational materials to help patients understand comprehensive genomic profiling and is dedicated to reducing financial barriers that may keep patients from benefiting from our products. We offer a financial assistance program to help patients navigate the insurance billing process and reduce the out-of-pocket costs for FoundationOne and FoundationOne Heme. Foundation Medicine also offers the FoundationOne CareLine to help patients access any relevant targeted therapies identified by our tests and selected by oncologists as an appropriate treatment option. Through the FoundationOne CareLine, patients are assigned an individual case manager to navigate the reimbursement process, appeal for coverage on the patient’s behalf or secure compassionate use.

Tricia Musslewhite is manager, Marketing & Communications, with ION Solutions.
ION Solutions' Educational Programs

2014-2015 Meeting Schedule
Save the Date

<table>
<thead>
<tr>
<th>Meeting Date</th>
<th>Meeting Name</th>
<th>Location</th>
<th>Venue</th>
</tr>
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<tbody>
<tr>
<td>Nov. 7-9, 2014*</td>
<td>ION National Meeting</td>
<td>Nashville, TN</td>
<td>Loews</td>
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<tr>
<td>Jan. 23-25, 2015</td>
<td>ASH Review</td>
<td>Orlando, FL</td>
<td>Renaissance Sea World</td>
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<tr>
<td>March 6-8, 2015</td>
<td>Oral Therapies</td>
<td>Atlanta, GA</td>
<td>JW Marriott</td>
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<tr>
<td>May 15-17, 2015</td>
<td>Business of Oncology</td>
<td>Nashville, TN</td>
<td>Loews Vanderbilt</td>
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<tr>
<td>Sept. 18-20, 2015</td>
<td>National Healthcare Practitioners Meeting</td>
<td>New Orleans, LA</td>
<td>Hotel Monteleone</td>
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<tr>
<td>Nov. 6-8, 2015</td>
<td>ION National Meeting</td>
<td>Phoenix, AZ</td>
<td>Sheraton Wild Horse Pass</td>
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*Meeting dates subject to change.*

*Registration now open*

Registration will be available approximately 60 days prior to each event. To register, visit www.iononline.com.
The historical lack of payer reimbursement for nursing time spent monitoring patient compliance and providing education for oral oncolytic therapy has been a financial drain for many oncology practices.

That could start to change in 2015 under a proposal by the Centers for Medicare & Medicaid Services (CMS) to pay for what it calls Chronic Care Management (CCM) services. CMS is proposing to create a new separately payable G-code to report non-face-to-face CCM-related services that could be used starting Jan. 1, 2015. The code would be applicable for patients with two or more chronic diseases that are expected to last at least 12 months or until the patient’s death. The chronic conditions would also have to place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

In cancer care, patients often have co-morbid conditions and rely on their oncologists to coordinate all of their medical care. As described in the 2015 Medicare Physician Fee Schedule (MPFS) Proposed Rule, the work relative values for the new CCM code would be comparable to Transitional Care Management and the code would pay approximately $40 per month. While that amount would likely not cover all practice costs, it is a welcome start for oncology practices that for years have been providing these services and frequently not getting paid for them.

Under the CCM proposal, only one physician per patient per month could bill for the G-code. Clinical staff working on the CCM service would not need to be employees of the practice and general supervision (not direct) would be acceptable for those coordinating care “incident to” a physician’s service.

The Rise of Oral Oncolytics

The rise of oral anticancer agents means that oncology treatment is in many ways shifting away from the traditional inpatient and outpatient sites of care and moving into patient homes and other non-medical venues. Treatment with oral oncolytics offers patient advantages such as convenience, minimal travel time, fewer office visits, and improved quality of life. For providers, however, managing these therapies poses unique challenges, including monitoring for drug interactions and adverse effects, educating patients on complex dosing schedules and adherence, navigating provider reimbursement and patient financial assistance, and overcoming other access barriers.

Focusing on high-touch, coordinated patient care is even more critical as treatment moves from directly observed injectable therapy to self-administered oral therapy.

