CareManagement

OFFICIAL JOURNAL OF THE ACADEMY OF CERTIFIED CASE MANAGERS AND COMMISSION FOR CASE MANAGER CERTIFICATION

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Gary S. Wolfe

Challenges for Medicare

Medicare provides a vital foundation for the health and wellness of Americans who are 65 or older or have significant disabilities. The program currently covers a portion of health care costs for over 56 million individuals in the United States. Although Medicare is critical in helping older people and people with disabilities pay for necessary services, beneficiaries are often required to share in those costs. It is estimated that by 2024 Medicare will cover one-fifth of the US population.

Medicare has relatively high cost sharing and no limit on patient liability for covered benefits. Individuals who are covered by Medicare and who are hospitalized pay $1,300 for each hospitalization and 20% of the bills for physician care. The premium for Part B medical services is $1,600 a year. These health care costs represent a large burden for middle- and lower-income beneficiaries. Some facts:

In 2012, health expenses accounted for 14% of household budgets for individuals who were covered by Medicare, on average nearly 3 times the share of health spending among individuals who were not covered by Medicare (5%); these shares remained virtually unchanged from 2002 to 2012 although absolute spending levels have increased.

Health insurance premiums comprised the largest share of average out-of-pocket health care spending among Medicare households in 2012—nearly two-thirds of overall health spending.

Health spending as a share of Medicare household spending increases with age because health and long-term care needs increase and spending on other items declines.

Medicare households with modest incomes devote a greater share of their household budgets to health care than the highest-income Medicare households, whereas Medicaid substantially reduces health care spending in low-income Medicare households whose beneficiaries are eligible for both Medicare and Medicaid.

The impact for Medicare beneficiaries who have a high cost burden is significant. The high cost burden endangers their financial stability and the health of these vulnerable beneficiaries. These beneficiaries are:

- Less likely to access care.
- Less likely to shop for care or use over-the-counter products.
- More likely to not fill prescriptions.
- More likely to take less than the prescribed amount of a medication.
- More likely to have limited healthcare access and less likely to be able to pay for services.

Delaying care may backfire and lead to much higher overall costs because beneficiaries who do not participate in prevention programs and put off care may eventually need expensive emergency care.

The case manager plays a significant role in helping Medicare beneficiaries navigate the Medicare system. Some strategies the case manager should consider:

- Discuss costs and educate patients about compliance and impact on health.
- Educate patients about available programs and resources that might help with costs such as Medicare Advantage plans.
- Monitor patient adherence to treatments and ensure that patients keep their appointments and fill their prescriptions.

As the overall cost of health care continues to rise and as the population gets older, Medicare beneficiaries will continue to face challenges to meet out-of-pocket costs for health care.

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What the CCMC-CMSA Collaboration Means for Case Managers

By MaryBeth Kurland, CAE, CEO, *Commission for Case Manager Certification*

The decision seems like a natural one: collaboration between the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers, and the Case Management Society of America (CMSA), the oldest and largest case management membership organization.

Although the two organizations have worked together in the past, their new collaborative agreement will mean greater advocacy and promotion for the professional practice of case management. Although separate organizations, CCMC and CMSA have a shared vision around case management. Now, they will speak with a more powerful, unified voice on issues regarding case management in the evolving health care environment. Collaboration between CCMC and CMSA will put the professional case manager in the spotlight as an important member of interdisciplinary care teams, pursuing positive and desirable outcomes.

For case managers practicing today, there are many benefits to the CCMC-CMSA collaboration, both practical and strategic:

- CMSA members will receive a 20% discount when applying for the Certified Case Manager (CCM®) credential, as well as upon renewal
- Those holding the CCM credential will receive a 20% discount on CMSA membership

We believe these mutual benefits reflect the dedication of both organizations to help advance the career growth and professionalism of case managers. As Kathleen Fraser, MSN, MHA, RN-BC, CCM, CRRN, said in our joint statement, "Through this collaboration, two premier organizations in the case management field are now working together to establish a roadmap for the future of case management education, certification, and recognition."

CCMC administers the CCM credential, which is held by more than 42,000 case managers practicing in settings across the health care spectrum. They come from a variety of professional disciplines, including nursing, social work, rehabilitation counseling, mental health counseling, occupational therapy, and pharmacy. By attaining the CCM, health and human services professionals adhere to quality and ethical standards of case management practice while remaining in their fields of discipline. The CCMC also sets forth the Code of Professional Conduct for Case Managers, which serves as guidelines for ethical case management practice (For more information on the Commission, visit www.ccmcertification.org).

CMSA is the leading nonprofit association dedicated to the support and development of the profession of case management. CMSA serves more than 36,000 members, subscribers, and participants and over 80 local and international chapters through educational forums, networking opportunities, legislative advocacy, and its Standards of Practice for Case Management. (For more information about CMSA, visit www.cmsa.org.)

More than ever in today's complex health care environment, professional case managers are key members of interdisciplinary teams, promoting patient-centered practice and team-based models that emphasize coordinated, effective care delivery. To continue to provide these services in the future, a viable case manager workforce must be developed and prepared.

We know from the most recent CCMC Role and Function Study that the case manager population is maturing: Nearly half (47%) of respondents in the study survey were between the ages of 51 and 60. Succession planning to replace highly experienced case managers as they retire will require educating more nurses, social workers, and practitioners from other disciplines about the practice of case management. Both CMSA and CCMC are committed to this mission and now are working collaboratively to promote the practice of case management and the professional development of case managers. CM

MaryBeth Kurland, CAE, *is the CEO of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers. (For information about CCM certification, please see https://ccmcertification.org/)*

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How many Ethics CEUs will CCMC require?

- *Certifications expiring in 2017: four (4) Ethics CEUs will be required for renewal.*
- *Certifications expiring 2018 and after: eight (8) Ethics CEUs will be required for renewal.*

Discharge from Hospitals with Dignity

By Elizabeth Hogue, Esq.

An important article entitled "Discharge with dignity: hospital case managers must transform as the hospital transitions to the role of payer" by Josh Luke, PhD, appeared in the March 15, 2017, edition of *Becker's Hospital Review*. A key point of the article is that hospital discharge planners/case managers routinely send patients to post-acute care facilities unnecessarily and have been doing so as the norm for many years. As hospitals become more responsible for payments and are penalized more frequently for inefficient, ineffective care, the practice of routinely referring patients to facilities must cease.

As a former hospital CEO and the son of a mother with stage 7 Alzheimer's disease, Dr. Luke says that the inadequacy of the discharge planning process has come into clear focus.

First, doctors often advise patients and their families that patients are being "transferred" to rehabilitation facilities to recover. Use of the word "transfer" suggests that care plans are being implemented and are not complete. If doctors said that patients were being discharged from hospitals to nursing homes, it might signal to patients and their families that there are choices to be made.

According to Dr. Luke, there is also a great deal of confusion about what "going to a rehabilitation facility" really means. Patients and their families often discover later that "rehabilitation facility" really means nursing home.

In addition, hospitals do not clearly communicate to patients and their families that they have a choice about whether to go to post-acute care facilities at all. Hospitals do not routinely tell patients and their families that they may go home to recover instead.

Hospital discharge planners/case managers routinely send patients to post-acute care facilities unnecessarily and have been doing so as the norm for many years.

Finally, patients may be inappropriately referred to more expensive higher levels of care on discharge from the hospital only because their insurance will pay for such services. This may be especially true for Medicare patients who are referred inappropriately to long-term acute care hospitals, acute rehabilitation hospitals, and nursing homes because it is a covered benefit of the Medicare program. The incentives to simply discharge patients and to shorten the length of stay through referrals to these types of facilities are very powerful.

In short, Dr. Luke says:

"So to summarize these four points: Patients are often being sent to post-acute institutions unnecessarily and are not being educated thoroughly enough about post-acute options because the incentives for hospitals, doctors, and case managers to communicate and educate thoroughly contrast the hospitals' financial incentives...Until now. The rules have changed. Those hospitals and health systems who don't acknowledge these bad habits and create a plan to address them will suffer the financial consequences."

As the Centers for Medicare & Medicaid Services forces health systems into accountable care organizations and bundled payment programs, health systems are now at risk and are makeshift payers. Dollars spent on post-acute care are increasingly dollars spent by health systems. As a result, doctors and hospitals are now engaging in "gentle steering" to preferred home care providers.

Now is the time for post-acute home care providers of all types to swing into action to provide alternatives to post-acute care in facilities. There is a key role to be played by Medicare-certified home health agencies, private duty or nonmedical home care agencies, hospices, and home medical equipment companies to keep patients at home where they most want to receive care. Home care providers should cement their status as preferred providers with preferred provider agreements. Do not delay! CM

Elizabeth Hogue, Esquire, *is an attorney who represents health care providers. She has published 11 books, hundreds of articles, and has spoken at conferences all over the country.*

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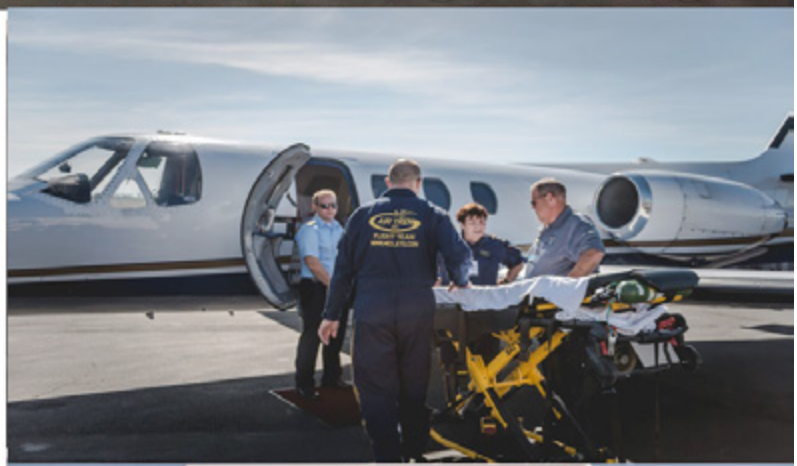

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Understanding Disability Management

By Lisa Scotton, MJ, RN, CCM, COHN, CDMS

Sixteen years ago, I started working for a health and disability insurance carrier. As a registered nurse and Certified Case Manager (CCM), my focus was on managing care for individuals during acute or chronic health care events, with the goal of returning them to optimal health and productivity. I had no idea that disability case managers existed or that there were certified specialists who focused on disability prevention and workplace productivity.

Today, I am dually certified, as a CCM and Certified Disability Management Specialist (CDMS). Now, when I meet with my fellow CCMs, I often find they are curious about disability management practice. Disability managers specialize in disability prevention as well as return-to-work and stay-at-work programs for those who experience occupational and nonoccupational illnesses and injuries. Disability managers are the bridge to help the individual cross from health care case management back into the workplace.

The integration of case management with a healthcare focus and disability management is best seen in workers' compensation. Disability case managers coordinate health care and facilitate return to work for injured workers. Unfortunately, this ideal scenario is less common for nonoccupational conditions, which makes the role of the CDMS even more critical.

The CDMS draws upon knowledge of health conditions and surgeries, workplace interventions, ergonomics, and benefits to facilitate a safe, timely, and productive return to work. The CDMS works in a variety of settings, such as employer workplaces, benefits departments, insurance carriers, and claim administrators.

Disability managers specialize in disability prevention as well as return-to-work and stay-at-work programs for those who experience occupational and nonoccupational illnesses and injuries.

To demonstrate the CDMS's role, consider this scenario: John needs surgery to repair a large tear in the rotator cuff of his left shoulder. After a period of postoperative recovery and physical therapy, John is cleared by his doctor to return to work but is cautioned not to lift anything heavier than 10 pounds for the next 4 weeks. John's short-term disability benefits provided by his employer pay less than his full salary, so he is anxious to return to work. A CDMS working for the disability insurance carrier helps facilitate his return to work by contacting his doctor for a work release, which specifies the details and duration of his work limitations. With knowledge of John's essential physical job functions, his medical condition, and employment benefits, the CDMS contacts his employer and facilitates a temporary transitional return to work for 4 weeks. The CDMS then monitors his return until John is released to resume his usual work duties.

This is just one small example of how CDMSs play a significant role in helping individuals navigate the challenges of illness and injury and workplace productivity. CDMSs draw on many disciplines: clinical, vocational rehabilitation, employer benefits, and regulatory absence programs (eg, Americans with Disabilities Act [ADA]) to support their clients.

