Annual Conference Issue

Robert E. Moffit, PhD

Risk Contracting in Medicare Advantage Improves Survival, p.18

An IPA’s Rationale in Pursuing Alternative Payment Models, p.20
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From the President

A MESSAGE FROM DONALD CRANE, PRESIDENT AND CEO, CAPG

CAPG members and friends,

Welcome to the CAPG Health 2017 Conference edition. This special issue includes several articles contributed by speakers at the CAPG Annual Conference 2017. I hope they’ll inspire and engage you, whether you’re able to attend the conference in person or in spirit.

The Conference theme—From Volume to Value in the New World Order: What Now?—reflects the current embattlement of healthcare under a new administration. With the Affordable Care Act’s fate still up in the air, many are feeling anxious and wondering in particular if the move to value will go on.

CAPG is committed to ensuring it does. In spite of the political fighting, the value movement has drawn strong bipartisan support, shown in the near-unanimous Congressional passage of MACRA (the Medicare Access & CHIP Reauthorization Act). This almost unheard-of accord confirms that 1) While they disagree on the how-to of healthcare reform, both parties agree it’s imperative; and 2) Both recognize what CAPG members have long known: Moving to alternative payment models is a proven nonpartisan solution for improving care delivery and cutting costs.

Our resolve to stay the course is more important than ever. CAPG continues to strongly advocate for value, as well as develop education and resources to help physician groups thrive in MACRA and APMs. Along with the Annual Conference and CAPG Colloquium (www.capgcolloquium.com), November 8-10, we recently launched our complimentary Educational Series 2017: Quality Payment Program Webinars with CMS (www.capg.org/qpp). Under a cobranding agreement with the Centers for Medicare & Medicaid Services, the webinars combine the agency’s MACRA expertise with CAPG members’ knowledge of its implementation on the ground. I also invite you to visit capg.org to find additional resources and publications such as our Guide to APMs, Risk Readiness Tool, and Pharmacy Case Studies.

Regardless of the political ups and downs, CAPG is convinced that value will win the day—and we’ll continue working hard to advance the movement and help our members succeed.

Donald Crane
CAPG President and CEO

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## Names in the News

**WELCOME TO OUR NEWEST MEMBERS**
CAPG warmly welcomes these members who have recently joined:

**Organizational Members**
- Advantage Medical Group, LLC, Orlando, FL
- Agilon Health, Long Beach CA
- Jade Health Care Medical Group, Inc., San Francisco, CA
- New England Quality Care Alliance, Braintree, MA
- Primary Care of St. Louis, LLC, Ballwin, MO
- PriMed Physicians, Cincinnati, OH
- Tri Valley Internal Medicine Group, Murrieta, CA

**Corporate Partner**
- Continuum Health Alliance, Marlton, NJ

**Affiliate Partners**
- Canvas Medical, San Francisco, CA
- Synergy Pharmaceuticals, Rossmoor, CA

**Associate Partner**
- HealthAxis Group, LLC, Tampa, FL

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**NEWS FROM ORANGE COAST MEMORIAL MEDICAL CENTER**

Orange Coast Memorial Medical Center (OCMMC), part of the Southern California–based MemorialCare Health System, recently opened a Health and Wellness Pavilion at 18035 Brookhurst Street, Fountain Valley. The new facility provides the community access to high-quality medical care and specialty services:

- MemorialCare Medical Group
- Orange Coast Memorial Center for Spine Health
- MemorialCare Heart and Vascular Institute
- Orange County Brain and Spine Group
- Orthopedic Surgery, Sports and Pain Center
- Orange Coast Memorial Outpatient Pharmacy
- Pain Medicine Associates
- The Coast Resource Center
- Community Conference Center

The MemorialCare Medical Group office, located in Suite 2100, is staffed with 15 healthcare providers including board-certified OB/GYNs, certified nurse midwives, and board-certified primary care physicians specializing in family medicine, internal medicine and pediatrics. Laboratory, digital x-ray, ultrasound, non-stress test services and retail pharmacy services are available on-site for patient convenience. For more information, call 1-800-MEMORIAL (636-6742).

OCMMC also was recently recognized for its dedication to patient safety with an “A” Hospital Safety ScoreSM by The Leapfrog Group, an independent national nonprofit run by employers and other large health benefit purchasers.

“We are extremely proud to receive another top grade in patient safety, which validates our tireless commitment to the well-being of our patients and served communities,” said Marcia Manker, CEO of OCMMC. “Providing the highest quality care and patient safety remains among our top priorities and it is our responsibility to continue to enhance our efforts.”

An “A” grade is one of the most meaningful honors a hospital can achieve, and one of the most valuable indicators for patients looking for a safe place to receive care. The Hospital Safety Score, the gold standard rating for patient safety, is compiled under guidance of leading patient safety experts and administered by The Leapfrog Group. The first and only hospital safety rating to be peer-reviewed in the Journal of Patient Safety, the Score is free to the public and designed to give consumers information they can use to protect themselves and their families when facing a hospital stay.
Healthcare Facilities & Services

Who We Are
Leading Independent Advisory Firm

- Independent financial, valuation, and strategic advisory
- Significant experience and tenure; partners average over 25 years of experience
- Nationwide presence with offices in Chicago, Cleveland, Irvine, Philadelphia, and San Antonio
- Deep healthcare industry experience in hospitals, health systems, physician groups, and ancillary services
- Widely recognized expertise in physician group alignment with health systems; especially with respect to transaction structure formation, incentive alignment, and risk mitigation
- Broad, national, health system client base
- Subgroup dedicated to healthcare real estate advisory and brokerage

Comprehensive Capabilities

CORPORATE DEVELOPMENT
Buy-Side M&A Advisory
Asset and Service Line Divestitures
Affiliations and Joint-Venture Formations
Sell-Side M&A Advisory

FINANCIAL & STRATEGIC ADVISORY
Fair Market Value Opinions
Fairness Opinions
Litigation Support and Benchmarking
Regulatory Compliance Advisory
Strategic Options Assessments
General Finance and Strategy Advisory
Healthcare Real Estate Brokerage & Advisory

Who We Serve

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Select Experience

Transactions involving securities are conducted at the Chicago and Cleveland offices.

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CAPG EDUCATIONAL SERIES 2017
Quality Payment Program Webinars with CMS
Friday, July 7; Friday, September 15; Monday, October 2; Friday, December 1
capg.org/app

CAPG COLLOQUIUM 2017
Wednesday-Friday, November 8-10
Washington, Hyatt Regency on Capitol Hill
capgcolloquium.com

CLINICAL QUALITY LEADERSHIP COMMITTEE
Saturday, June 24
CAPG Annual Conference 2017

FEDERAL POLICY COMMITTEE
Tuesday, July 11
WebEx

CONTRACTS COMMITTEE
Thursday, July 20
CAPG

PRIMARY CARE PRACTICE TRANSFORMATION COLLABORATIVE
Wednesday, August 16
CAPG

STATE POLICY COMMITTEE
Thursday, August 17
WebEx

PHARMACEUTICAL CARE COMMITTEE
Wednesday, August 23
CAPG

COLORADO REGIONAL MEETING
Thursday, August 24
Denver, Marriott Denver Tech Center

PUBLIC RELATIONS AND MARKETING COMMITTEE
Tuesday, September 5
WebEx

STATE GOVERNMENT PROGRAMS COMMITTEE
Tuesday, September 12
Sacramento, location TBD

INLAND EMPIRE REGIONAL MEETING
Tuesday, September 19
Riverside, Mission Inn

SAN DIEGO REGIONAL MEETING
Wednesday, September 20
San Diego, location TBD

GENERAL MEMBERSHIP—SOUTHERN CALIFORNIA
Wednesday, September 27
CAPG

HUMAN RESOURCES COMMITTEE
Wednesday, September 27
CAPG

GENERAL MEMBERSHIP—NORTHERN CALIFORNIA
Thursday, September 28
Oakland, Hilton Oakland Airport

NORTHWEST REGIONAL MEETING
Tuesday, October 3
Philadelphia, location TBD

PRIMARY CARE PRACTICE TRANSFORMATION COLLABORATIVE
Tuesday, October 3
Portland, location TBD

COMMERCIAL ACO COMMITTEE
Wednesday, October 4
CAPG

MIDWEST REGIONAL MEETING
Thursday, October 5
Chicago, location TBD

APM COMMITTEE
Tuesday, October 10
WebEx

NORTHEAST REGIONAL MEETING
Tuesday, October 10
Philadelphia, location TBD

SOUTHEAST REGIONAL MEETING
Thursday, October 12
Orlando, location TBD

CLINICAL QUALITY LEADERSHIP COMMITTEE
Tuesday, October 17
CAPG

CONTRACTS COMMITTEE
Thursday, October 19
CAPG

PHARMACEUTICAL CARE COMMITTEE
Wednesday, November 1
Location TBD

STATE GOVERNMENT PROGRAMS COMMITTEE
Tuesday, November 14
CAPG

SOUTHWEST REGIONAL MEETING
Tuesday, November 28
Phoenix, location TBD

STATE POLICY COMMITTEE
Tuesday, November 28
WebEx

TEXAS REGIONAL MEETING
Thursday, December 7
Houston, location TBD

FEDERAL POLICY COMMITTEE
Thursday, December 14
WebEx
Colloquium 2017

Healthcare Reform: The Saga Continues
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Featured Sessions

Representative
Greg Walden, R-OR
Keynote Address

Joseph R. Swedish
Chairman, President, and CEO,
Anthem, Inc.

Senator Ron Wyden,
D-OR
Keynote Address

Panel: Is Past Prologue?
Moderated by Donald Crane,
President and CEO, CAPG

Healthcare Reform
Debate—R vs. D
Moderated by John Michael
Gonzalez, Principal, Peck
Madigan Jones

Pearls of Wisdom:
Extraordinary Innovations
in Coordinated Care
Moderated by Mara McDermott,
VP of Federal Affairs, CAPG
Health care is the Rubik’s Cube of domestic policy. Policymakers struggle to neatly align measures that will expand access, control cost, and improve quality—often achieving one of these goals, but falling short on the others.

Consider the Affordable Care Act of 2010 (ACA). President Obama’s signature legislative achievement significantly expanded health insurance coverage, estimated at roughly 20 million newly insured persons (mostly through Medicaid). However, for millions of individuals, businesses, and families, it failed to control insurance costs, particularly in the individual and small group markets.

Nationwide premiums for standard plans have increased by an average of 25 percent and persons in those markets have experienced shocking deductibles—$6,092 for single and $12,383 for low cost “bronze” coverage, on average. In the ACA exchanges, competition has declined to the point where almost 70 percent of U.S. counties have only one or two insurers. Meanwhile, those enrolled in smaller-than-anticipated exchange pools must navigate narrow networks. This year has seen 500,000 fewer enrollees than in 2016. The law’s individual mandate proved feckless. Based on 2015 data, for example, 6.5 million persons paid the mandate penalty and 12.7 million got exemptions.

Now, consider the American Health Care Act of 2017 (AHCA). In March, the House Republican leadership unveiled the bill as the first step to repeal and replace the ACA. The AHCA turned out to be a loser on two fronts: cost and coverage. The Congressional Budget Office’s initial assessment of the House bill was devastating. Beginning in 2018 and through 2020, health insurance premiums in the non-group market would jump between 15 to 20 percent—higher than even the ACA’s skyrocketing premiums. An estimated 24 million Americans would lose coverage by 2026. Congressional conservatives were livid over the projected premium hikes, and House Speaker Paul Ryan pulled the bill.

Fixing financing begins with fixing tax policy. Outstanding economists of every political persuasion have highlighted the inequity and inefficiency of the federal tax treatment of health insurance.

“Fixing financing begins with fixing tax policy. Outstanding economists of every political persuasion have highlighted the inequity and inefficiency of the federal tax treatment of health insurance.”

Fixing financing begins with fixing tax policy. Outstanding economists of every political persuasion, including the late Nobel Laureate Milton Friedman, have highlighted the inequity and inefficiency of the federal tax treatment of health insurance. By exempting money spent on employer-sponsored health insurance from any taxation, Congress continues to frustrate normal economic incentives to control health costs, either on the
part of employers or employees. Business health benefit expansions, whatever their cost to businesses, became a large chunk of tax-free compensation for employees. As Douglas Elmendorf, former Director of the Congressional Budget Office (CBO), has observed:

Many analysts would agree that our current tax treatment of health insurance is an important part of the problem, and that reforming that system would be a key component of a broader solution. Reforms that promote broad coverage and high-value care can foster innovation and quality and help our health care dollar go further.