The first oral oncolytic was approved in the U.S. in 1953. Since then, approvals for oral therapies have ballooned. Today, on average, the Food and Drug Administration (FDA) approves one new oral oncolytic every four months. With an oncology pipeline of 400 drugs, 25 to 30 percent are oral agents. Moreover, oral oncolytics represent 10 to 25 percent of all anticancer treatments prescribed.
Reimbursement Watch

Oral Oncolytics: New Reimbursement Opportunities in a Shifting Landscape

**Oral Oncolytic Drug Approvals, By Year**

<table>
<thead>
<tr>
<th>Year</th>
<th>Drug</th>
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<tbody>
<tr>
<td>2020</td>
<td>Affinitor, Sprycel, Tasigna, Tarceva, Tykerb</td>
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<tr>
<td>2011</td>
<td>Jakafi, Ferriprox, Xalkori, Zelboraf, Sutent, Affinitor, Zytris, Vandetanib</td>
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<tr>
<td>2012</td>
<td>Iclusig, Zytris, Cometriq, Sivarga, Bosulif, Xlane, Votrient, Gleevec, Envedge, Inlyta</td>
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<tr>
<td>2013</td>
<td>Gilotrif, Mekinist, Tafinlar, Pomalyst</td>
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Growth of oral oncolytic approvals is expected to continue in 2015 and beyond. More than 35 drugs are in phase III clinical trials and 50+ drugs are in phase II review, as noted in the figure below.¹

As the availability of oral anticancer agents has grown, so has the intensity of payer management. Oral oncology account for one of the fastest growing payer expenditures, to the tune of $8,000 per month per prescription.² Oral oncologies are now among the top five management priorities of payers, due in part to the expanding oral oncology market, in addition to payer access to new information technology and enhanced data capture capabilities. Payers are already requiring patients to manage a greater portion of the cost of oral anticancer drugs by placing them on higher, specialty tiers. Payers will likely set more rigorous prior authorization criteria in order to limit the use of high-cost oral oncologies that do not offer substantially improved clinical profiles. Additionally, payers may use compendia to enforce clinical pathways. This increased scrutiny may drive utilization to be more closely aligned with labeled indications and favorable compendia listings, and also require line-of-therapy trials.³

**Patient Identification, Adherence, and Education**

High-cost oral oncologies increasingly coming to market, patient stratification and evaluation of candidacy for this type of therapy becomes even more critical. Specifically, while many patients may appear to be eligible for oral chemotherapy, only a subset will be willing to both take an oral therapy and successfully adhere to the regimen.⁴

When providing anticancer treatment through oral oncologies, patient adherence becomes much more complex and potentially more confusing for patients.⁵

### Potential Causes of Nonadherence to Oral Oncology

- Cognitive impairment or psychological problems, especially depression
- Treatment of asymptomatic disease
- Inadequate follow-up or discharge planning
- Adverse effects of medication
- Lack of belief in the benefits of treatment or insight into the illness
- Missed appointments
- Poor provider-patient relationship
- Presence of barriers to medications or care
- Complexity of treatment regimen and dosing schedule
- Cost of medication and high out-of-pocket costs

### Potential Impacts of Nonadherence to Oral Oncology

- Increase in physician visits
- Increased hospitalization rates and longer hospital stays
- Decreased patient satisfaction
- Poor patient-provider relationships
- Compromised disease outcomes, such as decreased time to relapse and decreased survival

Conducting a formal baseline assessment to identify if the patient is an appropriate candidate for oral anticancer treatment is an important preliminary step. While various assessment templates exist, the common core components include the following:¹¹

### Physical Ability

- Are you able to swallow pills or tablets? If no, explain.
- Are you able to open your other medicine bottles or packages?

### Cognitive Ability

- What have you been told about this treatment plan with oral medications?
- Do you know what could happen if you don’t take your medication as prescribed?

### Safety

- Where will you store your medications?
- How will you discard your medications?

### Social Support

- Is anyone helping you during your treatment, such as family members, friends, partners, or caregivers?
- Do you feel you will be able to take your medication based on a regular schedule, as prescribed?

