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Studies have shown that breast cancer nurse navigators—that is, specialized case managers who are educated and certified in breast cancer therapies and patient care—improve outcomes and quality of care, enhance access to services for all patients, remove barriers to care, improve care delivery, enhance relationships with the community, and increase patient satisfaction and referrals of new patients to health care systems. Hear about the role of the breast cancer nurse navigator in one community hospital and find resources for starting or enhancing your own program.

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Gary S. Wolfe

Health Care Trends: 2012

What will health care look like in 2012? What are the trends? What impact will these trends have on case managers?

Perhaps the biggest event in 2012 affecting health care will be the election. The political rhetoric has already begun. The courts as well as the election could change the recently passed health care reform legislation. If the makeup of the Congress changes, will health care reform as we know it be repealed? Will it be amended? Whatever happens could have a major effect on case managers. There is cause for you as a case manager to stay informed and talk with your elected representatives and candidates for office. Who knows better what the challenges are in the health care delivery system than case managers? As a case manager, you need to tell your story of what you do, of the challenges you face in coordinating care, and what some of the solutions could be. Make an appointment to see your elected representatives or staff person. Attend candidate forums. Recruit your neighbors, your patients, and all the stake holders in the health care delivery system. Tell it like it is! Make a difference!

Some of the trends that will impact case management include:

- Defining and paying for value. Value in health care has no standard definition, but everyone can define value as they see it. Value-based insurance plans will be introduced where proven treatment costs will be reimbursed at a higher rate than new treatments that are unproven. Choice will be restricted according to cost. There will be explicit use of plan incentives to encourage adoption and appropriate use of high-value services, healthy lifestyles, and use of high-performance providers who adhere to evidence-based treatment guidelines. Seventy-eight percent of consumers

are interested in value health solutions. Health plans will be more oriented toward provider performance with policies that will be pricing based on provider performance.

- Providers and payors will team up. There will be more sharing of data between providers and payors. New partnerships will be formed with enhanced intergration. Data sharing can improve care coordination; it will promote real-time decision making and support provider performance analysis as well as identify patients at risk.
- State insurance exchanges will be used to purchase competitive health plans. There will be fierce competition between health plans for members. High-risk individuals will turn to insurance exchanges to get the best value.
- Social media will play a bigger role in our lives. Half of the people under the age of 35 years have used social media in sharing information with health providers and connecting with health organizations.
- Medical and health care applications are the third fastest growing category for iPhones and Android phones. The Apple store has 17,000 health care-related applications. Sixty percent are aimed at consumers. People are changing their behavior, actions, and wellness along with day-to-day routines in which they actually manage their health circumstances through their personal digital assistant that are becoming an ingrained part of their life.
- Costs will be lower and cost increases will slow. Prescription drug costs are forecast to decline 2% for active participants and early retirees. Inflation for services and supplies will be the biggest element of overall medical plan increases. To date health care reform has had minimal effect on cost trends and that will continue for 2012. Expect to see more cost shifting particularly

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CARF and the Development of Standards, Both New and Revised

By **Chris MacDonald**, *Managing Director, Medical Rehabilitation and International Aging Services/Medical Rehabilitation, CARF*

As case managers, you work in a variety of settings and with individuals of all ages with unique needs. Many of the venues that you are in or refer to are CARF accredited. CARF is a strong believer of a case-managed approach within our accredited programs. CARF uses a field-driven approach when developing sets of standards, starting with an International Standards Advisory Committee (ISAC). The ISAC represents persons served, providers, payers, and other interested parties from around the world. Its task is to either develop or revise a set of standards. These proposed standards are then posted for a public comment, called a field review.

Service providers, consumers, caregivers, payers, and other interested parties are invited to provide feedback to ensure the relevancy of the standards before they are adopted and published in a standards manual.

The field review process is an integral part of representing a wide variety of individuals in a very focused process that gives them the opportunity to affect change in standards.

As case managers, your feedback is essential to maintaining the relevancy and currency of CARF standards. We value your opinions, comments, and suggestions on these standards. All field review responses are anonymous.

CARF conducted 2011 field reviews of new or revised standards in the areas listed below for inclusion in 2012 standards manuals. CARF 2012 Standards

Manuals are published in January 2012 and are used on all surveys from July 1, 2012, to June 30, 2013.

Employment and Community Services

- Employment Services Principle Standards
- Employment Services Coordination
- Employment Transition Services
- Employment Planning Services
- Employee Development Services
- Employment Skills Training Services
- Organizational Employment Services
- Community Employment Services

Medical Rehabilitation

• Independent Examination Services
These service standards will be a new set of standards. The International Standards Advisory Committee was held September 18-19, 2011, in Toronto, Ontario, Canada. Many case managers may have workers comp cases, catastrophic cases, or auto accident cases that have had an IME (independent medical examination) ordered. There has been a wide variety in the quality of examiners and reports that are generated. These standards are the first attempt to bring consistency to the field. We received a good field review response and made changes to the standards to reflect the feedback received. These standards will be printed in the 2012 CARF Medical Rehabilitation Standards Manual. They will be used on all surveys from July 1, 2012 through June 30, 2013. We are expecting to have many insurance carriers

look to these standards as guidelines that will provide greater consistency in practice in a field in which this has previously been problematic.

Behavioral Health:

- Student Counseling

Child and Youth Services:

- Individualized Plan
- Person-Centered Care
- Program/Service Structure
- Quality Records Review
- Records of the Persons Served
- Screening and Access to Services
- Transition/Discharge
- Case Management/Services Coordination
- Community Housing and Shelters Counseling
- Intensive Family-Based Supports Group Home Care
- Residential Treatment
- Specialized or Treatment Foster Care Promotion/Prevention
- Early Intervention/Diversion

Employment and Community Services:

- Community Services Principle Standards
- Child and Youth Services
- Community Transition Services
- Family Services
- Foster Family Services
- Host Family Services
- Respite Services
- Mentor Services

In 2012 CARF's Medical Rehabilitation Service Unit will hold International
continues on page 28

OIG Advisory Opinion on Provision of Items and Services Below Cost or Free of Charge to Referral Sources in Exchange for Referrals

By Elizabeth E. Hogue, Esq.

In an Advisory Opinion in 2011, the Office of Inspector General (OIG) of the US Department of Health and Human Services (HHS) concluded that the provision of items and services below cost or free of charge to referral sources likely violates the federal anti-kickback statute. A home medical equipment (HME) company requested the Advisory Opinion.

The HME supplier provides medical supplies and equipment to skilled nursing facilities (SNFs). When the medical supplies and equipment that the HME company furnishes to SNFs are covered by Medicare Part B, the HME company bills the Medicare program for them. When they are not covered under Medicare Part B, the HME supplier bills the SNF for the supplies. The HME supplier usually charges SNFs amounts in excess of the cost of the noncovered supplies in order to cover the cost of related services such as inventory control, visits by customer service representatives, customized patient-specific packaging, etc., plus overhead and profit.

In this case, SNFs requested proposals for exclusive suppliers of items covered by Medicare. Bidders were also required to submit pricing for items not covered by Medicare that SNFs may purchase at their option. The HME

supplier wanted to submit bids offering pricing for the noncovered items and related services that were below the HME supplier's costs. The HME company acknowledged that the payments it would receive from Medicare Part B as SNF's exclusive suppliers for covered

motives to trade below-cost payment rates or free items and services for referrals of patients whose care will be paid for by Medicare.

The OIG then pointed out that providers may be "swapping" the below-cost rates on certain types of business in exchange for other profitable Federal business from which providers can recoup losses incurred on the below-cost business. The OIG stated that providers likely engage in such practices with the intent of inducing referrals of more lucrative business paid for by Medicare.

The antikickback statute is implicated if any direct or indirect link exists between a price offered by a supplier or provider to referral sources for items or services that referral sources pay for and referrals of Federal business for which the supplier or providers can bill a Federal health care program.

items would more than offset any losses it would incur to furnish the noncovered items and related services below its costs.

Anti-Kickback Statute Implicated

In response to the suppliers' request, the OIG first stated that the anti-kickback statute is implicated if any direct or indirect link exists between a price offered by a supplier or provider to referral sources for items or services that referral sources pay for and referrals of Federal business for which the supplier or providers can bill a Federal health care program. According to the OIG, both referral sources and providers that receive referrals have obvious

Beware of Service Swapping

It is worth considering this Advisory Opinion in light of the practices of some hospital discharge planners/case managers. They may require post-acute providers to give services and/or supplies to patients for whom there is no payer source or payer sources that do not reimburse at rates that cover providers' costs in order to receive referrals of patients whose care will be paid by Medicare. If post-acute providers are unwilling to render services free of charge, hospitals may bear the risk of continued care of such patients. This type of "swapping" may also be prohibited by the OIG based upon the Advisory Opinion described above. **CM**

Case Managers: Demonstrating Value, Committed to Knowledge

Barbara Johansson, RN, BSN, CCM, CPUM *Commissioner, CCMC*

The value of board certification in case management is indisputable. First and foremost, it establishes a standard. Case management lends itself to doing different things in different ways, but there must be a consistent level of quality. Board certification provides that seal of quality while ensuring standardization of health practice and health care across the continuum.

Raised Expectations

Knowing a case manager is board certified raises expectations. Certified case managers must meet a high standard; that inspires confidence in those with whom we work as well as those for whom we advocate. Historically, the occupation of “case manager” has had many definitions and lacked clear and consistent standards. The CCM® certification provides evidence the board-certified case manager can be held to the highest standard. That’s a critical distinction.

We need to raise awareness among lawmakers and policymakers. Individually and as an organization, we should be involved with legislative and policy activity at both the local and national levels. We know health care is at a tipping point, and case management and coordination of care will be foundational to how we handle its future. Board-certified case managers have the ability to ensure patients get the right services, in the right place, at the right time. Federal and state legislators and agencies alike need to understand what case managers are,

how we do our business and the impact we have on the overall cost and quality of services. The Commission serves as a resource for better understanding this distinction.

Such understanding is particularly important when it comes to Medicaid populations. I see this every day. My work focuses on implementation of programs and services for Medicaid and Medicare beneficiaries including the aged, blind, and disabled populations and the dual-eligible populations—those who qualify for both. The aged, blind, and disabled populations account for approximately 25% of the total Medicaid population—65% of the total Medicaid dollars spent. Many may have anywhere from 1 to 10 chronic conditions and need to take as many as 20 medications each day.

Multiple physical as well as behavioral health diagnoses, psychosocial challenges, and financial problems put this population particularly at risk. The health care system can be difficult to navigate in the best of situations; when adding the complexities of many Medicaid beneficiaries, it is critical to have a resource, such as a board-certified case manager, to advocate, educate, and assist. If those three things do not happen, there can be a substantial increase in utilization and inappropriate use of resources.

Employer Commitment

Employer commitment is vital in advancing the role of the board-certified case manager. I first became board

certified because the management team at the company I worked for saw the value in it, promoted it, and funded the fee for the exam. As with other professions, board certification became part of the career ladder in our organization. I recognized its value and, when I came to Molina, I brought with me a commitment to board certification. My current employer also now encourages and financially supports staff pursuing certification.

As the case manager’s role becomes more and more critical in the future, I would like to see a substantial increase in the number of people seeking certification. It’s a standard that elevates the practice of case management. The demographics of our nation point to a large, rapidly aging generation that will increasingly need services and support to continue living independently. Case management is the profession at the core of the future of health care delivery. The board-certified case manager has the tools in his or her toolbox to make this happen. **CM**

The Commission for Case Manager Certification (www.ccmcertification.org) is the first and largest nationally accredited organization that has certified more than 30,000 professional case managers. The Commission is a nonprofit, volunteer organization that oversees the process of case manager certification with its CCM® credential. The Commission is positioned as the most active and prestigious certification organization supporting the case management, defined more accurately. We need to dispel myths about what case managers do and don't do.

