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Research Updates from ION’s ASH 2013 Review
Getting Started on ICD-10

Breakthroughs in Hematology

Community Counts
The median age of patients in the VISTA trial was 71 years (range: 48 – 91).

Survival never gets old

VELCADE® (bortezomib) delivered >13-month overall survival advantage in combination with MP† vs MP alone for previously untreated multiple myeloma (median 56.4 vs 43.1 months [HR=0.695; 95% CI, 0.57– 0.85; p<0.05]; 60.1-month median follow-up)

VELCADE® (bortezomib) Indication and Important Safety Information

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.

WARNINGS, PRECAUTIONS, AND DRUG INTERACTIONS

▼ Peripheral neuropathy: Manage with dose modification or discontinuation. Patients with preceding severe neuropathy should be treated with VELCADE 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 antiemetics and antiarrhythmic medications or fluid replacement.

▼ Thrombocytopenia or Neutropenia: Monitor complete blood counts regularly throughout treatment.

▼ Tumor lysis syndrome: Closely monitor patients with high tumor burden.

▼ Hepatic toxicity: Monitor hepatic enzymes during treatment.

▼ Embryo-fetal risk: Women should avoid becoming pregnant while being treated with VELCADE. Advise pregnant women of potential embryo-fetal harm.

▼ 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, neuropathy, anemia, leukopenia, constipation, vomiting, lymphopenia, rash, pyrexia, and anemia.

Please see Brief Summary for VELCADE on next page.

* The reconstituted concentration for subcutaneous administration (2.5 mg/mL) is greater than the reconstituted concentration for IV administration (1 mg/mL). *Melphalan+prednisone.

### VISTA TRIAL:

A randomized, open-label, international phase 3 trial (n=682) evaluating the efficacy and safety of VELCADE administered intravenously in combination with MP vs MP in previously untreated multiple myeloma. The primary endpoint was TTP. Secondary endpoints were ORR, PFS, and overall survival. At a pre-specified 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.
VELCADE is associated with thrombocytopenia and neutropenia. Patients with pre-existing symptoms of thrombocytopenia (e.g., purpura, mucosal bleeding) may be at increased risk for new thrombocytopenia when VELCADE is used in combination with concomitant medications. Thrombocytopenia/Neutropenia: Thrombocytopenia and neutropenia have occurred with VELCADE therapy. In a clinical trial of patients who received high-dose cytarabine (2 g/m² per day) by continuous infusion, grade 4 thrombocytopenia (platelet count <50,000/µL) occurred in 46% of patients with acute myeloid leukemia. The mean platelet count nadir measured was approximately 40% of baseline. The platelet count began to decrease 3 days after the start of VELCADE and remained low for the duration of the treatment cycle. Thrombocytopenia has also been reported with VELCADE in combination with other drugs. Thrombocytopenia/Neutropenia: Thrombocytopenia and neutropenia have occurred with VELCADE treatment. In a clinical trial of patients who received high-dose cytarabine (2 g/m² per day) by continuous infusion, grade 4 thrombocytopenia (platelet count <50,000/µL) occurred in 46% of patients with acute myeloid leukemia. The mean platelet count nadir measured was approximately 40% of baseline. The platelet count began to decrease 3 days after the start of VELCADE and remained low for the duration of the treatment cycle. Thrombocytopenia has also been reported with VELCADE in combination with other drugs.

Pulmonary Toxicity: Pulmonary toxicity (including pulmonary edema, cardiac failure, congestive cardiac failure, cardiogenic shock) was ≤1% for each individual trial. Pulmonary toxicity was reported in 9 (14%) of 65 patients who received VELCADE as a single agent. Pulmonary edema, cardiac failure, congestive cardiac failure, and cardiogenic shock were reported in 9 (14%), 5 (8%), 3 (5%), and 3 (5%), respectively.

Cardiac Toxicity: Cardiac toxicity (including decreased left ventricular ejection fraction have occurred during VELCADE therapy, including congestive heart failure in patients with pre-existing symptoms of left ventricular dysfunction. Patients with pre-existing cardiac disease should be closely monitored for the development of new cardiac disease. Cardiac Toxicity: Cardiac toxicity (including decreased left ventricular ejection fraction) has occurred during VELCADE therapy, including congestive heart failure in patients with pre-existing symptoms of left ventricular dysfunction. Patients with pre-existing cardiac disease should be closely monitored for the development of new cardiac disease.

Peripheral Neuropathy: Peripheral neuropathy was reported in 48% of patients with ≥Grade 2 peripheral neuropathy receiving VELCADE. Patients experiencing new or worsening peripheral neuropathy during VELCADE therapy may benefit from the use of VELCADE subcutaneously. VELCADE subcutaneously may be considered for patients with pre-existing or at high risk of peripheral neuropathy. In a randomized Phase 3 study comparing VELCADE subcutaneous vs intravenous in relapsed multiple myeloma, the incidence of peripheral neuropathy was 27% vs 47% in the subcutaneous vs intravenous groups, respectively.

Hypotension: Hypotension may be monitored in patients who are dehydrated. Management of orthostatic/postural hypotension may include adjustment of rehydrations, medications, and/or administration of vasoconstrictors or antihypertensives.

Geriatric Use: VELCADE is safe and effective in patients ≥65 years of age. No overall differences in safety or effectiveness were observed between elderly patients and younger patients. However, geriatric patients may be more susceptible to the effects of hypotension associated with VELCADE.

Hypoglycemia: Patients with diabetes mellitus may be at increased risk for hypoglycemia when VELCADE is used in combination with strong CYP3A4 inducers; therefore, concomitant hypoglycemic agents should be adjusted. Hyperglycemia: Patients with diabetes mellitus may be at increased risk for hyperglycemia when VELCADE is used in combination with strong CYP3A4 inducers; therefore, concomitant hypoglycemic agents should be adjusted.

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As we were putting the finishing touches on this issue of Oncologistics, Congress passed, and President Obama signed, legislation to provide a one-year patch, the Protecting Access to Medicare Act of 2014, for the sustainable growth rate (SGR), deferring for 12 months the 24 percent physician pay cut scheduled to take effect April 1. The bill replaces the cut with a 0.5 percent increase in payments through December of this year and a 0 percent update from January 1 to April 1, 2015.

Among other provisions, the measure also extends the implementation deadline for ICD-10 diagnostic and procedural codes until at least Oct. 1, 2015. Even with this delay, we encourage you to use the additional time to your advantage so you can minimize the risk associated with this transition. We will continue to push education and training around ICD-10, including “Getting Started on ICD-10,” on page 20.

This issue of Oncologistics also explores some of the clinical issues related to hematology studies. Updates from the 2013 ASH Review are discussed in detail, beginning on page six.

We are continuing our efforts to ensure the viability of the community oncology setting. We look forward to bringing you clinical updates via publications and meetings throughout 2014, and we will continue to offer practice management tools that will help you increase efficiency and effectiveness within your office. Thank you for your continued support of ION Solutions.

Sincerely,
Mark Santos
President
ION GPO
RESEARCH UPDATES FROM ION’S ASH 2013 REVIEW

By: Danielle Briscoe

At ION’s ASH Review meeting in January, attendees heard from experts on the latest and most clinically relevant research news in hematology. Below are highlights from the presentations on chronic lymphocytic leukemia (CLL), myelodysplastic syndromes (MDS), and chronic myelogenous leukemia (CML).