ISSUES WITH CURRENT TAX POLICY

The current tax policy encourages systemic over-insurance. Even routine, predictable medical services are covered by insurance, driving up health care costs. Jonathan Gruber, professor of economics at MIT, was incorrect in predicting lower costs in the ACA's individual markets, but his analysis of the economic impact of the current tax policy is right on the mark:

The tax exclusion of employer expenditures from individual taxation has three flaws. First, $250 per year is an enormous sum of money which could be more effectively deployed elsewhere, especially through alternative approaches to increasing insurance coverage. Second, this is a regressive entitlement, since higher income families with higher tax rates get a bigger tax break; about three quarters of these dollars go to the top half of the income distribution. Third, this tax subsidy makes health insurance, which is bought with tax-sheltered dollars, artificially cheap relative to other goods bought with taxed dollars, leading to over-insurance for most Americans. As a result of these limitations, no health expert today would ever set up a health system with such an enormous tax subsidy to a particular form of insurance.

Households, not employers, pay 100 percent of the nation's health care costs. Because every dollar spent on health benefits is a dollar less for wages and other compensation, the current policy contributes to sluggish wage growth. A change in tax policy would help to reverse that pattern.

Beyond undercutting rational cost control, current federal policy distorts the health insurance market, and is incompatible with fully portable and affordable health insurance that can be taken from job to job and through different stages of life—where health changes and the utilization of medical services normally increase. Michael Tanner, a senior fellow at the Cato Institute, neatly summarizes the benefits of reform:

The lesson is clear: Changing the tax treatment of insurance will help solve two of the most important problems facing the health care system in the United States. By encouraging Americans to move away from first-dollar third-party insurance, changing the tax code will help reduce health care costs. Moreover, it will break the link between insurance and employment, thereby helping to extend coverage to the uninsured.

If the liberal Gruber and the libertarian Tanner, the ultimate strange bedfellows, can agree, Congress should take note.

NATIONAL TAX CREDIT SYSTEM

Congress should replace the existing tax exclusion with a national tax credit system, which would address simultaneously problems of cost and coverage. Senator John McCain has provided a particularly attractive model for this approach. Individual tax relief for health insurance, as Senator McCain has prescribed, would not only expand private coverage, but also reduce dependence on Medicaid. It would foster personal choice, portability, and ownership of health plans, enhancing continuous coverage and care. It would unleash intense and unprecedented competition among insurance carriers, who would contract with the most efficient and effective medical professionals to secure the best medical outcomes and the highest value for health care dollars.

Such market dynamics would intensify consumer demands for transparency of price and performance on the part...
Policy Briefing

“Why are Provider Directories So Darned Hard to Get Right?”

BY BILL BARCELLONA, SENIOR VP FOR GOVERNMENT AFFAIRS, CAPG

Many states are grappling with the problem of inaccurate provider directories and the inability to track physician participation in health plan networks. Recently passed state and federal laws have aimed at improvement, but to date only modest progress has been made. CAPG has been in the lead nationally to develop a solution to this problem, and we have a few observations and suggestions.

We jumped into the fray in 2014 during the passage of California’s SB 137. The new law was implemented on July 1, 2016, and requires all health plans to validate their provider information at least annually. The first annual deadline, July 1, is approaching. Some issues are expected. For example, health plans have largely overlooked the fact that no matter how they handle their internal provider information validation process, every other plan does it differently.

From the provider side, it’s a mess. Most physician groups contract with 12 to 25 different plans. Complying with each plan’s vague and imprecise process is mind-bending. Individual physicians have it even worse: Typically, they directly contract with several additional PPO payers—sometimes as many as 35 total plans. Individual providers have no means to begin to comply with so many differing processes.

I attended an excellent seminar on the directory issue sponsored by the California Association of Health Plans in April—and health plan compliance staff were complaining of only 30 percent response rates from individual physicians. So, the most important point in developing a solution is that it must be simple, fast, and automated—through a single reporting portal. Physicians and physician groups need a once-and-done means of reporting.

The new directory laws across the U.S. require much more information per provider than ever before. There are commercial market standards, Medicare Advantage, and Medicaid Managed Care—and these are similar, but do contain some varying content requirements. A single reporting portal must accommodate all the information fields required under the main reporting standards.

CAPG advocated for the creation of a cloud-based, statewide multiplan directory that could act as single source of reference for payers, providers, and consumers. California’s Department of Managed Health Care (DMHC) mandated a statewide effort to develop the standards, governance, and creation of such a portal, which led to the formation of the California Provider Directory Collaborative. Work has progressed very quickly and the effort should result in active bid submittals to build and manage the new portal by the end of 2017.

Precision in defining information fields is the next most difficult issue. Something as simple as a “primary telephone number” field can elicit responses that are often 19 percent inaccurate across a reporting physician population. Many directory standards now require the listing of phone numbers at all the locations at which an individual physician practices within that plan’s network. That 19 percent number
correlates with the incidence of physicians who practice at multiple locations. Individual physicians may not always know which number to report when they practice in differing locations. Forms and fields that more precisely define the requested information must be developed and standardized, so responders can supply the same answers to each of their contracted payers. Over time, standardizing fields for individual phone numbers, location phone numbers for multiple locations, multiple tax identification numbers, and facility names have systematically reduced errors in reported information.

Another significant problem arises from the failure of plans to recognize the difference in how data should be collected between an individual physician and a physician group. We've observed several examples of plans contacting independent practice associations to obtain a validation of an individual physician's direct contract with a PPO plan. The physician group doesn't have the contract responsibility for the individual provider and can't respond on their behalf.

We think the problem stems from an inability within the plan's various departments to link their contract database to their contracted provider network information. With the number of tailored networks proliferating rapidly, it will become critical to accurately list the physicians within narrow and specific product networks where a single plan has multiple networks. The new California law requires plans to send a list of individual providers (a group “roster”) to the provider group that correlates any variation by product, network, and individual provider. So far, we've only seen a handful of plans that can accurately tie their contracted product and networks to a provider group roster. This remains one of the biggest problems for health plans to solve before they can reach compliance with the new directory laws.

The table below represents findings to date by Gaine Healthcare during the first nine months of provider information validation on behalf of 41 CAPG member physician groups for 13 specific health plans. You'll notice a large amount of variation and omission across the plan community in the specific fields for data collection. Some plans have been very helpful in improving the information reporting process, while others have not. Regardless, CAPG members have found a cheap, simple way to comply with the new process. Meanwhile, state regulators are watching the compliance efforts very closely.

Fortunately, just prior to the enactment of SB 137, CAPG found a very able partner in Gaine Healthcare. Gaine worked with our members to create a web-based reporting portal that acts as a registry of provider information, called Sanator. Our members subscribe directly to the portal and report their roster information to Gaine. Gaine processes and reports the validated roster information to all the provider group's contracted health plan payers in each required format. Gaine has also developed specific reporting standards applicable to provider group reporting that have been recognized by the California Provider Directory Collaborative. We are now working to have these standards adopted by the California DMHC and California Department of Insurance, later this year. Find more information at https://plus.google.com/communities/112670235620127621740.

Last year, Gaine Healthcare began providing briefings at several of our CAPG regional meetings across the country. It is now engaged in several pilots between plans and CAPG member groups to help shape the development of more accurate provider directory reporting.

We want to thank Gaine Healthcare, the developer of the Sanator provider registry, for supplying the data used in this article, as well as for their superb work in solving so many of these problems for our subscribing members. More information on the provider directory findings is available at www.providerregistry.com.

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In the shadow of the American Health Care Act (AHCA), the Medicare Access and CHIP Reauthorization Act (MACRA) has remained largely untouched. The AHCA, House Republicans’ bill to repeal and replace the Affordable Care Act (ACA), envisions significant change to the individual market and Medicaid, among other things. But efforts to repeal and replace have, to date, left untouched the delivery system reforms that were set in motion by the ACA and built upon by MACRA.

MACRA implementation and the value movement are critical to building an affordable, efficient healthcare delivery system. The value movement is intended to eliminate waste, encourage primary care and prevention, and increase accountability for quality and cost. The new system will be designed to keep patients healthier, reduce unnecessary utilization of services, and eliminate duplicative services. It will strive to ensure that patients are treated in the most appropriate, lowest-cost setting, and focus on coordinating care across different providers. The potential for the value movement is a better system of care delivery for Medicare, and eventually, across all payers.

Now entering its second year of rulemaking, the Administration has important choices to make about MACRA implementation. The choices they make can accelerate or decelerate the transformation of the healthcare delivery system.

MACRA REFRESHER

MACRA creates two options for physician payment in traditional Medicare. The first, the Merit-based Incentive Payment System (MIPS), creates a budget-neutral pay-for-performance program for traditional Medicare. Eligible clinicians will be judged across four categories: quality, cost, improvement activities, and advancing care information (previously meaningful use). Clinicians will be arrayed based on their score across these four domains. Physicians who exceed a certain threshold of performance will receive either a zero percent update to their payment or a positive adjustment. Those below the threshold will receive a negative adjustment. In general, MIPS is “budget neutral,” which means that the money from those below the threshold forms the pool to pay bonuses to those above the threshold. If there are no “losers” there will essentially be no money to pay bonuses to “winners.”

There is one exception to this general principle, which is the exceptional performer bonus. The Centers for Medicare & Medicaid Services (CMS) has an additional pool of funds to pay out to those with exceptional MIPS scores.

The second pathway is the Advanced Alternative Payment Model (APM). Physicians who participate in advanced APMs are eligible for a five percent bonus on their Part B covered services. To achieve this bonus, the APM entity
must exceed a certain threshold of risk – either 25 percent of their Part B revenue or 20 percent of their Part B patients. A handful of models through the CMS Innovation Center and the Track 2 and Track 3 Medicare Shared Savings Program ACOs have been deemed qualifying APMs.

**BALANCING THE COMPETING MIPS INTERESTS OF SMALL GROUPS AND LARGE GROUPS**

For 2017, CMS announced “Pick Your Pace.” Under this approach to MACRA implementation, CMS offered many options for physicians to phase into the Quality Payment Program (QPP). Eligible clinicians can submit a minimum of data in 2017 (for example, one quality measure or one improvement activity) and avoid a downward adjustment. By submitting “something” clinicians can avoid penalties under MIPS.

The policy has set a low bar for the first year of MACRA. As a result, CMS anticipates that very few physicians will receive a penalty. This policy is intended to increase buy-in and reduce penalties for solo practitioners and small groups.

But we anticipate that the effect of this policy will be to nearly zero out the MIPS pool. Because MIPS is budget neutral, there will be very little in the way of bonus money to pay out to those that have invested for success in CMS performance measurement programs. While this policy choice was likely necessary for the first year, when MACRA was new, it is critical that CMS stays the course with the Quality Payment Program and continues to increase the requirements and the standards for performance in future years. This means phasing in the cost measure, increasing the number of measures that must be reported, and increasing the level of accountability in MIPS over time.

**INCREASING THE AVAILABILITY OF ALTERNATIVE PAYMENT MODELS**

In the development of MACRA’s legislative text, it seemed clear from the beginning that MIPS was intended to guide physicians and physician groups to alternative payment models and away from fee-for-service. The idea was that MIPS would become so undesirable that it would serve as an additional push into models that did not use the flawed “pay per click” methodology.

This need to move from MIPS to APMs is exacerbated by the flat fee schedule updates that occur beginning in 2020. The zero percent update to the fee schedule, combined with small MIPS adjustments, means a likely difficult landscape for physician payment in future years, and an additional driver toward accountable care models.

However, for CMS to achieve the promise of MIPS in its second implementation, the agency must rapidly implement new, qualifying APM options. The existing options do not accommodate a wide enough variety of models and practice types.

CAPG is advocating for two specific fixes in this regard. The first is to encourage CMS to count risk relationships between plans and physician groups in Medicare Advantage as risk relationships toward the MACRA threshold requirements. Under our concept, to qualify as advanced alternative payment models, contracts between health plans and physician groups would have to meet MACRA’s criteria around (1) more than nominal risk; (2) accountability for quality metrics; and (3) use of certified electronic health records. This model would increase the number of physicians who can qualify as advanced APM participants and escape from MIPS.