General Electric Wins CDMS Commission 2011 Quality Leadership Award

Leadership in Integrated Disability Management, Health & Productivity Honored

The Certification of Disability Management Specialists Commission has chosen General Electric Co. as the recipient of the 2011 Quality Leadership Award in recognition of its long-standing commitment to disability management and its innovation in health and productivity initiatives.

Each year, the CDMS Commission presents the award to an organization that demonstrates best practices in disability and absence management. This year, GE, which operates in more than 100 countries and employs more than 300,000 people worldwide, is being honored for its contribution to the disability management field, and its commitment to helping its employees lead healthier and more productive lives.

For many years, GE has championed integrated disability management from both a workforce health and productivity perspective, with programs directed and managed by Certified Disability Management Specialists and other certified professionals. “GE has been an industry leader in integrated disability management, even before the term became part of the widely accepted nomenclature,” stated Edwin Quick, MA, MBA, CDMS, CRC, CCM, GPHR, chair of the CDMS Commission. “Through consistent and progressive leadership in integrated disability management, GE has leveraged its business acumen and Six Sigma approach to bring accountability and efficiencies to the often complex world of integrated disability,

health, and wellness initiatives.”

Among GE’s numerous programs is HealthAhead, a global effort to motivate employees and their dependents to achieve the best possible health outcomes.

“HealthAhead is an integral part of the company’s ‘Healthmagination’ program and an extension of our philosophy of disability management to help employees become healthier, more productive, and engaged in all aspects of their lives,” said Marybeth Stevens-Carhidi, MS, CCM, CDMS, Leader of Health Administration for GE’s US Employee Services, Healthcare Benefits Delivery. “As a global initiative, we believe HealthAhead will result in stronger individuals and a stronger GE.”


Employee satisfaction and health-related absence data will be used to assess the effectiveness of HealthAhead in the long term. For the past seven years, GE has seen a reduction in its U.S. days-away-from-work metric. The company expects its HealthAhead will continue or even accelerate this trend. “Our expectation is that healthier employees will have fewer lost work days due to health issues, and will be more productive while at work,” Stevens-Carhidi added.

Central to HealthAhead is a unique effort to measure and certify GE worksites on the basis of critical elements including: site leadership and wellness teams, education and prevention, nutrition, physical activity, tobacco cessation, stress management,

health-related absences, and an assessment of health risk.

More than 300 GE worksites around the world are expected to be certified in 2011, an increase from 87 sites globally in 2010. All GE sites with at least 100 employees (about 500 locations globally) are required to be certified by 2012, and all are actively working toward this goal. These 500 sites reach at least 80% of GE employees and their dependents.

Although the program addresses corporate-wide health priorities, such as cessation of tobacco use, a key component is autonomy on the local level. “We believe that while good health should be promoted, driven, and invested in company-wide, it needs to be delivered locally to be effective,” Stevens-Carhidi said. “The health issues that our employees face vary greatly from site to site and business to business. Peers, managers, and the site where employees work impact our employees’ ability to get healthy and to maintain a healthy lifestyle.”

Through HealthAhead, GE continues to demonstrate its commitment to inspiring employees to embrace a healthier lifestyle, while giving them the tools and resources they need to achieve wellness goals. The CDMS Commission salutes GE for its long-standing leadership in integrated disability management, absence management, and health and productivity. The company has demonstrated that wellness and preventing disability are critical to good stewardship of human capital. 

Medicare Medical Necessity—More Important Than Ever

By Barbara Aubry, RN, CCM, CPC, CLNC, DABQAURP

It's been a busy week, and Friday has finally arrived. You are not scheduled to work the weekend and you're looking forward to the time off. As usual, you are trying to complete all tasks by the end of your shift. Somehow, you've managed to place most of the usual Friday discharges and are awaiting callbacks from three nursing facilities and your favorite transport company. Once you get these last three patients placed, you will be caught up for the day. You've already reported 'clinical' on your commercial admissions—too bad you have to attend the 3:00 pm meeting with your facility's compliance officer or there might be a chance you could head home on time for once. Wonder what she is so concerned about? Something must be going on if she is calling a mandatory meeting for all case managers, documentation improvement specialists, and utilization review staff. What on earth is so important that she had to schedule this urgent meeting on a Friday afternoon?

As you file into the conference room you notice others are wondering about the timing as you overhear discussions regarding the hope for a brief meeting. Your compliance officer begins by thanking you for attending and says she hopes you will soon appreciate the urgency of the meeting. Next, she relates her intention to share with you important testimony recently given by Daniel R. Levinson, Inspector General of the US Department of Health and Human Services (HHS) to the members

of the federal subcommittee tasked with identifying health care fraud and abuse. Who is Daniel Levinson? What has this got to do with you and your work? Why is this so important now? How does this information impact your facility?

Who?

Daniel R. Levinson is the top attorney and Inspector General responsible for oversight of audits, evaluations, investigations, and law enforcement efforts covering Medicare, Medicaid, public health, medical research, food and drug safety, welfare, child and family services, disease prevention, Indian health, and behavioral health services. He reports directly to Congress and is responsible for oversight of the several Federal audit programs currently in operation for both Medicare and Medicaid services. These programs seek to identify fraud, waste, and abuse of resources provided to patients covered by these programs. The Office of the Inspector General (OIG) is tasked to work closely with the Department of Justice (DOJ) in joint efforts to identify those clinicians and other providers who seek to defraud the trust fund. The OIG is charged with protecting the integrity of HHS reimbursement programs in conjunction with guardianship of the health and welfare of its program beneficiaries. Mr. Levinson works with agents from both the OIG and DOJ in their investigative and enforcement activities. Their combined efforts have returned billions of dollars in improper payments to the Medicare Trust Fund.

What?

Now that you know who Mr. Levinson is and have a better understanding of his tasks, what has this got to do with your day-to-day work? Perhaps you have heard of Executive Order 13520? If not, you're not alone, but its requirements directly impact your daily process. If your facility has been visited by a Recovery Audit Contractor (RAC) auditor or has received requests for copies of medical records, you are already familiar with one segment of the recovery efforts. The actions of the OIG, DOJ, and federal and state auditors are mandated by Executive Order 13520, which states, "every effort must be made by the Federal Government to confirm that the right provider receives the right reimbursement for the right reason at the right time." President Obama signed the order to help pay for the cost of funding health care reform. In addition, the Deficit Reduction Act calls for a savings of \$340 billion in Medicare and Medicaid spending by 2021. Executive Order 13520 has provided the 'teeth' federal agencies require to actively pursue payment errors, medical necessity issues, and questionable services. This directly impacts the way you manage your CMS (Centers for Medicare & Medicaid Services) admissions. The need to review a CMS patient on the date of admission has never been more important than now. (For more information, see <http://www.whitehouse.gov/the-press-office/2011/04/13/fact-sheet-presidents-framework-shared-prosperity-and-shared-fiscal-res.>) ▶

Why?

Now that you know who and what, why is this so important today? Granted, the government spends a lot of money on patient care, but isn't it all warranted? Apparently not. According to Mr. Levinson's testimony, CMS reported improper Medicare payments of \$47.9 billion dollars in 2010. Fee-for-service care made up 10.5% or \$34.3 billion dollars in errors. The remaining \$13.6 billion or 14% of errors was attributed to managed Medicare or Medicare Part C claims. The Inspector General suggests some improper payments are due to fraud and abuse, but much is the result of charges for medically unnecessary care in addition to claims and eligibility errors and a case manager's nightmare—insufficient clinical documentation to support services provided. Because of the need for spending cuts by CMS to fund health care reform and help support deficit reduction, the actions of the OIG, DOJ, and auditors are at the forefront now. Each agency is 'beefing up' its investigative and auditing operations. To get a better idea of their efforts, consider a recent blog post by Frank E. Sheeder and colleague, a health care attorney and compliance expert. They noted that federal criminal prosecutions of health care fraud have increased significantly. According to their analysis of the Transactional Records Access Clearinghouse or TRAC, the DOJ began more criminal health care fraud investigations in 2011 to date than they did in the entirety of 2010. This represents an 85% increase. For more information, see www.thecomplianceblog.com.

With this information in mind, it's clear that your facility will likely be under increased scrutiny by both the OIG, DOJ, and federal and state

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auditors. If you haven't paid much attention to your hospital's Comprehensive Error Rate Testing (CERT) report or have never worked with it in the past, now is the time to learn more. Each year CMS uses your hospital's claims data to identify improper payments and areas of overutilization. Per CMS, "(We) will analyze the improper payment data to determine if there are geographic trends that can assist in identifying errors that highlight programmatic weaknesses. CMS will review trends by types of service to locate potential vulnerabilities." Ask your compliance officer to meet with your team to help you get a better idea of which services are triggering OIG investigations and audits. This knowledge can be used to better inform your CMS case review process. To date, 27 high-risk areas have been identified by the OIG using claims data mining. Problem areas specific to your hospital are included in your hospital's CERT report. Knowledge of your problem areas can help your team focus on those problem areas. The continuous data mining efforts of the OIG, RAC, and DOJ identify those providers who hit the high-risk areas. The data help determine which providers should be audited. The data are specific; they can arrive at your facility with a pre-identified list of your problem claims for review. Upping the ante? You bet. Perhaps now you understand the "why" of the problem and your compliance officer's need to call the urgent Friday afternoon meeting.

How?

Your facility will be affected by the current actions of the federal and state payers. Exactly how this will affect your facility will be determined largely by your current rate of compliance. Medicare is the largest health insurer in the world. Its annual expenses are greater than \$200 billion dollars. Medicare covers more than 40 million individuals and operates under

the longstanding expectation found in Section 1862(a)(1)(a) of the Social Security Act that states, "no payment shall be made for items or services that are not reasonable and necessary." To quantify the financial impact of aggressive compliance on your facility, you will need to know the number of CMS admissions and their cost per year. Suffice it to say, when the largest health care payer in the United States is actively data mining your claims to identify problems, the likelihood of a visit from the RAC, OIG, and DOJ increases exponentially. The likely outcome for hospitals and other providers will be an increased focus on compliance resources including internal audit, case management, medical necessity determination, accurate patient status assignment, clinical documentation improvement, utilization review, claims accuracy, and medical oversight. In addition, since CMS is now auto-denying claims based on data mining analysis, your reimbursement may drop, and the cost of denials and appeals is likely to increase.

Now that your compliance officer has given you a better idea of the ramped-up compliance challenges facing your facility, she adjourns the meeting but warns that she will be scheduling additional meetings going forward to keep everyone up-to-date. She also requests that each department examine and update their process in case the OIG or DOJ announces an audit.

Next Steps

To get a better idea of just how the increased scrutiny and data mining affect case managers, let's look more closely at the information the government is releasing to get a better idea of its actions and expectations.

Targets

OIG has identified 27 high-risk target areas. Some, like duplicate payments for manufacturer rebates, fraudulent

billing patterns, coding errors, and high dollar claims scrutiny, are largely the aegis of the Health Information Management or HIM department. Case managers are directly involved in targets including postacute transfers, patient status assignments, short stays, observation services, and medically unnecessary services and may also be involved in documentation validity for durable medical equipment (DME), home health, skilled nursing facilities (SNF), unreported hospital-acquired conditions (HACs), and supporting documentation for appeals. A relatively new approach by the OIG with regard to audits of predetermined target areas involves sending attestation statements to be completed by your facility before the audit begins. Sometimes sent to the compliance officer, Chief Financial Officer (CFO), HIM Director, or Chief Medical Officer (CMO), the questionnaire includes statements such as “describe your general and specific process and key internal controls” among others and requires a signature from the individual or individuals completing the forms. Questions that directly affect case management might include “results of all current and previous internal and external audits of documentation, coding, and billing processes” or “your processes to determine the accuracy and proper documentation of physician orders” and “how do you ensure correct coding of DRG [diagnosis-related groups] and proper medical record documentation?” It appears that the OIG and DOJ have less tolerance for excuses.