CHRONIC LYMPHOCYTIC LEUKEMIA
Dr. Javier Pinilla-Ibarz of H. Lee Moffitt Cancer Center in Tampa, Fla., discussed novel advances in CLL.

ASH 2013 brought us several updates from trials of front-line therapies in CLL. Eichhorst et al. presented the results of an interim analysis of a Phase III study comparing the standard combination of fludarabine (Fludara®), cyclophosphamide, and rituximab (Rituxan®) (FCR) to bendamustine (Treanda®)/rituximab (BR) in previously untreated, physically fit patients (n=550) with advanced CLL.1 With a median follow-up of over two years, the interim analysis showed that FCR had higher efficacy in treatment-naïve CLL compared to BR. The complete response (CR) rate with FCR was 47% compared to 38% with BR arm; PFS was not reached in the FCR arm and was 44.9 months in the BR arm (P=0.041). Both arms had similar overall response rates (ORR; 98%) and 2-year overall survival (OS) rates (>94%). Minimal residual disease (MRD) negativity was significantly improved in the FCR arm in peripheral blood and bone marrow compared to BR. However, the FCR arm was associated with more frequent and severe adverse events (AEs), including grade ≥3 neutropenia (82% vs. 57%, respectively; P<0.001) and infection (39% vs. 25%, respectively; P<0.001). Overall, these data show that FCR is still the standard of care in young and fit CLL patients without chromosome deletion 17p.

Goede et al. presented the final stage two results of the Phase III CLL11 trial, which compared obinutuzumab (GA101) plus chlorambucil (Leukeran®) to rituximab plus chlorambucil in 780 previously untreated CLL patients with comorbidities typical of CLL patients seen in daily practice.2 With a median follow-up time of 19 months, obinutuzumab/ chlorambucil demonstrated superiority over rituximab/ chlorambucil (Table 1).

NOT ALL PATIENTS WITH A BCR-ABL VALUE ABOVE 10% AT THREE MONTHS HAVE A HIGH ONGOING RISK OF TREATMENT FAILURE.24 INSTEAD, ANY BCR-ABL REDUCTION BELOW 10% BY SIX MONTHS OF THERAPY SIGNIFICANTLY IMPROVES OUTCOMES IN THOSE WHO HAD A POOR RESPONSE AT THREE MONTHS. THIS REVEALS THE PROGNOSTIC IMPORTANCE OF ASSESSING THE SIX-MONTH MOLECULAR RESPONSE IN CML PATIENTS.
Table 1. Key Efficacy Results from Stage 2 of the CLL11 Trial

<table>
<thead>
<tr>
<th>Treatment</th>
<th>ORR (%)</th>
<th>CR (%)</th>
<th>PFS (months)</th>
<th>MRD negativity (bone marrow)</th>
<th>MRD negativity (blood)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obinutuzumab + Chlorambucil (n=333)</td>
<td>78%</td>
<td>21%</td>
<td>26.7 months</td>
<td>20%</td>
<td>38%</td>
</tr>
<tr>
<td>Rituximab + Chlorambucil (n=330)</td>
<td>65%</td>
<td>7%</td>
<td>15.2 months</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>P-value</td>
<td>&lt;0.0001</td>
<td></td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Abbreviations: ORR, overall response rate; CR, complete response rate; PFS, progression-free survival; MRD, minimal residual disease.

The most common AE observed with obinutuzumab/ chlorambucil was neutropenia (33% vs. 28% rituximab/ chlorambucil). This combination was also associated with a higher rate of infusion-related reactions during cycle 1 (20% vs. 4% rituximab/chlorambucil), but, overall, had an acceptable safety profile. These results support obinutuzumab plus chlorambucil as a new frontline therapy for older and unfit patients.

We may also see obinutuzumab in combination with chlorambucil coming up in the front line for this patient population. In a Phase III study of frontline treatment in CLL patients who were elderly or otherwise unfit for fludarabine-based therapy (n=447), obinutuzumab/chlorambucil demonstrated clinical improvements over chlorambucil alone, with a manageable side effect profile. The combination treatment improved PFS by 71% compared to single-agent chlorambucil (22.4 months vs. 13.1 months, respectively) and was also durable. The improved efficacy with combination treatment was observed irrespective of patient age or fitness. Although elevated grade 3/4 AEs, including mild infusion-related reactions and neutropenia, were observed with obinutuzumab/chlorambucil, this was not reflected in withdrawals or infections.

The combination of obinutuzumab and chlorambucil improved ORR, CR, and PFS compared with chlorambucil alone. The combination was well tolerated and induced a high rate of durable remissions in high-risk CLL. Similarly, in a Phase II study in combination with BR, this agent demonstrated an acceptable safety profile and showed activity in patients with relapsed/refractory CLL. Response to ibrutinib/BR was associated with improved hemoglobin and platelet counts and resulted in an ORR of 93.4%. Median PFS has not been reached. This combination is the subject of an ongoing global Phase III study (NCT01611090).

The PI3K inhibitor idelalisib is also active and well tolerated in relapsed/refractory CLL patients and is likely coming soon for this indication in combination with rituximab. In a Phase III, randomized, placebo-controlled study, adding idelalisib to rituximab improved PFS in patients with heavily pre-treated, relapsed CLL that was not suitable for chemotherapy (hazard ratio [HR] = 0.15; P <0.0001), including in patients with del(17p)/TP53 mutation. It also improved OS (HR = 0.28; P=0.018), ORR (odd ratio [OR]= 29.92; P <0.0001) and lymph node response (OR = 264.46; P <0.0001).

Finally, it will be interesting to see the results of future combination trials with the Bcl-2 inhibitor ABT-199, which produced significant CR rates (23%) in relapsed/refractory CLL patients as a monotherapy, including in patients with del(17p) and fludarabine-refractory disease. An ORR of over 80% was reported for both relapsed/refractory patients and for those with high-risk CLL.

### MEYOLODYPLASTIC SYNDROMES

The MDS update was presented by Dr. Alan List of H. Lee Moffitt Cancer Center in Tampa, Fl.

New data has shed light on specific gene mutations and the impact of mutation load in MDS. In an International Cancer Genome Consortium study, investigators performed targeted sequencing of 111 genes in 738 MDS patients, showing that the majority (78%) of patients had one or more oncogenic mutations in 41 genes. Leukemia-free survival was inversely related to the number of mutations (P<0.0001), highlighting the prognostic significance of driver mutation load. Driver mutations had the same prognostic impact whether clonal or subclonal.

Recent studies show that TP53 mutations, which appear limited in therapy-related MDS (tMDS) and therapy-related acute myeloid leukemia (tAML). However, whole genome sequencing performed by Wong et al. shows that driver mutation load and type in therapy-related MDS/AML is similar to de novo MDS/AML. Therefore, TP53 mutations in therapy-related MDS/AML are not treatment-induced. Additional analyses by that team instead demonstrate that MDS/AML arises from preferential expansion of pre-existing mutant clones that emerge with senescence, rather than from genotoxic injury from cytotoxic therapy pre se.