The second CAPG strategy is to design new advanced APMs that bear significant risk. We have advocated for the creation of a capitated accountable care model: CAPG’s Third Option. This model would fill an existing gap in the CMS Innovation Center portfolio by providing an option for physician organizations that are ready to take a capitated payment for their Part B patients. And the model would provide additional tools to encourage beneficiaries to receive care within the ACO network.

Both policy changes would allow more CAPG members to qualify as advanced APM participants and avoid MIPS adjustments or flat payments.

**CONCLUSION**

As we await MACRA’s next round of regulatory implementation, we know that CMS has some difficult choices to make. We look forward to working with the Administration to share our members’ experiences around MIPS and APMs and to share what is working and what needs improvement. CAPG will continue to serve as a resource for both the government and our members as MACRA moves forward.
Risk Contracting in Medicare Advantage Improves Survival

BY SCOTT C. HOWELL, DO, AND ALOKE K. MANDAL, MD, PHD

In a seminal paper, “Value-Based Contracting Innovated Medicare Advantage Healthcare Delivery and Improved Survival,” published in the American Journal of Managed Care, we tested the hypothesis of payer-provider risk contracting promoting high-value care within Medicare Advantage (MA). This program has grown significantly, now representing over 30 percent of all Medicare enrollees. With different statutory authority, private Medicare Advantage organizations (MAOs) perform an annual risk-adjusted competitive bid process based on a county fee-for-service benchmark.

Familiar to many CAPG members, the Centers for Medicare & Medicaid Services (CMS) reimburses MAOs with prospective, monthly, severity of illness, or risk-adjusted, capitated payments. CMS adopted a risk-adjusted methodology as part of the Balanced Budget Act of 1997, in response to favorable selection bias reducing incentives for MAOs to enroll healthier members.

The subsequent Benefits Improvement and Protection Act (BIPA) of 2000 required implementation of the hierarchical condition category (HCC) payment model, better known as the CMS-HCC model. This model recompenses MAOs based on disease burden, demographic factors, and Medicaid eligibility status. In return for providing healthcare benefits to MA enrollees during the calendar year (CY), MAOs receive risk-adjusted payments based on the CMS-HCC model during the following payment year, modified by a risk adjustment factor (RAF). The RAF coefficient is predictive of future healthcare Part C expenditures for the following year.

Section D1854 (a)(6)(B)(iii) of the Social Security Act prohibits CMS from requiring an organization to contract with a particular healthcare provider or to use a particular price structure for payment under such a contract (the “non-interference clause”). As a result, CMS is not involved in pricing or contract discussions between MAOs and participating providers. Given the CMS-HCC model, MAOs have the unique ability to provide percent of premium contracting downstream to medical groups. This model offers both stability and transparency, enabling medical groups to typically contract between 30 percent to over 80 percent of the MAO premium. This unique contracting capability allows for downstream innovation at a local provider level—the core business unit of healthcare. Because little has been written on the impact of such risk-based contracting on generating cost efficiencies and improving clinical outcomes, it was our intent to study this aspect of the MA program.

Much has been written on cost savings and quality improvement in different delivery systems of accountable care organizations (ACOs) or the patient-centered medical home (PCMH). In many reviews, the methodology has used a future expected cost to evaluate the performance of the delivery system over a time period duration. To truly evaluate the performance of a delivery system, a control and interventional group with similar characteristics must be compared over time. The healthcare industry has developed a set of outcome measures of quality and efficiency. Many reported studies do not take the next step of asking whether these outcome measures impact the ultimate quality indicator, namely survival.
To determine if risk-based contracting improved clinical outcomes, we chose to analyze statistically similar groups of MA enrollees within one metropolitan statistical area, who were cared for by two provider groups with two different contracting arrangements. One provider group was reimbursed through a standard fee-for-service schedule (control group) and another through risk-based contracting with full-risk capitation (interventional group). Specifically, starting in 2009, for intervention-group MA enrollees, the MAO and a provider group agreed to full-risk capitation combined with a revenue gainshare. For the control group, the MAO continued to reimburse another provider group through fee-for-service. The two medical groups were subsequently followed for a four-year period until December 31, 2012.

The interventional group used the CMS-HCC model as a guide to identify and stratify members with certain disease states, such as congestive heart failure, chronic obstructive pulmonary disease, and complex frail individuals who were at high risk for hospitalization. Innovative processes were instituted that had been designed with intense outpatient management, including triage systems, coordinated care, and regular contact with high-risk individuals.

As shown in the left panel of the figure, the interventional group increased office-based visits (P <.001) while emergency department visits (P <.001) and inpatient hospital admissions (P = .002) decreased. This change in utilization saved $2,071,293 per 1,000 enrollees. Of most significance, as depicted in the right panel of the figure, the interventional group through practice transformation was able to demonstrate a six percent survival benefit with a 32.8 percent lower hazard of death (P <.001).

This study supports risk-based contracting by demonstrating superior clinical outcomes and a survival benefit. The recent proposals of including 1115A waivers for average manufacturer prices (AMPs) in MA may accelerate the development of further risk-based contracting to achieve the Triple Aim and improve the lives of our patients.

Scott C. Howell, DO, is Executive Medical Director, Heritage Provider Network. Alok K. Mandal, MD, PhD, is Medical Director, for the Risk, Quality, and Network Solutions group at Optum. They will participate in a CAPG Annual Conference panel, MA Improves Survival: The Ultimate Quality Measure, on Friday, June 23, at 2:30 pm.

Established in 1995, Physicians of Southwest Washington (PSW), an independent physician association (IPA) located in Olympia, Washington, has found success in our core business line of managing global risk contracts with Medicare Advantage payers. Throughout our 21-year history, PSW has built and supported a multi-county provider network, launched and sold our ownership in a Medicare Advantage health plan, and ultimately carved out a foundation to support the physician-patient relationship in the independent practice of medicine.

Compared to other burgeoning healthcare systems in Washington State, PSW may be considered small, but nonetheless mighty. At one time it was estimated that 25 IPAs existed across Washington State; today PSW is one of only two remaining.

NAVIGATING CHANGE

As it did for many healthcare organizations, learning to navigate a significantly changing landscape became a strategic priority for PSW. In 2016, it also proved pivotal to sustaining the organization’s future. Burdened by the growing realization that Medicare Advantage could no longer suffice as the IPAs only line of business, our managing board sought to find a new direction. Board members recognized the continued implications of state and federal policies facing physicians, and understood how these changes would ultimately impact the network’s physicians and practices.

ADAPTABLE. FLEXIBLE. NIMBLE.

These are the strengths of maintaining “small but mighty” status. Our leadership understood that the ability to innovate would define PSW’s future. Initial steps focused on evaluating nearly every business activity and operation to determine what worked, what didn’t, and what needed to change to serve the organization’s growth and diversification. This process included our looking to the Centers for Medicare & Medicaid Innovation (CMMI) for new healthcare models that would deliver value to stakeholders.

MACRA = PHYSICIAN ENGAGEMENT

PSW plunged head first into the world of the Medicare Access and CHIP Reauthorization Act (MACRA) and its pathways of Merit-based Incentive Payment System (MIPS) or Alternative Payment Models (APMs). Over the course of a year, PSW management acted as a sponge, absorbing everything that could be learned about MACRA.

This intensive learning enabled leadership to identify that the APMs

<table>
<thead>
<tr>
<th>PSW’S REVIEW OF THE NEXT GENERATION ACO MODEL</th>
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<tr>
<td><strong>Opportunities</strong></td>
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<tr>
<td>• Ability to choose risk arrangement</td>
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<tr>
<td>• Hierarchical conditional categories (HCC) risk adjustment in benchmarks</td>
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<tr>
<td>• Waiver options for skilled nursing facilities, home health, and telehealth</td>
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<tr>
<td>• Beneficiary engagement via $25 coordinated care reward</td>
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<tr>
<td>• Prospective attribution</td>
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<tr>
<td>• Multiple payment options</td>
</tr>
<tr>
<td><strong>Risks and Uncertainties</strong></td>
</tr>
<tr>
<td>• No guarantees to the benchmark</td>
</tr>
<tr>
<td>• New administration and risk to CMMI's longevity</td>
</tr>
<tr>
<td>• Early ACO reports not yielding desired cost savings results</td>
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<tr>
<td>• Ability to meet beneficiary requirements year-over-year</td>
</tr>
<tr>
<td>• Challenging to change beneficiary behavior with no parameter enforcements</td>
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</table>

Initial steps focused on evaluating nearly every business activity and operation to determine what worked, what didn’t, and what needed to change to serve the organization’s growth and diversification.”
offered the preferred strategic considerations for both PSW and our provider network. Strategic considerations included PSW’s strong history of successfully managing risk, along with the opportunity to gain five percent in additional reimbursement in future years, remove the burden of quality reporting, offer early-adopter leadership, and engage providers in common purpose and direction to meet desired results.

Given that physician engagement is always a top priority for any critical initiative being considered, we were pleasantly surprised to receive an overwhelming and positive response from PSW’s network in regard to our desire to lead the MACRA effort. Years of industry changes, new models, and government requirements required many of PSW’s independent practices to choose to either adapt to these impacts by using scarce resources or accept the financial risk. The introduction of MACRA and PSW’s commitment to spearhead a regional APM movement seemingly changed that position overnight. The knowledge and opportunity that healthcare providers would come together created much-needed momentum for engagement.

NEXT GENERATION ACO MODEL

PSW submitted an application to participate in the Next Generation Accountable Care Organization model (NGACO) in 2015, but was waitlisted for a year. In hindsight, this was a beneficial move as it provided us the time to gain additional education and prepare for implementation relating to the identified opportunities and risks.

In August 2016, following acceptance to participate in the NGACO model, we fervently began planning implementation for 2017. The timeline was short and the action list long; however, between August and December we achieved the following major steps:

- Finalized NGACO provider network
- Developed and distributed all provider network contracts
- Conducted financial modeling and risk assessments
- Launched NW Momentum Health Partners (NWMHP) ACO, LLC
- Confirmed equity partnership
- Established the ACO’s board of directors

Ultimately, the PSW board and ACO board agreed that the official launch of NextGen ACO would be put on hold until we received the final Centers for Medicare & Medicaid Services (CMS) financial benchmark files, expected in late January 2017. This critical data would indicate the feasibility—the “make or break”—if we were to move forward.

With all possible data in hand, and risk and uncertainty waiting in the wings, NW Momentum Health Partners ACO launched the Next Generation ACO in February 2017.

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<table>
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<tr>
<th>LEVERS OF SUCCESS</th>
<th>THE ROLE OF PROVIDERS/PRACTICES</th>
<th>THE ROLE OF NW MOMENTUM HEALTH PARTNERS</th>
</tr>
</thead>
</table>
| 1. Beneficiary Engagement | - Provide beneficiaries info on the Next Gen ACO and the benefit to them for care coordination  
- Promote CMS $25 member incentive for completing annual wellness visit – accurate HCC coding  
- Refer to PSW as a resource  
- Refer to PW case management and encourage member engagement | - Provide effective materials for providers and practice staff  
- Conduct face-to-face visits to identify needs and gaps  
- Provide health risk assessments  
- Coordinate ancillary, home and community-based services  
- Promote “care team” family involvement  
- Serve as conduit of communication between delivery system, patient and provider  
- Be the resource (i.e., Medicaid coordination, advanced care planning, transportation)  
- Identify and resolve gaps in care |
| 2. Provide Timely Access to Care | - Same day appointments for sick call  
- Encourage calling after hours  
- How and where to access urgent care?  
- Utilize direct admit to preferred, Skilled Nursing Facilities  
- Refer to ACO hospital partner | - Provide material to meet practice needs  
- Share best practices  
- Engage members to select PCP/specialists  
- Assist with Skilled Nursing Facilities direct admits  
- Partner with Skilled Nursing Facilities, Home and Community Services, and Home Health |
| 3. Practice Engagement | - Provide PSW access to EHR system  
- Communicate concerns and opportunities | - Report quality measures  
- Work with ACO hospital partner  
- Support provider/practice relationships |
Within the first two weeks of the launch, PSW connected in person with more than 60 physicians, providers, and practice staff on what being in the ACO meant and what their roles would be going forward. Understanding the complexities of MACRA is complicated and overwhelming for practices of any size. Our commitment strategy for success is to stay provider-facing, ensure consistent communication, and offer the “ACO road show” across the network with continued education and training.