As a nurse, I believe my clinical knowledge and skills are enhanced by my understanding of disability management, and more importantly, my ability to assist clients in achieving optimal health and return to productivity. Clinicians eager to pursue a new discipline that complements their clinical knowledge should consider pursuing disability management certification. CM

Lisa Scotton, MJ, RN, CCM, COHN, CDMS, *is assistant vice president and lead clinician in Aon's National Absence Management Practice. The Certified Disability Management Specialist (CDMS) credential is managed and governed by the Commission for Case Manager Certification. (See www.cdms.org/CDMS-Certification/Content/becoming-certified.html)*

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CareMore: Improving Outcomes and Controlling Health Care Spending for High-Needs Patients

By Martha Hostetter, Sarah Klein, and Douglas McCarthy

Introduction

When people talk about bending the health care cost curve, CareMore is often held up as an example that it's possible. Founded more than 20 years ago by a group of physicians, the Medicare Advantage plan and medical provider based in Cerritos, California, operates on the premise that one-third or more of health care spending on frail and chronically ill patients can be eliminated by restructuring the way their care is delivered.

CareMore has built its business around identifying high-risk patients who have a high likelihood of developing problems as they age and surrounding them with coordinated services. CareMore's effort to improve care for frail or chronically ill patients—especially the sickest 15% of its membership that accounts for some 75% of spending—is part of its strategy to spend more preventing and slowing the progression of disease than treating it. To do that, it invests the capitated payments it receives from Medicare in prevention and early intervention programs for all members and on supplemental benefits that Medicare's fee-for-service program typically doesn't cover—including patient education programs and transportation to its Care Centers. At the Care Centers, multidisciplinary teams of clinicians collaborate to identify what it will take to keep members with the most complex needs healthy.

As a result, CareMore says the company spends about twice as much as traditional Medicare keeping sick patients from getting sicker but only half of what the program spends on the sickest patients. Much of the savings result from keeping patients healthy enough to avoid hospitalizations. In 2015, CareMore members had 20% fewer hospital admissions, 23% fewer bed days, and a 4% shorter length-of-stay than beneficiaries covered under fee-for-service Medicare. How close CareMore comes to meeting its goal of reducing spending for the frail and chronically ill by one-third is unknown; utilization patterns suggest the company is making headway, as does pricing information on its Medicare Advantage products, which include special needs plans for patients with diabetes, lung disorders, end-stage renal disease (ESRD), and heart disorders.

This case study describes key features of CareMore's approach, which include:

- Partnering with independent primary care physicians (PCPs) in its networks to identify and refer high-risk patients who would benefit from receiving care at its Care Centers, where multidisciplinary teams deliver and coordinate primary care, behavioral health care, and specialty care services these patients need;
- Relying on employed staff including nurse practitioners, medical assistants, and other lower-cost providers in its Care Centers to provide high-touch primary care services, while reserving the time of "extensivist" physicians for overseeing patients' care before, during, and after hospitalizations and for other acute needs;
- Encouraging prevention and wellness and identifying health risks in all members; and
- Developing emotional connections with patients to encourage shared decision-making, particularly around end-of-life care.

We also examine the company's efforts to spread its model, both by serving Medicaid beneficiaries and by partnering with health systems that are moving toward risk-based contracting.

CareMore Model

Creating a Parallel System of Care for High-Needs Patients

CareMore's leaders recognize that many of the independent PCPs serving its Medicare Advantage members do not have enough time and resources to give sufficient attention to those with multiple or pressing needs, particularly those with chronic conditions. Whereas some care management programs seek to support primary care providers by embedding nurses or social workers in their practices, for example, CareMore believes that it is better to create a parallel system of care for complex patients given the level of coordination required to manage their needs.

The company uses a number of techniques to identify

Martha Hostetter, Sarah Klein, *and* ***Douglas McCarthy*** *are researchers for The Commonwealth Fund.*

members who might benefit from clinic services. First, it encourages every new enrollee to come to a Care Center for an in-depth examination. Staff use laboratory tests, physical examinations, and an extensive survey to identify those who might need extra support. (The results of these examinations are also shared with patients' PCPs.) High-needs patients are also identified through claims, authorizations, physician referrals, and individual chart review (eg, prescription history, laboratory test results, and diagnoses) or when they are hospitalized. "We can't wait for patients to get sick and treat the problem," says Balu Gadhe, MD, CareMore's chief medical officer of specialty care. "We have to be proactive in understanding their needs and what will help them stay well."

Once CareMore identifies patients, it is able to quickly deploy resources—chronic disease management programs, behavioral health therapy, social support referrals, nutritional counseling, and others—because it is not a telephone-based care management company that depends on third parties to deliver services.

At any given time, about 20% of CareMore members receive services from teams. Among them are patients with multiple chronic conditions, the frail elderly, and those with comorbid behavioral and physical health problems. Many of the patients are poor (about 30% of CareMore's members are very low income).[1] Many choose CareMore because it offers benefits such as no-cost transportation to and from clinics, no copayments for medications or supplies needed to manage chronic conditions, and 24/7 access to providers. In most markets, there are no premiums and no copayments for primary care or Care Center visits.

Some patients use the Care Centers on a short-term basis, for instance after a hospitalization, and then transition back to their PCPs. Other very sick patients, such as those with ESRD, receive care there for years. As people's conditions stabilize, they may receive less intensive oversight, but they are still monitored by CareMore's team. "We learned that when members are stable and we discharge them back to their primary care provider, they fall off the wagon because somebody's not holding them accountable," says Heather Del Villar, CNP, chief nurse practitioner.

Relatively healthy CareMore members who do not need hands-on support may take advantage of CareMore's wellness programs, including an exercise program customized for older adults ("Nifty After Fifty"), nutrition counseling, and a diabetes education program.

To encourage support for this model, CareMore offers PCPs an incentive package that rewards jointly supported goals such as the delivery of comprehensive health assessments and preventive tests as well as performance on other quality measures including patient satisfaction. The plan pays PCPs capitated rates, so PCPs do not have a disincentive to refer patients to the Care Centers. Comanagement of chronically ill patients also may give PCPs more time to see new patients.

Interdisciplinary Team Care

At each Care Center, teams work together to ensure coordinated care, following detailed care protocols and making parsimonious use of specialists in a narrow referral network.[2] In addition to protocols for treatment of common diseases such as diabetes, chronic obstructive pulmonary disease, or dementia, CareMore has guidelines to address particular risks common to older adults, such as falls or drug interactions.

To make its high-touch model of care cost effective, CareMore uses nurse practitioners, medical assistants, and other nonphysician clinicians to deliver most services, relying on more highly paid physicians to oversee care for hospitalized patients and those admitted to skilled nursing facilities. Clinicians use whiteboards and team meetings to track care plans. Team members who aren't available for an in-person consult may use videoconferencing for quick consultations.

The care team is supported by nutritionists, social workers, psychiatrists, psychiatric nurse practitioners, behavioral health therapists, exercise specialists, and pharmacists. Pharmacy staff review laboratory test results (eg, to monitor medication effects), which are then shared with patients during visits. Behavioral health providers, including a psychiatrist or psychiatric nurse practitioner and a therapist, work in Care Centers to provide as-needed consultations and therapy.

CareMore's nurse practitioners deliver some services typically provided by physicians. For example, nurse practitioners care for diabetics' wounds—treatment that might otherwise be undertaken by PCPs or, if the wounds are slow to heal, vascular surgeons. Working under the general supervision of physicians, nurse practitioners see patients every other day to ensure their wounds are healing and change their dressings. With this approach, CareMore's patients had 66% fewer diabetic amputations from gangrenous infections than the average among Medicare fee-for-service beneficiaries.[3]

CareMore's nurse practitioners also explore the root causes of a patient's problems. After treating a diabetic patient's wound, for example, they may assess whether his or her diet, home situation, or mood may be hurting his health, bringing in other team members as needed. "Half of what we do is education," Del Villar says. Nurse practitioners also may be deployed to visit patients in postacute care settings or at home.

CareMore also has redefined the role of hospitalists, typically internists who provide general medical care for hospitalized patients. Its employed physicians are known as "extensivists" because their oversight extends beyond the

Case management provided by nurses is "the glue that holds the model together."

hospital to monitor patients leading up to, during, and after their hospital stays. With responsibility for 6–8 patients per day, extensivists check patients before procedures, visit them while they are hospitalized, then follow up with them until they are stabilized, making rounds in Care Centers and skilled nursing facilities.

Extensivists play a key role by overseeing the work of medical specialists and ensuring that treatment recommendations take into account the whole patient and his or her quality of life. Gadhe notes that well-informed patients and families often make conservative choices about treatment. He cites the example of an 89-year-old bedbound woman with advanced Alzheimer's who was hospitalized after a gallbladder attack. Although a scan showed the gallstone had passed, the patient's gastroenterologist recommended that she have surgery to remove her gallbladder to prevent future attacks.

After a CareMore extensivist stepped in to explain the risks of the surgery to the family, including worsening her dementia and potentially inducing life-threatening pneumonia, the family opted against surgery. She recovered and was able to go home and celebrate her birthday. Our goal is "dignity, palliation, and real end-of-life management," Gadhe says.

Case management provided by nurses is "the glue that holds the model together," he adds. Case managers meet daily with extensivists to review hospitalized patients' progress and preparations for discharge. In collaboration with extensivists, they develop a plan of care for members who are experiencing care transitions and/or are at high risk for readmission. They also help to assess and validate member needs; act as a first point of contact and facilitate communication with members, their families, and other providers; educate members and their caregivers on self-management skills under the guidance of the extensivist and nurse practitioner; and coordinate care for very sick patients, such as those with ESRD.

Care coordinators (typically specially trained medical assistants) coordinate postacute care, under the direction of the care manager, by setting follow-up appointments and ensuring that medical equipment and other supportive services are in place. Medical assistants perform diagnostic tests, help educate patients, and track their progress over time.

Engaging Patients and Addressing Nonmedical Needs

Nonmedical issues such as unstable housing, social isolation, food insecurity, stress, domestic abuse, unsafe neighborhoods, discrimination, and other factors can have an outsize impact on peoples' health and ability to care for themselves. CareMore teams use a number of tactics to identify such issues, such as asking about patients' social circumstances during initial interviews and making home visits. Social workers and case managers then link patients to services offered by their networks of community partners.

Instead of pointing the finger at "noncompliant" patients, CareMore teams make efforts to help patients manage their conditions. They don't charge any copayments for insulin and other maintenance medications and they offer home visits for those who don't or can't come in to the Care Centers; they also offer remote monitoring and send reminders to help people follow their treatment plans.

CareMore teams also seek to cultivate meaningful connections with patients by taking time to listen to them and by offering practical advice and support. Building trust enables providers to persuade many of their patients that they can feel better—that it's possible for them to avoid crises and control their conditions.

This also lays the groundwork for shared decision-making, particularly related to end-of-life care. CareMore teams initiate conversations about end-of-life care early and often, making sure patients and their families understand their options and potential consequences.

Integrated Behavioral Health Care

CareMore is better able to care for the whole person because behavioral health care is central to its approach. If CareMore clinicians suspect one of their patients has a behavioral health problem, they are able to make "warm handoffs" to psychiatrists, psychiatric nurse practitioners, or therapists working on site at the Care Centers and they also can get help from staff social workers and addiction specialists.

Like other CareMore clinicians, behavioral health staff treat a patient's symptoms but also work to uncover and address the root causes of problems. For example, when a behavioral health team encountered a 50-year-old member who had mood swings, heard voices, and struggled with addiction—leading to frequent hospitalizations—they developed a plan to create greater stability in her health and her life. They prescribed a long-acting injectable antipsychotic medication and enrolled her in a group residential living program. Since then, she has not been hospitalized.

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CareMore is better able to care for the whole person because behavioral health care is central to its approach.

Results

CareMore's approach improves management of chronic conditions and reduces hospitalizations. For example, close monitoring of members with chronic kidney disease, including secondary risk factors such as high blood pressure and uncontrolled diabetes, delays the onset of ESRD and reduces hospital admissions. According to the company, the 2015 hospital admission rate among CareMore's ESRD patients is 45% lower than the national average, with 85% fewer bed days.