At ASH 2013, Jabbour et al. reported on the outcome of 438 patients with IPSS-R to monitor for clonal evolution. Patients with IPSS low to intermediate-1 risk MDS who had failed treatment with a hypomethylating agent (HMA). Outcomes after HMA failure were poor, and HMA failure in this group was better predicted by the MD Anderson Cancer Center global prognostic scoring system (MDASS) than the IPSS-R.
Finally, a report by Chen et al.\textsuperscript{17} provides new insights into MDS pathogenesis by showing that myeloid-derived suppressor cells (MDSC) are markedly increased in MDS, directly suppress hematopoiesis, and have a pathogenic role in this disease. These cells now represent a prime biological therapeutic target in MDS.

**CHRONIC MYELOGENOUS LEUKEMIA**

Dr. Tapan Kadia of MD Anderson Cancer Center in Houston, Texas, presented the update on CML.

At this winter’s ASH meeting, there were multiple updates from large, prospective CML trials testing tyrosine kinase inhibitors (TKIs). First, Castagnetti et al. presented long-term data on 559 early chronic phase CML patients who received frontline imatinib mesylate (Gleevec\textsuperscript{®}) treatment in a multicenter, prospective, GIMEMA CML Working Party trials.\textsuperscript{18} With a median follow-up of 6.5 years, the cumulative probability of achieving a major molecular response (MMR; BCR-ABL ≤ 0.1% with imatinib as a frontline treatment for CML was 86%, while the cumulative probability of achieving a deep molecular response (MRD; BCR-ABL ≤ 0.01% or undetectable disease with ≥ 10,000 ABL copies) was 66%, but stable MRD was only 19%. The median time to MMR was 8 months and the median time to MRD was 42 months. Overall survival was 85%, while leukemia-related survival was 94%. Deaths were attributable equally to CML-related causes (i.e., progression to accelerated phase/blast phase [AP/BP]) and to other causes (i.e., while in remission) (P<0.001).

Four-year follow-up of the randomized, Phase III DASISION trial (n=519) continues to support the use of frontline dasatinib (Sprycel\textsuperscript{®}) over imatinib in patients with newly diagnosed chronic phase CML (CML-CP).\textsuperscript{19} At four years, the cumulative rate of MMR was 76% on the dasatinib arm compared to 63% on the imatinib arm (P<0.0001), with a 1.6-fold higher likelihood of achieving MMR with dasatinib at any time. Similarly, the cumulative probability of achieving MRD\textsuperscript{2} was higher with dasatinib compared to imatinib (53% vs. 42%, respectively), as was the cumulative probability of achieving MR4\textsuperscript{+} (BCR-ABL > 0.0032%; 37% vs. 30%, respectively). Cumulative MMR rates by Hasford Risk Score category are presented in Table 2.

As of the three-year database lock, 8 patients in the dasatinib arm and 14 patients in the imatinib arm had transformed to AP/BP on study, and 12 and 18 patients, respectively, had transformed when follow-up beyond discontinuation was considered. In an exploratory analysis, the number of mutations was similar in both arms, but the majority of mutations in the dasatinib arm were T315I mutations. In both arms, the number of deaths, OS, and PFS were similar. However, dasatinib was related to a greater rate of cardiac ischemia compared to imatinib (0.9% vs. 1.2%, respectively).

Leber et al. reported three-year data from the ENESTcmr study, which found that patients with CML-CP and ongoing residual disease on imatinib achieved better and deeper molecular responses when switched to nilotinib rather than continued on imatinib at two years.\textsuperscript{21} Interestingly, among patients with residual disease on imatinib at two years, none were able to achieve a cytogenetic molecular response (CMR) by three years if they continued on imatinib. In sensitivity analyses by 36 months up to crossover, 47% in the nilotinib arm and 24% of patients in the imatinib arm achieved MRP\textsuperscript{3} (P=0.0003).

In the Phase III LASOR trial, Cortes et al. evaluated switching from imatinib to nilotinib in a different set of patients: those with a suboptimal cytogenetic response on imatinib.\textsuperscript{22} Although the primary endpoint (complete cytogenetic response at six months by intent-to-treat [ITT] analysis) was not met, analyses accounting for crossover and more sensitive molecular monitoring found higher rates of response related to switching to nilotinib versus escalating the imatinib dose.

Table 2. DASISION: Four-Year Cumulative Rates of MMR by Risk Category

<table>
<thead>
<tr>
<th>Hasford Risk Score</th>
<th>Dasatinib 100 mg daily (n=259)</th>
<th>Imatinib 400 mg daily (n=260)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>90%</td>
<td>69%</td>
</tr>
<tr>
<td>Intermediate High</td>
<td>70%</td>
<td>63%</td>
</tr>
<tr>
<td>High</td>
<td>65%</td>
<td>52%</td>
</tr>
</tbody>
</table>

Abbreviations: MMR, major molecular response.

Saglio et al. presented the five-year follow-up of the ENESTnd study, which compared frontline nilotinib (Tasigna\textsuperscript{®}) to imatinib in newly diagnosed patients with Philadelphia chromosome-positive (Ph+) CML-CP.\textsuperscript{23} At five years, the cumulative rates of MMR were 71% in the nilotinib arms (300 and 400 mg bid) and 60% in the imatinib arm (400 mg daily) (P<0.0001). The cumulative rate of MRD\textsuperscript{2} was 54% with nilotinib 300 mg bid, 52% with nilotinib 400 mg bid, and 31% with imatinib 400 mg daily (P<0.0001 for comparisons of nilotinib vs. imatinib).

There were no new progressions on core treatment (excluding or including clone evolution) in year five of the trial. Selected cardiac and vascular events were slightly more frequent with nilotinib (particularly at the higher dose) compared to imatinib. Fewer patients who achieved an early MMR on the nilotinib arms experienced early molecular response failure compared to those on the imatinib arm.

Apperley et al. found that interrupting or reducing the dose of a TKI within the first three months of CML treatment was associated with inferior early molecular responses and predicted an increased likelihood of discontinuing the first-line agent.\textsuperscript{24}

Findings from Branford et al. show that not all patients with a BCR-ABL value above 10% at three months have a high ongoing risk of treatment failure.\textsuperscript{25} Instead, any BCR-ABL reduction below 10% by six months of therapy significantly improves outcomes in those who had a poor response at three months. This reveals the prognostic importance of assessing the six-month molecular response in CML patients.

A preliminary report from the STIM2 study shows that imatinib can be safely discontinued in patients with a sustained deep molecular response.\textsuperscript{26} All patients who relapsed were sensitive to rechallenge with a TKI, including imatinib (n=33), dasatinib (n=3), and nilotinib (n=6). The median time to achieve a complete MR (CMR) from molecular relapse was 7 months, and the median time to CMR from restart of therapy was 4 months.

Finally, ponatinib (Iclusig\textsuperscript{®}) was shown to be active as a frontline treatment for newly diagnosed patients with CML-CP\textsuperscript{27} and in CML patients who are resistant/intolerant to dasatinib or nilotinib, or who have the T315I BCR-ABL mutation.\textsuperscript{28} However, venous occlusion events reported with this agent warrant deeper investigation.
References:
GETTING STARTED ON ICD-10
8 EASY STEPS

By: Gordon Kuntz

EDITOR’S NOTE: At press time, Congress passed and President Barack Obama signed legislation that will delay the implementation of ICD-10 until at least Oct. 1, 2015. We encourage you to continue your diligent efforts toward ICD-10 compliance. Given your busy schedules, the temptation will be strong to put this off until next year, but it is more prudent to continue your efforts on a paced schedule.

You’ve heard about it and, if you are like many practices, you’ve put off doing much about it.