In addition to developing a new ACO website and distributing the CMS beneficiary letter and beneficiary cards, we created an ACO toolkit that includes a provider scorecard, coding resources, monthly beneficiary attribution lists, and a reference sheet on “How to be Successful in an ACO.”

**THE REARVIEW MIRROR**
Reflecting on the last year, it’s remarkable that we have grown from taking global risk for 7,600 Medicare Advantage lives to impacting more than 22,000 member lives through a diversified number of contracts, including the Next Generation ACO. We refer to this achievement and our ongoing strategies to redefine the organization via innovation as PSW 2.0.

The CMS Next Generation ACO model fits that need. PSW’s learning curve has been steep, and transitioning from implementation to management of the ACO continues to be a major undertaking with questions far outweighing the answers. However, we applaud CMS for their continued efforts to create new healthcare models that can be advantageous for so many.

As PSW navigates this relatively new model of care, we remain positive that our network of healthcare providers is committed to transforming clinical practice with the goal of improving quality, reducing expenditures, and enhancing the patient and provider experience.

Melanie Lite Matthews is CEO of Physicians of Southwest Washington, a member of CAPG. She will participate in a CAPG Annual Conference panel, MACRA: Checking in With Physician Group Leaders in Year One, on Friday, June 23, at 10 am.

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### GOOD TO KNOW about your ACO and PSW

<table>
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<tr>
<th>PLAN INFORMATION</th>
<th>PSW</th>
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<td>Plan names</td>
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<td>Next Generation ACO</td>
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<td>SNF Direct Admits</td>
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<td>ID Cards</td>
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<tr>
<td>Annual Wellness Visit</td>
<td>Yes</td>
<td>Yes – $25 beneficiary incentive</td>
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</tbody>
</table>

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### ABOUT NW MOMENTUM HEALTH PARTNERS

- **Next Generation ACO** launched by NW Momentum Health Partners on February 28, 2017
- **64** Thurston County practices in the ACO Network:
  - 30 Participating Providers
  - 34 Preferred Providers
- A qualifying alternative payment model, Next Generation ACO supports:
  - **Attribution**: the risk-sharing model is based on beneficiary attribution and built around Medicare fee-for-service (FFS) payments.
  - **Medicare beneficiaries**: 9,025 attributed to the ACO for 2017.
  - **Beneficiary choice**: ACO Medicare patients will see no change in their original Medicare benefits and retain the freedom to see any Medicare provider.
  - **Shared savings**: Once the ACO succeeds in delivering both high-quality care and spending health care dollars more wisely, achieved savings will be shared.

---

### FOR MORE INFORMATION

- **NW Momentum Health Partners**
  - NWMomentumHealthACO.com
- **Physicians of Southwest Washington**
  - pswipa.com
  - 360-943-4337
  - 1-877-943-4337 (toll free)
  - 360-754 4324 (fax)
  - 319 Seventh Avenue SE STE 201
  - Olympia WA 98501
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- ProHealth Physicians, CT
- Southwest Medical, NV
- WellMed, FL and TX
- USMD Health System, TX

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Research Partnerships Tackle Population Health Management Challenges

BY AMY ADOME, MD, MPH; DILESH DOSHI, PHARMD; AND JOSHUA LIBERMAN, PHD

The continually evolving healthcare landscape requires partnerships between a variety of stakeholders to find evidence-based solutions to population health challenges. The road toward value-based healthcare demands unconventional thinking, bringing together interested parties across silos within health systems, in the community, and other sectors who care about achieving better health for all. To this end, Sutter Health and Sharp HealthCare have independently partnered with Janssen Scientific Affairs on research collaborations to address important population health management questions.

Janssen recently formed the Population Health Research team to work with health systems in identifying areas of mutual interest that fill gaps in knowledge and generate evidence around best practices in providing care in a value-driven environment. Typically using data already collected by the health systems, these projects focus on the whole patient and link together disparate data sources (e.g., survey data, clinical data, claims data, and social factors).

For leaders at Sutter Health and Sharp HealthCare, working with Janssen’s Population Health Research team provided an opportunity to expand their existing focus on advancing patient care and population health management.

“Few, if any, organizations have the resources, expertise, and experience in all the different disciplines needed to solve challenges in healthcare,” said Josh Liberman, Executive Director, Research, Development, and Dissemination at Sutter Health. “Bringing together experts from different fields and teams fosters new ideas, new ways of thinking. Despite being in different industries, we all share a common mission—to improve the health and well being of the patients we serve. Partnering helps us achieve that mission faster by bringing together resources, expertise, ideas, and perspectives from various organizations all working on similar challenges.”

TAKING ON TOUGH POPULATION HEALTH ISSUES

Sharp HealthCare and Janssen’s research teams are studying the incremental impact of adding behavioral health data to a readmission risk model used to identify inpatients at high risk for 30-day readmissions.

“Progressive health systems across the country understand the need to utilize more predictive analytics techniques to better serve populations so their interventions of care can be effective and truly drive the value proposition,” said Amy Adome, Senior Vice President, Clinical Effectiveness at Sharp HealthCare. “One of the challenges they face is allocating the required time and resources towards identifying feasible evidence-based solutions in an environment where reimbursement models are not yet well aligned to easily allow for the necessary resource allocation. The research partnership between Sharp and Janssen enabled both parties to share the responsibility, expertise, and resource burden in studying an issue of mutual interest.”

In another initiative, Janssen’s research team is also working with researchers at Sutter Health’s Palo Alto Medical Foundation Research Institute (PAMFRI) to identify
dimensions of patient experience and satisfaction associated with adherence to medications for cardiometabolic diseases.

Already, both research efforts have started to generate learning. Interim results were recently presented at peer-reviewed conferences, including the 2017 Health Care Systems Research Network meeting March 21-23 in San Diego. Study lead Kristina Greenwood, PhD, Outcomes Research Specialist, Sharp HealthCare, and Cecile Davis, MSN, PHN, RN-BC, Manager with the Sharp Care Transitions Program, and Joy LaMori, MHS, MBA, Director, Population Health Research, Janssen Scientific Affairs, presented preliminary findings from their project, “Using Data Analytics and Innovation Partnerships to Reduce Hospital Readmissions: Can Behavioral Health Data Improve Predictive Accuracy?” as part of a panel presentation entitled Innovative Uses of Data Sources.

Earlier data from the Sutter-PAMFRI research project were shared in an oral presentation at the Society for Medical Decision Making 38th Annual North American Meeting, held in October 2016 in Vancouver, British Columbia. The presentation, “Patients’ Involvement in Treatment Decision-Making is Associated with Improved Adherence to Chronic Disease Medications in an Ambulatory Care Setting,” was given by study lead Robert Romanelli, PhD, MPH, Assistant Scientist at PAMFRI as part of a set of sessions focused on chronic disease management.

INFORMING FUTURE IMPROVEMENTS IN PATIENT CARE

This approach to research partnerships allows Janssen to generate meaningful insights using unique data sources, which can help inform future clinical development plans, as well as better understand unmet medical needs in its therapeutic areas of interest. By working together to generate rigorous evidence, Sharp, Sutter, and Janssen aim to identify approaches that are generalizable across systems and can help drive improvements in patient care.

For instance, insights from the project with Sharp are being used to inform and guide their ongoing readmission reduction strategies, including optimization of the care pathway for discharged inpatients.

Further impact can be driven by disseminating study findings to other health systems and healthcare stakeholders through conference presentations and posters, and, ultimately, publishing results in peer-reviewed manuscripts. Beyond adoption of more evidence-based practices by individual health systems, the bigger vision is to serve up evidence-based solutions that influence changes in healthcare policy for the benefit of the society at large.

Amy Adome, MD, MPH, is Senior Vice President, Clinical Effectiveness at Sharp HealthCare in San Diego, California. Dilesh Doshi, PharmD, serves as Senior Director, Population Health Research with Janssen Scientific Affairs, LLC, based in Titusville, New Jersey. Joshua Liberman, PhD, is Executive Director, Research, Development, and Dissemination for Sutter Health, Walnut Creek, California.
An Urgent Case: Treating and Preventing Physician Burnout

BY AMY NGUYEN HOWELL, MD, MBA

Today’s political climate evokes feelings of chaos and uncertainty regarding healthcare policy and clinical developments. Polarizing political debates often overshadow real-life issues affecting countless lives. And I’m not talking about patients—I’m referring to doctors on the frontlines of patient care.

The growing problem of physician burnout is real. It exists in thousands of offices nationwide. Don’t ignore it, because it won’t go away on its own. Instead, it will grow like an unwanted weed and may kill like a contagion if left untreated. Physician burnout can manifest itself in a lack of enthusiasm for work, growing cynicism about patients or career, and a poor sense of self-worth. It also can lead to poor job performance and in serious cases, suicide.1 Alarming, feelings of burnout have become more prevalent over time, increasing twofold from 2011 to 2015, according to a Mayo Clinic study.2

Administrators and healthcare experts have been trying to solve this problem on an individual, case-by-case basis. Meanwhile, a case is warranted to work together as a community to identify root causes and manage burnout on an organizational level. We cannot afford to sit idle as this issue grows into a national epidemic.

As a practicing female physician in our current schizophrenic healthcare state, I’m frightened at the statistics and stories about burnout. While I battle daily with issues like equality, women in the workplace, and millennial philosophies, I’m sobered hourly by the stories on physician shortage, career unfulfillment, and physician suicide. It’s predicted that in a mere eight years we may have a shortfall of around 17,000 primary care physicians, as our growing population ages and more physicians and internists will be needed.3,4

More and more colleagues are turning to part-time or non-clinical positions because they’re faced with physician burnout and are ill-equipped with adequate resources for sustainability and growth.
Studies have shown that primary care physicians have issues with clinician satisfaction. For example, in a survey of nearly 500 internists and family physicians, 48 percent found the work pace chaotic, 78 percent felt little control over their work, and 30 percent were likely to leave their practice within two years.\textsuperscript{5} Another study found that 30 to 40 percent of doctors feel they’re definitely burning out.\textsuperscript{6} This problem not only threatens physician recruitment and retention, it also increases medical errors, reduces quality of care, lowers patient satisfaction, reduces patient adherence to treatment care plans, and reduces patient empathy.\textsuperscript{5,7,8}

Physician “unwellness” has many root causes, often related to time pressures: insufficient time to spend with patients or away from the office. Competitors for that time include hassle factors, such as administrative burdens and inefficiencies introduced by electronic health records (EHR), superimposed on the increasing needs of a sicker, more engaged patient population.\textsuperscript{9} Additional influences are decreasing autonomy, increasing payment inequity, and greater physical disconnection from colleagues as professional work shifts from the hospital to the community.

Empowering physicians to take action to reduce burnout and increase practice satisfaction is expressed by several commentators calling for society to value the well being of physicians and other healthcare team members, to fulfill the Quadruple Aim.\textsuperscript{10,11} CAPG is going on its third year with our Primary Care Practice Transformation Program, which is designed to innovate practices to improve care delivery while reducing burnout at all career stages.

A 2013 article in the \textit{Annals of Family Medicine}\textsuperscript{12} describes practical ways in which medical offices can make practice more joyful through workflow redesigns that reduce practice hassles. CAPG’s experience with practice transformation parallels their findings. Greater delegation of tasks to other members of the patient care team, smarter use of the EHR, and pre-visit planning (a.k.a. “the huddle”) are just a few of the tools that our members have used to increase satisfaction and regain control over their time at work.