CareMore has seen similar results from careful management of patients with congestive heart failure and chronic obstructive pulmonary disease (COPD). Patients in the heart failure program receive wireless scales that alert clinicians about rapid weight gain. Same-day appointments are available to quickly address concerns. Patients with COPD and heart failure receive ongoing help with medication management and coaching from nurse practitioners and dieticians in effective self-care. In 2015, readmissions for patients receiving these services were lower than for comparable Medicare beneficiaries in the fee-for-service program.

In general, CareMore members are also much less likely to be hospitalized than Medicare fee-for-service beneficiaries. From 2011 to 2015, unadjusted all-cause 30-day readmission rates among all CareMore members fell from 16.1% to 13.9%, according to the company. When they are hospitalized, CareMore members spend fewer days in the hospital and are less likely to have unplanned readmissions.

On average, CareMore has somewhat higher skilled nursing facility admissions per thousand patients than traditional Medicare. When appropriate, the company prefers to divert patients from the emergency department and hospital to short stays in nursing homes, where they can often be treated for a fraction of the cost. CareMore members who are placed in skilled nursing facilities are there for only half as long, on average, as fee-for-service beneficiaries—a fact its leaders attribute to their providers' frequent visits and careful oversight (it also may reflect differences in the types of patients admitted to skilled nursing facilities). Overall, CareMore members spent 39% fewer days in skilled nursing facilities in 2015 than beneficiaries in the fee-for-service program on average, according to CareMore.

CareMore is able to provide benefits at a lower cost than comparable plans and puts these savings toward providing "extras" for its members such as transportation to visits. Our analysis of Medicare Advantage "bids" and government payments finds that CareMore's plans provided Medicare benefits for beneficiaries in average health at a generally lower cost (1%–8% less, on average) than similar types of plans in seven counties where CareMore competed in 2014 (the most recent data available). Consequently, CareMore had a greater amount of "rebate" to spend on extra benefits compared with similar plans in the same county. CareMore's efficiencies varied by type of plan and by county, and were greatest in Los Angeles, California, and Pima County (Tucson), Arizona, where CareMore enrolled its largest membership. A comparison of CareMore's bids to payment benchmarks set by the federal government suggests that its plans offer standard Medicare benefits at a lower cost than the traditional Medicare program before adjusting for differences in the health status of beneficiaries.

CareMore also appears to perform relatively well on quality-of-care metrics reported by the federal government's Medicare Health Plan Finder tool. In Southern California, for example, CareMore's offering in Los Angeles County has garnered 4.0–4.5 stars (on a 5-star rating scale) over the past 3 years, which placed it among the top-ranked Medicare Advantage plans in the county.

Spreading the Model

CareMore's model for managing and coordinating care for Medicare beneficiaries is possible because the company can leverage risk-adjusted capitated payments to offer intensive, flexible services. "Risk adjustment is frankly the fuel that we need for our clinical model, which is so focused on the frail elderly, people with chronic disease who need differentiated care delivery models," says Sachin H. Jain, MD, CareMore's CEO.

This approach worked well until the federal government changed its risk adjustment methodology and reduced payments to Medicare Advantage plans out of concern plans were gaming the system.[9] The declining reimbursement, which has made it more difficult to offer supplemental services to its high-needs members, led CareMore to develop

new business lines. Under the banner of Anthem, Inc., which acquired CareMore in 2011, it is spreading the model to Medicaid beneficiaries in Tennessee and Iowa. And it entered into the competitive market of partnering with health systems to help them succeed in risk-based contracts that depend on reducing utilization and improving health outcomes.

Spreading the CareMore Approach to Medicaid Beneficiaries

Since January 2015, CareMore has been serving 42,645 Medicaid beneficiaries in Memphis, Tennessee, including 6,413 who qualify for the program under the category of aged, blind, and disabled. For 14,400 of the Tennessee beneficiaries, CareMore is providing direct primary care through its Care Centers as well as care management services. This expanded model proved necessary because there was insufficient primary care capacity in some of the neighborhoods it serves. For the remaining members, CareMore provides supplemental services to high-needs patients.

Although the Memphis approach is similar to the model CareMore uses for Medicare beneficiaries—proactive chronic disease management and use of nurse practitioners in care teams—there is a much greater need to reach out to Medicaid members and engage them in their care. According to CareMore, Memphis members have almost twice as many emergency department visits (1,936 visits per thousand) than the state's Medicaid population as a whole (891 visits per thousand), which the company attributes to the high prevalence of chronic conditions and behavioral health needs as well as to social challenges tied to poverty.

The Memphis team is taking several approaches to engage members. Three navigators work at each of the three Care Centers, trying to reach members by telephone and encourage them to come in for a visit. A community relations manager visits churches and schools, and clinicians make rounds at public housing complexes to offer health screenings and free flu shots to help spread the word about CareMore's services. The Care Centers also offer extended and weekend hours, same-day appointments, and drop-in appointments for minor services such as wound care. Amerigroup, the Anthem subsidiary that runs the Medicaid plan, also alerts CareMore when one of its members visits an emergency department, giving staff members a chance to engage members while they wait to be seen there.

The 6,413 aged, blind, and disabled beneficiaries are the linchpin to making the Medicaid venture viable because their greater use of services and correspondingly higher spending produces greater opportunities for savings. With those savings, CareMore is expecting to break even in 2 years. But the larger opportunity, leaders say, is in serving as a neighborhood resource for residents who have grown to distrust the care system and in some cases given up on their own health.

One challenge to spreading this model is that the company lacks longitudinal data on disease prevalence and the impact of different interventions in the Medicaid population—data that's necessary to set performance expectations in a new market. "One of the biggest tools in our Medicare replication efforts is that every market measured the same metrics and published them so that everyone understands what outcomes are expected for all patients, in all disease categories. With Medicaid we're managing adolescents for the first time, so we don't know exactly what the norms are," says Leeba Lessin, the company's former CEO, who is now a consultant to the company.

Spreading the CareMore Approach to Health Systems

In 2014, CareMore entered into a partnership with Atlanta's Emory Health System to implement its care model among Emory patients enrolled in Medicare Advantage plans for whom Emory assumes financial risk. CareMore is training Emory clinicians in its approach to care management, serving as a consultant, and also sharing in financial risk and potential savings. "Health systems are looking for a way out of fee-for-service," says Margaret Marcus, former vice president for clinical program development. "Because of this, a lot of opportunity opened up." This approach allows CareMore to spread its model without hiring new staff and creating new facilities from the ground up.

An analysis of the program found that the readmission rate for patients who were seen by an extensivist physician was 8.9% (by contrast, the rate among all patients treated at Emory University Hospital is no different than the national rate of 15.6%).[10]

Still, as CareMore grows, it faces several challenges in building on its early success, as discussed below.

Challenges

Changing Clinical Cultures

As CareMore has branched into different markets, it has encountered some opposition to its model from physicians, health system leaders, and others whose ways of working may be disrupted by the company's approach. To succeed in new markets, CareMore first seeks to earn the trust and support of the PCPs in its network so it has a critical mass of patients to serve. In some cases, PCPs have been reluctant to refer their patients to Care Centers—even though they don't lose financially for doing so. Some may be concerned about further fragmenting primary care services. Others are hesitant to cede control to lower-level clinicians, Gadhe says, but tend to be convinced over time. "Once they have about 40

At each Care Center, teams work together to ensure coordinated care, following detailed care protocols and making parsimonious use of specialists in a narrow referral network.

or 50 patients, they start realizing, 'Okay, wow. I'm not seeing very many complex patients but my patients are doing better. They're having better clinical outcomes. I'm having more time to expand my practice.'"

But this strategy doesn't always work. In Arizona, for instance, CareMore has found greater success in Tucson than in Phoenix. In Tucson, the health plan was able to partner with a large integrated delivery system (Carondolet Health System), which offered an established physician network. It also helped that Tucson is a relatively small, tight-knit community where word about the CareMore model spread quickly, says Dan Peterson, senior general manager for CareMore's central region. But without similar relationships with hospitals in the more competitive and sprawling Phoenix market, it was difficult for the company to refer members to facilities staffed by their extensivists. "When patients go to hospitals that are not manned by our extensivists, then the model falls apart," says Peterson. Engaging specialists is also important—particularly in academic medical centers, which tend to be specialty-driven.

Hiring and Training Staff Willing to Challenge the Status Quo

In addition to finding like-minded clinical partners, CareMore has had to refine its approach to recruiting and training staff to focus on changing practice patterns. Initially, new staff members learned by shadowing mentors, but as CareMore grew it found it needed more formal training methods, including a CareMore Academy where all new staff members come together for case-based learning and role-playing in teams. The approach, Marcus says, is to build on people's enthusiasm for helping patients—something they look for when recruiting—by teaching the particular skills they'll need to work in CareMore teams. "If they're an extensivist, they need to be able to manage the specialists, for example, and if they're a case manager they need to be able to make decisions on where the best care is provided," she says.

"Through our training programs, we push our clinical staff to constantly question prevailing wisdom in the search for better patient care. Do certain types of care really require physician input or can care be safely delivered by a medical assistant? Does every patient with chest pain truly require a cardiology consult?" Jain says.

Adapting the Model

As CareMore seeks to adapt and spread its model to serve new patient populations, its leaders are confronted by the question of how to stay true to the principles that have made the model effective while adapting it for diverse organizational and payment environments. CareMore's approach may generate pushback from providers concerned about job-shifting—from moving patients away from specialists and acute care toward lower-cost clinicians and outpatient care settings. The company has had difficulty in places like Tennessee, where scope-of-practice regulations limit what midlevel providers can do. In academic health systems, it may be important to create reimbursement models that include specialists and other providers in sharing the risk for total costs—as well as rewards for savings.

More broadly, CareMore faces an uphill battle to spread its model in a health system still dominated by fee-for-service reimbursement. But leaders of health systems such as Emory have approached CareMore precisely because they see the industry moving beyond paying for services to holistically managing patients, says Anthony Nguyen, MD, former regional medical officer for provider collaboration. "They want to be responsible and accountable for all those other aspects," he says, naming social services, preventive care, patient and family education, and proactive end-of-life discussions.

Conclusion

As these challenges suggest, spreading the CareMore model and achieving savings on a national scale may depend on the willingness of the country's health systems and providers to reconsider their roles—to focus more attention on keeping patients out of hospitals, reduce dependence on some types of specialty care that could be provided by PCPs, and assign some of their duties to midlevel providers and medical assistants. Even institutions that have committed to accountable care contracts have difficulty challenging providers to change practice patterns, Lessin says. It's part of the reason that Jain, when he was chief medical officer, was actively involved in hiring every new CareMore physician. "I want someone who can ask hard questions and push limits," he says. **CE 1**

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continues on page 34

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CE II Medicare Beneficiaries' High Out-of-Pocket Costs: Cost Burdens by Income and Health Status

The Commonwealth Fund

Introduction

For more than 50 years, Medicare has been a stable trusted source of health insurance that provides basic access and financial protection for elderly and disabled beneficiaries for acute hospital and medical care services.[1] The program has directly contributed to sharp declines in mortality and longer life expectancy for those age 65 and older.[2] It also has succeeded in holding spending per beneficiary nearly flat over the past 5 years, below private insurance increases.[3]

To assess the level of financial burden, we use two indicators of beneficiary health care spending relative to income:[4]

- High total cost burden: Spending on insurance premiums plus medical care, including copayments, coinsurance, and uncovered expenses, amounts to 20% or more of annual income.
- Underinsurance: Spending on medical care, excluding insurance premiums, that amounts to 10% or more of annual income.

Although someone may have a high total cost burden, he or she may not be underinsured if they have purchased robust coverage that does not require large copayments, deductibles, or other cost sharing to access health care. When someone is underinsured, his or her coverage does not provide adequate financial protection from health care costs. Our measure of underinsurance captures spending on health services not covered by Medicare or supplemental coverage.

The analysis reveals that millions of beneficiaries spend substantial shares of their income on health care costs. Thus, any proposals to change Medicare must proceed with caution. Already-high financial burdens mean any changes to the program must be assessed to safeguard beneficiaries' access and affordability.

Background: Medicare Benefits and Low-Income Policies

Currently, 56 million people—17% of the US population—rely on Medicare. By 2024, Medicare will cover one-fifth of the population.[5] As the population ages and becomes eligible for the Medicare, people will discover they need to supplement their coverage to ensure financial protection because the program has relatively high cost sharing and no limit on patient liability for covered benefits.