In January 2014, ION Solutions launched an ICD-10 readiness survey to learn how prepared member practices are for this significant change. Of the practices that responded, only eight percent judged themselves as very prepared and 51 percent assessed themselves as somewhat or very unprepared.

It’s time to start or finish the work you’ve already begun.

WHY TRANSITION TO ICD-10?

As of Oct. 1, 2015, the U.S. will join the rest of the developed world in using ICD-10 as the diagnosis and procedure-coding standard, at least more or less. Hospitals must use the ICD-10 code set for both diagnoses and inpatient procedures. Physicians can continue to use ICD-9 procedure codes (CPT codes) but must use ICD-10 for diagnosis codes.

Use of ICD-10 diagnosis codes is mandated for all transactions and reporting with the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid as of Oct. 1, 2015. Payers are already well under way with implementation and testing, and most expect to be ready by the deadline.

If a practice is not able to bill or report services that occur on or after Oct. 1, 2015, using the appropriate ICD-10 diagnosis codes, CMS is expected to reject those claims. Most private payers also will reject claims that continue to use ICD-9 diagnosis codes or use ICD-10 coding incorrectly. Practices not compliant with ICD-10 can expect serious interruptions in collections and cash flow.
Getting Started

A project this large can feel overwhelming. If you haven’t started, don’t panic. If you have started and may have stalled, get organized and get finished – the sooner the better.

1. Organize Your Project Team. Identify one person who will have overall responsibility and authority to complete this project. One of the first things your project team will want to do is identify the other team members and any additional resources you need. Especially if you are just getting started, this will not be an inexpensive proposition. Industry estimates put the cost of conversion to ICD-10 at about $200,000 for a 10-physician practice. Make sure that the person you task with project management has experience with large complex projects and has the organizational authority to ask for and receive support in all departments. Your project team will need to include representation from the following areas:

- Medical records & coding
- Information technology, analytics, and reporting
- Payor contracts
- Billing and prior authorization staff
- Nursing
- Physicians

If you do not believe that you can maintain current operations and manage an ICD-10 conversion project, you may need to bring in a project manager. You may be well served by using an outside project manager to get and keep things organized. It will not be inexpensive. You may need someone 20 to 40 hours per week, depending on your practice, at a rate of no less than $90 to $100 per hour.

Industry Estimates

Put the Cost of Conversion to ICD-10 at About $200,000 for a 10-Physician Practice.

2. Identify the Goal. Understand what you need to do to be compliant with ICD-10. A few suggestions to help with that process:

- Review the information provided by CMS [http://www.cms.gov/Medicare/Coding/ICD10/ProviderResources.html].
- Ensure that you are looking at the information for physician practices not hospitals, as hospitals have additional coding changes for inpatient services that don’t apply to physician practices.
- Check with your payers regarding timelines and testing. They may have additional resources available for you.
- Check with your state or national professional societies to see if there are resources or coding classes offered.
- Talk to your systems vendors (EMR, practice management, patient portal, CPOE, claims clearinghouse, etc.). Note that your system vendor should be able to help you but cannot do it for you. If they do not yet have a plan or have not already released an ICD-10 compatible version, you will need to take extra steps at extra cost to either change systems or otherwise mitigate this serious issue. A systems vendor not being prepared or at least not having an announced release schedule is a serious red flag.

3. Identify Where You Use ICD-9 Diagnosis Codes Today. This will likely include places like medical records entry, billing and claims, superbills, reporting to government agencies or payers, etc. Check not only systems but also paper forms, reports, etc. Do not forget that some payer fee schedules or reimbursement arrangements may depend on the diagnosis as well as the procedure. Be sure to check contracts. Anywhere that you use ICD-9 today, you will need to understand how to use ICD-10 in the future.

4. Conduct a Gap Analysis. Determine how to address each use of ICD-9 from your list. If the item is “Diagnosis entry into EMR,” you have multiple steps to consider:

- Who identifies the diagnosis today? Do you collect sufficient data to code it under ICD-10? You may need more information than was previously collected and everyone involved needs training.
- The coders need to be trained, and you need to be able to handle exceptions and problems.
- When will the EMR system be able to accept ICD-10 entries?
- How will you verify the entry during the transition period to minimize disruption?

Planning is very important in this step. Think through all the steps everyone involved takes in creating a piece of data or report that involved ICD-9 today. Extra time spent planning here will pay off in the end.

5. Identify Resources. Many of the steps you will identify above will require a third party resource to help. Things like your IT systems or clearinghouse are obvious places to use third party resources, but there may be other less obvious ones. How will the coders, physicians, and nurses be trained on ICD-10 coding? How will forms (superbills, referral forms, PA requests, etc.) be updated? Be sure to identify the sources of this information and assistance. Understand the timeline, availability, and dependencies for each item, as well as the cost.

6. Develop an ICD-10 plan. Gather all the materials you have so far and develop a written plan with timelines and specific responsibilities and accountabilities. Establish a meeting schedule for the project team and stick with it. You may start with bi-weekly meetings and move to a weekly schedule as you get closer. Be sure to account for vacations and maintaining the current flow of business as well as a hefty dose of testing. Leave a little slack in the plan – things will take longer than you think. Be sure to prioritize the work that needs to be done (your most dominant payers before smaller contracts, external or mandated reports before internal reports, etc.).

Take the opportunity to review and streamline your processes as you go. You are already doing so much in the way of retraining that you might as well eliminate steps you find to be redundant along the way. How much you can accomplish in the way of process redesign during the transition will be a function of time, resources, and workload. If you get pushed into a corner, you won’t do much to help yourself in the end. Leave a little more time and you can benefit from the transition.

Payer Topics

“Getting Started on ICD-10: 8 Easy Steps” is part of the Payer Topics article series developed by the ION Solutions Payer Team. These timely, provider-focused articles are available for download on the Meetings, Education, and Publications tab at www.iononline.com. Other available titles include:

Affordable Care Act Series
- A Quick Guide to the Affordable Care Act for Providers
- Understanding Public Healthcare Exchanges
- Understanding Private Health Insurance Exchanges

CMS Series
- CMS Final CY2014 Physician Fee Schedule and Outpatient/ASC Payment Rules
- 2014 Milestones for Providers

Payer Alert
- HHS/Private Payers Target Double Billing
7. Contingency Planning – A very important part of your overall ICD-10 plan. Moving to a new coding scheme with upgraded software - and similar projects going on with all of your trading partners - almost certainly will result in disruptions in internal efficiency, payment lags, and the like. You will be well-served by planning for a 10 to 20 percent reduction in productivity for 90 to 120 days, coupled with a 10 to 15 percent reduction in cash flow for up to six months, as well as the direct and indirect costs associated with the transition itself. The practice may need additional cash flow financing, and now is the time to talk to the bank, not when bills are not being paid. It is better to plan for a significant disruption and be pleasantly surprised not the other way around.

It is important to note that the disruption could conceivably be caused as much by your trading partners as by your staff. Most payers have been working on this for months but when they actually go live, there are likely to be errors that will take time to fix. Similarly, most system vendors have been working on new versions for months, but there could well be remaining issues in some cases. Combine that with needing to retrain 80 percent or more of your staff on key information and one can easily see the potential for major disruption. Plan ahead.

8. Implement – Get going! Execute and adjust the plan as you go. If you missed a step, make sure to add it. If something is taking longer than it should, adjust your timeline. Be sure to communicate progress – success as well as issues – to the staff and to management so that adjustments can be made along the way. Track your progress and adjust resources if need be to stay on track for the bulk of the work that needs to be done.