This new approach to managing workflow requires another cultural change that must begin with executive

\textit{continued on page 46}
Improving Patient Engagement Boosts Colorectal Cancer Screening Rates

BY MOHINI SINHA, MD

Today’s emphasis on quality is driving a renewed focus on prevention and early detection of disease—including colorectal cancer (CRC), which is the second-leading cause of cancer-related death in the United States, with annual treatment costs totaling more than $14 billion.\(^1\)\(^2\) Screening procedures play a critical role in helping to prevent CRC and to detect precancerous polyps so they can be removed. According to the American Cancer Society, 90 percent of CRC deaths can be prevented with early screening.\(^3\)

Rates of recommended screenings in people aged 50 to 75 have been increasing but still lag behind goals set by the National Colorectal Cancer Roundtable (NCCRT).\(^4\) In order to raise these rates, healthcare efforts must include a strategy to motivate difficult-to-engage patients to complete their screening. Monarch HealthCare, an independent physician association and part of OptumCare\(^8\), piloted an innovative colorectal screening program in 2016 in which we sought to eliminate barriers to screening in this population.

Other healthcare organizations have found success with targeted efforts to activate difficult-to-engage patients, with some approaches resulting in screening-rate increases as high as 15 percent.\(^5\) In this article, we share outcomes and lessons learned from our pilot, conducted at three of our healthcare practices in Orange County, California.

GUIDED BY BEST PRACTICES

In partnership with Genentech, we implemented our initiative using resources and best practices outlined in Genentech’s Love Your Colon CRC screening program (www.loveyourcolon.org). This program contains tools designed to activate patients, along with an associated guide for health systems to consider when developing their own processes for patient outreach and screening.\(^6\) Genentech was responsible for the creation of the Love Your Colon tools, while Monarch practices were fully accountable for implementation of the program.

We knew that a successful screening program deploys the right interventions at the right time. At each of the three pilot offices, we made observations about primary care authorization processes, timing of referrals, and workflow efficiency. These reviews enabled us to optimize a cancer screening process flow and develop standard operating procedures for documenting screening information in the electronic health record.

Monarch HealthCare’s central office identified screening candidates, with patient eligibility determined according to American Cancer Society colorectal cancer screening criteria.\(^7\) Identified candidates received a letter from Monarch’s quality medical
director, informing them they were due for screening. The letter contained key messages—based on work by the NCCRT, a coalition of colorectal cancer screening experts—designed to help patients understand the need for screening, anticipate objections, and motivate them to get screened. In addition to the letter, candidates also received a graphically driven educational brochure that employed the same core messages.

With consent from their primary care providers (PCPs), candidates were preauthorized for a colonoscopy and directed in the letter to schedule a consultation with a gastroenterologist (GI). Our hope was that this “fast-track” approach, bypassing the PCP, would remove a time-related barrier to adherence.

After the mailing, all screening candidates who had not scheduled an appointment within two weeks received a phone call from Monarch’s central program coordinator, who used a patient-navigation call script to answer questions and address objections to CRC screening. The goal was to ensure that the patient either scheduled a screening consultation or consented to complete a fecal occult blood test (FOBT) kit.

Candidates who did neither within three months of program initiation automatically received an FOBT kit in the mail.

The central program coordinator also informed provider staff members of patients’ CRC screening preventive care gap. Providers were given the educational brochure and the patient-navigation call script to use in conversations with screening candidates who came into the office for an unrelated illness or to discuss colorectal screening with their PCP.

POSITIVE OUTCOMES

By the end of the program, the combined screening rate at the three pilot sites rose from 51 percent at baseline to 68 percent. At the onset, 219 patients had been identified as eligible for screening but nonadherent; by the end, 32 percent of them completed either an FOBT or a colonoscopy (Table 1). Among patients completing colonoscopies, polyps were removed in 17 and none were found to be malignant.

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California Quality Collaborative and CAPG Members Improve Healthcare Value in California

BY DIANE STEWART AND BART WALD, MD

The California Quality Collaborative (CQC) and CAPG share a mission to improve the quality and value of healthcare provided to patients through clinically integrated and coordinated care.

A multi-stakeholder improvement organization, CQC is housed at the Pacific Business Group on Health and partners with other improvement organizations, including CAPG, to assist healthcare leaders in adopting system changes to significantly improve clinical outcomes, patient satisfaction, and affordability. Many CAPG members take advantage of CQC training programs to create scalable, measurable improvement in clinical quality, patient experience, and cost of care—a reflection of the collaborative’s decade of working with physician groups to advance efficient, quality healthcare.

This past year saw tremendous progress, and 2017 offers even greater opportunities for physician groups. Here is a quick look back at 2016 accomplishments and important resources for physician groups, along with a snapshot of opportunities ahead.

CQC recently released a 2016 Impact Report summarizing the work of 135 organizations, including many CAPG members, to improve cost of care and care coordination for medically complex patients and to promote practice transformation. In 2016, CQC published a summary of best practices from 23 provider organizations participating in the Intensive Outpatient Care Program (IOCP), a Center for Medicare & Medicaid Innovation (CMMI) Innovation Award winner, and its IOCP Toolkit, aimed at building programs for medically complex Medicare patients. Physician groups can gain insights into how to best manage patients with complex needs by downloading the toolkit at www.calquality.org.

Last year CQC also summarized interview findings from leading accountable care organizations (ACOs) and provider organizations addressing cost of care in Managing Cost of Care: Lessons from the Field. In addition, the collaborative engaged 13 delivery systems and 3,036 clinicians in practice transformation, including monthly reporting on 13 Triple Aim measures. Also in 2016, CQC prepared 55 organizations for the Health Homes program in California, a federal initiative to help states develop models designed to improve care coordination and reduce costs for high-need Medicaid populations.

This year offers physician groups many new opportunities to participate and improve their practices, including:

Complex Patients: Building Care Solutions for Older Adults with Complex Needs is an action-oriented learning community targeting the medically complex senior population. Building on the successful work of the IOCP, CQC is expanding the model to include the latest research on how to identify and engage providers and patients, and create a strong business case for program sustainability. Organizations experimenting with better ways to work with high-need, high-cost patients will work together to provide better care for those patients with the most complicated needs, and consuming the highest amount of resources. For more information, contact Margie Powers, mpowers@calquality.org.
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Organizational Quality and Superior Patient Outcomes—A Holistic Approach

BY SAYEED KHAN, MD

Managed health organizations across the country have been asked to improve overall quality in an effort to ensure that excellent care is available to all patients, regardless of income. Utilizing measures such as Healthcare Effectiveness Data and Information Set (HEDIS) scores to quantify the care patients receive allows the Centers for Medicare & Medicaid Services to compare plans directly and reimburse organizations like Molina Medical Group (MMG) based on actual patient outcomes.

Molina Medical Group has taken a holistic approach to improving organizational quality, an approach that directly relates to a better patient experience and improved health outcomes—ensuring MMG members that they are getting the most from their benefits.

“Delivering quality care is part of Molina’s corporate DNA,” said Carrie Harris-Muller, Senior Vice President, Care Delivery and Strategic Partnerships at Molina Healthcare. “Our business was created to serve patients, so incentives to improve the quality of care are beneficial to our business and our members.”

“Better scores = Better business”

The key thing to focus on in terms of organizational quality improvement is that there are no losers. The more organizations improve their processes and HEDIS scores, the better care and attention they provide to members. It’s a win-win.

Molina offers a direct-delivery system of 26 company-owned-and-operated primary and specialty care clinics in California, Florida, Michigan, New Mexico, Utah, and Washington. In each of these clinics, the focus is on the motto, “Every visit is a golden opportunity.” Every visit is a chance to provide quality care and health enhancement. “Even if a patient comes in for a sore throat, it’s an opportunity to review their chart and ensure they are up to date on all their shots and health measures,” said Andrew Reno, Associate Vice President of Quality for Care Delivery, MMG.

Prior to every appointment, clinic medical assistants examine a patient’s chart for any missing health screenings. This chart “triage” allows the assistant and doctor to provide the best possible service based on the most recent health information available for each patient.

MMG’s policy of never turning away an appointment means that same-day and next-day appointments are often available to members, and these quick-turnaround visits provide a face-to-face chance for providers to assess issues beyond the one for which the patient walked in. The increased focus on patient history and health measures is paying off—the California clinics have already received recognition for increased HEDIS measures. This isn’t just good for Molina—it also translates directly into improved patient health outcomes and satisfaction. Our Press Ganey customer service scores are consistently improving and remain in the high 80s. Our culture of customer service is to ensure every visit delivers high-quality, cost-effective care.

“Delivering quality care is part of Molina’s corporate DNA. Our business was created to serve patients, so incentives to improve the quality of care are beneficial to our business and our members.”
NO “SLIPPING THROUGH THE CRACKS”

We utilize a community engagement team to identify members in need and make sure they find their way to a clinic. MMG has developed partnerships with local mammography mobile units and retina scan mobile units to identify members with unaddressed issues so they get the care they need. The goal is to offer on-site services that can address all member healthcare needs in an easily accessible way.

PATIENTS ARE THE CUSTOMERS

“Every patient’s time is valuable,” said Reno. “We really strive to demonstrate that we understand that.” In addition to the chart triage performed before every visit, the in-office team prepares that patient, walking them through every detail of their visit, including next steps and any necessary follow-up care, to provide a positive patient experience. In Washington, the increased focus on service has dramatically decreased the “no-show” rate to below 20 percent, while in New Mexico, the rate has fallen from 50 percent to 22 percent in less than two years.

In order to gauge the level of patient satisfaction, many clinics have implemented a post-visit survey, which some states administer before patients leave the office. In other places, patients are mailed or emailed a survey to evaluate their visit.

Molina CareConnections employs a workforce of nurse practitioners focused on catering to patients’ needs, including meeting them in a familiar environment. In recognition of the value of delivering care to patients where they feel both safe and secure, providers have visited patients in their van, at a local McDonald’s, and even at a community shelter. CareConnection’s nurse practitioners educate all patients on the importance of completing a healthcare screening exam and describe in detail how they can access additional care services. It is common to find patients unaware of the extent of available services. In addition to providing a wellness exam, the nurse practitioner can complete several quality measures, including HgbA1C, retinal screenings, PHQ9 screening, urine microalbumins and protein, and diabetic foot exams, as well as advise on the proper way to obtain a fecal occult blood screening.

It’s critical to remember that healthcare is essentially a customer-service business. This focus is allowing Molina Medical Group to improve member health outcomes while improving our business at the same time.

Sayeed Khan, MD, is President, Molina Medical Group.
of plans and medical professionals alike. Equity in the application of the tax policy would create a level playing field—essential for a functioning market—with the government no longer able to favor one type of health insurance over another or one class of consumers over another. A genuinely open and competitive market for health insurance, fostered by individual tax relief, would also exert a powerful downward pressure on health care costs.

Short of a comprehensive overhaul of the federal tax policy, Congress should provide individual tax relief for those who cannot get health insurance through the place of work, such as those struggling with shocking health insurance costs in the relatively small individual market. Although the individual market covers only about 7 percent of the total insured population, this assistance would achieve elemental fairness in the tax treatment of health insurance. Because of the ACA’s income eligibility standards, many middle class taxpayers do not get any tax relief to offset their premium costs. Employers and employees of small businesses, where job-based coverage is not economically feasible, also need relief. Individual tax relief for health insurance would be ideal for them.

The AHCA’s age-based tax credit proposal is conceptually sound—health care costs rise with age—but it should be more generous than the proposed annual credit of $4,000 for the small number of persons over the age of 60 enrolled in the individual market. In the meantime, Congress could preserve the existing employment-based tax regime for employees of large businesses, thus avoiding any disruption. Still, Congress should at least impose a simple cap on the tax exclusion for high cost health plans, encouraging more cost-effective and flexible coverage, such as high deductible, consumer-driven health insurance. That would result in a systemic downward pressure on health care costs.

HELP FOR ALL ECONOMIC LEVELS

For middle class Americans, tax relief can take the form of a nonrefundable tax credit.

Low-income individuals should be integrated into the private health insurance market, which would provide them the same access to private physician networks that serve their fellow citizens.

The best mechanism to accomplish that integration is through a new “premium support” program—in effect, a refundable tax credit, using Medicaid acute care spending as the funding base. Executed in a fiscally responsible way, with appropriate offsets in federal spending, such a policy not only would improve our fellow Americans’ access to better health care, but would better integrate younger and healthier persons into the nation’s health insurance pools, exerting a welcome downward demographic pressure on average claims costs.

No magic bullet exists in health care policy, and that includes changing federal tax policy. That is why health reform will remain a process, rather than a single legislative event.