Medicare Current Benefits

Medicare benefits include substantial cost sharing as well as no limit on out-of-pocket costs for covered services. For example, beneficiaries pay $1,300 each time they are hospitalized and pay 20% of bills for physician care. Beneficiaries also pay a premium of $1,600 a year for Part B medical services. Such costs alone, not counting other health care expenses, represent a large burden for middle- and lower-income beneficiaries.

Supplemental coverage to fill in Medicare's cost sharing, known as Medigap, is costly. Annual premiums average $2,000 per person but can be much higher, exceeding $200 a month in areas like New York City.[6] Medigap has notably high overhead costs: administrative costs and profits absorb 20% of premiums on average.[7]

Beneficiaries may opt out of traditional Medicare to enroll in a private Medicare Advantage (MA) plan. These plans generally have lower cost sharing than traditional Medicare. However, in recent years MA plan cost sharing has increased substantially.[8]

Medicare's Low-Income Provisions

An estimated 25 million Medicare beneficiaries (45%) have incomes below 200% of the federal poverty level (just under $24,000 for a single person) and one-third are poor or near-poor with incomes below 150% of poverty (below $18,000 for a single person) with, at best, limited assets to last their lifetimes.

Current policies to help low-income beneficiaries pay for premiums and care are limited and require beneficiaries to navigate complex eligibility rules. Some individuals with incomes below poverty may qualify for full Medicaid, which pays Medicare premiums and cost-sharing expenses and provides expanded benefits, including long-term care (although this varies by state of residence).[9] Beneficiaries with incomes up to 135% of poverty (about $16,000 for a single person) may be eligible for partial subsidies through the Medicare Savings Programs. Under these programs, Medicaid will pay for Medicare's Part B premium and cost sharing for individuals with incomes up to the federal poverty level and will pay for Part B premiums (but not cost sharing) for beneficiaries with incomes between 100% and 135% of poverty as long as

Millions of beneficiaries spend substantial shares of their income on health care costs

their assets are no more than $7,290 for a single person or $10,930 for a couple.

An estimated 11 million Medicare beneficiaries have dual Medicare and Medicaid coverage. But only half of Medicare beneficiaries with incomes below poverty and less than one-fourth of those with incomes between 100% and 150% of poverty have full protection.

Low-income beneficiaries apply separately for Medicare Part D subsidies for premiums and cost sharing. Subsidies are available on a sliding scale up to 150% of poverty for those with assets of no more than $13,640 if single and $27,250 if a couple.

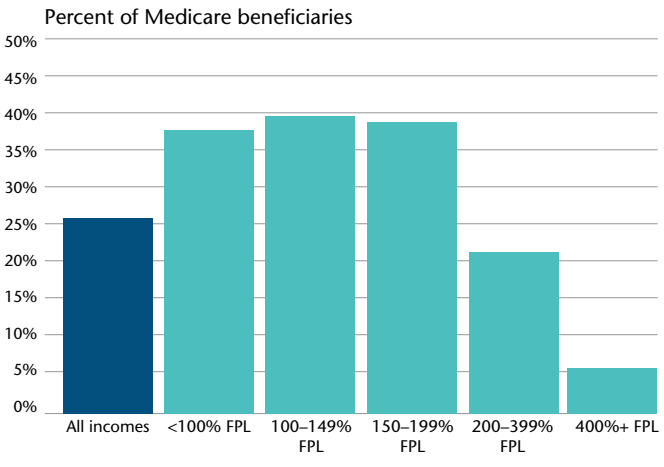
Beneficiaries' High Financial Burdens

Particularly for people living on low or modest incomes, Medicare can leave beneficiaries exposed to substantial out-of-pocket costs. When premiums, cost sharing, and spending on uncovered services are included, more than one-fourth of all beneficiaries (27%)—an estimated 15 million people—and 2 of 5 beneficiaries with incomes below 200% of the federal poverty level spent 20% or more of their income on health care and premium costs in 2016. As Figure 1 illustrates, burdens are high for all low-income groups below twice the federal poverty level. The share of middle-income beneficiaries—those between 200% and 399% of the federal poverty level, or $24,000 to $36,000 for a single person—incurring high costs is also notably high (22%).

But Medicare's benefit design also includes high cost sharing and no limit on out-of-pocket costs. Although prescription drugs were added in 2006, beneficiaries are required to purchase a separate private plan. If they want to buy private Medigap supplemental coverage for cost sharing, they incur significant additional premiums. Even after they pay for supplemental drug and Medigap plans, beneficiaries face the cost of dental, hearing, vision, and long-term services—all excluded from Medicare. For beneficiaries with multiple illnesses or serious functional limitations, out-of-pocket costs can easily add up to thousands of dollars per year. The resulting out-of-pocket costs for health care and premiums can add up to a substantial share of income, especially for those living on modest or low incomes.

To inform discussions of such potential changes, this

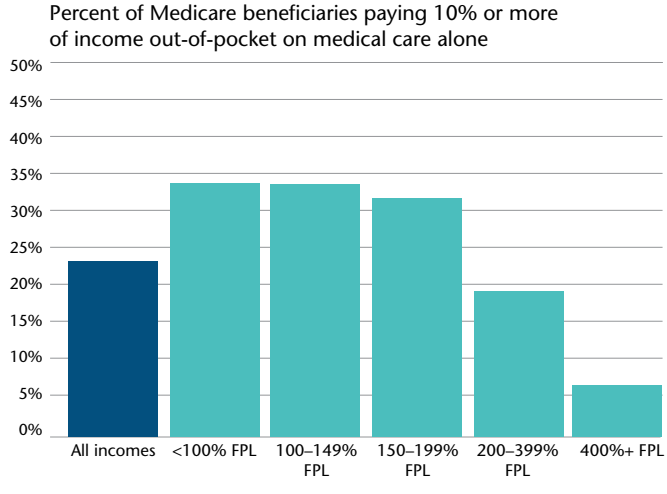
FIGURE 1 Medicare beneficiaries spending 20% or more of income on premiums and care, by poverty level



Note: FPL = federal poverty level.

Data: Roger C. Lipitz Center analysis of 2012 Medicare Current Beneficiary Survey projected to 2016.

FIGURE 2 One of four Medicare beneficiaries is underinsured



Note: FPL = federal poverty level.

Data: Roger C. Lipitz Center analysis of 2012 Medicare Current Beneficiary Survey projected to 2016.

Particularly for people living on low or modest incomes, Medicare can leave beneficiaries exposed to substantial out-of-pocket costs

brief looks at beneficiaries' financial burdens using 2012 Medicare Current Beneficiary Survey data projected to 2016. The analysis includes spending on premiums and care, including services not covered by Medicare. We profile financial burdens by beneficiary income and also health.

Medicare's Underinsured

Using our other measure of financial burden, we found that one-fourth of beneficiaries are underinsured—that is, they spend at least 10% of their total annual incomes on medical care services, excluding premiums. Of beneficiaries with incomes below the poverty level, one-third spent 10% or more (Figure 2). Despite having Medicare or supplemental coverage, these people are effectively underinsured.[10] The risks of being underinsured are highest for people with low incomes. Such cost burdens point to gaps in current low-income provisions to cover costs of needed health care, including services not covered by Medicare.

Poor Health as Well as Low Income Intensify Risk of High Cost Burdens

Beneficiaries with high needs—those with multiple chronic conditions or functional limitations that are either physical or cognitive in nature—are at significant financial risk. Nearly one-third (29%) of beneficiaries with 3 or more chronic conditions and 38% of beneficiaries with physical and/or cognitive limitations spent 20% or more of their annual incomes on premiums and medical care (Figure 3).

Low income and complex health conditions often go together: 68% of beneficiaries with incomes below 200% of

FIGURE 3 High cost burden for high-need and low-income Medicare beneficiaries

	Number of beneficiaries (in millions)	High total cost burden: spent 20% or more of income on premiums and out-of-pocket medical care	Underinsured: spent 10% or more of income on premiums and out-of-pocket medical care alone
All beneficiaries	**56.1**	**27%**	**24%**
Income			
<100% FPL	9.0	38.7%	35.2%
100%–149% FPL	9.2	41.0%	34.9%
150%–199% FPL	7.1	40.4%	33.4%
200%–399% FPL	18.4	22.4%	19.6%
400%+ FPL	12.5	5.8%	7.3%
Health			
3 or more chronic conditions	30.3	29.1%	26.6%
Serious physical and/or cognitive impairment	13.7	38.2%	38.5%
Income and Health			
<200% FPL and 3 or more chronic or functional limitations	17.0	42.4%	38.8%
200%–399% FPL 3 or more chronic or functional limitations	11.1	26.5%	24.6%
400%+ FPL 3 or more chronic or functional limitations	6.3	8.0%	10.1%

Note: FPL = federal poverty level.
Data: Roger C. Lipitz Center analysis of 2012 Medicare Current Beneficiary Survey projected to 2016.

Despite the substantial set of benefits that Medicare provides, many beneficiaries are left vulnerable because of financial burdens and unmet needs.

poverty have 3 or more chronic conditions and/or functional limitations. Among those with low income and poor health, 42% spent 20% or more of their incomes on premiums and care and 39% would be considered underinsured based on medical care costs alone (Figure 3).

Out-of-Pocket Spending: Covered and Excluded Services

The medical care cost burdens reflect the limited scope of benefits as well as Medicare's uncapped cost sharing. Excluding premiums, Medicare beneficiaries spent an average of $3,024 per year on out-of-pocket costs. Of this, more than one-third was spent on cost sharing for medical and hospital care, 25% on prescription drugs, and 39% on services Medicare does not cover, including dental and long-term care. Looking at beneficiaries who live in communities (that is, those not living in long-term care facilities), 45% of expenses went toward medical and hospital cost sharing, 33% toward drugs, and 22% toward services not covered by Medicare. Notably, beneficiary spending on drugs has increased in absolute dollars and as a share of total out-of-pocket costs.

Not surprisingly, the 5.4 million beneficiaries with only Medicare and no supplemental coverage of any kind face higher health care costs. These beneficiaries spent an estimated $5,374 on out-of-pocket costs in 2016 compared with $2,587 for beneficiaries who received supplemental coverage from Medicaid. With incomes too high to qualify for Medicaid but too low to afford supplemental coverage, 32% of Medicare-only beneficiaries spent 10% or more of their income on health care (data not shown).

Out-of-pocket spending increases steeply for those with multiple chronic diseases or serious cognitive or physical impairments. Beneficiaries with serious cognitive and/or physical impairments spend more than 3 times as much out of pocket, on average, as those without chronic disease or disability ($5,519 vs. $1,549). Without supplemental coverage, high-need, low-income beneficiaries are at particularly high risk: out-of-pocket spending averages more than $7,000 a year for those with only Medicare. This high cost burden is the result of cost sharing for covered services and out-of-pocket expenses for uncovered care.

Dental, Vision, and Hearing: Evidence of Unmet Need

Medicare promises to cover all essential medical care but explicitly excludes dental, vision, and hearing. Few beneficiaries have insurance for these services. Medicaid does not always cover such care, with wide state variations. As a result, most beneficiaries face the full costs of such services.

Access and spending follow a steep income gradient; low- and middle-income beneficiaries are far less likely to receive care during the year. Compared with their higher-income counterparts, beneficiaries with low incomes were less likely to have vision or dental care during the year and more likely to have problems seeing, hearing, or eating. In fact, 74% of Medicare beneficiaries below the poverty level had no dental care during the year and less than half had an eye examination.

Summary and Implications

Despite the substantial set of benefits that Medicare provides, many beneficiaries are left vulnerable because of financial burdens and unmet needs. As Medicare enters its sixth decade and the baby boom population becomes eligible, the costs of the program will increase, likely placing it on the policy agenda. Despite Medicare's notable recent success in controlling costs per beneficiary, total spending will increase as the program covers more people.[11]

The high financial burdens documented in this brief illustrate the need for caution. Half of Medicare beneficiaries have low incomes; one-third have modest incomes (200% to 399% of poverty). Any potential policy should first consider the impact on beneficiaries.

Access and affordability remain key concerns. In any discussions of potential Medicare reform, it will be important to pay particular attention to consequences for those vulnerable because of poor health or low income. Indeed, the findings point to the need to limit out-of-pocket costs and enhance protection for low-income or sicker beneficiaries.