Cost is typically the most significant driver of nonadherence. While most injectable oncology medications are covered under patients’ medical benefits, oral oncologies are nearly always managed under the pharmacy benefit, which ultimately results in higher copays. In one study, 10 percent of patients prescribed treatment with oral oncologies did not actually fill their prescriptions because of prohibitive cost sharing. In another study, approximately 84 percent of oncologists considered patient cost-sharing requirements when determining a course of therapy.⁶

Another major factor in adherence is where patients fill prescriptions. Only 7 percent of oral oncologies are dispersed at the oncologist’s office, compared to 45 percent at retail pharmacies, 31 percent at specialty pharmacies, and 16 percent at mail order pharmacies. Physician office dispensing fosters continuity of care within the same setting. Once the patient acquires a prescription in a different site, the level of coordination among all members of the care team becomes much more complex and potentially more confusing for patients.⁶

<table>
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<th>Oral Oncology: Timeline of events shows a dynamic and evolving market</th>
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<td><strong>FDA Approval Dates for Oral Oncology</strong></td>
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**As of December 2013**
Reimbursement Watch

Treatment Access & Financial Assistance

- Will you have regular transportation to help you to fill your prescription?
- Have you had any problems with your insurance that has interfered with obtaining your medications?

Once a patient has been identified as an appropriate candidate for oral anticancer therapy, education is the key to managing and reinforcing compliance with prescribed treatments. Information provided to patients during their first visit, along with consistent follow-up, contributes to good adherence. However, as integral as education is to successful compliance and overall management of oral oncologics, most payers do not pay for nursing time spent educating patients. This underscores the importance of CMS’ proposal to pay for CCM services starting in 2015. Offering oncology practices new opportunities to secure reimbursement for critical patient care services will support successful compliance and overall management of oral oncologics.

Offering oncology practices new opportunities to secure reimbursement for critical patient care services will support optimal outcomes in oral oncologic therapy.

References


Roshan Rahnama, MPH, and Aileen Soper are assistant directors, Reimbursement Strategy & Tactics, with Xcenda.

Highlights of Medicare’s 2015 Proposal to Pay for Chronic Care Management (CCM)

- CMS finalized the scope of CCM services to include:
  - 24-hour/day access to address patient care needs
  - Continuity of care with a designated practitioner or member of the care team
  - Care management, including assessment of medical, functional, and psychosocial needs; access to recommended preventive care services; medication reconciliation; oversight of patient self-management of medications; and patient-centered care plan of physician, mental, cognitive, psychosocial, functional, and environmental needs
  - Management of care transitions
  - Coordination with home- and community-based clinical service providers

- CMS is deviating from its proposal to add 2 separately payable G-codes; it will create 1 new separately payable alphanumeric G-code for CY 2015:
  - GXXX1 – Chronic care management services furnished to patients with multiple (2 or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; 20 minutes or more; per 30 days

- CMS shortened billing for chronic care management services from at least 60 minutes of services every 90 days to 20 minutes of service every 30 days

- CMS indicated it would consider using a revised CPT code that meets its policy requirements instead of creating a new G-code

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Michigan Oncology Medical Home Demonstration Project: First-Year Results

By: Gordon Kuntz, Jane M. Tozer, Jeff Snegosky, John Fox, MD, MHA, and Kurt Neumann, MD


Abstract
Launched in May 2012, the Michigan Oncology Medical Home Demonstration Project is an innovative multipractice oncology medical home model supported by payment reform. In the first year of the project, four oncology practices (29 physicians) participated and enrolled 85 patients receiving chemotherapy for a cancer diagnosis (96 new chemotherapy starts). By creating an oncology medical home for patients, the project reduced costs associated with unnecessary emergency room visits and inpatient admissions, with an average estimated cost savings of $550 per patient, while also enhancing payments to providers. The total estimated cost savings for year 1 was $46,228. In addition to the financial savings realized through reductions in emergency room visits and hospitalizations, the program also demonstrated that participating practices had high adherence to national and practice-selected guidelines, instituted advance care planning, and provided effective and standardized symptom management. The results are promising and provide evidence that community oncology practices will embrace the transformation to a patient-centered model with properly aligned incentives and administrative assistance.