CMS and Medical Necessity

Let’s take another look at Section 1862(a)(1)(a) of the Social Security Act, which states, “no payment shall be made for items or services that are not reasonable and necessary.” This is the bedrock upon which third-party reimbursement is built. Unfortunately, CMS has said repeatedly they do not necessarily embrace the utilization rules used

by commercial payers. There are several reasons for this, but CMS focuses its attention on its beneficiary demographics, which are different than those of commercial lives. CMS creates its own set of utilization policies that many of you are familiar with. Their policies are of two types. The first is called the National Coverage Determination (NCD). The second is the Local Coverage Determination (LCD). CMS writes national utilization policies it expect its contracted payers to promulgate based on geographic practice variance. Medical necessity rules found in national policies are expected to be reflected in the local policy as well. Many of the policies target outpatient services. This seems to have created a false sense of comfort with regard to inpatient services because of DRG reimbursement. It is still essential for case managers to be familiar with the policies and here’s why: the DOJ is auditing medical records in search of specific clinical documentation required in an NCD or LCD. When the records are absent the documentation, the DOJ may conclude a false claim has been submitted for medically unnecessary or inappropriate services. This can carry a heavy penalty. Let’s look at an example.

NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1)

The policy outlines at length the type of surgical procedures performed that CMS considers covered services when medical necessity has been established. As of February, 21, 2006, “Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS), and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body-mass index of 35 or more, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. These procedures are only covered when performed at

facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence.” For more information, see: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=3&bc=AAAAgAAAAAAA&>.

There are a few operative terms in the policy that must be present in your physician’s clinical documentation, among other information. First, the type of surgery must be a covered service. Next, the record must document a BMI of 35 or higher. And, the patient must have at least one co-morbidity documented. As of February 12, 2009, CMS determined that type 2 diabetes mellitus is considered applicable for the purposes of this NCD, in addition to others. Finally, the documentation must be clear that the patient failed previous medical treatment for obesity.

If the OIG or DOJ reviews your clinical records and cannot find documentation of expressed criteria, it may determine the service was not medically necessary and perhaps not in the best interests of the beneficiary.

False Claims Act

For a more complete understanding of concern regarding the possibility of being considered to be involved in submission of a false claim, let’s take a closer look at the regulation. According to CMS, the False Claims Act (FCA), provides in part, that:

“(a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false ▶

or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;. . . or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. . .

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages, which the Government sustains because of the act of that person (b) For purposes of this section, the terms “knowing” and “knowingly” mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.”

Without delving deeper into the quite lengthy FCA, as a case manager,

you could potentially be considered to “know or should have known” (based on publication of NCD and LCD medical necessity policies and your access to them) that specific clinical requirements need to be documented to satisfy utilization rules. For more information, see <https://www.cms.gov/smdl/downloads/smdl032207att2.pdf> and “DOJ Auditors Are Looking.”

Take Action

You’re right—this is not great news. CMS is leading the way in audit and reimbursement recovery activity. But, as they say in sports, a good defense is a coordinated offense. So what can you do? Create a strike force team and work together. Time permitting, review every CMS admission (including observation services) within the first 8 hours. Assign a case manager to oversee the high-risk outpatient services such as insertion of pacemakers, defibrillators, and percutaneous transluminal angioplasty. If you have documentation improvement specialists, make the CMS hot spots top priority for them. Educate your

physicians and staff nurses regarding the need for specific documentation for CMS services based on the NCD requirements. Ask utilization review to monitor changes in the NCD and LCD rules—they are updated ad lib and are often a moving target. Be sure you are working with the latest policies. Focus on at least quarterly reviews of the policies to determine if they have added, modified, or removed a clinical requirement, ICD, or CPT code. Work in conjunction with your compliance officer and HIM professionals.

If your resources are already stretched, consider working with a clinical documentation improvement specialist (CDIS) consultant. Often they can see the ‘forest for the trees,’ so to speak, and are able to rapidly help with process improvement. Sometimes physicians and staff are more receptive to a new voice. Finally, look to your hospital association for information. They have useful tools, processes, and recommendations that can be useful when you are facing challenges on all sides. **CEU**

Exam starts on page 14

Some of the other NCDs that DOJ auditors are looking at include:

Review: Treatment of Obesity, NCD (40.5)@ <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=38&ncdver=3&DocID=40.5&SearchType=Advanced&bc=IAAAAgAAAA&>

Review: National Coverage Determination (NCD) for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13)@ <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=151&ncdver=1&DocID=160.13&SearchType=Advanced&bc=IAAAAgAAAA&>

Review: National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (280.13) <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=273&ncdver=1&DocID=280.13&SearchType=Advanced&bc=IAAAAgAAAA&>

Review: National Coverage Determination (NCD) for Cardiac Pacemakers (20.8) <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=238&ncdver=2&DocID=20.8&SearchType=Advanced&bc=IAAAAgAAAA&>

Review: National Coverage Determination (NCD) for Bladder Stimulators (Pacemakers) (230.16) <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=243&ncdver=1&DocID=230.16&SearchType=Advanced&bc=IAAAAgAAAA&>

Review: National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4) <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110&ncdver=3&DocID=20.4&SearchType=Advanced&bc=IAAAAgAAAA&>

Review: National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7) <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=201&ncdver=9&DocID=20.7&SearchType=Advanced&bc=IAAAAgAAAA&>

A First-Hand Look at the Role of the Breast Cancer Nurse Navigator

By **Cathy McDonald, RN, MS, CNS**

The following is a first-hand report of the role of a breast cancer nurse navigator at one small community hospital. Breast cancer nurse navigators are specialized case managers who perform the roles of a case manager as defined by the Case Management Society of America. That is, they “assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet an individual’s health care needs, using communication and available resources to promote quality, cost-effective outcomes.” Studies have shown the effectiveness of breast cancer navigator programs in promoting breast-conserving surgery, adjuvant radiation therapy, reconstruction, and axillary node dissection.¹ The programs improve coordination of high-quality care, enhance access to services for all patients, remove barriers to care, improve care delivery efficiency, improve outcomes, improve sharing of resources, enhance relationships with the community, increase patient satisfaction, and increase referrals of new patients to the system.²

At the end of this article are resources for those who may be interested in pursuing such a role for themselves or incorporating a cancer care navigator program within their own hospital setting.

The Breast Program at Mercy Hospital has been serving the Portland, Maine, community in a leadership role since its inception on January 8, 1996. The Breast Center nurse has been an integral part of the navigation team. With patient-centered care as our focus, our Center’s goal is to create a standard of care and network of safety for our patients and their family/support. As nurses, we foster this goal by acknowledging the uniqueness of each patient’s journey and supporting their needs.

Our Center is staffed with two breast surgeons. The surgeon director is Melinda Molin, MD, FACS. As nurses, our primary focus is preparing patients and supporting them through their surgical experience. Our role is primarily a resource role and as nurses, we wear two hats. We are both providers of care and facilitators of the coordination process, which is presently referred to as navigation. We introduce patients and families to Mercy and become the consistent contact person. We rely on our integrative navigation team in the navigation process.

Appropriate team members can be accessed at any point along the patient’s care continuum. Breast nurse initial contact with our patients could be:

1. Presurgery/diagnosis
2. At time of biopsy
3. At the time of surgical diagnosis when we sit with the physician and patient as pathology and plan of care information is reviewed
4. By phone

Once the first contact has been made, the plan of care is initiated and developed.

Our primary focus at that time is support: support of the patient family unit and their decision-making and support in clarification of the information provided by the physician to the patient/family. Our secondary goal is identification of the patient/family needs both immediate and long-term. We provide information regarding available local, state, and national resources and make the appropriate connections ►

Cathy McDonald, RN, MS, CNS, has been in the role of nurse navigator since 1996. She received her undergraduate and graduate nursing education at University of Southern Maine. She maintains her CNS certification in adult health. She received her navigator certification in 2010 through the National Consortium of Breast Centers. In this article she addresses the nurse navigator role in a small community hospital setting.

for our patients both within Mercy and in the community.

The integrative navigation team includes physicians, nurses, ancillary services, and community services/resources.

- Physicians include:
 - Primary care physician (PCP), breast surgeon, radiologist, radiation oncologist, oncologist, plastic surgeon or second opinion physician (surgeon, oncologist, pathologist)
- Nurses include:
 - Breast nurses, interventional radiology nurse, plastic surgeon's office nurse, primary nurse, oncology nurse, clinical trials nurse, PCP office nurse, or visiting nurse
- Ancillary staff include:
 - Mammography or ultrasound technologist, administrative/secretarial staff, lymphedema therapist, physical/occupational therapist, social services, registered dietitian, financial assistant and pastoral care services
- Community resources include:
 - Local community support groups, American Cancer Society, Maine Breast Cancer Coalition, complementary/integrative therapist, Maine Breast and Cervical Health Program and Prosthetic Resources, interpretive services

With advances in cancer treatment, patients need to make more complex decisions today than in the past. This can be overwhelming when they are faced with a life-threatening diagnosis. The importance of consistency and continuity in relation to care is paramount to helping our patients navigate the health care system. We help them make sense of information at a time when almost nothing makes sense. Our communication with the navigation team and the patient helps facilitate the navigation process. Our team's goal is timely access to quality care and optimal patient outcomes.

Patient navigation has become of increased interest in the breast cancer community. The focus has been on the role of oncology nurse navigators. Nurses have functioned in this role for many years but under varying titles: coordinator/case manager being the most common. In 2008, the National Consortium of Breast Centers recognized the need for a standardization of the breast patient navigator role to minimize variances in care across the continuum. A peer committee was formed to develop a certification program designed to validate the skill set of breast patient navigators. I received certification in 2010, and my colleague will pursue certification in 2012. I have been in the role of "navigator/coordinator" since the Center opened in 1996. Prior to this, I worked in a medical/surgical setting. My colleague has been in this role for 4 years. Her prior experience included medical/surgical nursing and lymphedema therapy. Receiving certification did not change but rather validated my practice

and broadened my collegiality in practice. It also reinforced the need for collaboration/mentoring of new navigators within the health care community.