Transitioning to ICD-10 will be a significant project. If you start now (or finish what already has been started), you may find that your practice becomes more efficient over time. But, the most important thing you can do today is start!

ION Solutions offers an “ICD-10 and What it Means for Your Practice” webinar. During the webinar, Risë Marie Cleland, president of Oplinc Inc., explains:

> What ICD-10 is
> Who is required to use it
> Similarities to ICD-9-CM and the significant changes
> ICD-10-CM for oncology

Cleland give you tips, tools, and resources to prepare your practice for the Oct. 1, 2015, required compliance date.

Visit www.iononline.com, click on Providers and then on Meetings, Education, and Publications to view the archived webcast.

Gordon Kuntz is senior director, Payer Solutions, at ION Solutions.

MORE PATIENTS. MORE PRESCRIPTIONS. A MORE COMPLETE CONTINUUM OF CARE WITHIN YOUR PRACTICE.
THE SPECIALTY ONCOLOGY NETWORK FROM ION SOLUTIONS.

Establishing your own in-practice dispensing service through ION Solutions not only allows your patients more convenient access to medication, but it also enhances your control and oversight of their therapy. The Specialty Oncology Network (SON) exists to help community oncology practices successfully optimize in-practice dispensing services — in fact, the majority of all dispensing oncology practices are part of SON. With the largest and longest-tenured pharmacy program in the market, and 12 GPO contracts currently in place, ION Solutions harnesses the collective power of community oncology to accelerate practice growth and improve patient care.

For additional information, please visit iononline.com or email SON@iononline.com.
WHAT’S NEWS AT ION

COA AND ASCO ISSUE JOINT STATEMENT ON ONCOLOGY PAYMENT REFORM

In February, COA and ASCO issued a joint statement on payment reform in cancer care. The statement results from collaboration between the two organizations, in concert with AmeriSourceBergen/ION and McKesson/US Oncology, to arrive at principles to guide the evolution of healthcare payment systems that support high-quality, high-value cancer care. The goal is to improve the lives of individuals with cancer, in part by developing and supporting payment systems based on evidence-based medicine and measures of quality and value in cancer care. The full statement is below:

PRINCIPLES TO GUIDE THE EVOLUTION OF HEALTHCARE PAYMENT SYSTEMS THAT SUPPORT HIGH-QUALITY, HIGH-VALUE CANCER CARE

A JOINT STATEMENT BY THE COMMUNITY ONCOLOGY ALLIANCE AND THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

The Community Oncology Alliance (COA) and the American Society of Clinical Oncology (ASCO) are working on strategies to improve the lives of individuals with cancer. As stakeholders who care for individuals with cancer, we provide the following joint statement on payment models that support high-quality, high-value cancer care.

Joint Principles

1. Oncology professionals are uniquely positioned to play leadership roles in the development of innovative models for oncology care. Any new model must promote access to evidence-based care, improve quality, support the efficient use of resources, and help control the overall growth of healthcare costs. COA and ASCO are actively working on potential solutions to the challenges facing the oncology community, and these organizations embrace the opportunity to collaborate with other stakeholders to explore the viability of innovative strategies.

2. Traditional reimbursement models currently do not provide adequate support for the care coordination and complex disease management necessary for delivery of high-quality, high-value care in oncology. Improving the quality and value of the care provided to individuals with cancer may require changes that ensure adequate financial, administrative, and data support for oncology providers to engage in new approaches that reduce the frequency and severity of clinical complications.

3. Considerable resources, time, and effort must be invested by oncology providers to implement many of the changes in delivery models that promise to improve clinical outcomes and reduce overall costs in oncology care. As a result, changes in payment models should be phased in over multi-year periods. Oncology providers should be protected against significant swings in reimbursement or abrupt changes in future reimbursement policies, especially in the early years of adoption.

4. There are multiple models for the delivery of oncology care that show promise, and oncology providers should have the option to select the approaches that fit the best with the challenges and opportunities in their local community. Among the models that show promise, COA and ASCO highlight two that should be considered for early piloting:

   > Oncology Medical Home. Investing in changes to clinical practices and operations under an oncology medical home model can improve the quality of care and significantly reduce the aggregate costs of cancer care by reducing the frequency of avoidable complications, emergency department visits, and unscheduled hospitalizations. Adopting the oncology medical home requires investment in information technology infrastructure and other practice support to provide the full range of services needed by patients with cancer—throughout the course of their treatment and transition to survivorship.

   > Monthly Payments. Monthly, non-visit based payment provides flexible and predictable payment to support comprehensive disease management, including telephone and email contact between physicians and patients, visits with non-physician staff, proactive outreach for medication and symptom management, extended practice hours, and other services in addition to traditional office visits with physicians. These monthly payments would be higher for patients with conditions requiring more labor-intensive services or patients who are at more acute stages of illness. In return for this more flexible payment methodology, the oncology practice may be required to take responsibility for whether patients avoid oncology-related emergency department visits, hospitalizations, and complications.

5. The quality of oncology care should be measured in meaningful ways, and quality measures should play an important role in the evaluation and reimbursement of oncology providers under new delivery models.

6. The current payment methodology used under Medicare Part B of average sales price (ASP) plus six percent is inadequate to cover the costs and risks that oncology providers currently experience in purchasing and maintaining an inventory of expensive cancer drugs with specialized storage requirements. This inadequacy is exacerbated by the cut to Medicare drug payments under sequestration.

ASCO CONTINUES TO CALL FOR SGR REPEAL

ASCO is deeply frustrated by the failure of Congress to permanently repeal the flawed sustainable growth rate (SGR) formula used to set Medicare physician payments and passage of the 17th patch to the system.

Visit www.asco.org to read a statement by ASCO President Clifford A. Hudis, MD, FACP.
COMMUNITY COUNTS PRACTICE EFFECTIVENESS WEB SERIES
Hosted By: Risë Marie Cleland

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 the SGR repeal bill and preparing for ICD-10 implementation.

2014 Topics:
- March 27: SGR Repeal Bill Update: What’s the Status? What Does It Mean?
- April 10: ICD-10 and Oncology: What You Need To Do Now and In the Near Future
- May 15: Quality Programs in Oncology: What’s Available, What Makes Sense for You
- June 26: Medicare EHR: Preparing for 2015

All events will take place at 3 p.m. EST, and ION Solutions members can register at www.ionline.com. Click on Meetings, Education & Publications.

HABITS OF A SUCCESSFUL ONCOLOGY PRACTICE VIDEO SERIES

As part of Community Counts, ION Solutions has released a five-part video series highlighting The Habits of a Successful Oncology Practice.

Visit ourcommunitycounts.org to view the series and learn these habits:
- Manage Drug Inventory
- Control the Revenue Cycle
- Offer Pharmacy Services within Your Practice
- Hire a Benefits Coordinator
- Maximize Staff

ION SOLUTIONS RECOGNIZES CONGRESSIONAL MEMBERS’ SUPPORT

In February, ION Solutions leadership met with congressional members and their staffs to discuss the recent Medicare cuts and the effect they are having on cancer patients across the country. In each meeting, ION leadership thanked the congressional and staff members for their support of cancer care legislation, especially the Prompt Pay bill and Rep. Renee Ellmers’ sequester legislation.