Robert Emmet Moffit, PhD, is a Senior Fellow at The Heritage Foundation’s Center for Health Policy Studies. He will present a CAPG Annual Conference keynote address, Market-Based Health Reform: A Process, Not an Event, on Friday, June 23, at 1:00 pm.

References

10 “Health Insurance Coverage of the Total Population 2015,” Kaiser Family Foundation, http://kff.org/other/state-indicator/total-population/?dataView=1&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
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• 7 approvals in less than 4 years2-5
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*Based on IMS data November 2013 to January 2017

Please see Important Safety Information on back page, and accompanying Brief Summary.
IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage - Fatal bleeding events have occurred in patients treated with IMBRUVICA®. Grade 3 or higher bleeding events (intracranial hemorrhage [including subdural hematoma], gastrointestinal bleeding, hematuria, and postprocedural hemorrhage) have occurred in up to 6% of patients. Bleeding events of any grade, including bruising and petechiae, occurred in approximately half of patients treated with IMBRUVICA®.

The mechanism for the bleeding events is not well understood. IMBRUVICA® may increase the risk of hemorrhage in patients receiving antplatelet or anticoagulant therapies and patients should be monitored for signs of bleeding. Consider the benefit-risk of withholding IMBRUVICA® for at least 3 to 7 days pre- and postsurgery depending upon the type of surgery and the risk of bleeding.

Infections - Fatal and nonfatal infections have occurred with IMBRUVICA® therapy. Grade 3 or greater infections occurred in 14% to 29% of patients. Cases of progressive multifocal leukoencephalopathy (PML) and Pneumocystis jiroveci pneumonia (PJP) have occurred in patients treated with IMBRUVICA®. Evaluate patients for fever and infections and treat appropriately.

Cytopenias - Treatment-emergent Grade 3 or 4 cytopenias including neutropenia (range, 13% to 29%), thrombocytopenia (range, 5% to 17%), and anemia (range, 0% to 13%) based on laboratory measurements occurred in patients treated with single agent IMBRUVICA®. Monitor complete blood counts monthly.

Atrial Fibrillation - Atrial fibrillation and atrial flutter (range, 6% to 9%) have occurred in patients treated with IMBRUVICA®, particularly in patients with cardiac risk factors, hypertension, acute infections, and a previous history of atrial fibrillation. Periodically monitor patients clinically for atrial fibrillation. Patients who develop arrhythmic symptoms (e.g., palpitations, lightheadedness) or new-onset dyspnea should have an ECG performed. Atrial fibrillation should be managed appropriately and if it persists, consider the risks and benefits of IMBRUVICA® treatment and follow dose modification guidelines.

Hypertension - Hypertension (range, 6% to 17%) has occurred in patients treated with IMBRUVICA® with a median time to onset of 4.6 months (range, 0.03 to 22 months). Monitor patients for new-onset hypertension or hypertension that is not adequately controlled after starting IMBRUVICA®. Adjust existing antihypertensive medications and/or initiate antihypertensive treatment as appropriate.

Second Primary Malignancies - Other malignancies (range, 3% to 16%) including non-skin carcinomas (range, 1% to 4%) have occurred in patients treated with IMBRUVICA®. The most frequent second primary malignancy was non-melanoma skin cancer (range, 2% to 13%).

Tumor Lysis Syndrome - Tumor lysis syndrome has been infrequently reported with IMBRUVICA® therapy. Assess the baseline risk (e.g., high tumor burden) and take appropriate precautions. Monitor patients closely and treat as appropriate.

Embryo-Fetal Toxicity - Based on findings in animals, IMBRUVICA® can cause fetal harm when administered to a pregnant woman. Advise women to avoid becoming pregnant while taking IMBRUVICA® and for 1 month after cessation of therapy.

References:
1. Data on file. Pharmacyclics LLC.
Clinical trials procedural hemorrhage) have occurred in up to 6% of patients. Bleeding events [including subdural hematoma], gastrointestinal bleeding, hematuria, and post-

DRUG INTERACTIONS
CYP3A Inhibitors - Avoid coadministration with strong or moderate CYP3A inhibitors. If a moderate CYP3A inhibitor must be used, reduce the IMBRUVICA® dose.

CYP3A Inducers - Avoid coadministration with strong CYP3A inducers.

SPECIFIC POPULATIONS
Hepatic Impairment - Avoid use in patients with moderate or severe baseline hepatic impairment. In patients with mild impairment, reduce IMBRUVICA® dose.

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Embryo-Fetal Toxicity: Based on findings in animals, IMBRUVICA can cause fetal harm when administered to a pregnant woman. Administration of ibrutinib to pregnant rats and rabbits during the period of organogenesis caused embryofetal toxicity including malformations at exposures that were 2-20 times higher than those reported in patients with hematologic malignancies. Advise women to avoid becoming pregnant while taking IMBRUVICA and for 1 month after cessation of therapy. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus [see Use in Specific Populations].

ADVERSE REACTIONS

The following adverse reactions are discussed in more detail in other sections of the labeling:

• Hemorrhage [see Warnings and Precautions]
• Infections [see Warnings and Precautions]
• Cytopenias [see Warnings and Precautions]
• Hypertension [see Warnings and Precautions]
• Second Primary Malignancies [see Warnings and Precautions]
• Tumor Lysis Syndrome [see Warnings and Precautions]

Clinical Trials Experience: Because clinical trials are conducted under widely variable conditions, adverse event rates observed in clinical trials of a drug cannot be directly compared with rates of clinical trials of another drug and may not reflect the rates observed in practice.

Mantle Cell Lymphoma: The data described below reflect exposure to IMBRUVICA in a clinical trial that included 111 patients with previously treated MCL treated with 560 mg daily with a median treatment duration of 8.3 months.

The most commonly occurring adverse reactions (≥ 20%) were thrombocytopenia, diarrhea, neutropenia, anemia, fatigue, musculoskeletal pain, peripheral edema, upper respiratory tract infection, nausea, bruising, dyspnea, constipation, rash, abdominal pain, vomiting and decreased appetite (see Tables 1 and 2).

Most of the common Grade 3 or 4 non-hematological adverse reactions (≥ 5%) were pneumonia, abdominal pain, atrial fibrillation, diarrhea, fatigue, and skin infections.

Fatal and serious cases of renal failure have occurred with IMBRUVICA therapy. Increases in creatinine 1.5 to 3 times the upper limit of normal occurred in 9% of patients.

Adverse reactions from the MCL trial (N=111) using single agent IMBRUVICA 560 mg daily occurring at a rate of ≥ 10% are presented in Table 1.

Table 1: Non-Hematologic Adverse Reactions in ≥ 10% of Patients with MCL (N=111)

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Diarrhea</td>
<td>51</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
<td>31</td>
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</tr>
<tr>
<td></td>
<td>Constipation</td>
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<td>0</td>
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<td></td>
<td>Abdominal pain</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Stomatitis</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Dyspepsia</td>
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<tr>
<td>Infections and infestations</td>
<td>Upper respiratory tract infection</td>
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<tr>
<td></td>
<td>Urinary tract infection</td>
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<td>3</td>
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<tr>
<td></td>
<td>Pneumonia</td>
<td>14</td>
<td>7</td>
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<tr>
<td></td>
<td>Skin infections</td>
<td>14</td>
<td>5</td>
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<tr>
<td></td>
<td>Sinusitis</td>
<td>13</td>
<td>1</td>
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<tr>
<td>General disorders and administration site conditions</td>
<td>Fatigue</td>
<td>41</td>
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<tr>
<td></td>
<td>Peripheral edema</td>
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<td></td>
<td>Pyrexia</td>
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<tr>
<td></td>
<td>Asthenia</td>
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<td>3</td>
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<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Bruising</td>
<td>30</td>
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</tr>
<tr>
<td></td>
<td>Rash</td>
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<td></td>
<td>Petechiae</td>
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<td>Musculoskeletal and connective tissue disorders</td>
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<td>1</td>
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<tr>
<td></td>
<td>Muscle spasms</td>
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<td></td>
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<td></td>
<td>Cough</td>
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<td>Metabolism and nutrition disorders</td>
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<td></td>
<td>Dehydration</td>
<td>12</td>
<td>4</td>
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<td>Nervous system disorders</td>
<td>Dizziness</td>
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<tr>
<td></td>
<td>Headache</td>
<td>13</td>
<td>0</td>
</tr>
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</table>
Ten patients (8%) discontinued treatment due to adverse reactions in the trial (N=111). The most frequent adverse reaction leading to treatment discontinuation was subdural hematoma (1.8%). Adverse reactions leading to dose reduction occurred in 14% of patients. Patients with MCL who develop lymphocytosis greater than 400,000/mL have developed intracranial hemorrhage, lethargy, gait instability, and headache. However, some of these cases were in the setting of disease progression. Forty percent of patients had elevated uric acid levels on study including 13% with values above 10 mg/dL. Adverse reaction of hyperuricemia was reported for 15% of patients.

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: The data described below reflect exposure in one single-arm, open-label clinical trial and three randomized controlled clinical trials in patients with CLL/SLL (N=1278 total and N=668 patients exposed to IMBRUVICA). Study 1 included 51 patients with previously treated CLL/SLL. Study 2 included 391 randomized patients with previously treated CLL or SLL who received single agent IMBRUVICA or ofatumumab. Study 3 included 269 randomized patients 65 years or older with treatment naive-CLL or SLL who received single agent IMBRUVICA or chlorambucil and Study 4 included 578 randomized patients with previously treated CLL or SLL who received IMBRUVICA in combination with bendamustine and rituximab or placebo in combination with bendamustine and rituximab.

The most commonly occurring adverse reactions in Studies 1, 2, 3 and 4 in patients with CLLS/L (N=51) in Study 1 (continued) and at least 2% greater in the IMBRUVICA treated arm were neutropenia, thrombocytopenia, anemia, diarrhea, musculoskeletal pain, nausea, rash, bruising, fatigue, pyrexia and hemorrhage. Four to 10 percent of patients receiving IMBRUVICA in Studies 1, 2, 3 and 4 discontinued treatment due to adverse reactions. These included pneumonia, hemorrhage, atrial fibrillation, rash and neutropenia (1% each). Adverse reactions leading to dose reduction occurred in approximately 6% of patients.

Study 3: Adverse reactions and laboratory abnormalities from the CLL/SLL trial (N=51) using single agent IMBRUVICA 420 mg daily in patients with previously treated CLLS/L occurring at a rate of ≥ 10% with a median duration of 15.6 months are presented in Tables 3 and 4.

Table 3: Non-Hematologic Adverse Reactions in ≥ 10% of Patients with CLLS/L (N=51) in Study 1

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
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<td>Gastrointestinal disorders</td>
<td>Diarrhea</td>
<td>59</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Constipation</td>
<td>22</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
<td>20</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Stomatitis</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Dysepsia</td>
<td>12</td>
<td>0</td>
</tr>
</tbody>
</table>

Infections and infestations

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory tract infection</td>
<td>47</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Sinusitis</td>
<td>22</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Skin infection</td>
<td>16</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>12</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>12</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

General disorders and administration site conditions

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>33</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>24</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Peripheral edema</td>
<td>22</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Asthenia</td>
<td>14</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Chills</td>
<td>12</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Skin and subcutaneous tissue disorders

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruising</td>
<td>51</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>25</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Petechiae</td>
<td>16</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Respiratory, thoracic and mediastinal disorders

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oropharyngeal pain</td>
<td>14</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>12</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Musculoskeletal and connective tissue disorders

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Musculoskeletal pain</td>
<td>25</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Arthralgia</td>
<td>24</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>18</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Nervous system disorders

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dizziness</td>
<td>20</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>18</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
Subjects with multiple events for a given ADR term are counted only once for each ADR term.
The body system and individual ADR terms are sorted in descending frequency order in the IMBRUVICA arm.
* Includes multiple ADR terms

Table 6: Treatment-Emergent* Decrease of Hemoglobin, Platelets, or Neutrophils in Patients with CLL/SLL in Study 2

<table>
<thead>
<tr>
<th>Body System</th>
<th>IMBRUVICA (N=195)</th>
<th>Ofatumumab (N=191)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades (%)</td>
<td>Grade 3 or 4 (%)</td>
</tr>
<tr>
<td>Neutrophils Decreased</td>
<td>51</td>
<td>23</td>
</tr>
<tr>
<td>Platelets Decreased</td>
<td>52</td>
<td>5</td>
</tr>
<tr>
<td>Hemoglobin Decreased</td>
<td>36</td>
<td>0</td>
</tr>
</tbody>
</table>

* Based on laboratory measurements per IWCLL criteria.