In approaching the process of coordination/navigation in this practice and the expansion of our role, I view the nursing role from two different perspectives: traditional and nontraditional. Both roles are encompassed by a subset of responsibilities and competencies, and they both support care. The responsibilities for the traditional role are:

1. Clinical management/practice

- Demonstrates a commitment to Mercy's breast health program
 - Participates in multidisciplinary conferences
- Problem-solves patient care issues
 - Assesses support needs from physical, informational, psychosocial, and spiritual perspectives
 - Provides support
 - Assesses coping skills with intervention as needed
 - Assesses cultural beliefs and biases
 - Makes referrals for individual counseling support, as needed, both in-house and in the community
 - Provide information about and has a working knowledge of support groups
 - Has a working knowledge of complementary/integrative therapies
- Acts as collaborator/change agent with in-house staff and multidisciplinary team to evaluate and improve the patient care process
 - Is present with patients and accompanies them to procedures
 - Participates in community outreach
- Public relations
- Professional education
 - Determines own goals within the context of professional role and the mission of Mercy
 - Participates in professional development opportunities that increase awareness of one's role
- Research
 - Keeps self and team informed of current research findings related to breast health issues
 - Demonstrates skill in promoting initiatives that relate to research, program development/expansion, and policy development

2. Patient/family education and triage

- Introduction of patient/family to system
- Provision of appropriate patient information and education as needed
- Being the consistent contact person for the patient after

consultation with the breast surgeon

- Facilitating appropriate referrals based on assessment and identifying patient needs

3. Administrative responsibilities

- Have a working knowledge of Breast Care Specialists of Maine reimbursement issues based on individual insurance coverage in regard to breast care, lymphedema treatment, post-breast surgery syndrome, plastic surgery, integrative/complementary therapy, home health, and discharge planning
- When appropriate, institute contact with insurance carriers
- Arrange for remote accommodation as needed
- Make referrals for consultation in relation to financial assistance

From the nontraditional role perspective, I have received training as a facilitator of Peggy Huddleston's Prepare for Surgery-Heal Faster mind/body relaxation workshop and therapeutic touch (see "Resources"). Both of these are available for any patient interested. My co-navigator has certification in lymphedema therapy and provides ongoing education/hands-on support in relation to lymphedema and/or post-breast surgery syndrome issues. The nurse's role has evolved, and our focus has expanded based on our assessment of patient and/or community needs and the influence of our patients' "wish list."

The responsibilities associated with the nontraditional role are provider specific:

Clinical management/practice

- Demonstrates a commitment to Mercy's breast program
 - Assesses patients needs and incorporates appropriate

RESOURCES

Peggy Huddleston's Prepare for Surgery, Heal Faster is a guide to mind-body techniques that can be found at www.healfaster.com.

A forum for discussion of issues related to post-mastectomy pain syndrome can be found at <http://community.breastcancer.org/forum/91/topic/747016>

Judy Kneece's Breast Cancer Treatment Handbook can be found at www.judykneece.com.

A wealth of information can be found at the National Accreditation Program for Breast Centers (NAPBC) at <http://napbc-breast.org/>.

More information about the Breast Patient Navigator Certification Program is available at www.bpnc.org.

therapies when needed

- Facilitates Peggy Huddleston's Prepare for Surgery-Heal faster: Mind body relaxation techniques
- Provides therapeutic touch as appropriate
- Provides lymphedema/Post-Breast Surgery Syndrome Therapy education

The above-noted wish list began when the center first opened. I visited area support groups and asked what they wish had been available when they were diagnosed. From these meetings, a support group evolved that looked at transitional issues patients face after treatment ends. A partner's support group for patients in treatment and their support person was also the result. These groups transitioned to the Cancer Community Center that was formed after we opened. This center is available in our community for patients. It provides classes as well as support both in the format of traditional, facilitated groups but also individually through their "buddy program." The buddy program is for newly diagnosed patients to connect with another who has completed her treatment. My pursuit of training for mind-body relaxation, therapeutic touch, our teaching packets, and the Judy Kneece book that we provide to all our patients were the result of the "wish list" as well.

In relation to education/support, at the time of our initial contact, we provide our patients with the above-mentioned Judy Kneece Breast Cancer Treatment handbook and our teaching/resource packet. We review comprehensive educational material including procedural information, pathology information, as well as information regarding postop wound care, activity restrictions, pain control, lymphedema, available supports, and follow-up. We are available by phone and beeper for our patients and their family at any time they have questions. A great deal of our time entails phone communication with patients and with members of our team. We maintain open communication with the preadmission testing nurse who is gathering patient information for the anesthesiologist to review before surgery and to follow through on any concerns we or they may have. We are also in contact with other involved physician offices.

On the day of surgery, we see patients to clarify questions preop and, at times, accompany patients for presurgery procedures such as needle localization procedures. We handle discharge teaching for both inpatients and outpatients. We assist discharge planning and initiate any needed referrals as well.

We see patients at their post-op appointments with the breast surgeon and continue to follow some patients for assessment of wound healing, range of motion issues, psychosocial support needs, and referral as appropriate.

continues on page 27

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Exam 1

Medicare Medical Necessity—More Important Than Ever

1. The Inspector General of HHS is responsible for identifying _____ for both Medicare and Medicaid services:
 - a. Fraud
 - b. Waste
 - c. Abuse
 - d. All of the above
2. The Office of the Inspector General works with the Department of Justice to identify clinicians and other providers who seek to defraud Medicare.
 - a. True
 - b. False
3. Executive Order 13520 is the mechanism that directs various government agencies to confirm the right provider received the right reimbursement for the right reason at the right time.
 - a. True
 - b. False
4. The Deficit Reduction Act, which will help pay for health care reform, calls for what amount of savings in Medicare and Medicaid by 2021?
 - a. \$240 billion
 - b. \$300 billion
 - c. \$340 billion
 - d. \$400 billion
5. How much did CMS report in improper Medicare payments in 2010?
 - a. \$18.0 billion
 - b. \$25.9 billion
 - c. \$36.8 billion
 - d. \$47.9 billion
6. Insufficient clinical documentation to support provided services is one of the reasons for improper payments.
 - a. True
 - b. False
7. The Comprehensive Error Rate Testing report is one tool to identify improper payments and overutilization.
 - a. True
 - b. False
8. Federal auditors are using data mining to identify problem areas for each provider.
 - a. True
 - b. False
9. If your clinical records are reviewed and the auditors cannot find documentation, it may be determined that the services were not medically necessary and perhaps not in the best interest of the beneficiary.
 - a. True
 - b. False
10. An action plan to reduce liability in submitting false claims may include:
 - a. A review of every CMS claim within the first 8 hours
 - b. Assigning a case manager to oversee high-risk services
 - c. Educating physicians and nurses regarding the need for specific documentation for CMS services
 - d. All of the above

Exam 2

A First-Hand Look at the Role of the Breast Cancer Nurse Navigator

1. Navigators are specialized case managers who perform the role of the case manager.
 - a. True
 - b. False
2. Patient centered navigation programs:
 - a. Improve coordination of high-quality care
 - b. Enhance access to services
 - c. Remove barriers to care
 - d. All of the above
3. The case manager is an integral part of the navigation team.
 - a. True
 - b. False
4. The case manager's primary focus is preparing patients and supporting them through their health experience.
 - a. True
 - b. False
5. The plan of care should be initiated and developed once the first contact with the patient has been made.
 - a. True
 - b. False
6. The integrative navigation team includes:
 - a. Physician
 - b. Nurses and case managers
 - c. Ancillary services
 - d. All of the above
7. The communication of the case manager with the navigation team and the patient helps facilitate the communication process.
 - a. True
 - b. False
8. The responsibilities of the case manager include roles of:
 - a. Clinical management/practice
 - b. Patient/family education and training
 - c. Administrative responsibilities
 - d. All of the above
9. A buddy program for newly diagnosed patients to connect with another patient who has completed similar treatment is an effective way of reducing anxiety.
 - a. True
 - b. False
10. The case manager makes a significant contribution by providing support and coordinating care within the navigation process.
 - a. True
 - b. False

These educational manuscripts have been approved for 2 hours of CCM and CDMS education credit each by The Commission for Case Manager Certification and the Certification of Disability Management Specialists Commission. Provider #00059431. The answer sheet for these tests must be received by March 31, 2012. Expired exams cannot be returned. Faxed exams cannot be accepted. You may submit one or both exams; credits will be granted accordingly.

Exam 1: Medicare Medical Necessity—More Important Than Ever

Please indicate your answer by filling in the letter:

1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8. _____ 9. _____ 10. _____

Exam 2: A First-Hand Look at the Role of the Breast Cancer Nurse Navigator Programs

Please indicate your answer by filling in the letter:

1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8. _____ 9. _____ 10. _____

Continuing Education Program Evaluation

Please indicate your rating by circling the appropriate number using a scale of 1 (low) to 5 (high).

	Exam 1:					Exam 2:				
1. The article was clear and well organized.	1	2	3	4	5	1	2	3	4	5
2. The topic was both relevant and interesting to me.	1	2	3	4	5	1	2	3	4	5
3. The amount and depth of the material was adequate.	1	2	3	4	5	1	2	3	4	5
4. The quality and amount of the graphics were effective.	1	2	3	4	5	1	2	3	4	5
5. I would recommend this article.	1	2	3	4	5	1	2	3	4	5
6. This has been an effective way to present continuing education.	1	2	3	4	5	1	2	3	4	5
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MMWR Morb Mortal Wkly Rep. 2011 Dec 2;60:1618-23.

Vital signs: HIV prevention through care and treatment—United States.

Centers for Disease Control and Prevention (CDC).

BACKGROUND: An estimated 1.2 million persons in the United States were living with HIV infection in 2008. Improving survival of persons with HIV and reducing transmission involve a continuum of services that includes diagnosis (HIV testing), linkage to and retention in HIV medical care, and ongoing HIV prevention interventions, including appropriately timed antiretroviral therapy (ART). **METHODS:** CDC used three surveillance datasets to estimate recent HIV testing and HIV prevalence among US adults by state, and the percentages of HIV-infected adults receiving HIV care for whom ART was prescribed, who achieved viral suppression, and who received prevention counseling from health care providers. Published data were used to estimate the numbers of persons in the United States living with and diagnosed with HIV and, based on viral load and CD4 laboratory reports, linked to and retained in HIV care. **RESULTS:** In 2010, 9.6% of adults had been tested for HIV during the preceding 12 months (range by state: 4.9%-29.8%). Of the estimated 942,000 persons with HIV who were aware of their infection, approximately 77% were linked to care, and 51% remained in care. Among HIV-infected adults in care, 45% received prevention counseling, and 89% were prescribed ART, of whom 77% had viral suppression. Thus, an estimated 28% of all HIV-infected persons in the United States have a suppressed viral load. **CONCLUSIONS:** Prevalence of HIV testing and linkage to care are high but warrant continued effort. Increasing the percentages of HIV-infected persons who remain in HIV care, achieve viral suppression, and receive prevention counseling requires additional effort. **IMPLICATIONS:** Public health officials and HIV care providers should improve engagement at each step in the continuum of HIV care and monitor progress in every community using laboratory reports of viral load and CD4 test results.

J Heart Lung Transplant. 2011 Nov 22. [Epub ahead of print]

Cost-effectiveness of the implantable HeartMate II left ventricular assist device for patients awaiting heart transplantation.

Moreno SG, Novielli N, Cooper NJ.

BACKGROUND: Left ventricular assist devices (LVADs) are being proposed as a life-saving therapeutic alternative to conventional medical management for people with end-stage heart failure awaiting transplantation. However, cost-effectiveness assessments of first-generation LVADs have not been encouraging. The cost-effectiveness of the enhanced second-generation LVAD HeartMate II (Thoratec, Pleasanton, CA) is estimated here. **METHODS:** A probabilistic Markov model was developed to extrapolate survival, utility, and resource use over the total lifetime of a hypothetical cohort of patients with end-stage heart failure under the 2 competing therapeutic strategies, using the most robust and recently published evidence about their performance. Cost data are based on UK activity to consider reimbursement in the UK National Health Service setting. **RESULTS:** HeartMate II had a mean cost per quality-adjusted life-year (QALY) of £258,922 (\$414,275). The sensitivity analysis showed that 2 factors mainly explain why HeartMate II is not a cost-effectiveness strategy as a bridge-to-transplant: (1) the survival of heart transplant candidates treated conventionally while on the waiting list has significantly improved in recent years, and (2) the high acquisition cost of the device, £94,200 (\$150,720). **CONCLUSIONS:** Although HeartMate II LVAD implantation significantly increases survival compared with conventional medical management, it does not provide good value for the money spent according to established thresholds of cost-effectiveness in the UK. HeartMate II is unlikely to become cost-effective unless the additional survival gained by its use raises and/or the device is given free of charge. Therefore, its implantation to transplant candidates lacks justification in terms of cost-effectiveness.