Rita Norton, AmerisourceBergen senior vice president, Government Affairs, (center) and Barry Fortner, Ph.D., president, ION Solutions (right), recognize Rep. Charlie Dent, co-chair of the House Cancer Caucus (left), for his recent letter to CMS expressing opposition to the 2014 Medicare Physician Fee Schedule rule.
Important Safety Information

WARNINGS AND PRECAUTIONS
- Treatment with ISTODAX® (romidepsin) has been associated with thrombocytopenia, leukopenia (neutropenia and lymphopenia), and anemia; therefore, monitor these hematological parameters during treatment with ISTODAX and modify the dose as necessary
- Serious and sometimes fatal infections have been reported during treatment and within 30 days after treatment with ISTODAX. The risk of life-threatening infections may be higher in patients with a history of extensive or intensive chemotherapy
- Electrocardiographic (ECG) changes have been observed with ISTODAX
- In patients with congenital long QT syndrome, patients with a history of significant cardiovascular disease, and patients taking anti-arrhythmic medicines or medicinal products that lead to significant QT prolongation, appropriate cardiovascular monitoring precautions should be considered, such as monitoring electrolytes and ECGs at baseline and periodically during treatment
- Ensure that potassium and magnesium are within the normal range before administration of ISTODAX

ADVERSE REACTIONS

Peripheral T-Cell Lymphoma
The most common Grade 3/4 adverse reactions (>5%) regardless of causality in Study 3 (N=131) were thrombocytopenia (24%), neutropenia (20%), anemia (11%), asthenia/fatigue (8%), and leukopenia (6%), and in Study 4 (N=47) were neutropenia (47%), leukopenia (43%), thrombocytopenia (36%), anemia (28%), asthenia/fatigue (19%), pyrexia (17%), vomiting (9%), and nausea (6%).

Demonstrated efficacy in PTCL after at least 1 prior therapy in Study 3rd
- 15% (19/130) Complete Response Rate (CR+CRu) by independent central review (95% CI: 9.0, 21.9)
- Similar complete response rates in the 3 major PTCL subtypes (NOS, AITL, ALCL)
- ~60% (11/19) of Complete Response (CR+CRu) exceeded 9.2 months
- Follow-up was discontinued in the remaining 8 patients prior to 9.2 months
- 25% (33/130) Objective Response Rate (CR+CRu+PR) by independent central review (95% CI: 18.2, 33.8)
- 1.8 months (~2 cycles) median time to Objective Response

*Efficacy based on 130 patients with histological confirmation by independent central review.1

Infections were the most common type of serious adverse event reported in Study 3 (N=131) and Study 4 (N=47). In Study 3, 25 patients (19%) experienced a serious infection, including 6 patients (5%) with serious treatment-related infections. In Study 4, 11 patients (23%) experienced a serious infection, including 8 patients (17%) with serious treatment-related infections.

The most common adverse reactions regardless of causality in Study 3 (N=131) were nausea (59%), asthenia/fatigue (55%), thrombocytopenia (41%), vomiting (39%), diarrhea (36%), and pyrexia (35%), and in Study 4 (N=47) were asthenia/fatigue (77%), nausea (75%), thrombocytopenia (72%), neutropenia (66%), anemia (62%), leukopenia (55%), pyrexia (47%), anorexia (45%), vomiting (40%), constipation (40%), and diarrhea (36%).

DRUG INTERACTIONS
- Monitor prothrombin time and International Normalized Ratio in patients concurrently administered ISTODAX (romidepsin) and warfarin sodium derivatives
- Romidepsin is metabolized by CYP3A4
- Monitor patients for toxicity related to increased romidepsin exposure and follow dose modifications for toxicity when ISTODAX is initially co-administered with strong CYP3A4 inhibitors
- Avoid co-administration of ISTODAX with rifampin and other potent inducers of CYP3A4
- Exercise caution with concomitant use of ISTODAX and Pglycoprotein (P-gp, ABCB1) inhibitors

USE IN SPECIFIC POPULATIONS
- Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from ISTODAX, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother
- Patients with moderate and severe hepatic impairment and/or patients with end-stage renal disease should be treated with caution

Please see Brief Summary of Full Prescribing Information, including WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS, on the following pages.

1 INDICATIONS AND USAGE

ISTODAX is indicated for:

• Treatment of peripheral T-cell lymphoma (PTCL) in patients who have received prior chemotherapy and who have had a drug-resistant infection.

This indication is based on response rate. Clinical benefit such as improvement in overall survival has not been demonstrated.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Information

The recommended dosing is romidepsin 14 mg/m² administered intravenously over a 4-hour period on days 1, 8, and 15 of a 28-day cycle. Cycles should be repeated every 28 days provided that the patient continues to benefit from and tolerate the drug.

2.2 Dose Modification

Dose modifications should be made as follows:

• Grade 2 or greater toxicity: Treatment with romidepsin should be delayed until toxicity returns to Grade 1 or baseline and the dose should be permanently reduced to 10 mg/m².

• Grade 4 toxicity: Treatment with romidepsin should be delayed until toxicity returns to Grade 1 or baseline, then the dose should be permanently reduced to 10 mg/m².

• Romidepsin should be discontinued if Grade 3 or 4 toxicities recur after dose reduction.

Nonhematologic toxicities except alopecia

• Grade 3 or 4 neutropenia or thrombocytopenia: Treatment with romidepsin should be withheld. The specific cytopenia returns to Grade 1 or baseline, then the dose should be permanently reduced to 10 mg/m².

• Grade 4 febrile (≥38.5°C) neutropenia or thrombocytopenia that requires hospitalization with romidepsin should be discontinued until the specific cytopenia returns to Grade 1 or baseline, and then the dose should be permanently reduced to 10 mg/m².

3 Precautions for Preparation and Intravenous Administration

ISTODAX is a cytotoxic drug that is associated with serious adverse reactions including severe and fatal reactions. The following guidelines should be followed carefully:

7.3 Drugs that Induce Cytochrome P450 3A4 Enzymes

Romidepsin is a substrate of the efflux transporter P-glycoprotein (P-gp, ABCB1). Romidepsin is not expected to significantly influence drug exposure. The effect of co-administration of ISTODAX with strong CYP3A4 inhibitors has not been formally studied. Physicians should consider monitoring PT and INR in patients co-administering ISTODAX with CYP3A4 inhibitors (see Clinical Pharmacology (12.2)).

7.4 Drugs that Inhibit Drug Transport Systems

In a pharmacokinetic drug interaction trial with the strong CYP3A4 inhibitor ketoconazole, romidepsin exposure was increased by approximately 80% and 60% for AUC0-12h and Cmax, respectively (see Clinical Pharmacology (12.3)).

10 OVERDOSAGE

Emergency procedures are available on the treatment of overdose of ISTODAX. Toxicity in a single-dose study in rats or dogs, at intravenous romidepsin doses up to 2.5 mg/kg, included hyperreflexia, tachypnea when exposed to romidepsin. In an animal reproductive study, romidepsin was embryocidal and resulted in adverse effects on the development of fetuses at exposures below those in patients at the recommended dose. In Study 2, 11% of patients (7/64) experienced a serious infection, including 8 patients (13%) with sepsis, and 2 patients (3%) with fungal infections. In Study 3, 23% experienced a serious infection, including 8 patients (17%) with sepsis, and 2 patients (4%) with fungal infections. In Study 4, 11% of patients (7/64) experienced a serious infection, including 8 patients (13%) with sepsis, and 2 patients (3%) with fungal infections.