As the single largest purchaser of health care in the country, Medicare policies directly influence insurance and care systems across the country. With a projected one-fifth of the population on Medicare by 2024, keeping beneficiaries healthy and financially independent is important to beneficiaries, their families, and the nation. **CE II**

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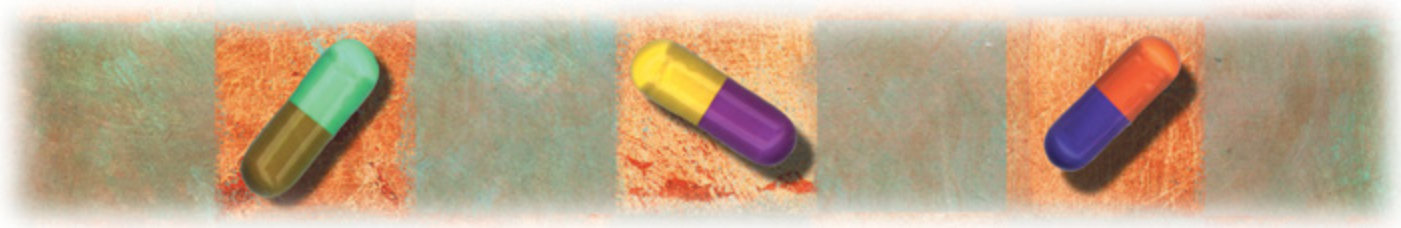
PharmaFacts for Case Managers



Endari (L-glutamine oral powder)

INDICATIONS AND USAGE

Endari is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

DOSAGE AND ADMINISTRATION

Dosage

Administer Endari orally, twice per day at the dose based on body weight according to Table 1.

TABLE 1

Recommended Dose Adjustments

Weight in kilograms	Weight in pounds	Per dose in grams	Per day in grams	Packets per dose	Packets per day
<30	<66	5	10	1	2
30-65	66-143	10	20	2	4
>65	>143	15	30	3	6

Preparation of Product

Mix Endari immediately before ingestion with 8 oz. (240 mL) of cold or room temperature beverage, such as water, milk or apple juice, or 4 oz. to 6 oz. of food such as applesauce or yogurt. Complete dissolution is not required prior to administration.

DOSAGE FORMS AND STRENGTHS

Oral powder: 5 grams of L–glutamine as a white crystalline powder in paper-foil-plastic laminate packets

CONTRAINDICATIONS

None

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to Endari in 187 patients, including 136 exposed for 6 months and 109 exposed for ≥1 year. Endari was studied in 2 placebo-controlled clinical trials (a phase 3 study, n=230 and a phase 2 study, n=70). In these trials, patients with sickle cell anemia or sickle β^0 thalassemia were randomized to receive Endari (n=187) or placebo (n=111) orally twice daily for 48 weeks followed by 3 weeks of tapering. Both studies included pediatric and adult patients (5-58 years of age) and 54% were female. The majority of patients were black (97.3%), had a diagnosis of sickle cell anemia (89.9%), and were receiving hydroxyurea at baseline (63.4%).

Treatment discontinuation due to adverse reactions was reported in 2.7% (n=5) of patients receiving Endari. These adverse reactions included one case each of hypersplenism, abdominal pain, dyspepsia, burning sensation, and hot flash.

Serious adverse reactions were reported in both treatment groups, more frequently in the placebo group, and were consistent with the underlying disease.

Three deaths (3/187=1.6%) occurred during the study in the Endari treatment group but none occurred in the placebo treatment group. None of the deaths were considered to be related to Endari treatment. Adverse reactions occurring in >10% of patients treated with Endari include constipation, nausea, headache, abdominal pain (abdominal pain and upper abdominal pain), cough, pain extremity, back pain, and chest pain.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no available data on Endari use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. Animal reproduction studies were not conducted with Endari.

Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The background risk of major birth defects and miscarriage for the indicated population are unknown. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively.

Lactation

Risk Summary

There are no data on the presence of Endari in human milk, the effect on the breastfed infant, or the effect on milk production. The developmental and health benefits from breastfeeding should be considered along with the mother's clinical need for Endari and any potential adverse effects on the breastfed child from Endari or from the underlying maternal condition.

Pediatric Use

The safety and effectiveness of Endari have been established in pediatric patients 5 years and older. Use of Endari is supported by evidence from 2 placebo-controlled studies in adult and pediatric patients with sickle cell disease. The clinical studies enrolled 110 pediatric patients in the following age groups: 46 children (5 years up to <12 years) and 64 adolescents (12 years to <17 years).

The safety and effectiveness of Endari in pediatric patients with sickle cell disease younger than 5 years old has not been established.

Geriatric Use

Clinical studies of Endari did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

OVERDOSAGE

Single oral doses of L-glutamine at about 20 g/kg to 22 g/kg, 8 g/kg to 11 g/kg, and 19 g/kg were lethal in mice, rats, and rabbits, respectively. Supportive measures should be undertaken in the event of overdose of Endari.

Clinical Studies

The efficacy of Endari in sickle cell disease was evaluated in a randomized, double-blind, placebo-controlled, multi-center clinical trial entitled "A Phase III Safety and Efficacy Study of L-Glutamine to Treat Sickle Cell Disease or Sickle β^0-thalassemia" [NCT01179217]. The median number of sickle cell crises was 3 for the Endari group and 4 for the placebo group. The median number of hospitalizations for sickle cell pain was 2 for the Endari group and 3 for the placebo group. The median cumulative days in hospital was 6.5 for the Endari group and 11 for the placebo group. The median time to first sickle cell crisis was 84 days for the Endari group and 54 for the placebo group. Thirteen (8.6%) of patient had occurrences of acute chest syndrome compared with 18 (23.1%) of patients in the placebo group.

HOW SUPPLIED/STORAGE AND HANDLING

Endari is supplied in paper-foil-plastic laminate packets containing 5 grams of L-glutamine white crystalline powder.

Carton of 60 packets: NDC 42457-420-60
Store at 20°C-25°C (68°F-77°F) away from direct sunlight.
Endari is manufactured by Emmaus Medical.

Bevyxxa™ (betrixaban) capsules, for oral use

WARNING: SPINAL/EPIDURAL HEMATOMA

Epidural or spinal hematomas may occur in patients treated with betrixaban who are receiving neuraxial anesthesia or undergoing spinal puncture. The risk of these events may be increased by the use of in-dwelling epidural catheters or the concomitant use of medical products affecting hemostasis. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures.

INDICATIONS AND USAGE

Bevyxxa is indicated for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE.

Limitations of Use:

The safety and effectiveness of Bevyxxa have not been established in patients with prosthetic heart valves because this population has not been studied.

DOSAGE AND ADMINISTRATION

Recommended Dose

The recommended dose of Bevyxxa is an initial single dose of 160 mg, followed by 80 mg once daily. Daily oral doses should be given at the same time of day with food.

The recommended duration of treatment is 35-42 days.

Severe Renal Impairment

For patients with severe renal impairment (CrCl ≥15 to <30 mL/min computed by Cockcroft-Gault using actual body weight), the recommended dose of Bevyxxa is an initial single dose of 80 mg followed by 40 mg once daily. The recommended duration of treatment is 35–42 days.

Use with P-gp Inhibitors

For patients receiving or starting concomitant P-gp inhibitors the recommended dose of Bevyxxa is an initial single dose of 80 mg followed by 40 mg once daily. The recommended duration of treatment is 35–42 days.

Missed Dose

If a dose of Bevyxxa is not taken at the scheduled time, the dose should be taken as soon as possible on the same day. The Bevyxxa dose should not be doubled to make up for a missed dose.

DOSAGE FORMS AND STRENGTHS

40-mg and 80-mg capsules

- 80 mg, size 2 hard gelatin capsules are light grey with 80 printed in black and have a blue cap with PTLA printed in white.
- 40 mg, size 4 hard gelatin capsules are light grey with 40 printed in black and have a light blue cap with PTLA printed in white.

CONTRAINDICATIONS

Bevyxxa is contraindicated in patients with:

- Active pathological bleeding
- Severe hypersensitivity reaction to betrixaban

WARNINGS AND PRECAUTIONS

Risk of Bleeding

Bevyxxa increases the risk of bleeding and can cause serious and potentially fatal bleeding. Promptly evaluate any signs or symptoms of blood loss.

Concomitant use of drugs affecting hemostasis increases the risk of bleeding. These include aspirin and other antiplatelet agents, other anticoagulants, heparin, thrombolytic agents, selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors, and nonsteroidal anti-inflammatory drugs (NSAIDs).

Advise patients of signs and symptoms of blood loss and to report them immediately and seek emergency care. Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue Bevyxxa in patients with active pathological bleeding.

There is no established way to reverse the anticoagulant effect of Bevyxxa, which can be expected to persist for at least 72 hours after the last dose. It is unknown whether hemodialysis removes Bevyxxa. Protamine sulfate, vitamin K, and tranexamic acid are not expected to reverse the anticoagulant activity of Bevyxxa.

Spinal/Epidural Anesthesia or Puncture

When neuraxial anesthesia (spinal/epidural anesthesia) or spinal/epidural puncture is employed, patients treated with antithrombotic agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma that can result in long-term or permanent paralysis.

Do not remove an epidural catheter earlier than 72 hours after the last administration of Bevyxxa. Do not administer the next Bevyxxa dose earlier than 5 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of Bevyxxa for 72 hours.

Monitor patients frequently for signs and symptoms of neurological impairment (eg, numbness or weakness of the legs, bowel, or bladder dysfunction). If neurological compromise is noted, urgent diagnosis and treatment is necessary. Prior to neuraxial intervention, consider the potential benefit versus the risk in anticoagulated patients or in patients to be anticoagulated for thromboprophylaxis.

Use in Patients with Severe Renal Impairment

Patients with severe renal impairment (CrCl ≥15 to < 30 mL/min computed by Cockcroft-Gault using actual body weight) taking Bevyxxa may have an increased risk of bleeding events. Reduce dose of Bevyxxa, monitor patients closely, and promptly evaluate any signs or symptoms of blood loss in these patients.

Use in Patients on Concomitant P-gp Inhibitors

Patients on concomitant P-gp inhibitors with Bevyxxa may have an increased risk of bleeding. Reduce dose of Bevyxxa in patients receiving or starting P-gp inhibitors. Monitor patients closely and promptly evaluate any signs or symptoms of blood loss in these patients.

Avoid use of Bevyxxa in patients with severe renal impairment receiving concomitant P-gp inhibitor.

ADVERSE REACTIONS

- Risk of bleeding
- Spinal/epidural anesthesia or puncture

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of Bevyxxa was evaluated in the Acute Medically Ill Prevention with Extended Duration Betrixaban (APEX) Study, including 3,716 patients treated with Bevyxxa for a median of 36 days compared with 3,716 patients treated with enoxaparin for a median of 9 days. Patients in both treatment groups were followed for safety, including bleeding events, for up to 77 days.

Hemorrhage

The most common adverse reactions with Bevyxxa were related to bleeding (>5%), with major bleeding occurring in <1% of patients (see Table 1).

Overall, 54% of patients receiving Bevyxxa experienced at least 1 adverse reaction vs. 52% with enoxaparin. The frequency of patients reporting serious adverse reactions was similar between Bevyxxa (18%) and enoxaparin (17%). In the APEX trial, the most frequent reason for treatment discontinuation was bleeding, with an incidence rate of 2.4% for Bevyxxa vs.1.2% for enoxaparin.

The primary and secondary safety outcomes in APEX were bleeding-related events.

Most clinically relevant non-major (CRNM) events (86%) were mild to moderate in severity, and the majority (62%) did not require medical intervention. The incidence of fatal bleeding was the same in the Bevyxxa and enoxaparin treatment groups (1 in each group).

The most common bleeding-related adverse reactions that occurred in ≥2% of patients were epistaxis and hematuria. The most common nonbleeding adverse reactions that occurred in ≥2% of patients were urinary tract infection, constipation, hypokalemia, and hypertension.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no data for the use of Bevyxxa in pregnant women, but treatment is likely to increase the risk of hemorrhage during pregnancy and delivery. Betrixaban was studied in reproductive and developmental toxicology studies in rats and rabbits during the period of organogenesis at exposures up to 44 times the recommended clinical dose of 80 mg daily. Although betrixaban was not associated with adverse developmental fetal outcomes in animals, maternal toxicity (ie, hemorrhage) was identified in these studies. Bevyxxa should be used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus.

Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%–4% and 15%–20%, respectively.

Lactation

Risk Summary

No data are available regarding the presence of betrixaban or its metabolites in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Bevyxxa and any potential adverse effects on the breast-fed child from Bevyxxa or from the underlying maternal condition.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Of the total number of patients in the APEX clinical study, 90% were 65 years and over whereas 68.6% were ≥75 years. No clinically significant differences in safety or effectiveness were observed between older and younger patients.

Renal Impairment

Patients with severe renal impairment (CrCl ≥15 to <30 mL/min computed by Cockcroft-Gault using actual body weight) may have an increased risk of bleeding events. Reduce the Bevyxxa dose for patients with severe renal impairment. Monitor patients closely and promptly evaluate any signs or symptoms of blood loss in these patients. No dose adjustment is needed for mild or moderate renal impairment (CrCl >30 mL/min, computed by Cockcroft-Gault using actual body weight).

Hepatic Impairment

Bevyxxa has not been evaluated in patients with hepatic impairment because these patients may have intrinsic coagulation abnormalities. Therefore, the use of Bevyxxa is not recommended in patients with hepatic impairment.

OVERDOSAGE

Overdose of Bevyxxa increases the risk of bleeding.

CLINICAL STUDIES

The clinical evidence for the effectiveness of Bevyxxa is derived from the APEX clinical trial [NCT01583218]. APEX was a randomized, double-blind, multinational study comparing extended duration Bevyxxa (35-42 days) to short duration of enoxaparin (6-14 days) in the prevention of venous thromboembolic events (VTE) in an acutely medically ill hospitalized population with risk factors for VTE.

Eligible patients included adults who were at least 40 years of age, hospitalized for an acute medical illness, at risk for VTE due to moderate or severe immobility, and had additional risk factors for VTE (described below). Expected duration of hospitalization was at least 3 days and patients were expected to be moderately or severely immobilized for at least 24 hours. The causes for hospitalization included heart failure, respiratory failure, infectious disease, rheumatic disease, or ischemic stroke. At study initiation, eligible patients were required to have one of the following additional risk factors for VTE:

- ≥75 years of age,
- 60 through 74 years of age with D-dimer ≥2 upper limit of normal, or
- 40 through 59 years of age with D-dimer ≥2 upper limit of normal and a history of either VTE or cancer.

A total of 7,513 patients were randomized 1:1 to:

- Bevyxxa arm (Bevyxxa 160 mg orally on Day 1, then 80 mg once daily for 35- 42 days AND enoxaparin subcutaneous placebo once daily for 6-14 days),

OR

- Enoxaparin arm (enoxaparin 40 mg subcutaneously once daily for 6-14 days AND Bevyxxa placebo orally once daily for 35-42 days).

Patients with severe renal impairment (creatinine clearance ≥15 and <30 mL/min) received reduced doses of study medications (Bevyxxa 80-mg loading dose, then 40 mg once daily or enoxaparin 20 mg once daily) along with corresponding placebo.

Patients taking a concomitant P-gp inhibitor received Bevyxxa 80-mg loading dose, then 40 mg once daily or enoxaparin 40 mg subcutaneously once daily for 6–14 days along with corresponding placebo.

Baseline characteristics were balanced between the treatment groups. The population was 55% female, 93% White, 2% Black, 0.2% Asian, and 5% others. The most prevalent acute medical illness at hospitalization was acutely decompensated heart failure (45%), followed by acute infection without septic shock (29%), acute respiratory failure (12%), acute ischemic stroke (11%) and acute

continues on page 35

LITSCAN FOR CASE MANAGERS

LitScan for Case Managers reviews medical literature and reports abstracts that are of particular interest to case managers in an easy-to-read format. Each abstract includes information to locate the full-text article if there is an interest. This member benefit is designed to assist case managers in keeping current with clinical breakthroughs in a time-effective manner.

Circ Heart Fail. 2016 Jul;9(7). pii: e002851. doi: 10.1161/CIRCHEARTFAILURE.115.002851.

Marijuana and listing for heart transplant: a survey of transplant providers.

Neyer J, Uberoi A, Hamilton M, Kobashigawa JA.

BACKGROUND: There is no consensus within the heart transplant community about whether patients who use marijuana should be eligible for transplant listing, but several states have passed legislation prohibiting marijuana-using patients from being denied transplant listing based on their use of the substance. METHODS AND RESULTS: We conducted an independent, voluntary, web-based survey of heart and lung transplant providers to assess current practice patterns and attitudes toward marijuana use in patients with advanced heart failure being considered for transplant. A total of 360 heart transplant providers responded from 26 countries. Nearly two thirds of respondents (n=222, 64.4%) supported listing patients with advanced, end-stage heart failure for transplant who use legal medical marijuana. Significantly, fewer respondents (n=96, 27.5%) supported transplant listing for patients using legal recreational marijuana. The majority of providers currently make patients eligible for transplantation after a period of abstinence from marijuana (n=241, 68.3%). There were no differences between the proportion of respondents supporting transplant listing after stratification by profession or country/region. Most (78.4%) survey respondents from states with laws prohibiting marijuana-using patients from being denied transplant listing reported denying all marijuana-using patients or mandating abstinence before transplant listing. CONCLUSIONS: The majority of heart and lung transplant providers in our study sample supports the listing of patients who use medical marijuana for transplant after a period of abstinence. Communication and collaboration between the medical community and legislative groups about marijuana use in transplant candidates is needed to ensure the best patient outcomes with the use of scarce donor organs.

J Heart Lung Transplant. 2017 May 23. pii: S1053-2498(17)31798-9. doi: 10.1016/j.healun.2017.05.017. [Epub ahead of print]

Cardiac rehabilitation and readmissions after heart transplantation.

Bachmann JM, Shah AS, Duncan MS, et al.

BACKGROUND: Exercise-based cardiac rehabilitation (CR) is under-utilized. CR is indicated after heart transplantation, but there are no data regarding CR participation in transplant recipients. We characterized current CR utilization among heart transplant recipients in the United States and the association of CR with 1-year readmissions using the 2013-2014 Medicare files. METHODS: The study population included Medicare beneficiaries enrolled due to disability (patients on the transplant list are eligible for disability benefits under Medicare regulations) or age ≥65 years. We identified heart transplant patients by diagnosis codes and cumulative CR sessions occurring within 1 year after the transplant hospitalization. RESULTS: There were 2,531 heart transplant patients in the USA in 2013, of whom 595 (24%) received Medicare coverage and were included in the study. CR utilization was low, with 326 patients (55%) participating in CR programs. The Midwest had the highest proportion of transplant recipients initiating CR (68%, p = 0.001). Patients initiating CR attended a mean of 26.7 (standard deviation 13.3) sessions, less than the generally prescribed program of 36 sessions. Transplant recipients age 35 to 49 years were less likely to initiate CR (odds ratio [OR] 0.39, 95% confidence interval [CI] 0.23 to 0.66, p < 0.001) and attended 8.2 fewer sessions (95% CI 3.5 to 12.9, p < 0.001) than patients age ≥65 years. CR participation was associated with a 29% lower 1-year readmission risk (95% CI 13% to 42%, p = 0.001). CONCLUSIONS: Only half of cardiac transplant recipients participate in CR, and those who do have a lower 1-year readmission risk. These data invite further study on barriers to CR in this population.

AIDS. 2017 Jul 1;31(Suppl 3):S253-S260. doi: 10.1097/QAD.0000000000001538.

Optimizing linkage to care and initiation and retention on treatment of adolescents with newly diagnosed HIV infection.

Ruria EC, Masaba R, Kose J, et al.

OBJECTIVE: Unsuccessful linkage to care and treatment increases adolescent HIV-related morbidity and mortality. This study evaluated the effect of a novel adolescent and youth Red Carpet Program (RCP) on the timing and outcomes of linkage to care. DESIGN: A prepost implementation evaluation of the pilot RCP program. SETTINGS: Healthcare facilities (HCFs) and schools in Homa Bay County, Kenya. STUDY PARTICIPANTS: HIV-infected adolescents (15-19 years) and youth (20-21 years). INTERVENTIONS: RCP provided fast-track peer-navigated services, peer counseling, and psychosocial support at HCFs and schools in six Homa Bay subcounties in 2016. RCP training and sensitization was implemented in 50 HCFs and 25 boarding schools. MAIN OUTCOME MEASURES: New adolescent and youth HIV diagnosis, linkage to and retention in care and treatment. RESULTS: Within 6 months of program rollout, 559 adolescents and youths (481 women; 78 men) were newly diagnosed with HIV (15-19 years n=277; 20-21 years, n=282). The majority (n=544; 97.3%) were linked to care, compared to 56.5% at preimplementation (P<0.001). All (100.0%; n=559) adolescents and youths received peer counseling and psychosocial support, and the majority (n=430; 79.0%) were initiated on treatment. Compared to preimplementation, the proportion of adolescents and youths who were retained on treatment increased from 66.0 to 90.0% at 3 months (P<0.001), and from 54.4 to 98.6% at 6 months (P<0.001). CONCLUSION: Implementation of RCP was associated with significant improvement in linkage to and early retention in care among adolescent and youth. The ongoing study will fully assess the efficacy of this linkage-to-care approach.

J Acquir Immune Defic Syndr. 2017 Jun 22. doi: 10.1097/QAI.0000000000001489. [Epub ahead of print]

Progressive brain atrophy despite persistent viral suppression in HIV over age 60.

Clifford KM, Samboju V, Cobigo Y, et al.

BACKGROUND: Current HIV treatments are successful at suppressing plasma HIV RNA to undetectable levels for most adherent patients. Yet, emerging evidence suggests viral suppression will inadequately control inflammation and mitigate risk for progressive brain injury. We sought to quantify differences in longitudinal brain atrophy rates among older virally suppressed HIV-infected participants compared to that of healthy aging. METHODS: We examined longitudinal structural brain MRI atrophy rates employing region of interest assessments and voxel-wise tensor-based morphometry in HIV-infected participants over age 60 years (n=38) compared to age-matched HIV-uninfected healthy and cognitively normal controls (n=24). RESULTS: The mean age of participants was 63 years, the mean estimated duration of infection was 21 years and the median of duration of documented viral suppression was 3.2 years. Average proximal and nadir CD4 counts were 550 and 166, respectively; 15/38 (39%) met criteria for HIV-associated neurocognitive disorder. In models adjusting for age and sex, HIV serostatus was associated with more rapid average annualized rates of atrophy in the cerebellum (0.42% vs. 0.02%, p=0.016), caudate (0.74% vs. 0.03%, p=0.012), frontal lobe (0.48% vs. 0.01%, p=0.034), total cortical gray matter (0.65% vs. 0.16%, p=0.027), brain stem (0.31% vs. 0.01%, p=0.026), and pallidum (0.73% vs. 0.39%, p=0.046). Among those with HIV, atrophy rates did not differ statistically by cognitive status. CONCLUSION: Despite persistent control of plasma viremia, these older HIV-infected participants demonstrate more rapid progressive brain atrophy when compared to healthy aging. Either HIV or other factors that differ between older HIV-infected participants and healthy controls could be responsible for these differences.

J Am Soc Hypertens. 2017 Jun 21. pii: S1933-1711(17)30192-4. doi: 10.1016/j.jash.2017.06.006. [Epub ahead of print]

White coat effect in hypertensive patients: the role of hospital environment or physician presence.

Wang XX, Shuai W, Peng Q, et al.

This study was to evaluate the role of hospital environment or physician presence for white coat effect (WCE) in hypertensive patients. At first, 54 hypertensive outpatients diagnosed on office blood pressure (OBP) were included for 2-week placebo run in. During the second week of the run in period, home BP was measured using electronic BP monitors for 5-7 days. Finally, 26 sustained hypertensive patients with home systolic BP/diastolic BP over 135/85 (but <180/110) mm Hg were enrolled for 8-week

treatment of nifedipine controlled-release tablet. In the visit day, BP was measured by patient-self (OBP-p) or by doctor (OBP-d) according to order determined with randomization method. The self-BP measurement was performed in a reception room of hospital. The differences between home BP and OBP-d or OBP-p were calculated as WCE calculated on doctor-measurement (WCE-d) or WCE calculated on patient-measurement (WCE-p), respectively. The home and OBP were measured with the same BP device for each patient during the study period. In the total 54 outpatients received placebo, the WCE-d was similar to the WCE-p (for systolic BP 6.6 ± 14.4 vs. 6.8 ± 15.8 mm Hg, NS; for diastolic BP 3.3 ± 8.8 vs. 2.9 ± 9.2 mm Hg, NS). Meanwhile, the 26 sustained hypertensive patients had similar systolic WCE-d and WCE-p (4.8 ± 10.3 vs. 5.0 ± 12.2 mm Hg, NS) at placebo stage. Similarly, these values were comparable (3.0 ± 14.0 vs. 2.2 ± 14.4 mm Hg, NS) in treatment stage. Hospital environment plays a main role for the WCE in hypertensive patients.