Department of Evaluation of Innovation & New Technologies, Fundació Clinic, Barcelona, Spain.

J Acquir Immune Defic Syndr. 2011 Nov 30. [Epub ahead of print]

Lipid profiles in young HIV-infected children initiating and changing antiretroviral therapy.

Strehlau R, Coovadia A, Abrams EJ, et al.

BACKGROUND: Both HIV infection and antiretroviral therapy are associated with dyslipidemias in adults but there are fewer data on outcomes in young children. Here we examined lipid profile changes in a cohort of young children before and after suppression on an initial ritonavir-boosted lopinavir (LPV/r)-based regimen and after switch to a nevirapine (NVP)-based regimen. **METHODS:** 195 HIV-infected children who initiated LPV/r-based therapy when <24 months of age at one site in Johannesburg, South Africa, and who achieved viral suppression (<400copies/ml sustained for \geq 3 months) were randomised to either continue on the LPV/r-based regimen (n=99) or to switch to a NVP-based regimen (n=96). Non-fasting concentrations of total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL) and triglycerides (TG) were measured pre-treatment, at randomization when suppressed, and at 9, 20 and 31 months post-randomization. **RESULTS:** Median age at treatment initiation was 9 months and the initial regimen was maintained for an average of 9 months before randomization. TC, LDL and HDL increased from pre-treatment to randomization ($P<0.0001$) and TC/HDL ratio and TG decreased ($P<0.0001$). After switching to NVP, HDL was significantly higher ($P<0.02$) and TC/HDL and TG significantly lower ($P<0.0001$) through 31 months post-switch relative to remaining on the LPV/r-based regimen. **CONCLUSION:** Initiating antiretroviral therapy was associated with changes to a more favorable lipid profile in young children. Switching from a LPV/r-based regimen to a NVP-based regimen accentuated and continued these improvements. Investigation of safe and effective methods for managing dyslipidemias in children of different ages in resource-limited settings is warranted.

Harriet Shezi Clinic, Chris Hani Baragwanath Hospital, University of the Witwatersrand, Johannesburg, South Africa; Mailman School of Public Health, Department of Pediatrics, and Gertrude H. Sergievsky Center, College of Physicians & Surgeons, Columbia University, New York.

Hepatology. 2011 Dec 2. doi: 10.1002/hep.25510. [Epub ahead of print]

Economic model of a birth cohort screening program for hepatitis C virus.

McGarry LJ, Pawar VS, Parekh HH, et al.

BACKGROUND: Recent research has identified high hepatitis C virus (HCV) prevalence among older US residents who contracted HCV decades ago and may no longer be recognized as high-risk. We assessed the cost-effectiveness of screening 100% of US residents born 1946-1970 over 5 years (birth-cohort screening) compared with current risk-based screening, by projecting costs and outcomes of screening over the remaining lifetime of this birth cohort. A Markov model of the natural history of HCV was developed using data synthesized from surveillance data, published literature, expert opinion, and other secondary sources. We assumed eligible patients were treated with pegylated interferon plus ribavirin, with genotype 1 patients receiving a direct-acting antiviral in combination. The target population is US residents born 1946-1970 with no prior HCV diagnosis. Among the estimated 102 million (1.6 million chronically HCV-infected) eligible for screening, birth-cohort screening leads to 84,000 fewer cases of decompensated cirrhosis, 46,000 fewer cases of hepatocellular carcinoma, 10,000 fewer liver transplants and 78,000 fewer HCV-related deaths. Birth-cohort screening led to higher overall costs than risk-based screening (\$80.4 billion vs. \$53.7 billion), but yielded lower costs related to advanced liver disease (\$31.2 billion vs. \$39.8 billion); birth-cohort screening produced an incremental cost-effectiveness ratio (ICER) of \$37,700 per quality-adjusted life-year gained versus risk-based screening. Sensitivity analyses showed that reducing the time horizon during which health and economic consequences are evaluated increases the ICER, whereas decreasing the treatment rates and efficacy increases the ICER. Model results were relatively insensitive to other inputs. **CONCLUSION:** Birth-cohort screening for HCV is likely to provide important health benefits by reducing lifetime cases of advanced liver disease and HCV-related deaths, and is cost-effective at conventional willingness-to-pay thresholds.

OptumInsight, Medford, MA.



BMC Gastroenterol. 2011 Nov 30;11(1):132. [Epub ahead of print]

Comparison of accuracy of fibrosis degree classifications by liver biopsy and non invasive tests in chronic hepatitis C.

Boursier J, Bertrais S, Oberti F, et al.

BACKGROUND: Noninvasive tests have been constructed and evaluated mainly for binary diagnoses such as significant fibrosis. Recently, detailed fibrosis classifications for several non-invasive tests have been developed, but their accuracy has not been thoroughly evaluated in comparison to liver biopsy, especially in clinical practice and for Fibroscan. Therefore, the main aim of the present study was to evaluate the accuracy of detailed fibrosis classifications available for non-invasive tests and liver biopsy. The secondary aim was to validate these accuracies in independent populations. **METHODS:** Four HCV populations provided 2,068 patients with liver biopsy, four different pathologist skill-levels and non-invasive tests. Results were expressed as percentages of correctly classified patients. **RESULTS:** In population #1 including 205 patients and comparing liver biopsy (reference: consensus reading by two experts) and blood tests, Metavir fibrosis (FM) stage accuracy was 64.4% in local pathologists vs. 82.2% ($P < .001$) in single expert pathologist. Significant discrepancy (≥ 2 FM vs reference histological result) rates were: Fibrotest: 17.2%, FibroMeter2G: 5.6%, local pathologists: 4.9%, FibroMeter3G: 0.5%, expert pathologist: 0% ($P < .001$). In population #2 including 1,056 patients and comparing blood tests, the discrepancy scores, taking into account the error magnitude, of detailed fibrosis classification were significantly different between FibroMeter2G (0.30 ± 0.55) and FibroMeter3G (0.14 ± 0.37 , $P < .001$) or Fibrotest (0.84 ± 0.80 , $P < .001$). In population #3 (and #4) including 458 (359) patients and comparing blood tests and Fibroscan, accuracies of detailed fibrosis classification were, respectively: Fibrotest: 42.5% (33.5%), Fibroscan: 64.9% (50.7%), FibroMeter2G: 68.7% (68.2%), FibroMeter3G: 77.1% (83.4%), $P < .001$. Significant discrepancy (≥ 2 FM) rates were, respectively: Fibrotest: 21.3% (22.2%), Fibroscan: 12.9% (12.3%), FibroMeter2G: 5.7% (6.0%), FibroMeter3G: 0.9% (0.9%), $P < .001$. **CONCLUSIONS:** The accuracy in detailed fibrosis classification of the best-performing blood test outperforms liver biopsy read by a local pathologist, i.e., in clinical practice; however, the classification precision is apparently lesser. This detailed classification accuracy is much lower than that of significant fibrosis with Fibroscan and even Fibrotest but higher

with FibroMeter3G. FibroMeter classification accuracy was significantly higher than those of other non-invasive tests. Finally, for hepatitis C evaluation in clinical practice, fibrosis degree can be evaluated using an accurate blood test.

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A prospective study of serum 25-hydroxyvitamin D levels, blood pressure, and incident hypertension in postmenopausal women.

Margolis KL, Martin LW, Ray RM, et al; for the Women's Health Initiative Investigators.

BACKGROUND: In randomized trials, the effect of vitamin D supplementation on blood pressure has been equivocal, while most prospective cohort studies have shown that the risk of incident hypertension is lower in people with higher levels of 25-hydroxyvitamin D (25(OH)D). The authors examined the association between levels of 25(OH)D and changes in blood pressure and incident hypertension in 4,863 postmenopausal women recruited into the Women's Health Initiative between 1993 and 1998. **RESULTS:** Over 7 years, there were no significant differences in the adjusted mean change in systolic or diastolic blood pressure by quartile of 25(OH)D. The covariate-adjusted risk of incident hypertension was slightly lower in the upper 3 quartiles of 25(OH)D compared with the lowest quartile, but this was statistically significant only in the third quartile (hazard ratio = 0.67, 95% confidence interval: 0.46, 0.96). There was no significant linear or nonlinear trend in the risk of incident hypertension by untransformed or log-transformed continuous values of 25(OH)D. **CONCLUSION:** In postmenopausal women in this study, serum levels of 25(OH)D were not related to changes in blood pressure, and evidence for an association with lower risk of incident hypertension was weak.

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Distinct effects of fixed combinations of valsartan with either amlodipine or hydrochlorothiazide on lipoprotein subfraction profile in patients with hypertension.

Christogiannis LG, Kostapanos MS, Tellis CC, et al.

BACKGROUND: The effect of antihypertensive drugs on

lipoprotein subfraction profile is still under investigation. In this study the effects of fixed combination of valsartan with either amlodipine (V-A) or hydrochlorothiazide (V-H) on low-density-lipoprotein (LDL) and high-density-lipoprotein (HDL) subfraction profile of patients with stage 2 or 3 hypertension were assessed. A total of 60 drug-naive patients were randomized to either V-A (160/5 mg, n=30) or V-H (160/12.5 mg, n=30). At baseline as well as 16 weeks post-treatment analysis of the LDL and HDL subfraction profile was conducted by using LDL Lipoprint System. Both V-A and V-H effectively reduced blood pressure (BP) to similar levels. **RESULTS:** An increase in the cholesterol concentration of small-dense LDL subfractions (by 18.2%, $P<0.05$) was observed in the V-H group, whereas this parameter remained unchanged in the V-A group. Therefore, mean LDL particle size was decreased in the V-H group (from 267 ± 5 to $266\pm 5\text{\AA}$, $P<0.05$). HDL-Cholesterol (HDL-C) levels were reduced by 4.7% ($P<0.05$) in the V-H group, mirrored by a reduction in the cholesterol mass of small and intermediate HDL particles. **CONCLUSION:** Despite similar reductions in BP, V-H combination may adversely affect serum lipids as well as LDL and HDL subfraction profile as compared with V-A.

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Usefulness of serum anti-p53 antibody assay for lung cancer diagnosis.

Park Y, Kim Y, Lee JH, et al.

CONTEXT: Some tumor markers, including carcinoembryonic antigen (CEA) and cytokeratin 19 fragment (CYFRA 21-1), are used for the detection of lung cancer; however, their use is limited because of low sensitivities and high false-positive rates. **OBJECTIVES:** To investigate the usefulness of an anti-p53 assay in detecting lung cancer and to compare the anti-p53 to CEA and CYFRA 21-1 tumor markers. **DESIGN:** Serum samples were collected from 82 patients with lung cancer. Sera were also collected from 79 patients with or without benign pulmonary disease for the control group. All 161 specimens were assayed for CEA, CYFRA 21-1, and anti-p53. The diagnostic performances of these markers were compared using receiver operating characteristic analysis. **RESULTS:** The receiver operating characteristic area under the curve values of CYFRA 21-1, CEA, and anti-p53 for discriminating lung cancers from benign or healthy conditions were 0.79, 0.81, and 0.79, respectively.