Table 7: Adverse Reactions Reported in ≥ 10% of Patients and at Least 2% Greater in the IMBRUVICA Treated Arm in Patients with CLL/SLL in Study 3

<table>
<thead>
<tr>
<th>Body System Adverse Reaction</th>
<th>IMBRUVICA (N=136)</th>
<th>Chlorambucil (N=132)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades (%)</td>
<td>Grade 3 or 4 (%)</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>42</td>
<td>4</td>
</tr>
<tr>
<td>Stomatitis*</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>36</td>
<td>4</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>16</td>
<td>1</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>Eye Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry eye</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>Lacrimation increased</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Vision blurred</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Visual acuity reduced</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash*</td>
<td>21</td>
<td>4</td>
</tr>
<tr>
<td>Bruising*</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin infection*</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>Pneumonia*</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>Urinary tract infections</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>22</td>
<td>0</td>
</tr>
<tr>
<td>Cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>19</td>
<td>1</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>17</td>
<td>0</td>
</tr>
</tbody>
</table>

The body system and individual ADR terms are sorted in descending frequency order in the IMBRUVICA arm.
* Includes multiple ADR terms

Study 4: Adverse reactions described below in Table 8 reflect exposure to IMBRUVICA + BR with a median duration of 14.7 months and exposure to placebo + BR with a median of 12.8 months in Study 4 in patients with previously treated CLL/SLL.

Table 8: Adverse Reactions Reported in at Least 10% of Patients and at Least 2% Greater in the IMBRUVICA Arm in Patients with CLL/SLL in Study 4

<table>
<thead>
<tr>
<th>Body System Adverse Reaction</th>
<th>IMBRUVICA + BR (N=287)</th>
<th>Placebo + BR (N=287)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades (%)</td>
<td>Grade 3 or 4 (%)</td>
</tr>
<tr>
<td>Blood and lymphatic system disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutropenia*</td>
<td>66</td>
<td>61</td>
</tr>
<tr>
<td>Thrombocytopenia*</td>
<td>34</td>
<td>16</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash*</td>
<td>32</td>
<td>4</td>
</tr>
<tr>
<td>Bruising*</td>
<td>20</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>36</td>
<td>2</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal pain*</td>
<td>29</td>
<td>2</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>12</td>
<td>&lt;1</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>25</td>
<td>4</td>
</tr>
<tr>
<td>Vascular Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemorrhage*</td>
<td>19</td>
<td>2</td>
</tr>
<tr>
<td>Hypertension*</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bronchitis</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>Skin infection*</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>10</td>
<td>2</td>
</tr>
</tbody>
</table>

The body system and individual ADR terms are sorted in descending frequency order in the IMBRUVICA arm.
* Includes multiple ADR terms

<1 used for frequency above 0 and below 0.5%

Atrial fibrillation of any grade occurred in 7% of patients treated with IMBRUVICA + BR and 2% of patients treated with placebo + BR. The frequency of Grade 3 and 4 atrial fibrillation was 3% in patients treated with IMBRUVICA + BR and 1% in patients treated with placebo + BR.

The most commonly occurring adverse reactions in Studies 5 and 6 (≥ 20%) were thrombocytopenia, diarrhea, neutropenia, fatigue, bruising, hemorrhage, anemia, rash, musculoskeletal pain, and nausea.

Nine percent of patients receiving IMBRUVICA across Studies 5 and 6 (≥ 20%) were thrombocytopenia, diarrhea, neutropenia, fatigue, bruising, hemorrhage, anemia, rash, musculoskeletal pain, and nausea.

Study 5: Adverse reactions and laboratory abnormalities described below in Tables 9 and 10 reflect exposure to IMBRUVICA with a median duration of 11.7 months in Study 5.
IMBRUVICA® (ibrutinib) capsules

Table 9: Non-Hematologic Adverse Reactions in ≥ 10% in Patients with WM in Study 5 (N=63)

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Diarrhea</td>
<td>37</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Stomatitis*</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Gastroesophageal reflux disease</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Rash*</td>
<td>22</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Bruising*</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Pruritus</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>General disorders and administrative site conditions</td>
<td>Fatigue</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Muscle spasms</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Arthropathy</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Upper respiratory tract infection</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sinusitis</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Pneumonia*</td>
<td>14</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Skin infection*</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Epistaxis</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Cough</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Dizziness</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Headache</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Neoplasms benign, malignant, and unspecified (including cysts and polyps)</td>
<td>Skin cancer*</td>
<td>11</td>
<td>0</td>
</tr>
</tbody>
</table>

The body system and individual ADR preferred terms are sorted in descending frequency order.

* Includes multiple ADR terms.

Table 10: Treatment-Emergent* Decrease of Hemoglobin, Platelets, or Neutrophils in Patients with WM in Study 5 (N=63)

<table>
<thead>
<tr>
<th>Body System</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Diarrhea</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Stomatitis*</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Gastroesophageal reflux disease</td>
<td>13</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Rash*</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>Bruising*</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Pruritus</td>
<td>11</td>
</tr>
<tr>
<td>General disorders and administrative site conditions</td>
<td>Fatigue</td>
<td>21</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Muscle spasms</td>
<td>21</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Upper respiratory tract infection</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Sinusitis*</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Bronchitis</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Pneumonia*</td>
<td>11</td>
</tr>
</tbody>
</table>

Percent of Patients (N=63)

<table>
<thead>
<tr>
<th>Problem</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelets Decreased</td>
<td>43</td>
<td>13</td>
</tr>
<tr>
<td>Neutrophils Decreased</td>
<td>44</td>
<td>19</td>
</tr>
<tr>
<td>Hemoglobin Decreased</td>
<td>13</td>
<td>8</td>
</tr>
</tbody>
</table>

* Based on laboratory measurements.

Study 6: Adverse reactions and laboratory abnormalities described below in Tables 11 and 12 reflect exposure to IMBRUVICA with a median duration of 11.6 months in Study 6.

Table 11: Non-Hematologic Adverse Reactions in ≥ 10% in Patients with MZL in Study 6 (N=63)

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Diarrhea</td>
<td>43</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
<td>25</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Dyspepsia</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Stomatitis*</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Constipation</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain Upper</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>General disorders and administrative site conditions</td>
<td>Fatigue</td>
<td>24</td>
<td>2</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Musculoskeletal pain*</td>
<td>40</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Arthralgia</td>
<td>24</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Muscle spasms</td>
<td>19</td>
<td>3</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Upper respiratory tract infection</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sinusitis*</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Bronchitis</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Pneumonia*</td>
<td>11</td>
<td>10</td>
</tr>
</tbody>
</table>

The body system and individual ADR preferred terms are sorted in descending frequency order.

* Includes multiple ADR terms.

Table 12: Treatment-Emergent* Decrease of Hemoglobin, Platelets, or Neutrophils in Patients with MZL in Study 6 (N=63)

<table>
<thead>
<tr>
<th>Problem</th>
<th>All Grades (%)</th>
<th>Grade 3 or 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelets Decreased</td>
<td>49</td>
<td>6</td>
</tr>
<tr>
<td>Neutrophils Decreased</td>
<td>43</td>
<td>13</td>
</tr>
<tr>
<td>Hemoglobin Decreased</td>
<td>22</td>
<td>13</td>
</tr>
</tbody>
</table>

* Based on laboratory measurements.

Additional Important Adverse Reactions: Diarrhea: Diarrhea of any grade occurred at a rate of 43% (range, 36% to 59%) of patients treated with IMBRUVICA. Grade 2 diarrhea occurred in 9% (range, 3% to 14%) and Grade 3 in 3% (range, 0 to 5%) of patients treated with IMBRUVICA. The median time to first onset of any grade diarrhea was 10 days (range, 0 to 627), of Grade 2 was 39 days (range, 1 to 719) and of Grade 3 was 74 days (range, 3 to 627). Of the patients who reported diarrhea, 82% had complete resolution, 1% had partial improvement and 17% had no reported improvement at time of analysis. The median time from onset to resolution or improvement of any grade diarrhea was 5 days (range, 1 to 418), and was similar for Grades 2 and 3. Less than 1% of patients discontinued IMBRUVICA due to diarrhea.

Visual Disturbance: Blurred vision and decreased visual acuity of any grade occurred in 10% of patients treated with IMBRUVICA (8% Grade 1, 2% Grade 2). The median time to first onset was 85 days (range, 1 to 414 days). Of the patients with visual disturbance, 61% had complete resolution, 1% had partial improvement and 38% had no reported improvement at time of analysis. The median time from onset to resolution or improvement was 29 days (range, 1 to 335 days).

Postmarketing Experience: The following adverse reactions have been identified during post-approval use of IMBRUVICA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Hepatobiliary disorders: hepatic failure

Respiratory disorders: interstitial lung disease

Metabolic and nutrition disorders: tumor lysis syndrome [see Warnings & Precautions]

Immune system disorders: anaphylactic shock, angioedema, urticaria

Skin and subcutaneous tissue disorders: Stevens-Johnson Syndrome (SJS), onycholysis

DRUG INTERACTIONS

CYP3A inhibitors: Ibrutinib is primarily metabolized by cytochrome P450 enzyme 3A (CYP3A). In healthy volunteers, co-administration of ketoconazole, a strong CYP3A inhibitor, increased Cmax and AUC of ibrutinib by 29- and 35-fold, respectively. The highest ibrutinib dose evaluated in clinical trials was 12.5 mg/kg (actual doses of 840 – 1400 mg) given for 28 days with single dose AUC values of 1445 ± 869 ng • hr/mL which is approximately 50% greater than steady state exposures seen at the highest indicated dose (560 mg).

Avoid concomitant administration of IMBRUVICA with strong or moderate inhibitors of CYP3A. For strong CYP3A inhibitors used short-term (e.g., antifungals and antibiotics for 7 days or less, e.g., ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin, telithromycin) consider interrupting IMBRUVICA therapy during the duration of inhibitor use. Avoid strong CYP3A inhibitors that are needed chronically. If a moderate CYP3A inhibitor must be used, reduce the IMBRUVICA dose. Patients taking concomitant strong or moderate CYP3A4 inhibitors should be monitored more closely for signs of IMBRUVICA toxicity [see Dosage and Administration (2.4) in Full Prescribing Information].
IMBRUVICA® (ibrutinib) capsules

Avoid grapefruit and Seville oranges during IMBRUVICA treatment, as these contain moderate inhibitors of CYP3A [see Dosage and Administration (2.4), and Clinical Pharmacology (12.3) in Full Prescribing Information].

CYP3A Inducers: Administration of IMBRUVICA with rifampin, a strong CYP3A inducer, decreased ibrutinib Cmax and AUC by approximately 13- and 10-fold, respectively.

Avoid concomitant use of strong CYP3A inducers (e.g., carbamazepine, rifampin, phenytoin, and St. John’s Wort). Consider alternative agents with less CYP3A induction [see Clinical Pharmacology (12.3) in Full Prescribing Information].

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary: IMBRUVICA, a kinase inhibitor, can cause fetal harm based on findings from animal studies. In animal reproduction studies, administration of ibrutinib to pregnant rats and rabbits during the period of organogenesis at exposures up to 2-20 times the clinical doses of 420-560 mg daily produced embryofetal toxicity including malformations [see Data]. If IMBRUVICA is used during pregnancy or if the patient becomes pregnant while taking IMBRUVICA, the patient should be apprised of the potential hazard to the fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Animal Data: Ibrutinib was administered orally to pregnant rats during the period of organogenesis at doses of 10, 40 and 80 mg/kg/day. Ibrutinib at a dose of 80 mg/kg/day was associated with visceral malformations (heart and major vessels) and increased resorptions and post-implantation loss. The dose of 80 mg/kg/day in rats is approximately 14 times the exposure (AUC) in patients with MCL and 20 times the exposure in patients with CLL/SLL or WM administered the dose of 560 mg daily and 420 mg daily, respectively. Ibrutinib at doses of 40 mg/kg/day or greater was associated with decreased fetal weights. The dose of 40 mg/kg/day in rats is approximately 6 times the exposure (AUC) in patients with MCL administered the dose of 560 mg daily. Ibrutinib was also administered orally to pregnant rabbits during the period of organogenesis at doses of 5, 15, and 45 mg/kg/day. Ibrutinib at a dose of 15 mg/kg/day or greater was associated with skeletal variations (fused sternebrae) and ibrutinib at a dose of 45 mg/kg/day was associated with increased resorptions and post-implantation loss. The dose of 15 mg/kg/day in rabbits is approximately 2.0 times the exposure (AUC) in patients with MCL and 2.8 times the exposure in patients with CLL/SLL or WM administered the dose of 560 and 420 mg daily, respectively.