Clin Lung Cancer. 2017 May 10. pii: S1525-7304(17)30138-9. doi: 10.1016/j.cllc.2017.05.003. [Epub ahead of print]

Attitudes about lung cancer screening: primary care providers versus specialists.

Rajupet S, Doshi D, Wisnivesky JP, Lin JJ.

BACKGROUND: On the basis of the results of the National Lung Screening Trial, the US Preventive Services Task Force now recommends yearly low-dose computed tomography (LDCT) for lung cancer screening among high-risk individuals. There is limited information regarding physician attitudes toward LDCT screening and whether these vary according to provider specialty. MATERIALS AND METHODS: Primary care providers (PCPs) and specialists were surveyed about their knowledge and attitudes toward lung cancer screening and likelihood to order an LDCT screening. Descriptive and univariate analyses were used to assess differences between PCPs versus specialists. RESULTS: Of the 103 respondents 69% were PCPs, 45% were attending-level physicians, 42% were male, and most (51%) worked in mixed outpatient/inpatient practice settings. Compared with specialists, PCPs were less likely to feel confident in their ability to identify appropriate patients for lung cancer screening (63.8% vs. 93.5%; P < .01) or to decide the workup of patients with positive LDCT findings (52.9% vs. 93.5%; P < .01). PCPs were also less likely to believe that the recommended yearly screening interval is feasible (27.5% vs. 86.7%; P < .01), to feel comfortable counseling patients on LDCT (51.4% vs. 82.8%; P = .01) or have sufficient time for counseling (14.3% vs. 50%; P < .01). Despite these differences, PCPs were equally as likely as specialists to recommend LDCT for their high-risk smokers. CONCLUSION: Despite feeling less confident and knowledgeable about lung cancer screening, PCPs are as likely as specialists to recommend LDCT screening. However, PCPs need further education to ensure the success of lung cancer screening programs.

Gut. 2017 Mar;66(3):446-453. doi: 10.1136/gutjnl-2015-310196. Epub 2015 Dec 11.

Risk stratification of individuals with low-risk colorectal adenomas using clinical characteristics: a pooled analysis.

Gupta S, Jacobs ET, Baron JA, et al.

OBJECTIVE: For individuals with 1-2 small (<1 cm) low-risk colorectal adenomas, international guidelines range from no surveillance to offering surveillance colonoscopy in 5-10 years. We hypothesized that the risks for metachronous advanced neoplasia (AN) among patients with low-risk adenomas differ based on clinical factors distinct from those currently used. DESIGN: We pooled data from seven prospective studies to assess the risk of metachronous AN. Two groups with 1–2 small adenomas were defined based on guidelines from the UK (n=4516) or the European Union (EU)/US (n=2477). RESULTS: Absolute risk of metachronous AN ranged from a low of 2.9% to a high of 12.2%, depending on specific risk factor and guideline used. For the UK group, the highest absolute risks for metachronous AN were found among individuals with a history of prior polyp (12.2%), villous histology (12.2%), age ≥70 years (10.9%), high-grade dysplasia (10.9%), any proximal adenoma (10.2%), distal and proximal adenoma (10.8%) or two adenomas (10.1%). For the EU/US group, the highest absolute risks for metachronous AN were among individuals with a history of prior polyp (11.5%) or the presence of both proximal and distal adenomas (11.0%). In multivariate analyses, strong associations for increasing age and history of prior polyps and odds of metachronous AN were observed, whereas more modest associations were shown for baseline proximal adenomas and those with villous features. CONCLUSIONS: Risks of metachronous AN among individuals with 1–2 small adenomas vary according to readily available clinical characteristics. These characteristics may be considered for recommending colonoscopy surveillance and require further investigation.

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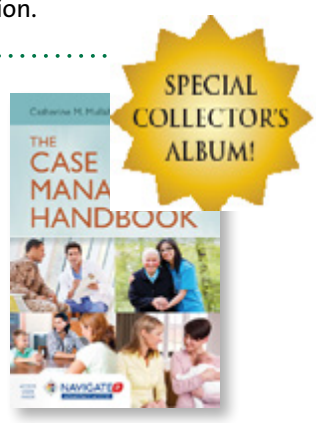

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Ann Surg Oncol. 2017 Jul 6. doi: 10.1245/s10434-017-5969-1. [Epub ahead of print]

The impact of facility volume on rates for pathologic complete response to neoadjuvant chemotherapy used in breast cancer.

Ajmani GS, James TA, Kantor O, Wang CH, Yao KA.

BACKGROUND: Patient and tumor factors have been associated with rates for pathologic complete response (pCR) to neoadjuvant chemotherapy (NAC) for breast cancer, but variation in pCR rates across facilities has not been studied. METHODS: This study used the National Cancer Data Base to identify women with clinical stages 1-3a breast cancer undergoing NAC from 2010 to 2013. Generalized estimation equation models were used to examine the relationship between facility characteristics and pCR rates, with adjustment for patient and tumor factors, while accounting for patient clustering at facilities. Analyses were stratified by tumor molecular subtype. RESULTS: Overall, 16,885 women underwent NAC, of whom 3130 (18.5%) were hormone receptor-positive (HR+) and human epidermal growth factor 2-positive (HER2+), 7045 (41.7%) were HR+HER2-, 1847 (10.9%) were HR-HER2+, and 4863 (28.8%) were HR-HER2-. Overall, 4002 of the patients (23.7%) achieved a pCR. The pCR rates were 29.5% for HR+HER2+, 10.8% for HR+HER2-, 45.3% for HR-HER2+, and 30.5% for HR-HER2- tumors. Multivariable analysis showed that pCR rates were significantly higher at high-volume facilities (>75th vs. <25th percentile) for all tumor subtypes except HR+HER2- tumors. Facility location and type were not significant. Adjustment for time from NAC to surgery decreased the likelihood of a pCR in high- versus low-volume facilities, but facility volume remained significantly associated with pCR. CONCLUSION: Facility volume, not location or type, was significantly associated with higher pCR rates in this exploratory analysis. Time to surgery has a modest impact on pCR rates across facilities, but further study to identify other potentially modifiable factors is needed.

Int J Cancer. 2017 Jul 3. doi: 10.1002/ijc.30866. [Epub ahead of print]

Cervical cancer incidence after up to 20 years of observation among women with HIV.

Massad LS, Hessol NA, Darragh TM, et al.

In order to estimate the incidence of invasive cervical cancer (ICC) across up to 21 years of follow-up among women with human immunodeficiency virus (HIV) and to compare it to that among HIV-uninfected women, we reviewed ICC diagnoses from a 20-year multi-site U.S. cohort study of HIV infected and uninfected women who had Pap testing every six months. Incidence rates were calculated and compared to those in HIV-negative women. Incidence ratios standardized to age-, sex-, race-, and calendar-year specific population rates were calculated. After a median follow-up of 12.3 years, four ICCs were confirmed in HIV seropositive women, only one in the last 10 years of observation, and none in seronegative women. The ICC incidence rate did not differ significantly by HIV status (HIV seronegative: 0/100,000 person-years vs. HIV seropositive: 19.5/100,000 person-years; p=0.53). The standardized incidence ratio for the HIV-infected WIHS participants was 3.31 (95% CI: 0.90, 8.47; p=0.07). Although marginally more common in women without HIV, for those with HIV in a prevention program, ICC does not emerge as a major threat as women age.

Head Neck. 2017 Jul 6. doi: 10.1002/hed.24860. [Epub ahead of print]

Prognostic indicators and survival in salvage surgery for laryngeal cancer.

Fletcher KT, Gal TJ, Ebelhar AJ, et al.

BACKGROUND: Perineural invasion (PNI) and lymphovascular invasion (LVI) are known to be poor prognostic indicators in primary surgery. The purpose of this study was to determine their impact on survival in the setting of salvage laryngectomy. METHODS: We conducted a retrospective review of patients who underwent salvage laryngectomy between 2006 and 2014. RESULTS: Seventy-eight patients were included in this study; PNI was diagnosed in 48 patients (61.54%) and LVI in 25 patients (32.05%). Median overall survival was 32 months; PNI was associated with decreased survival; and the unadjusted hazard ratio (HR) was 2.69 (P = .006). Cases of LVI trended toward a decreased survival; with an unadjusted HR of 1.74 (P = .076). On multivariate analysis, PNI, LVI, or both conferred decreased survival compared to having neither (P = .01). Extracapsular spread and nodal metastases significantly impacted survival, and positive margins trended toward significance. CONCLUSION: The presence of PNI, LVI, nodal disease, and extracapsular spread significantly affected survival in this cohort of patients with laryngeal cancer.

J Diabetes Complications. 2017 Jun 6. pii: S1056-8727(17)30470-1. doi: 10.1016/j.jdiacomp.2017.06.001. [Epub ahead of print]

Participation in a National Lifestyle Change Program is associated with improved diabetes control outcomes.

Jackson SL, Staimez LR, Safo S, et al.

AIMS: Clinical trials show lifestyle change programs are beneficial, yet large-scale, successful translation of these programs is scarce. We investigated the association between participation in the largest U.S. lifestyle change program, MOVE!, and diabetes control outcomes. METHODS: This longitudinal, retrospective cohort study used Veterans Health Administration databases of patients with diabetes who participated in MOVE! between 2005 and 2012, or met eligibility criteria (BMI ≥25kg/m2) but did not participate. Main outcomes were diabetic eye disease, renal disease, and medication intensification. RESULTS: There were 400,170 eligible patients with diabetes, including 87,366 (22%) MOVE! PARTICIPANTS: Included patients were 96% male, 77% white, with mean age 58years and BMI 34kg/m2. Controlling for baseline measurements and age, race, sex, BMI, and antidiabetes medications, MOVE! participants had lower body weight (-0.6kg), random plasma glucose (-2.8mg/dL), and HbA1c (-0.1%) at 12months compared to nonparticipants (each p<0.001). In multivariable Cox models, MOVE! participants had lower incidence of eye disease (hazard ratio 0.80, 95% CI 0.75-0.84) and renal disease (HR 0.89, 95% CI 0.86-0.92) and reduced medication intensification (HR 0.82, 95% CI 0.80-0.84). CONCLUSIONS: If able to overcome participation challenges, lifestyle change programs in U.S. health systems may improve health among the growing patient population with diabetes.

Laryngoscope. 2017 Jul 7. doi: 10.1002/lary.26717. [Epub ahead of print]

Treatment, short-term outcomes, and costs associated with larynx cancer care in commercially insured patients.

Day AT, Chang HY, Quon H, et al.

OBJECTIVES/HYPOTHESIS: To examine associations between treatment, complications, and costs in patients with laryngeal cancer. STUDY DESIGN: Retrospective cross-sectional analysis of MarketScan Commercial Claim and Encounters data. METHODS: We evaluated 10,969 patients diagnosed with laryngeal cancer from 2010 to 2012 using cross-tabulations and multivariate regression. RESULTS: Chemoradiation was significantly associated with supraglottic tumors (relative risk ratio [RRR] = 5.9 [4.4-7.8]), pretreatment gastrostomy (RRR = 4.0 [2.7-6.1]), and alcohol abuse (RRR = 0.5 [0.3-0.9]). Treatment-related complications occurred in 23% of patients, with medical complications in 22% and surgical complications in 7%. Chemoradiation (odds ratio [OR] = 3.7 [2.6-5.2]), major surgical procedures (OR = 4.9 [3.5-6.8]), reconstruction (OR = 7.7 (4.1-14.7)], and advanced comorbidity (OR = 9.7 [5.7-16.5] were associated with acute complications. Recurrent/persistent disease occurred in 23% of patients and was associated with high-volume care (OR = 1.4 [1.1-1.8]). Salvage surgery was performed in 46% of patients with recurrent/persistent disease and was less likely for supraglottic disease (OR = 0.5 [0.4-0.8]) and after chemoradiation (OR = 0.4 [0.2-0.6]). Initial treatment and 1-year overall costs for chemoradiation were higher than all other treatment categories, after controlling for all other variables including complications and salvage. High-volume care was associated with significantly lower costs of care for surgical patients but was not associated with differences in costs of care for nonoperative treatment. CONCLUSIONS: In commercially insured patients <65 years old with laryngeal cancer, chemoradiation was associated with increased costs, an increased likelihood of treatment-related medical complications, and a reduced likelihood of surgical salvage. Higher-volume surgical care was associated with lower initial treatment and 1-year costs of care. These data have implications for discussions of value and quality in an era of healthcare reform.