Area under the curve for the 3 markers in combination was 0.90. The sensitivities of those markers for lung cancer detection were respectively 39.0%, 53.7%, and 34.1% at 94.9% specificity, and the cutoff levels at those sensitivities and specificities were 4.5 ng/mL for CYFRA 21-1, 5.4 ng/mL for CEA, and 2.7 U/mL for anti-p53. We found 79.3% positive results for patients with lung cancer by any of the 3 markers, and 12.2% were positive only for anti-p53. All patients without cancer had negative results for 2 or all 3 markers. **CONCLUSIONS:** Anti-p53 combined with other conventional markers is helpful in increasing the sensitivity and specificity for detecting lung cancer.

Br J Cancer. 2011 Nov 29. doi: 10.1038/bjc.2011.512. [Epub ahead of print]

A longitudinal study of serum insulin and glucose levels in relation to colorectal cancer risk among postmenopausal women.

Kabat GC, Kim MY, Strickler HD, et al.

BACKGROUND: It is unclear whether circulating insulin or glucose levels are associated with increased risk of colorectal cancer. Few prospective studies have examined this question, and only one study had repeated measurements. **METHODS:** We conducted a prospective study of colorectal cancer risk using the subsample of women in the Women's Health Initiative study whose fasting blood samples, collected at baseline and during follow-up, were analysed for insulin and glucose. Cox proportional hazards models were used to assess associations with colorectal cancer risk in both baseline and time-dependent covariates analyses. **RESULTS:** Among 4,902 non-diabetic women with baseline fasting serum insulin and glucose values, 81 incident cases of colorectal cancer were identified over 12 years of follow-up. Baseline glucose levels were positively associated with colorectal cancer and colon cancer risk: multivariable-adjusted hazard ratio (HR) comparing the highest (≥ 99.5 mg dl⁻¹) with the lowest tertile (< 89.5 mg dl⁻¹): 1.74, 95% confidence interval (CI) 0.97-3.15 and 2.25, 95% CI: 1.12-4.51, respectively. Serum insulin and homeostasis model assessment were not associated with risk. Analyses of repeated measurements supported the baseline results. **CONCLUSION:** These data suggest that elevated serum glucose levels may be a risk factor for colorectal cancer in postmenopausal women.

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PharmaFacts for Case Managers



Intermezzo (zolpidem tartrate sublingual tablets)

The US Food and Drug Administration (FDA) has approved Intermezzo (zolpidem tartrate sublingual tablet) C-IV for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Intermezzo is not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the planned time of waking.

Middle-of-the-night awakening with difficulty falling back to sleep is a form of insomnia that is estimated to affect millions of adults in the United States. Intermezzo is the first and only prescription sleep aid indicated for dosing in the middle of the night to treat this form of insomnia.

Intermezzo is formulated as a sublingual tablet containing a bicarbonate-carbonate buffer. Intermezzo is rapidly absorbed in both women and men. The recommended dose of Intermezzo for non-elderly patients is 1.75 mg for women and 3.5 mg for men, taken only once per night as needed if a middle-of-the-night awakening is followed by difficulty returning to sleep. These recommended doses are specific to each gender because women clear zolpidem from the body at a lower rate than men. The 1.75 mg dose is recommended for patients over the age of 65. The recommended doses of other FDA approved zolpidem products range between 5 mg and 12.5 mg and are indicated for bedtime use.

The safety and efficacy of Intermezzo were evaluated in two placebo-controlled studies for the treatment of patients with insomnia characterized by difficulty returning to sleep after awakening in the middle of the night. In both a sleep laboratory study and an outpatient study, treatment with Intermezzo after a middle-of-the-night awakening helped patients return to sleep significantly faster than placebo. The most commonly reported adverse reactions in these studies were headache, nausea, and fatigue.

Transcept has agreed to FDA post-marketing commitments including a study of patient compliance with Intermezzo dosing instructions and pediatric use assessment in accordance with the Pediatric Research Equity Act (PREA).

Transcept and Purdue are parties to a collaboration agreement for the development and commercialization of Intermezzo in the United States. Under this collaboration agreement, Purdue has until December 8, 2011 to notify Transcept whether it will proceed with the commercialization of Intermezzo.

Important Safety Information

Intermezzo is contraindicated in patients with known hypersensitivity to zolpidem. Observed reactions with zolpidem include anaphylaxis and angioedema.

Intermezzo, like other sedative-hypnotic drugs, has central nervous system (CNS) depressant effects. Co-administration with other CNS depressants (eg, benzodiazepines, opioids, tricyclic antidepressants, alcohol) increases the risk of CNS depression.

The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated.

Angioedema, and additional symptoms suggesting anaphylaxis, may occur in patients taking Intermezzo and may be fatal. Patients who develop angioedema or anaphylaxis after treatment with zolpidem should not be re-challenged with Intermezzo.

Abnormal thinking and behavior changes have been reported to occur in association with the use of sedative-hypnotics, including decreased inhibition, bizarre behavior, agitation, and depersonalization, as well as visual and auditory hallucinations. Complex behaviors such as “sleep-driving” and “sleep-eating,” with amnesia for the event, have been reported with sedative-hypnotics. The use of alcohol and other CNS depressants with zolpidem appears to increase the risk of such behaviors. Discontinuation of zolpidem should be strongly considered for patients who report a sleep-driving episode. The emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.

In primarily depressed patients, worsening of depression, including suicidal thoughts and actions (including completed suicides), has been reported in association with the use of



sedative-hypnotics. Suicidal tendencies may be present in such patients and protective measures may be required. Intentional over-dosage is more common in this group of patients; therefore, the lowest number of tablets that is feasible should be prescribed for the patient at any one time.

Because persons with a history of addiction to or abuse of drugs or alcohol are at increased risk for misuse, abuse and addiction of zolpidem, they should be monitored carefully when receiving Intermezzo. Zolpidem tartrate is classified as a Schedule IV controlled substance by federal regulation. Post-marketing reports of abuse, dependence, and withdrawal resulting from the use of oral zolpidem tartrate have been received. There have been reports of withdrawal signs and symptoms following the rapid dose decrease or abrupt discontinuation of zolpidem.

Intermezzo should only be taken in bed. Intermezzo is not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the planned time of waking. Patients should not drive or undertake other dangerous activities after taking Intermezzo until they are fully awake. Patients should be cautioned about possible combined effects with CNS-depressant drugs. Intermezzo should not be taken with alcohol.

Eylea (aflibercept)

The FDA has approved a first-in-class drug, aflibercept (Eylea), for “wet” age-related macular degeneration (AMD).

Aflibercept, also known as VEGF Trap-Eye, is a peptide drug that soaks up vascular endothelial growth factor molecules, which help drive the abnormal growth of retinal blood vessels responsible for wet AMD. The drug includes fragments of human IgG and the VEGF receptor protein and scavenges placental growth factor as well as VEGF.

Clinical Studies

According to the manufacturer, Regeneron Pharmaceuticals, the approval was based on three phase III studies in which the drug was given by intraocular injection monthly for three months followed by injections every two months for a total of one year. The dose per injection was 2 mg.

Efficacy results indicated that the drug worked as well as ranibizumab (Lucentis), the only other drug specifically approved for wet AMD. The primary efficacy outcome in these studies was the proportion of patients whose visual acuity either improved or declined by less than 15 letters on a standard eye chart.

The main studies backing approval were dubbed VIEW 1 and 2. In those trials, the endpoint was achieved in 95.3% of patients receiving aflibercept and in 94.4% of those receiving ranibizumab.

A total of 2,457 patients were randomized in the two trials, with more than 90% completing the year-long study.

At baseline, best corrected visual acuity was 54 letters on the standard ETDRS chart on average, and mean retinal thick-

ness ranged from 313 to 324 microns in VIEW 1 and 326 to 343 microns in VIEW 2.

About 30% of patients gained at least 15 letters in visual acuity during the study in all four study arms. Specifically, 32.4% of the monthly ranibizumab and 31% of the bimonthly 2-mg VEGF Trap-Eye patients had such increases in acuity.

Only about 20% of patients lost acuity during the trial, again with virtually no difference between regimens.

Similarly, retinal thickness declined by about 130 microns in all four groups.

Adverse effects also did not differ markedly between treatment arms.

The VIEW 1/2 investigators paid special attention to hypertension, as it is a sensitive and important indicator of unwanted systemic anti-VEGF activity. Between 8% to 10% of patients in each of the four treatment groups had findings of high blood pressure at some point.

Indication

According to the FDA-approved labeling for aflibercept, the drug is indicated for the treatment of patients with neovascular age-related macular degeneration (wet AMD). It is contraindicated in patients with ocular or periocular infections or active intraocular inflammation.

It indicates that the product may be dosed as frequently as 2 mg every 4 weeks, but additional efficacy was not demonstrated with this schedule compared with the eight-week interval.

As with other VEGF inhibitors, there is a potential risk of arterial thromboembolic events, defined as nonfatal stroke, non-fatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of such events in the aflibercept trials was 1.8%.

Another version of aflibercept is under investigation for a range of solid-tumor cancers, which also depend on blood vessel growth.

Important Safety Information

EYLEA™ (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.

Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic ►



nerve head should be monitored and managed appropriately.

There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs with EYLEA in clinical trials was low (1.8%).

Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis, traumatic cataract, and increased intraocular pressure.

The most common adverse reactions ($\geq 5\%$) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.

Erwinaze (asparaginase Erwinmoa chrysanthemi)

Erwinaze (asparaginase *Erwinia chrysanthemi*) is approved to treat patients with acute lymphoblastic leukemia (ALL), who have developed an allergy (hypersensitivity) to *E. coli*-derived asparaginase and pegaspargase chemotherapy drugs used to treat ALL.

ALL is a type of cancer in which the bone marrow makes too many lymphocytes, a type of white blood cell. White blood cells help the body fight infection and are formed in the bone marrow.

Erwinaze is designed to break down amino acid (asparagine), one of the body's protein building blocks in the blood, necessary for the growth of all cells. Erwinaze treatment consists of three intramuscular injections per week and causes leukemia cells to die. Erwinaze therapy does not affect healthy human cells that are able to produce sufficient asparagines for their own needs through biosynthesis, but Leukemia cells are unable to produce asparagines.

Erwinaze is injected directly into the muscle three times a week and works by breaking down one of the body's protein building blocks (the amino acid, asparagine) that is present in the blood, and is necessary for the growth of all cells. Leukemia cells cannot produce this protein building block. When a patient is treated with Erwinaze the leukemia cells die. Normal human cells are able to make enough asparagine for their own needs through biosynthesis and will not be affected by treatment with Erwinaze.

"The approval of Erwinaze underscores the FDA's commitment to the approval of drugs for conditions with limited patient populations with unmet medical needs using novel trial endpoints" said Richard Pazdur, MD, director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research.

Clinical Studies

The safety and effectiveness of Erwinaze was evaluated in one clinical trial of 58 patients. Additional safety data were collected from the Erwinaze Master Treatment Protocol (EMTP), an expanded access program that enrolled 843 patients. Patients in both studies were unable to continue receiving pegaspargase or

asparaginase derived from *E. coli* due to allergic reactions.

In the trial to support efficacy, the main outcome (end-point) was the measurement of the proportion of patients with sustained asparaginase activity levels that correlate with better leukemia control and survival. All evaluable patients were shown to have maintained the pre-specified threshold for asparaginase activity at 48 or 72 hours after dosing.

Side Effects

Side effects associated with Erwinaze treatment include serious allergic reactions (anaphylaxis), inflammation of the pancreas (pancreatitis), high blood levels of liver enzymes (abnormal transaminases and bilirubin), blood clotting, bleeding (hemorrhage), nausea, vomiting, and hyperglycemia.

Prior to Erwinaze's approval there were two asparagine specific enzyme products—Elspar (asparaginase injection) and Oncaspar (pegaspargase)—approved by FDA to treat patients with ALL. Both of these products are *E. coli* derived.