Lactation: Risk Summary: There is no information regarding the presence of ibrutinib or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production.

The development and health benefits of breastfeeding should be considered along with the mother’s clinical need for IMBRUVICA and any potential adverse effects on the breastfed child from IMBRUVICA or from the underlying maternal condition.

Females and Males of Reproductive Potential: Pregnancy Testing: Verify the pregnancy status of females of reproductive potential prior to initiating IMBRUVICA therapy.

Contraception:

Females: Advise females of reproductive potential to avoid pregnancy while taking IMBRUVICA and for up to 1 month after ending treatment. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Males: Advise men to avoid fathering a child while receiving IMBRUVICA, and for 1 month following the last dose of IMBRUVICA.

Pediatric Use: The safety and effectiveness of IMBRUVICA in pediatric patients has not been established.

Geriatric Use: Of the 905 patients in clinical studies of IMBRUVICA, 62% were ≥65 years of age, while 21% were >75 years of age. No overall differences in effectiveness were observed between younger and older patients. Anemia (all grades) and Grade 3 or higher pneumonia occurred more frequently among older patients treated with IMBRUVICA.

Hepatic Impairment: Ibrutinib is metabolized in the liver. In a hepatic impairment study, data showed an increase in ibrutinib exposure. Following single dose administration, the AUC of ibrutinib increased 2.7-, 8.2- and 9.8-fold in subjects with mild (Child-Pugh class A), moderate (Child-Pugh class B), and severe (Child-Pugh class C) hepatic impairment compared to subjects with normal liver function.

The safety of IMBRUVICA has not been evaluated in cancer patients with mild to severe hepatic impairment by Child-Pugh criteria.

Monitor patients for signs of IMBRUVICA toxicity and follow dose modification guidance as needed. It is not recommended to administer IMBRUVICA to patients with moderate or severe hepatic impairment (Child-Pugh class B and C) [see Dosage and Administration (2.5) and Clinical Pharmacology (12.3) in Full Prescribing Information].

Plasmanpheresis: Management of hyperviscosity in WM patients may include plasmanpheresis before and during treatment with IMBRUVICA. Modifications to IMBRUVICA dosing are not required.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

- Hemorrhage: Inform patients of the possibility of bleeding, and to report any signs or symptoms (severe headache, blood in stools or urine, prolonged or uncontrolled bleeding). Inform the patient that IMBRUVICA may need to be interrupted for medical or dental procedures [see Warnings and Precautions].
- Infections: Inform patients of the possibility of serious infection, and to report any signs or symptoms associated with this event to their healthcare provider for evaluation [see Warnings and Precautions].
- Atrial fibrillation: Counsel patients to report any signs of palpitations, lightheadedness, dizziness, fainting, shortness of breath, and chest discomfort [see Warnings and Precautions].
- Hypertension: Inform patients that high blood pressure has occurred in patients taking IMBRUVICA, which may require treatment with anti-hypertensive therapy [see Warnings and Precautions].
- Second primary malignancies: Inform patients that other malignancies have occurred in patients who have been treated with IMBRUVICA, including skin cancers and other carcinomas [see Warnings and Precautions].
- Tumor lysis syndrome: Inform patients of the potential risk of tumor lysis syndrome and to report any signs and symptoms associated with this event to their healthcare provider for evaluation [see Warnings and Precautions].
- Embryo-fetal toxicity: Advise women of the potential hazard to a fetus and to avoid becoming pregnant during treatment and for 1 month after the last dose of IMBRUVICA [see Warnings and Precautions].
- Inform patients to take IMBRUVICA orally once daily according to their physician’s instructions and that the capsules should be swallowed whole with a glass of water without being opened, broken, or chewed at approximately the same time each day [see Dosage and Administration (2.1) in Full Prescribing Information].
- Advise patients that in the event of a missed daily dose of IMBRUVICA, it should be taken as soon as possible on the same day with a return to the normal schedule the following day. Patients should not take extra capsules to make up the missed dose [see Dosage and Administration (2.6) in Full Prescribing Information].
- Advise patients of the common side effects associated with IMBRUVICA [see Adverse Reactions]. Direct the patient to a complete list of adverse drug reactions in PATIENT INFORMATION.
- Advise patients to inform their health care providers of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, and herbal products [see Drug Interactions].
- Advise patients that they may experience loose stools or diarrhea, and should contact their doctor if their diarrhea persists. Advise patients to maintain adequate hydration [see Adverse Reactions].

Active ingredient made in China.

Distributed and Marketed by: Pharmacyclics LLC Sunnyvale, CA USA 94085

and Marketed by: Janssen Biotech, Inc. Horsham, PA USA 19044

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leadership, translate into operational implementation, and lead to a shift from the physician's traditional mindset of “If I don't do it myself, it won't get done or done right,” to comfort with delegating tasks to other care team members qualified to perform them. This change is at the core of the patient-centered medical home model that several CAPG practices have adopted.

Transforming practices into models that support physician wellness demands adequate resources and a sizable capital investment. The return on investment and business case both exist. Moreover, physicians must lead and advocate for needed resources, serving as leading examples in our clinics to adopt practice transformation programs and processes into our daily routines. We need to change the culture in which we have been delivering healthcare because it no longer works. To do so requires data and technology to effectively monitor and improve our processes by creating a robust digital infrastructure and increasing data velocity among providers.

In a sense, we need to deploy a “care management army” because sometimes it takes a village to manage population health and perform predictive modeling to optimize health outcomes. We need to place greater value in performance measurement and quality improvement, including advocating that provider experience be valued as a key metric, whether in evaluating healthcare organizations (insurers, hospitals, physician groups) or initiatives that potentially add to the workload and time demands of physicians.

In short, practice transformation requires four main components:

1. Executive leadership
2. Technology
3. Care management army
4. Performance measurement and quality improvement

At CAPG, we believe in our doctors. We believe they’re the future leaders, and we continue to advocate for the fulfillment of the profession, as we educate and provide our physician organizations with the necessary tools to carry out the honorable work of caring for patients. We are here to develop resiliency within physicians and their practices by improving the work environment for the entire care team. In doing so, we hope to bring light and solutions to the gnawing issue of physician burnout.
by developing programs that give agency to physicians to make the practice of medicine more rewarding and fulfilling.

You can find more information on CAPG’s Practice Transformation Program at capg.org/transformation and on CAPG’s Educational Series at capg.org/qpp.

Amy Nguyen Howell, MD, MBA, FAAFP, is Chief Medical Officer for CAPG.

13. David Margolius and Thomas Bodenheimer, Transforming Primary Care: From Past Practice To The Practice Of The Future, Health Affairs, May 2010 http://content.healthaffairs.org/content/29/5/779
Table 1. Outcomes at end of pilot

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number/Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of identified screening candidates (SCs)</td>
<td>219 (100 percent)</td>
</tr>
<tr>
<td>Number of SCs who followed up with a PCP or GI</td>
<td>119 (54 percent)</td>
</tr>
<tr>
<td>Number of SCs who completed screening</td>
<td>69 (32 percent)</td>
</tr>
<tr>
<td>Completed screenings: type of screening tests</td>
<td></td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>28 (41 percent)</td>
</tr>
<tr>
<td>Flex sigmoidoscopy</td>
<td>0 (0 percent)</td>
</tr>
<tr>
<td>FOBT</td>
<td>41 (59 percent)</td>
</tr>
<tr>
<td>Number of SCs who had polyps removed</td>
<td>17</td>
</tr>
<tr>
<td>Number of SCs with positive FOBT tests</td>
<td>0</td>
</tr>
<tr>
<td>Number of SCs diagnosed with colorectal cancer</td>
<td>0</td>
</tr>
</tbody>
</table>

Although it is difficult to attribute the increase in average screening rate to any single intervention, information gathered through formal surveys after the pilot completion gives us some clues. First, pilot site providers and staff reported that the outreach tools were highly effective at increasing patient awareness and activating them to get screened. Providers also reported having more frequent screening conversations with patients during the pilot.

Second, patients reported that the outreach tools were more effective at motivating them to receive screening than information they had received in the past. Finally, given the limited use of FOBTs in pilot sites (from January through June 2016, only 0 percent to 2 percent of patients completed FOBTs), it stands to reason that the availability and promotion of the FOBT during the pilot may have been one of the key drivers in increasing screening rates.

LESSONS LEARNED

We also attribute the higher screening rate in part to best practices that were built into the program. Those practices, and the valuable operational lessons that emerged, include:

**Best practice 1**: Establish measurable goals. At the three pilot sites, we sought to bring screening rates closer to the NCCRT goal of 80 percent of eligible patients screened by 2018. This was a patient-centered, aspirational goal, rather than one based on meeting requirements of a quality measure.
Best practice 2: Provide screening candidates with all available testing options. At-home testing kits for patients who did not want to complete a colonoscopy removed a significant barrier for difficult-to-engage patients, leading to higher screening rates.

Best practice 3: Analyze workflows and establish formal processes. Prior to this pilot, we did not have oversight over the patient screening journey (i.e., identifying eligible patients and following them through to completion of screening). This exercise enabled us to codify a workflow, integrate it into each office’s processes, and close a fundamental gap in quality of care.

Best practice 4: Use a centralized patient navigator. By moving the burden of patient outreach and follow-up to the central office, provider staff could devote more time to patient care, allowing us to use our patient navigator to fullest capacity.

Through a concerted effort to motivate difficult-to-engage patients, colorectal cancer screening rates meaningfully improved by the end of the pilot. We believe that the Love Your Colon program tools and suggestions for workflow optimization effectively contributed to this outcome. Genentech plans to expand the program tools from the pilot into additional Love Your Colon program resources.

The activities we undertook are applicable across health systems. Our next step will be to test this program at other sites, removing a few of the manual outreach steps that would cause significant hurdles to scalability.

Mohini Sinha, MD, is Quality Medical Director at Monarch HealthCare in Irvine, California.

References
Managing Cost of Care: CQC will launch **Cost of Care Action Community**, a 15-month program to address drivers of utilization and cost. Collaborative activities include a pre-work diagnostic to help participants target opportunities, in-person learning sessions with experts to help teams execute on targeted priorities, dedicated coaches to support teams and troubleshoot barriers, and supplemental webinars to learn more about promising practices from the field. For more information, contact Sandy Newman, snewman@calquality.org.

Practice Transformation: CQC is one of 29 Practice Transformation Networks selected by the Centers for Medicare & Medicaid Services (CMS) as part of its Transforming Clinical Practice Initiative. CQC’s **Practice Transformation Initiative** provides coaching and peer-to-peer network support for provider organization leaders and funding to hire practice coaches to work intensively with practices. The network also provides data feedback on a set of Triple Aim measures common across value-based payment programs in Medicare, commercial, and Medicaid lines of business, and supports provider organizations to strengthen internal reporting systems to practices. For more information, contact Diane Stewart, dstewart@calquality.org.

CQC also offers a variety of learning opportunities on such topics as medication adherence and motivational interviewing. Keep in touch by visiting www.calquality.org.

**Diane Stewart is Senior Director and Dr. Bart Wald is Medical Director at the California Quality Collaborative.**
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With Brown & Toland’s experience across numerous value-based accountable care projects for HMO and PPO patients, we have fine-tuned the formula for delivering high-quality, cost-effective care while succeeding in risk-adjustment payments models. One such example includes our participation in the CMS Pioneer Accountable Care program, which generated more than $15 million in savings for the care of 17,000 patients.

It is accountable care experiences like this that will help physician-led groups and their partners find the winning formulas for success in the new payment models to come.

To learn more about Brown & Toland Physicians and how we have achieved success through value-based payment models, please visit our website at brownandtoland.com.