Am J Kidney Dis. 2017 Jul 1. pii: S0272-6386(17)30736-9. doi: 10.1053/j.ajkd.2017.05.010. [Epub ahead of print]

Treatment of gabapentin toxicity with peritoneal dialysis: assessment of gabapentin clearance

Ibrahim H, Oman Z, Schuelke M, Edwards JC.

Gabapentin is almost exclusively cleared by the kidney and thus presents challenges in patients with kidney failure. Gabapentin is known to be effectively cleared by hemodialysis, but the efficiency of clearance by peritoneal dialysis (PD) has not been previously described. We report a case of gabapentin toxicity in a patient on long-term PD who was treated with continuous

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Providers Back Population Health Management Despite Affordable Care Act Uncertainty

A new Health Catalyst survey shows that population health management is going strong even amid the turmoil surrounding the failed efforts by Congress to repeal the Affordable Care Act. The July survey of 199 healthcare executives showed 68% of health care executives who responded indicated that population health management is "very important" to their health care delivery strategy over the next 2 years. Fewer than 3% assigned it "no importance at all."

The results coincide with recent studies showing growth in the use of population health technologies—including a July 2017 study from Signify Research that predicts that the number of lives managed by population health solutions in the United States and Canada will rise to 245 million in 2021, up more than 80% from 135 million lives in 2016. On the other hand, 4% of respondents said they were "pausing" their population health plans in response to the current political situation, and 10% of survey takers said they were undecided on the question.

Among the barriers to population health success included "financial issues," "getting paid for our efforts," and "balancing competing contract incentives," according to survey responses. "The bottom line is, providers see population health management as something they need to do and that they want to do to provide better care for patients, but they are struggling with the economics of operating in both the fee-for-service and value-based care worlds—having one foot in each canoe," Amy Flaster, MD, vice president of population health management and care management for Health Catalyst, said in a statement. ■

Tai Chi May Help Prevent Falls in Older and At-Risk Adults

An analysis of published studies indicates that tai chi may help reduce the number of falls in both the older adult population and at-risk adults. The findings, which are published in the *Journal of the American Geriatrics Society*, offer a simple and holistic way to prevent injuries.

Tai chi is an ancient Chinese practice focused on flexibility and whole body coordination that promotes harmonized motion in space. Previous research has shown that tai chi is an effective exercise to improve balance control and flexibility in older individuals. This suggests that the practice might help protect against falls, which are a primary cause of traumatic death for older adults.

To investigate, Rafael Lomas-Vega, PhD, of the University of Jaén in Spain and his colleagues searched the medical literature for relevant studies. The team identified 10 randomized controlled trials analyzing the effect of tai chi versus other treatments (such as physical therapy and low-intensity exercise) on the risk of falls in at-risk and older adults.

There was high-quality evidence that tai chi significantly reduced the rate of falls by 43% compared with other interventions at short-term follow-up (<12 months) and by 13% at long-term follow-up (>12 months). Regarding injurious falls, there was some evidence that tai chi reduced risk by 50% over the short term and by 28% over the long term. Tai chi practice did not seem to influence when an older or at-risk adult was likely to experience their first injurious fall.

"Tai chi practice may be recommended to prevent falls in at-risk adults and older adults. The length of the interventions ranged from 12 to 26 weeks. The frequency of the 1-hour sessions ranged from one to three times per week," said Dr. Lomas-Vega. "Due to the small number of published studies, further research is needed to investigate the effect of tai chi on injurious falls and time to first fall." ■

AstraZeneca Gets Breakthrough Status for Blood Cancer Drug

AstraZeneca said on Tuesday that US regulators had awarded its blood cancer drug acalabrutinib "breakthrough" status for the treatment of patients with mantle cell lymphoma, a rare type of blood cancer.

The U.S. Food and Drug Administration decision clears the way for a speedy regulatory review and comes a day after another of its drugs, Imfinzi (durvalumab), won breakthrough designation for non–metastatic lung cancer.

Both developments represent pluses for AstraZeneca's cancer portfolio following the initial failure of the key Mystic trial in lung cancer, which triggered the biggest ever daily fall in the company's shares last week. AstraZeneca acquired acalabrutinib after buying Acerta Pharma in 2015. The drug is being developed for a variety of cancer types. ■

Study Explores Why Some Pregnant Low-Income Women Rely on Emergency Care

Low-income pregnant women who use emergency obstetric triage repetitively (four or more times) do so because of an unmet clinical and psychosocial need. Individuals who are racial/ethnic minorities and of low socioeconomic status disproportionately experience poor pregnancy outcomes in the United States. Prenatal care has been hypothesized to be a key mediator in perinatal outcome, particularly low birth weight, based on a key Institute of Medicine report. However, despite increased access to and utilization of prenatal care and growing expenditures on hospital-based obstetric care, maternal and neonatal health disparities are worsening over time.

To understand why existing Medicaid–funded prenatal care may be inadequate to address complex needs during pregnancy, researchers from the Boston University School of Medicine and the Perelman School of Medicine at the University of Pennsylvania interviewed 40 Medicaid-insured pregnant women when they visited an emergency obstetric triage area. They recruited 20 women who were considered "high utilizers" during their pregnancy and 20 who had only been to the triage area once ("low utilizers"). Compared with low-utilizing women, high-utilizing women were more likely to report histories of childhood trauma and social isolation. During their pregnancy, both groups of women had difficulty accessing prenatal care, but high-utilizing women also frequently reported disorganized care, especially for complex illnesses. Most troublingly, high-utilizing women faced difficulty with basic needs like personal safety, housing, and healthy food.

According to the researchers, from the perspectives of these women, there are several steps that need to be taken to improve pregnancy care including expanding capacity and available appointments in prenatal clinics as well as improving provider continuity and quality in outpatient prenatal care. "It is also important that different hospitals and clinics have the ability to share medical records so that patients can go anywhere and their health information will be available," explained corresponding author Pooja K. Mehta, MD, assistant professor of obstetrics and gynecology at the Boston University School of Medicine.

The researchers encourage hospitals to partner with community-based services and home visiting organizations to improve the delivery of prenatal care outside the hospital. "We must recognize that high utilizing women face substantial challenges with social support, personal safety, housing, and food and work to address these needs to ensure a healthy pregnancy. ■

2017 Heart Failure Guidelines

A focused update on managing heart failure was published this spring by the American College of Cardiology, American Heart Association, and Heart Failure Society of America. Highlights include use of natriuretic peptide biomarkers for screening at-risk patients and to prevent development of left ventricular dysfunction or new-onset heart failure as well as for risk stratification. New recommendations are made for those with stage C heart failure and preserved ejection fraction, for target blood pressure levels, and for sleep assessment in patients with excessive daytime sleepiness or suspected of having sleep-disordered breathing problems. ■

Challenges for Medicare
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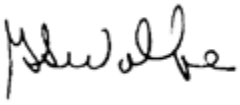
For more information, please read *Medicare Beneficiaries' High Out-of-Pocket Costs: Cost Burdens by Income and Health Status* published in this issue.



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CE 1 CareMore: Improving Outcomes and Controlling Health Care Spending for High-Needs Patients

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Notes

1. 31% of members meet the qualification for low-income subsidies under Medicare's Part D Prescription Drug Program (ie, have an income of $16,278 for individuals or less and limited assets).

2. In Southern California, CareMore employs its own cardiologists, pulmonologists, and dermatologists. As membership grows, CareMore may consider moving toward employed subspecialists in other markets.

3. Source for data on nontraumatic lower extremity amputation rate among CareMore members is from CareMore, 2013; rate is per thousand members per year, excluding individuals with end-stage renal disease. Source for data on nontraumatic lower extremity amputation rate among Medicare fee-for-service beneficiaries is from Kuo S, Fleming BB, Gittings NS, et al. Trends in care practices and outcomes among Medicare beneficiaries with diabetes. *Am J Prev Med.* 2005;29(5):396-403.

4. It is difficult to ascertain the actual plan-level savings to Medicare because of differences in diagnostic coding by Medicare Advantage plans compared with fee-for-service Medicare; see General Accounting Office, Medicare Advantage: Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments (GAO, Jan. 2013); Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (MedPAC, March 2014); and Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (MedPAC, March 2016)

5. Medicare Advantage special needs plans may be required, or in some cases allowed flexibility, to design benefit packages that go beyond Parts A and B benefits to meet the special needs of their populations; see Centers for Medicare & Medicaid Services, "Special Needs Plans (SNP) Frequently Asked Questions (FAQs)" (CMS, n.d.)

6. MedPAC reported that Medicare Advantage HMO plan bids for 2014 included a profit margin of 5% and administrative costs of 11%, on average. See Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (MedPAC, March 2014).

7. Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (MedPAC, March 2014); Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (MedPAC, March 2016); and General Accounting Office, Medicare Advantage: Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments (GAO, Jan. 2013).

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9. Kronick R, Welch WP. Measuring Coding Intensity in the Medicare Advantage Program. Medicare & Medicaid Research Review, published online July 17, 2014.

10. Jain S, M. Johns MME, Lewin JS. One Path to Value-Based Care for Academic Medical Centers. NEJM Catalyst, published online Sept. 12, 2016. For hospitalwide results from Emory University Hospital, see Medicare.gov's Hospital Compare tool at https://www.medicare.gov/hospitalcompare/profile.html.

11. We examined five counties in California (Los Angeles, Orange, San Bernardino, Santa Clara, and Stanislaus) and one county each in Arizona (Pima) and Nevada (Clark) where CareMore enrolls Medicare Advantage members. We excluded Riverside County, California, where CareMore enrolled less than 100 members in 2014; Maricopa County, Arizona, where CareMore had not fully implemented its standard model; and counties in Virginia.

12. We did not have data on CareMore's bids for special needs plans for end-stage renal disease; we excluded employer-group and Part D prescription drug–only plans from the analysis.

13. Payments to CareMore are included in county averages, but its membership accounted for only a small share (from 2% to 13%) of total Medicare Advantage enrollment in these counties (Table 1). Counties served by CareMore tended to be highly penetrated by Medicare Advantage, which accounted for 37%-57% of all Medicare beneficiaries in these counties, compared to a national average of 30% in 2014.

14. CareMore's bids for Chronic Condition Special Needs Plans (C-SNPs) for cardiovascular conditions mostly exceeded county average Parts A and B payments to all C-SNPs, whereas its bids for C-SNPs for diabetes were mostly lower than corresponding county average payments for all C-SNPs. We were not able to examine payments by type of chronic condition SNP. Therefore, we report on the experience of all C-SNPs together. Smaller enrollments for SNPs make these comparisons less reliable than for general enrollment HMO plans.

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CE II Medicare Beneficiaries' High Out-of-Pocket Costs: Cost Burdens by Income and Health Status *continued from page 21*

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rheumatic disorders (3%). The mean and median ages were 76.4 and 77 years, respectively, with 68% of patients ≥75 years of age, 97% were severely immobilized at study entry, and 62% had D-dimer ≥2 x upper limit of normal.

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automated cycling PD. We find that continuous PD provides significant clearance of gabapentin. With 2-L exchanges every 2 hours, we document an apparent elimination half-life of 41.33 hours, which is substantially shorter than the reported elimination half-life of 132 hours in the absence of kidney function. Further, our patient's symptoms of gabapentin toxicity gradually improved and had fully resolved after about 36 hours of dialysis. Gabapentin clearance by PD was estimated at 94% of urea clearance. We conclude that intensive PD provides gabapentin clearance that approximates that of urea and is an effective but slow method to treat gabapentin overdose and toxicity.

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