Introduction
The medical home model was first developed in the area of primary care to control health care costs and improve patient outcomes by improving the care delivery process. Similar models have been adopted in oncology, although strict definitions of an oncology specialist medical home and accreditation procedures are only now being developed. One of these models, the Michigan Oncology Medical Home Demonstration Project (MOMHDP), is an innovative multipractice oncology medical home model supported by payment reform. It was conceived and designed as a pilot project to support practices in beginning the transformation of the processes of clinical care inherent in the medical home concept: standardization of chemotherapy and symptomatic care within the practice, taking responsibility for comprehensive care of the oncology patient by the entire management team, and engaging in early end-of-life discussions. It was felt that these initial steps of transformation were necessary process changes within a practice to lay the foundation for a true specialist medical home if and when final criteria are recognized. This model is also (to our knowledge) the first multipractice oncology medical home pilot in the nation. As with primary care medical home models, the goal in oncology is to improve the quality of patient care and reduce costs through more comprehensive office-delivered care and better coordination of care delivery with primary and specialty care providers.

Implementing an Oncology Medical Home Program
Launched in May 2012, the MOMHDP is a tools-based model sponsored jointly by Michigan-based health insurer Priority Health, along with Physician Resource Management, which identified and recruited the participating community-based oncology practices, and ION Solutions, which provided the tools and technology to collect, aggregate, and measure the data generated by the participating practices. To insure reliability and reproducibility, the focus has been on embedding transformational changes into the daily work flow.

For the medical home concept to be successful in medical oncology, perhaps the most important transformative change is for the medical oncology office team to accept responsibility for the entire care of the oncology patient and for the patients to recognize and acknowledge this.
Michigan Oncology Medical Home Demonstration Project: First-Year Results

Four independent oncology practices (and a total of 29 physicians) participated in the first year of the demonstration project. Each practice was asked to standardize three elements of practice: development of preferred regimens, incorporation of advance care planning, and deployment of enhanced triage and access protocols. Each practice selected a preferred regimen of its choice for breast, colon, and lung cancers for adjudgnt and first-and second-line metastatic disease. All choices were consistent with national guidelines.

Existing technologies at each practice were supported with MOMHDP-provided tools, including:

- Evidence-based treatment guideline selection and compliance tracking
- A symptom management program with guidelines for standardized nurse phone triage and tracking of recommendations (e.g., “Seek emergency care,” “Provider appointment within 48 hours,” “Home care instructions”) made to the patient
- An advance care planning program to help define patient preferences for end-of-life care within 60 days of initiating treatment for malignant disease
- Automated physician order entry
- A patient portal with directed educational materials

The MOMHDP payment structure modified traditional provider payments to support quality-focused changes in care and practice administration. The model ties reimbursement to patient health outcomes and provision of quality care, rather than to the drugs that are prescribed. Specifically, the average sales price (ASP) payment methodology was replaced with drug acquisition reimbursement at fully loaded acquisition cost, plus a payment reform methodology was replaced with drug acquisition reimbursement of quality care, rather than to the drugs that are reimbursed for patient health outcomes and provision of quality care. The overall savings associated with reducing inpatient admissions was $41,735, and $4,492 for reducing ER visits, for overall savings of $46,227. The average number of ER visits and inpatient admissions per patient, along with estimates of cost savings, are presented in Table 1.

**Compliance**

National guideline compliance for the four practices for year one was 95 percent, and preferred regimen compliance was 78 percent. National and preferred guideline compliance by cancer type is presented in Figure 1. The general calculation for compliance was based on new chemotherapy starts; compliance with national guidelines was judged according to a combination of national evidence-based compendia. All practices met the criteria for shared savings.

**Results**

A total of 85 Priority Health oncology patients, representing 96 new chemotherapy starts, participated in the project. Physicians entered into the program with the intent of improving care for patients, improving outcomes, and eliminating unnecessary and avoidable services. Aligning the financial incentives, as in this pilot, allowed the practices to standardize their procedures to achieve these goals while maintaining or improving their revenues.