Erwinaze has been designated as an orphan drug, which identifies the disease as affecting fewer than 200,000 people in the US.

Jakafi (ruxolitinib)

The FDA approved Jakafi (ruxolitinib), the first drug approved to specifically treat patients with the bone marrow disease myelofibrosis.

Myelofibrosis is a disease in which the bone marrow is replaced by scar tissue resulting in blood cells being made in organs such as the liver and the spleen. This disease is marked by an enlarged spleen, anemia, decreased white blood cells and platelets, and myelofibrosis-related symptoms.

Symptoms include fatigue, abdominal discomfort, pain under the ribs, feeling full (satiety), muscle and bone pain, itching, and night sweats.

Jakafi, a pill taken 2 times a day, inhibits enzymes called JAK 1 and 2 (Janus associated kinase) that are involved in regulating blood and immunological functioning. Myelofibrosis is associated with the deregulation of JAK 1 and 2.

Clinical Studies

The FDA approval was based on results from two randomized Phase III trials (COMFORT-I and COMFORT-II), which demonstrated that patients treated with Jakafi experienced significant reductions in splenomegaly (enlarged spleen). COMFORT-I also demonstrated improvements in symptoms as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) v.2.0 electronic diary and the MFSAF Total Symptom Score (TSS) comprised of 6 specific symptoms (abdominal discomfort, pain under the left ribs, an early feeling of fullness, night sweats, bone and muscle pain and itching) all of which contributed to the overall benefit. Most patients taking placebo experienced worsening of these same parameters.



The COMFORT-I trial, conducted by Incyte, compared Jakafi to placebo in 309 patients with primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. The trial met the primary endpoint, showing that 41.9% of patients treated with Jakafi experienced a 35% or greater reduction in spleen volume at 24 weeks, compared with 0.7% of patients taking placebo ($P < 0.0001$). A 35% reduction in spleen volume correlates to approximately a 50% reduction in spleen size on palpation. At week 24, the percentage of patients with a greater than or equal to 50% improvement in the TSS was 45.9% and 5.3% in patients treated with Jakafi and placebo, respectively ($P < 0.0001$), with a median time to response of less than 4 weeks.

The COMFORT-II trial, conducted by Novartis, Incyte's collaboration partner outside of the US, compared Jakafi to best available therapy in 219 patients with primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. This trial also met the primary endpoint, showing that 28.5% of patients treated with Jakafi experienced a 35% or greater reduction in spleen volume at 48 weeks, compared with 0% of patients in the best available therapy arm ($P < 0.0001$).

The most common adverse reactions in both studies were thrombocytopenia and anemia. These events were manageable and rarely led to discontinuation of Jakafi treatment. The most common non-hematologic adverse reactions were bruising, dizziness, and headache.

Jakafi was reviewed under the FDA's priority review program, an expedited 6-month review of drugs that may offer significant advances in treatment over available therapy or that provide a treatment when no adequate therapy exists.

The drug designated as an orphan drug, which identifies the disease as affecting fewer than 200,000 people in the US.

Important Safety Information

Treatment with Jakafi can cause hematologic adverse reactions, including thrombocytopenia, anemia and neutropenia, which are each dose-related effects, with the most frequent being thrombocytopenia and anemia. A complete blood count must be performed before initiating therapy with Jakafi. Complete blood counts should be monitored as clinically indicated and dosing adjusted as required. The three most frequent non-hematologic adverse reactions were bruising, dizziness and headache. Patients with platelet counts less than $200 \times 10^9/L$ at the start of therapy are more likely to develop thrombocytopenia during treatment. Thrombocytopenia was generally reversible and was usually managed by reducing the dose or temporarily withholding Jakafi. If clinically indicated, platelet transfusions may be administered. Patients developing anemia may require blood transfusions. Dose modifications of Jakafi for patients developing anemia may also be considered. Neutropenia ($ANC < 0.5 \times 10^9/L$) was generally reversible and was managed by temporarily withholding Jakafi. Patients should be assessed for the risk of developing serious

bacterial, mycobacterial, fungal and viral infections. Active serious infections should have resolved before starting Jakafi. Physicians should carefully observe patients receiving Jakafi for signs and symptoms of infection (including herpes zoster) and initiate appropriate treatment promptly. A dose modification is recommended when administering Jakafi with strong CYP3A4 inhibitors or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy. There are no adequate and well-controlled studies of Jakafi in pregnant women. Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breast-feed. Discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Patient Assistant Program: IncyteCARES

Incyte has established IncyteCARES (Connecting to Access, Reimbursement, Education and Support), a comprehensive program that provides reimbursement support and educational resources for patients. Incyte is committed to providing financial assistance for patients in need who qualify for the available support programs. A toll-free number has been established to provide support regarding benefit verification, prior authorization and assistance with appeals. IncyteCARES also offers patient educational materials, resources and access to trained nurse professionals to answer questions regarding the program.

Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)

The FDA has approved Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate), a complete single-tablet regimen for the treatment of HIV-1 infection in treatment-naïve adults. Complera combines three antiretroviral medications in one daily tablet—Gilead's Truvada, which is a fixed-dose combination of the two nucleoside reverse transcriptase inhibitors emtricitabine and tenofovir disoproxil fumarate, and Tibotec Pharmaceuticals' non-nucleoside reverse transcriptase inhibitor, rilpivirine (marketed as Edurant in the United States by Janssen Therapeutics, Division of Janssen Products, LP). Truvada and rilpivirine were approved by the FDA in August 2004 and May 2011, respectively, for use as part of HIV combination therapy.

The approval of Complera is supported by 48-week data from two Phase III double-blind, active controlled, randomized studies (ECHO and THRIVE) conducted by Tibotec that evaluated the safety and efficacy of rilpivirine compared to efavirenz among treatment-naïve HIV-1 infected adults. Both arms of the study were administered with a background regimen, in which the majority of patients in the rilpivirine arm received Truvada. A bioequivalence study, conducted by Gilead, demonstrated that the co-formulated single-tablet regimen achieved the same levels of medication in the blood as emtricitabine plus rilpivirine ►



plus tenofovir disoproxil fumarate.

Complera does not cure HIV-1 infection or help prevent the transmission of HIV to others. Complera has Boxed Warnings including lactic acidosis/severe hepatomegaly with steatosis and post treatment acute exacerbation of hepatitis B; see below for additional important safety information. The following points should be considered when initiating therapy with Complera:

- More rilpivirine-treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure compared to subjects with HIV-1 RNA less than 100,000 copies/mL at the start of therapy.
- The observed virologic failure rate in rilpivirine-treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared to efavirenz.
- More subjects treated with rilpivirine developed lamivudine/emtricitabine associated resistance compared to efavirenz.
- Complera is not recommended for patients less than 18 years of age.

Important Safety Information

BOXED WARNINGS: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including tenofovir disoproxil fumarate, a component of Complera, in combination with other antiretrovirals.

Complera is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of Complera have not been established in patients coinfecting with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfecting with HBV and HIV-1 and have discontinued Emtriva or Viread, which are components of Complera. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfecting with HIV-1 and HBV and discontinue Complera. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Contraindications

Complera should not be co-administered with the following drugs, as significant decreases in rilpivirine plasma concentrations may occur due to CYP3A enzyme induction or gastric pH increase, which may result in loss of virologic response and possible resistance to Complera or to the class of NNRTIs:

- the anticonvulsants carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- the antimycobacterials rifabutin, rifampin, rifapentine
- proton pump inhibitors, such as esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole
- the glucocorticoid systemic dexamethasone (more than a single dose)
- St John's wort (*Hypericum perforatum*)

Warnings and Precautions

• New onset or worsening renal impairment

Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with the use of tenofovir disoproxil fumarate. Assess creatinine clearance (CrCl) before initiating treatment with Complera. Monitor CrCl and serum phosphorus in patients at risk for renal impairment, including patients who have previously experienced renal events while receiving Hepsera (adefovir dipivoxil). Avoid administering Complera with concurrent or recent use of nephrotoxic drugs. Patients with CrCl below 50 mL per minute should not receive Complera.

• Drug Interactions

Complera should be used with caution when given with drugs that may reduce the exposure of rilpivirine. Complera should be used with caution when co-administered with a drug with a known risk of Torsade de Pointes.


• Depressive Disorders

The adverse reaction depressive disorders (depressed mood, depression, dysphoria, major depression, mood altered, negative thoughts, suicide attempt, suicidal ideation) has been reported with rilpivirine. During the Phase III trials (N=1,368), the incidence of depressive disorders (regardless of causality, severity) reported among rilpivirine (N=686) or efavirenz (N=682) was 8% and 6%, respectively. Most events were mild or moderate in severity. The incidence of Grade 3 and 4 depressive disorders (regardless of causality) was 1% for both rilpivirine and efavirenz. The incidence of discontinuation due to depressive disorders among rilpivirine or efavirenz was 1% in each arm. Suicide attempt was reported in 2 subjects in the rilpivirine arm while suicide ideation was reported in 1 subject in the rilpivirine arm and in 3 subjects in the efavirenz arm. Patients with severe depressive symptoms should seek immediate medical evaluation to assess the possibility that the symptoms are related to Complera, and if so, to determine whether the risks of continued therapy outweigh the benefits.

• Decreases in bone mineral density

Bone mineral density (BMD) monitoring should be considered for patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. Cases of osteomalacia (associated with proximal renal tubulopathy and which may contribute to fractures) have been reported in association with the use of tenofovir disoproxil fumarate.

• Co-administration with other products

Complera should not be administered concurrently with other medicinal products containing any of the same active components, emtricitabine, rilpivirine, or tenofovir disoproxil fumarate (Emtriva, Edurant, Viread, Truvada, Atripla), with medicinal products containing lamivudine (Epivir, Epivir-HBV, Epzicom, Combivir, Trizivir), or with adefovir dipivoxil (Hepsera). 

The 21st Century Case Manager

by John Rossheim

It's really quite simple. To succeed in the 2010s, all a case manager must do is expand her practice to encompass the kinds of patients—millions of them—who will gain coverage under health care reform. Integrate into her care plans and their execution the ever-growing range of services that today's patients require. Coordinate care across the full range of psychosocial contexts. And perform wizardry with patient data to drive optimal care decisions and meet ever-tighter fiscal and regulatory standards.

Yes, the job of the 21st century case manager is much more complex and challenging than it was just a few decades ago. But the opportunity is greater as well.

"Case managers are working in new situations, in ways that will improve outcomes for patients and the bottom line," says Margaret Leonard, MS, RN-BC, senior vice president for clinical services at Hudson Health Plan, a managed care provider in New York.

Health Care Reform Expands Role of Case Manager

Even given the legal uncertainties swirling around The Patient Protection and Affordable Care Act, health care reform will drive many changes for leading-edge case managers in the 2010s.

"Health reform has care coordination written all over it," says Sheilah McGlone, RN, CCM, CPUM, director of case management and utilization review for Hudson. Bundled payments,

for example, are already motivating forward-looking hospitals to give a more prominent role to case managers. With courses of treatment for certain conditions reimbursed by a fixed, bundled payment, hospitals are likely to give case managers more resources and clout to coordinate care as efficiently and effectively as possible.

Meanwhile, given the demographics of patients to be newly covered by 2014, care coordination itself will require more advanced skills. "Under health care reform we're anticipating more people with coverage, and more people with preexisting conditions that will require extensive treatment — some very complicated cases," says Alan Boardman, an account manager for Beacon Health Strategies, a Boston-area provider of behavioral health care management services. "So case managers need to coordinate comprehensive care."