Serious Adverse Reactions

Infections (abscesses, bone marrow depression, fever, mycobacterial, and fungal infections, herpes zoster) are the most common type of SAE reported. In Study 3, 25% (19 patients) experienced a serious infection, including 6 patients (15%) with fungal infections. In Study 4, 11% of patients (7/64) experienced a serious infection, including 8 patients (17%) with sepsis, and 2 patients (4%) with fungal infections. In study 2, 11% of patients (7/64) experienced a serious infection, including 8 patients (13%) with sepsis, and 2 patients (3%) with fungal infections. In Study 4, 11% of patients (7/64) experienced a serious infection, including 8 patients (13%) with sepsis, and 2 patients (3%) with fungal infections.
LATEST DEVELOPMENTS ON HEALTH INSURANCE EXCHANGES

By: Aileen Soper

In this issue of Reimbursement Watch, we summarize the most impactful developments to date regarding Health Insurance Exchanges and explain the relevance to oncology and hematology practices.

The exchanges, or marketplaces, were created under the Affordable Care Act (ACA) to expand insurance coverage options and evaluate eligibility for premium tax credits and cost-sharing assistance designed to help more people afford insurance. People were eligible to begin signing up for qualified health plans sold through the exchanges beginning Oct. 1, 2013, with coverage starting Jan. 1, 2014.

> Previously, consumers could only access tax credits and other federal assistance for qualified health plans purchased directly through the exchanges.
> However, major technological issues hampered enrollment for many at the start of the open enrollment period, which ended March 31, 2014.
> The CMS guidance states that if a person could not get a timely eligibility determination and enroll in a qualified health plan during the initial open enrollment period, he might qualify for an exception. Additional criteria to qualify for an exception includes that the person would have to enroll in a qualified health plan off of the exchange and also eventually obtain an eligibility determination from the exchange. Under these circumstances, the person would be considered as having enrolled in an exchange plan. This would allow him to access premium tax credits and cost-sharing reductions if he qualifies based on income.
THE EXCHANGES, OR MARKETPLACES, WERE CREATED UNDER THE AFFORDABLE CARE ACT (ACA) TO EXPAND INSURANCE COVERAGE OPTIONS AND EVALUATE ELIGIBILITY FOR PREMIUM TAX CREDITS AND COST-SHARING ASSISTANCE DESIGNED TO HELP MORE PEOPLE AFFORD INSURANCE.

Payments of tax credits and cost-sharing reductions will be made to a qualified health plan retroactively, back to the effective date of exchange enrollment. There also will be a special enrollment period to allow these people to change plans at the time they get an eligibility determination from the exchange.

Impact to oncology and hematology: Some patients may be able to get assistance affording their premiums and/or out-of-pocket costs if they fit the criteria for an exception. This could help to mitigate financial issues for patients who initially could not enroll with an exchange plan but qualified for federal assistance based on income.

EXCHANGE ENROLLMENT ACCELERATES

Through the end of January 2014, 3.3 million people had enrolled in a qualified health plan through an exchange, including 1.9 million in the federal health exchange and 1.4 million in state-run exchanges.

That was a 53 percent increase over enrollment numbers from the previous month, according to statistics released in February 2014 by the U.S. Department of Health & Human Services (HHS).

The HHS report also gave a demographic snapshot of those enrolling in the exchanges:

\* 65 percent were female
\* 82 percent of those who selected an exchange plan qualified for financial assistance
\* Among the plans available:
  > 62 percent of enrollees chose silver-level plans
  > 19 percent chose bronze
  > 12 percent chose gold
  > 7 percent chose platinum
  > 1 percent chose catastrophic plans

By the March 31 deadline, ACA enrollment had exceeded 7 million. Those who began enrollment but did not finish, and those who could not finish due to technical difficulties, will have until April 15 to complete the process.

Impact to oncology and hematology: A large majority of those enrolling in exchange plans are choosing silver- and bronze-level plans, which have higher out-of-pocket costs compared to higher-tier plans in the gold and platinum categories. However, most of these patients are also qualifying for premium tax credits and/or cost-sharing assistance, which will help to minimize underinsurance among patients seeking treatment in oncology and hematology offices.

SOME ELEMENTS OF THE EMPLOYER MANDATE HAVE BEEN DELAYED

The Department of the Treasury and the Internal Revenue Service released final regulations governing the employer responsibility portions of the ACA that will delay penalties for some companies that do not provide coverage to workers:

\* Medium-sized companies with 50-99 employees will be required to report on health coverage for their full-time workers in 2015. Companies of this size that fail to offer adequate coverage in 2016 would have to pay a penalty.
\* Large companies with more than 100 employees will have to offer coverage to at least 70 percent of their employees in 2015. That benchmark will rise to at least 95 percent in 2016. Employers that do not meet the standard in 2015 would have to make an employer-responsibility payment.
\* Small companies with fewer than 50 employees (this group accounts for >95 percent of all employers) are not required to provide health insurance to full-time employees.

Impact to oncology and hematology: The delay in the employer mandate means that a handful of patients who work for large- or medium-sized employers may not have employer-sponsored commercial health insurance in 2015. However, this is unlikely to have a significant impact on oncology and hematology practices since most U.S. employers have indicated that they will continue providing health benefits to workers despite new requirements in the ACA. One thing to watch for will be how employers handle increased costs, such as raising the cost of premiums for workers or increasing cost-share requirements or reducing elective benefits.

CMS WILL REQUIRE EXCHANGE PLANS TO DISCLOSE ADDITIONAL INFORMATION ON FORMULARIES IN 2015

Insurers that participate in the federal health insurance exchange in 2015 will have to make their drug coverage information available to consumers without requiring passwords or other online registration steps, and also provide tier and cost-sharing information, according to a draft letter released by CMS.


Plans would be allowed to identify whether a drug is covered under the medical benefit when submitting their drug list for review to confirm it complies with essential health benefit standards, which are minimum coverage requirements.

CMS is proposing to review the provider networks of prospective qualified health plans to ensure "reasonable access" and will, in particular, consider access to hospital systems and oncology providers.

CMS may require plans to cover non-formulary drugs temporarily if they were on the formulary for the first 30 days of the calendar year.

Impact to oncology and hematology: The proposed changes could help to alleviate some of the challenges that affected exchange health plan enrollment in 2013 and 2014. For example, increasing the transparency of drug out-of-pocket costs could help patients better determine how their oncology or hematology drugs are covered under plan formularies. The review of exchange plan networks to ensure that patients would have adequate access to oncology providers could also add a layer of protection for patients undergoing treatment for cancer. Finally, the proposal to require plans to temporarily cover drugs that are moved off formulary could help to mitigate access barriers such as coverage denials or increased out-of-pocket costs for patients undergoing ongoing treatment on applicable drugs for oncology or hematology-related conditions.

Aileen Soper is assistant director, Xcenda Reimbursement Strategy and Trends
WHAT SAYS NOSTRADAMUS?
PROPHECIES ABOUT CANCER CARE AND THE FUTURE OF COMMUNITY ONCOLOGY

By Dr. Nash Gabrail

If Nostradamus knew the far-reaching complexities of cancer care delivery, he probably would have allowed his mind and spirit to wonder about the future of oncology centuries later. Well, there was no oncology in those days. Health and disease were the work of the devil and evil spirits. Nonetheless, some educated guessing - although it falls short of prophecy - can be made based on history, geopolitics, U.S. culture, and human psyche.