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### Table 1. Emergency Room visits, Inpatient Admissions, and Cost Savings Analyses

<table>
<thead>
<tr>
<th>Measure</th>
<th>Historical Control Data (n=434)</th>
<th>MOMHDP Year 1 Data (n=85)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ER visits per patient</td>
<td>0.34</td>
<td>0.18</td>
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<tr>
<td>Inpatient admissions per patient</td>
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<td>0.07</td>
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<tr>
<td>Estimated savings per patient</td>
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<td>$550</td>
</tr>
<tr>
<td>Estimated total savings</td>
<td>—</td>
<td>$46,227</td>
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</tbody>
</table>

**Figure 1.** National and preferred guideline compliance by cancer type.
Nine of out 15 patients (60%) called the practice before proceeding to the ER. For the remaining 40 calls, patients were given an appointment within 48 hours (50%) or were given home care instructions (50%). No patients were directly admitted for inpatient services via the nurse triage line.

The most common symptoms reported by callers were pain (n=12), fever (n=6), and dyspnea (n=6). Symptom management triage by symptom type is presented in Figure 2.

**Lessons for Success**

Several factors were identified as critical to the success of the MOMHDP. Lessons learned include:

- **Strong provider-payer collaboration is built on trust through transparent utilization and cost data.**
- **Independent clinical, administrative, and technical coordination improves provider-payer collaboration.**
- **The importance of patient education in making the medical oncologist the acknowledged “primary care physician” during active treatment.**
- **The planning of the timeline for implementation of clinical standardization changes must come from the practices so they can effectively absorb new approaches.**
- **Each office benefits from a physician, nurse, and administrator “champion” for the program.**
- **Practices that embeded changes into their daily workflow (e.g., advance care planning and triage algorithms) were most successful.**
- **Having comprehensive, written program documentation and consistently applied training facilitates practice understanding.**
- **Use of existing, off-the-shelf technologies, such as computerized physician order entry and patient portal, help control costs.**
- **Planning must take into account that everything takes longer than anticipated, including practice commitment, contracting, and technology implementation.**
- **It is possible to accurately model payment reform prospectively using past financial parameters.**

**Summary and Conclusions**

These results represent preliminary reporting from the first multipractice oncology medical home in the U.S. with payer support that includes payment reform. Transformation to a comprehensive oncology medical home requires both clinical and administrative changes within a practice. It is difficult to implement multiple changes simultaneously, and we have chosen a more modular approach by first emphasizing, measuring, and rewarding the clinical changes with the most positive impact on patient care: standardization of care, more comprehensive management, and early end-of-life discussions. These are important first steps in a practice change of culture and transformation. They are important and necessary, but not sufficient. Once these clinical improvements are in place, the practice is in position to become the focus of patient-centered care and the primary communicator to others in the care giving process, eventual necessary components of a true patient-centered medical home. MOMHDP is now concentrating on subsequent aspects of the medical home transformation, including distress management, patient communication through a portal, patient satisfaction surveys, survivorship, and communication of care plans to the patient and the external care team. The effectiveness of this stepwise approach is demonstrated by one practice that is now in the process of early recognition by the National Committee for Quality Assurance as a specialist patient-centered medical home.

For the medical home concept to be successful in medical oncology, perhaps the most important transformative change is for the medical oncology office team to accept responsibility for the entire care of the oncology patient and for the patients to recognize and acknowledge this. This requires a dual approach. The practices must develop processes to manage these additional responsibilities in an efficient and measurable manner. The patients and families need to be educated and reinforced to call the office early and often as the site of first contact for problems. We have even supplied wristbands for the patients with their individual office phone numbers as a reminder. Both the practices and patients need to focus on education to anticipate toxicities and symptoms and intervene early.

This project demonstrates that costs savings can be realized by implementing an oncology medical home focused on providing integrated, evidence-based quality care while maintaining or enhancing provider reimbursement. In addition to realizing financial savings, this physician-driven program also demonstrated that practices can achieve high levels of adherence to national and practice-selected guidelines, institute advance care planning, and provide effective and standardized symptom management. At the time of writing, data were not available on the frequency or cost of hospital versus office chemotherapy administration or on hospice use, but these data will be included in future analyses. In addition, the MOMHDP will be enhanced in its second year to include a survivorship program, patient distress screening, imaging guidelines, and standardized patient satisfaction surveys.

At a fundamental level, the project shows that oncology practices are willing to take on clinical standardization with payment reform, as neither practice size nor technology platform variation was a barrier to participation or success. The growth in provider revenue over the first year of the project shows that this model has the potential to be better than “business as usual,” an important consideration as many community oncology practices struggle to remain viable.