In addition, in the coming years the case manager will take on a much more challenging client-mentoring role. With patients who long lacked insurance, "we'll have to do more patient education about what primary care is, and more health care coaching," Boardman says.

Forward-Looking Case Managers Integrate Services

Case managers who seek to excel in these times are expanding the scope of their work, both within the health care system and beyond.

First, the case manager will be responsible for creating and implementing a more tightly synchronized care plan that crosses the boundaries of

specialties and institutions. "The trend in case management is integrating behavioral health with medical services," says Boardman.

Says McGlone, "One case manager handles all care coordination of the patient whether behavioral or physical; there's no handoff." Case managers are also forging a greater role for themselves in patient transitions.

Overall, case management, according to the 2010 revision of the CMSA Standards of Practice for Case Management, now means "expanding the interdisciplinary team to include clients and their identified support system, and health care providers including community-based and facility-based professionals."

Coordinating Care in Context

To serve their clients' diverse needs, leading-edge case managers now must venture beyond clinical settings into the community, to create care plans that contemplate the social, psychological and educational milieus of their clients. "One of our intensive case managers is a licensed clinical social worker with experience in schools, so she knows resources in the school system and attends meetings to create individualized education plans," says Boardman.

"We may need to meet the patient where she is; this is the new skill set," Leonard says.

With increasing numbers of vulnerable patients in troubled situations, many care coordinators must also engage the human service agencies that serve clients and their families. "Our

John Rossheim is a writer and editor who covers information technology, careers and other topics in health care.

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CMSA to Work With ABQAURP to Develop New Transitions of Care Credential

The Case Management Society of America (CMSA) and the American Board of Quality Assurance and Utilization Review Physicians, Inc. (ABQAURP) announced a joint collaboration to create a Sub-specialty certification for transitions of care (TOC). The new Sub-specialty certification is a part of the specialized credentials available through ABQAURP's Health Care Quality and Management Board Certification (HCQM). In recognizing the importance of transitions of care—a major provision within the Patient Protection and Affordable Care Act—this new credential is the first one to support professionals not only as a team, but also individually, who demonstrate competence and skills in providing the key elements of transitions of care.

“CMSA's and ABQAURP's first goal for the Transitions of Care Sub-specialty Certification is to allow professionals to demonstrate their ability to critically evaluate industry literature about TOC,” said Mary Beth Newman, MSN, RN-BC, CMAC, CCP, CCM. “In addition, we have worked hard to design the credential to help identify best practices, as well as to assist case managers in making recommendations that balance the

appropriateness of health care services with cost and quality as related to transitions. It is vital that the program address the need for effectiveness, efficiency, equity, safety, and timeliness in transitions of care. By assisting ABQAURP in creating a Transitions of Care Sub-specialty Certification, CMSA will expand its support of case managers and other health care professionals as they work to develop an ongoing commitment to patient safety, health care quality, and effective coordination of transition-related care.”

CMSA will assist ABQAURP in tailoring the Sub-specialty certification options to provide more relevance to individuals who perform or are involved in Case Management. Both Organizations hope to facilitate increased qualifications, competence, and authority within the case management field, as well as to accomplish the following:

- Provide more value to the case management industry as a whole
- Stimulate increased attention to case management, an often undervalued segment of the health care industry
- Increase the perceived value of case management activities ■

NCQA Accreditation of ACOs Begins

The National Committee on Quality Assurance has begun accrediting accountable care organizations (ACOs) using three levels of accreditation. CMS released a final ruling on ACO structuring and payment of providers in October. The NCQA is aligning its accreditation standards with the Medicare rules. Accreditation will be offered to providers in group practices, networks of individual practices, hospital-provider partnerships and joint ventures, hospitals and their contracted/employed providers, publicly governed entities, and partnerships with providers and health plans. ACOs will be required to serve 5,000 or more patients to qualify for accreditation. ■

FEW SMOKERS WHO TRY TO QUIT RECEIVE HELP

A study by the Centers for Disease Control and Prevention (CDC) shows that most US smokers want to quit, but very few receive medication or counseling from health care professionals to help them do so. Fewer than half of smokers who visited a health professional in the past year reported receiving advice to quit smoking last year. Women were more likely than men to get advice to quit, but Hispanics were less likely than white or blacks to receive such advice. Non-Hispanic blacks had the highest interest in quitting and the most attempts to quit, but the lowest success rates. The report notes that medications and counseling can double or triple success rates, yet the rate of counseling and prescribing such medications has fallen over the past year. ■

Patient-Centered Care for LGBT Patients

The Joint Commission is urging hospitals to create an inclusive environment that improves health care quality for lesbian, gay, bisexual, and transgender (LGBT) patients and their families. *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the Lesbian, Gay, Bisexual and Transgender Community: A Field Guide* is a resource for hospitals that can be used for staff training and compliance efforts to meet The Joint Commission patient-centered communication standards implemented in 2011.

Members of the LGBT community often have less access to insurance and health care services, experience higher rates of smoking, alcohol, and substance abuse, and are at increased risk for STDs and some cancers. ■

Marilyn B. Tavenner Nominated to Be CMS Administrator

President Obama nominated Marilyn B. Tavenner, RN, BSN, MA, currently the principal deputy administrator of CMS and previous acting administrator, to the chief role in November. Her nomination must be confirmed by the Senate. ■

DOOR-IN, DOOR-OUT PCI TIMES NOT BEING MET FOR STEMI PATIENT

Fewer than 10% of patients with ST-elevation myocardial infarction (STEMI) are being transferred from the emergency department to a facility that can perform percutaneous coronary intervention (PCI) within the 30-minute limit set by the Centers for Medicare & Medicaid Services (CMS). The door-in, door-out (DIDO) times exceeded an hour or more for more than 50% of patients, according to the first national assessment of performance supported by CMS and the National Heart, Lung and Blood Institute. Disparities in care were particularly notable: the time for transfer for women was 8.9 minutes longer than for men, the time for African Americans was 9.1 minutes longer than for whites, and young adults (aged 18–35) and elderly patients (aged older than 75) the time was more than 16 minutes longer than for patients aged 46–55. Read more at *Arch Intern Med.* 2011 Nov. 28 (doi:10.1001/archinternmed.2011.566). ■

A First-Hand Look at the Role of the Breast Cancer Nurse Navigator

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With survivorship care plans as part of the continuum of care focus in oncology nursing, through the Breast Center we support and begin the process by providing our patients with a summary plan of surgical treatment and follow-up after their postop recovery. This is supported by the navigation team.

In summary, the nurse navigator makes a significant contribution by providing supportive care to patients facing breast health concerns and facilitating the navigation process. The need for more nursing hours grew as our program expanded. The nurse's hands-on role has been noted in our patient satisfaction surveys. From my perspective, this hands-on care has led to better preparedness and decreased anxiety in our patients. Our leadership/navigation role has enhanced relationships with our patients, our navigation team, and our community. We continue to evaluate both program and patient needs and promote change as appropriate, keeping the patient as our central focus. **CEU**

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Breast Care Specialists of Maine has received a full three-year accreditation by the National Accreditation Program for Breast Centers (NAPBC), which is administered by the American College of Surgeons. Only breast centers that provide the highest level of diagnosis and treatment nationally are eligible for this distinction.

National Accreditation Program for Breast Centers (NAPBC)

Fact Sheet

In 2011, more than 230,000 new cases of invasive breast cancer were expected to occur among women in the US and an additional 2,100 among men. More than 57,000 new cases of in situ breast cancer were expected to occur, about 85% percent will be ductal carcinoma in situ (DCIS).¹

“The treatment of breast cancer has become more complex. Management requires imaging to direct surgical treatment. Pathologic evaluation determines the options of local and systemic treatment. The heterogeneity of breast cancer becomes much more important when dealing with cancers smaller than 1.5 cm. A variety of care providers will interact with the patient as this course progresses. As the size of breast cancer decreases, the complexity of decision-making increases, as well as the number of people involved with patient care. In the past, breast care used to depend solely on individual effort. Now, as the majority of cancers are non-palpable and sentinel node sampling becomes the standard, patients must depend on a coordinated interdisciplinary team to achieve a successful outcome. Breast centers have the opportunity to bring together all the members of the breast care team to perform optimally.² Breast centers were formalized more than 20 years ago when mammography became commonplace and recognized as a valuable screening procedure. The breast center models vary from freestanding to institution-based, from physician-owned to hospital-owned, from imaging only to comprehensive support programs, from cancer center-affiliated to women's center-affiliated and all the intervening gradations. There are no breast centers that are exactly alike.”³

The advantages of becoming an NAPBC accredited center include

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The 21st Century Case Manager

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case managers follow patients across the continuum of care and also weave in agencies such as the Department of Social Services and Child Protective Services," says Boardman.

Data Informs Care Decisions

Perhaps the most rapidly evolving area of expertise for care coordinators is their use of patient data. Long adept at describing their patients' medical conditions and history, case managers who lead must now bring data to the task. "Case managers need to do more than just narrative reporting," says Leonard. "They need to be working with fielded data, and they appreciate more and more that you can't develop a good care plan without data mining."

Indeed, gathering, analyzing and acting upon patient data plays a bigger part in the work of case managers than it has in the past. "I expect my case managers to analyze their patients' data immediately," says McGlone. "They download claims data, and that data can tell a story."

Case managers tend to be highly organized people, and that often

translates to an intuition for working with health care IS. But not always. "In a lot of settings we hire case managers who don't have a lot of information systems experience," Boardman says. "So we do a lot of training, which can be a challenge. There has to be an aptitude for technology."

Case managers who lead in the 2010s will play a very active role in the development of the information systems that inform their practice. "Case managers can get involved in designing the systems they work with," says Leonard. "If they don't take the opportunity, the system may not work for them and their patients."

What's in store for case managers with the training, organizational skills and energy to excel in these challenging times? "Case managers now have opportunities to hone their skills in ways that are making a difference in their patients' lives," says Leonard. "And they're getting opportunities to bring those achievements to the attention of their superiors." **CM**

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CARF and the Development of Standards, Both New and Revised

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Standards Advisory Committees (ISAC) for revision of Brain Injury and Interdisciplinary Pain Rehabilitation. If any of you have these populations as your main business and would like to participate in the field review, please contact Chris MacDonell at cmacdonell@carf.org by February 1, 2012.

Case managers have unique skills and scopes of practice. Your experience can add depth to CARF's standards development and revision

process, and we look forward to your active participation in the process.

We encourage you to participate in the 2012 field reviews. Please visit www.carf.org and follow the links to the field review documents. The process is done through Survey Monkey and is easy to follow. Remember that when you disagree with a proposed standard, providing us with your reasons and background information for suggestions for improved language or concepts is helpful in making certain that we address your issues. Standards are developed and revised by YOU. Please participate. **CM**

A First-Hand Look at the Role of the Breast Cancer Nurse Navigator

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national recognition, having a model for organization of a center, and access to performance measures to improve quality of care.

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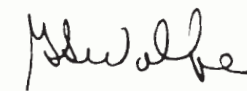
Health Care Trends 2012

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for Medicare. Out-of-pocket costs for health care will continue to rise, forcing people to think harder about whether to seek care at the doctor's office or emergency room. Rising out-of-pocket costs will cause people to skip physician visits and discontinue or cut back on prescription drugs.

- Wellness programs will increase and continue to be a priority as they attempt to control health care costs. Employers will be focusing on greater prevention of health conditions by exploring ways to integrate wellness initiatives into their benefits strategy.

The need for care coordination will continue to be a high priority. As case managers we see the problems, and we are part of the solution. Have a wonderful 2012!



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