Well, here are my prophecies about cancer care and the future of community oncology. But, before going there, it is critical to mention that the political landscape of the U.S. in the coming decade will have far-reaching consequences on cancer and other health-related services. Although we credit political contributions and the lobby power of organized medicine for the gradual shift of cancer care from the community to hospitals and large institutions, the fact is, large healthcare advocacy organizations and academic centers poured money into the campaigns of the politicians who share their philosophy and beliefs. Certainly, this is empowering them to push forward with their agendas.

It would have been a waste for these organizations to spend such monies on politicians and candidates who advocate local control and state's rights. Those politicians are in the camp that philosophically supports community oncology. Many of them are crusaders for our cause, despite the mediocre financial support they are getting from community oncology advocacy groups. That is tragic. The damage could have been minimized or even avoided if community oncologists were better self-advocates than they seem to be. Centralized healthcare, including cancer care delivery advocates, had a free ride in the absence of effective counter advocacy groups.

Our deafening absence from the scene has allowed obscenity to become the normal, acceptable alternative to a sensible, common sense philosophy. Otherwise, how can we explain the continued push for the exodus of community oncologists to hospital employment despite the evidence showing community oncology provides less expensive, more convenient, and equally effective cancer care? We know it, experts attest to it, and well-versed policy makers

EMPLOYERS, SICK AND TIRED OF THE RISING COST OF HEALTHCARE, ARE NO LONGER SITTING ON THE SIDELINES, WATCHING AS THEIR MONEY IS WASTED. THEY ARE REALIZING THAT NO ONE OTHER THAN THEM CARES ABOUT THEIR BOTTOM LINE. THEY ARE TAKING CHARGE.
seem to ignore this fact because of the powerful lobby that guides their decisions.

Centralized health care advocates claim hope or assume that the exodus of community oncologists and other physicians from private practice, albeit costly initially, will save money with time. They assume that future bundle payments contracted with large institutions that can provide A to Z care will cut costs, but we all know the contrary is more true. Unfortunately, what is obvious to most of us only will become a reality in the eyes of policymakers several years from now.

We have only two potential scenarios where this destructive trend is hampered: first, if we, community oncologists and other physicians, change gears and get more involved in politics and advocacy. That doesn’t seem to be happening any time soon.

The second and more hopeful scenario – although it seems to be unlikely to happen – is that we elect officials who actually care about the health of our healthcare system and its solvency. If we were fortunate to elect large numbers of such politicians, their first step would be to pass legislation that rewards the delivery of high value, patient-centered care.

However, it doesn’t stop there. Many employers are opening workplace clinics. We run such businesses in our region, and there are hundreds of such clinics nationwide with remarkable cost savings. This system, when collaborated with the third party administrators as we do, can have far-reaching positive consequences in trapping overutilization and irresponsible costly medical care. An unintended consequence of the workplace clinics is pressuring insurance companies to be more cost conscious, that is, if they want to keep their customer base. In fact, some insurance carriers are implementing some healthy plans, such as:

> Steering patients to more cost-effective centers for imaging, which is appealing to patients, especially those who have tangible out-of-pocket expenses. It is happening now on a limited scale, but I expect it to grow in the future.

> Terminating contracts with some providers based on cost and quality of care. We are seeing it happen, at least in Ohio. I am sure this will become a widespread policy, with or without legal repercussions. This is only the beginning. I think the day when any physician can be a provider on a plan, if he wishes, is soon to go. Profiling is coming. It is inevitable.

> Using the plan’s own clinical pathways. Following those guidelines is incentivized by preauthorization, waiver, and in some cases, financial incentives. Insurance companies, under pressure to contain costs, have concluded that pathways established by the providers and organized medicine are infested with conflict of interest and pushed from the pharmaceutical industry. They are taking charge and rightly so. I predict that this trend will grow fast in the coming years. There will be push back against such policies based on quality concerns. I doubt that will work because it is becoming obvious that more money spent does not necessarily translate in to better outcomes. The evidence points to the contrary.

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Very large employers, such as Walmart and Lowes, have established centers of excellence for heart and spine surgery where they fly their patients and a companion to the centers all expenses paid. They still save money and receive a proven superior quality of care. This is the beginning. Programs that are more robust are to come. Patients still can choose a local provider, but they have to pay their co-pay share per policy.

In the book I published five years ago, “Good Medicine is Cheaper Medicine,” I concluded that the only way we can improve quality and contain costs is through individual responsibility. That can come through monitoring out-of-pocket expenses by patients, and more dramatically, it is coming through the employers taking charge of their health plans. The latter seems to be shaping up as the holy grail of medicine.

My final prediction has to do with the big gorilla in the room: the Affordable Care Act (ACA.) When I wrote my book, I did not address ACA because it wasn’t conceived yet. Now it is born but with major physical and mental disabilities. Employers were concerned about the impact of ACA, they were frozen not knowing how to proceed, not knowing how it will play. Now there is ease. Either it is going to be dismantled or - to save face - it will be drastically modified. I believe the November 2014 election results will have critical consequences on how the government will proceed. One thing is clear: it is going to be more costly to the taxpayers and to the employers. The taxpayers are at the mercy of the policymakers, but the employers can read the crystal ball. The penalties will rise and drastically so. Hence, they are proceeding with their own reform, the American way, by taking charge of your own affairs and letting the government do what it does best: waste our money.

Dr. Nash Gabrail, oncologist/hematologist, is the president of Gabrail Cancer Center in Canton, Ohio. The views expressed on these pages are those of the author’s and do not necessarily reflect the views of ION Solutions or AmerisourceBergen.
Registration will be available approximately 60 days prior to each event. To register, visit www.iononline.com.

*Meeting dates subject to change.*

**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.

**WARNINGS, PRECAUTIONS, AND DRUG INTERACTIONS**

▼ Peripheral neuropathy: Manage with dose modification or discontinuation. Patients with preexisting severe neuropathy should be treated with VELCADE 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.

▼ Hepatic toxicity: Monitor hepatic enzymes during treatment.

▼ Embryo-fetal risk: Women should avoid becoming pregnant while being treated with VELCADE. Advise pregnant women of potential embryo-fetal harm.

▼ 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 on next page.

* The reconstituted concentration for subcutaneous administration (2.5 mg/mL) is greater than the reconstituted concentration for IV administration (1 mg/mL).

†Melphalan+prednisone.

‡

**ION Solutions’ Educational Programs**

2014 Meeting Schedule
Save the Date

**Business of Oncology**
Dedicated to the discussion of practice management and efficiencies
May 16-18, 2014
Orlando, FL

**National Healthcare Practitioners Meeting**
Intended for nurses, nurse practitioners, pharmacists, and physician assistants to discuss various tumor types and disease states
Sept. 12-14, 2014
Dallas, TX

**ION National Meeting**
Designed to share the latest news across multiple tumor types and disease states
Nov. 7-9, 2014
Nashville, TN
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 CommunityOncologyCounts
Follow us on Twitter @communitycts
Advocate for the future of cancer care #SaveCancerCare

OurCommunityCounts.org
CommunityCountsAdvocacy.org

Drug Update
IV Iron Therapy and the Management of Documented Iron Deficiency in Patients with Cancer: Case Studies
Getting Started on ICD-10