Payers will play an integral role in helping to support changes in the care delivery process with community oncology practices that are interested in transitioning to this model, but which may not have the resources to do so independently. Transitions in care and administrative models are costly. Practices incur administrative and staffing costs, which require compensation offsets by payers, and projects like this require infrastructure development, training, and analysis costs, which may be significant and may have to be initiated by payers as well. In this project, these costs were borne in part by Priority Health, Physician Resource Management, and ION Solutions. This collaborative approach from interested stakeholders provides a model for future projects for interested parties to work together in support of improved care, improved patient satisfaction, and more efficient practices.

Although this pilot preceded the American Society of Clinical Oncology–Community Oncology Alliance joint statement regarding principles of payment reform, its principles are entirely consistent and prove that such an approach to reform is feasible and can be embraced by practitioners. Now in its second year, the MOMHDP will continue to help define the links between costs, outcomes,
quality measures, and value in oncology and to prepare the practices to fulfill the evolving criteria of medical home, standardization of clinical care, more comprehensive care, and communication between all caregivers. We expect that the value of the oncology medical home will grow even more apparent as we compare the results over time. Overall, the results are promising, and the concept warrants further study, review, and reporting.

Authors’ Disclosures of Potential Conflicts of Interest

Although all authors completed the disclosure declaration, the following author(s) and/or an author’s immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a “U” are those for which no compensation was received; those relationships marked with a “C” were compensated. For a detailed description of the disclosure categories, or for more information about ASCO’s conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: Gordon Kuntz, ION Solutions (C); Jane M. Tozer, Physician Resource Management (C); Kurt Neumann, ION Solutions (C)

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Author Contributions

Conception and design: Gordon Kuntz, Jane M. Tozer, Jeff Snegosky, John Fox, Kurt Neumann

Financial support: John Fox

Collection and assembly of data: Jeff Snegosky, John Fox

Data analysis and interpretation: Jeff Snegosky, John Fox

Manuscript writing: All authors

Final approval of manuscript: All authors

Corresponding author: Gordon Kuntz, ION Solutions, 3101 Gaylord Pkwy, Frisco, TX 75034; e-mail: Gordon.Kuntz@iononline.com.

References


Protocol Analyzer is ION Solutions’ tool that helps practices better manage the decline in oncology reimbursements. By providing robust drug and protocol economic modeling, practices can quickly and efficiently determine the total cost of care.

Need help managing drug spend, optimizing reimbursement or determining total cost of care?

Save time. Reduce costs. Reclaim revenue.

For more information, visit www.IONonline.com or contact your ION Solutions Strategic Account Manager.
Enhance patient care and improve financial performance with Protocol Analyzer

By: Melissa Bradbury

To provide accurate economic calculations, the tool not only captures real time drug costs, but also considers chemotherapy chair time and administrative collection costs.

In today’s changing healthcare market, community oncologists face more pressures than ever before. The struggle between providing optimal patient care and maintaining necessary profit margins becomes more difficult every day. While patient health always will remain the primary and most influential factor in determining treatment plans, the financial health of the practice must be considered as well. As an ION Solutions member, you have access to Protocol Analyzer, a powerful tool that enables practices to meet both critical needs—patient health and practice economic stability.

More than 187 practices and 260 unique users per month use ION Solutions’ Protocol Analyzer—a cost analysis tool that allows users to combine practice specific contract pricing from Oncology Supply with individual overhead costs to provide a side-by-side economic analysis of one or more treatment protocols. Practices can use this analysis for patients covered by Medicare, private insurance, or a combination of payer sources for the patient. To provide accurate economic calculations, the tool not only captures real time drug costs, but also considers chemotherapy chair time and administrative collection costs. The robust search feature within Protocol Analyzer makes it easy for users to conduct searches by drug name or combination of drug names, diagnosis, as well as adding line of therapy to either drug name or diagnosis. Practices even have an opportunity to assess protocol selections by line of treatment prior to the new quarter’s Medicare reimbursement taking effect. Creating a list of favorite treatment protocols further streamlines the time needed to get this valuable information.

ION Solutions recommends some best practices to take advantage of this tool:

- **Load primary payer fee schedules.** This allows a practice to view reimbursement rates in the Protocol Analyzer Drug Classification report before treatment. Being able to properly assess reimbursement before treatment is critical to a practice’s financial viability.
- **Create a favorites list.** By using the favorites list in Protocol Analyzer, physicians and staff members can quickly view, within Protocol Cost analysis, the reimbursement dollars for a specific protocol grouping. The practice is able to define frequently used protocols, such as bone, breast, IV iron protocol, or even a set of protocols that use a specific high-dollar drug.
- **Export and review your favorites list regularly.** It is important for practices to review financially regularly, and this includes financials based upon protocol. Export favorite protocol listings from Protocol Analyzer monthly for review. The favorites report can be exported with information for all insurers to show the protocol financials based on the most current available NDC. The report also takes into account current product availability as well as current pricing from Oncology Supply.
- **Review the Drug Classification Report by MBU regularly.** This allows a practice to view multiple drugs within the same class at one time based upon reimbursement rates.
- **Prepare and print Patient Financial Estimates.** Create a patient estimate of out-of-pocket expenses for a treatment within minutes.

ION Solutions is constantly working to enhance Protocol Analyzer to enable community oncology practices to improve operational efficiency, financial performance, and quality of care. Some of the most recent enhancements to Protocol Analyzer include:

- Economics for protocols calculated by treatment days
- Customizable disclaimer paragraph within the Patient Financial Estimate
- Improved Protocol Cost Details screen layout

ION Solutions members can log in to Protocol Analyzer by visiting www.iononline.com and selecting Protocol Analyzer from the Member Tools section. For more information about Protocol Analyzer, or to view a demo of the tool, contact your ION Solutions strategic account manager, technology consultant, or send an email to ProtocolAnalyzerSupport@absg.com.

**Benefits of Protocol Analyzer**

**Accessibility**

- 24/7 Web-based application
- Protocols searchable by diagnosis, individual medication, or therapy

**Pricing and Cost Adjustments**

- Real-time pricing synchronized with the practice’s Oncology Supply (OS) account
- Pricing reflects front-end discounts from OS and frequent manufacturer pricing changes
- Practice-specific premeds and overhead costs can be entered

**Reimbursement**

- Preloaded with NCCN Compendia-approved protocols and corresponding J-Codes and CPT codes
- Reviewable economics for newly released medications without J-Codes
- Customized economics for a practice using private payer fee schedules to review individual medications and therapies

**Reporting**

- Create reports to compare Drug Cost versus Medicare reimbursement for all J-Codes
- Review and compare private payer economics by medication cost and protocol cost
- View the least costly alternative for a class of medicines that Medicare substitutes for reimbursement
- Provide patients with protocol descriptions and copay estimates for those with Medicare and for patients without insurance

Melissa Bradbury is manager, marketing and communications, at ION Solutions.
Newly diagnosed cancer patients often rely on the referral of a friend or family member when choosing where to seek care. Personal experience is credible information. The same is true in Washington, D.C., where legislators value personal stories about issues affecting constituents. ION Solutions and Oncology Supply have created materials to help your patients engage their congressional representatives and illustrate how sequestration cuts and other legislative issues affect their care. Front Range Cancer Specialists (FRCS), in Fort Collins, Colo., recently installed in its waiting room the new Community Counts kiosk filled with brochures and letters customized for its district. “There is great interest among our patients in what it is and how they can help,” said April Christensen, practice manager. The kiosk helped build on an effort FRCS had tried before. “We posted similar information in our lobby for our patients and did a similar campaign with a letter to local congressmen and state contacts to help us ensure patients knew their voices counted. So when I saw these kiosks I knew it was better because the kiosk will draw a lot of attention to the information in the lobby, and it’s just been great.” The materials educate patients about the legislative issues independent oncology practices are facing so they can advocate for effective, affordable, and accessible care in the community. In addition to engaging patients, Christensen also relies on conversations with legislators and collaboration with the local chapter of Coalition of Hematology and Oncology Practices (CHOP) to convey the mission of community oncology practices.
“We’re the only independent oncology practice in all of northern Colorado, southern Wyoming, and western Nebraska. We draw from a three state region, and in Colorado, there are only a few private oncology practices left. The other practices are hospital affiliated or are part of U S Oncology,” says Christensen.

However, FRCS is proving that having a small voice shouldn’t stop you from speaking up. “We’ve made some incredible changes and some incredible improvements just by asking. It doesn’t hurt to ask. Sometimes the answer is no. Sometimes you have to ask multiple times, but without asking, you’re going to get nothing,” adds Christensen.

To market the practice, FRCS physicians network with referring doctors to maintain, build, and protect the practice’s referral base. “Our physicians are very well known because of their compassion and care for their patients so most of our business is word of mouth, patient to patient out in the community,” adds Christensen. “We focus our marketing efforts on supporting community activities and supporting causes, which gives us visibility in the community.”

To receive the Community Counts kiosk and customized materials free of charge or for more information, email Chris Vorce, director, Marketing and Communications at chris.vorce@iononline.com.

Tricia Musslewhite is manager, Marketing & Communications, with ION Solutions.

In honor of a patient and in tandem with the practice’s tenth anniversary, FRCS executed the tenth annual Run for Hope, a 5K walk/run to empower people in the fight against cancer by educating them about cancer prevention, early detection and treatment, and raising funds for research to find a cure.

The future of your practice begins here and now.

It’s time to demonstrate the real, measurable value of community oncology.

To ensure the future of community oncology, we must communicate its value today. Community Counts is a physician-led movement that puts the power in your hands. Simply register at ourcommunitycounts.org and gain access to information and tools to help you learn how to navigate this new healthcare environment, and operate more efficiently in it.

So join the cause and make your voice count. Go to ourcommunitycounts.org today.
Community Counts Practice Effectiveness Web Series

As part of Community Counts, ION Solutions and Risë Marie Cleland are hosting a Webcast series throughout 2014 where members can receive valuable information and insight on a variety of topics, such as payment reform and the final 2015 Medicare Physician Fee Schedule.

Schedule of events
- Oct. 30: How Payment Reform will Transform the Oncology Practice
- Nov. 20: ICD-10 Update
- Dec. 18: Final 2015 Medicare Physician Fee Schedule

All events will take place at 3 p.m. EST. Visit www.iononline.com to register.

Access Meeting Materials on Your Mobile Devices

Download the myApps Store
At all upcoming ION Solutions meetings, you can now conveniently access meeting materials through a meeting app on your mobile devices. To make this transition as simple as possible, follow these two easy steps for downloading and installing the AmerisourceBergen myApps store on your iPhone, iPad, and Android devices.*

Step 1: Type the following link into your device browser (Safari for iOS, Chrome for Android):
    tiny.cc/ionmeetings

Step 2: Tap the orange sign in button and sign in using:
    Email Address: meeting@ion.com
    Password: ion

iOS Users: If prompted for a passcode, enter the code you use to unlock your device.

NOTE: If you downloaded the ABC myApps store at a previous ION Solutions meeting, you will not need to do so again.

Once you install the myApps store on your device, it will be empty until the upcoming meeting apps are published. Look for Informs communications before any ION Solutions’ meeting you are planning to attend with additional instructions for downloading that meeting’s app.

If you need assistance downloading the app, contact mobility@amerisourcebergen.com.

Managing growth, addressing change and planning for the future takes past experience as well as innovative, forward thinking. It takes a global healthcare solutions leader dedicated to enhancing patient care through end-to-end solutions for manufacturers, pharmacies and providers. It takes hindsight and foresight. It takes AmerisourceBergen.
community oncology: it’s a social issue
Join the cause to show the real value of community oncology.

What is the real, measureable value of treating cancer in a community setting? Join the conversation through Facebook and Twitter and be a part of Community Counts — the physician-led movement to preserve the future of community oncology.

Receive the latest legislative updates and links to valuable resources and practice tools to advocate the value of community oncology. Working together, online and offline, we can enact change.

Like us on Facebook Community Oncology Counts
Follow us on Twitter @communitycts
Advocate for the future of cancer care #SaveCancerCare

OurCommunityCounts.org
CommunityCountsAdvocacy.org