COVID-19 IMBALANCE
Payers Up, Providers Down — And Where Things Stand Now

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Managed Healthcare Executive.com
A Comprehensive Approach to Long-Term Narcolepsy Management Is Important for Patients During Their Journey¹⁻³

- Studies show that patients with narcolepsy are more likely to have certain comorbid medical conditions than those without narcolepsy⁴⁻⁶,a

- Narcolepsy is associated with substantial medical and economic burden, which may include emergency room visits, hospital visits, and/or absenteeism⁷,⁸,a

The payer-provider seesaw

COVID-19 has not been an equal opportunity pandemic. It is a now-familiar fact that the disease has had a disproportionate effect on older people and Black Americans. And, as we discuss in the cover story of this issue, the financial experience of payers and providers have been on a teeter-totter of opposites.

With the abrupt interruption of the provision of routine healthcare that started in mid-March and continued for months afterward, payers had few claims to pay. Meanwhile, premiums dollars continued to flow in. The result is exactly what one would expect: gigantic second quarter profits for-profit insurers and surpluses for the not-for-profit insurers (the many Blues plans, for example). Just one example: UnitedHealth posted net income of $6.6 billion in the second quarter, double the $3.3 billion in net income the company realized during the second quarter of last year.

Now let’s cross to the provider side of the street. Yes, there have been hotspots where hospitals and dedicated healthcare workers have been overwhelmed. But, in general, that same absence of care that reduced payer expenses meant the disappearance of revenue for providers. Kaufman Hall’s August “flash report” on hospital finances and patient volume shows that operating margins for the 800 hospitals in its representative sample were down 96% for the first half of 2020 relative to the first half of last year.

But the imbalance has started to even out. Many payers have advanced payments to providers and extended various forms of premium relief to employers and individuals. As Georgetown’s Sabrina Corlette explains, the premium relief is motivated, in part, by the fact that some of those profits and surpluses were going back to their customers anyway because of the ACA’s medical-loss ratio (MLR) rules. Premium relief now generates good will and may lower the MLR payments later.

And things are looking up for many providers. Routine healthcare is coming back. The Coronavirus Aid, Relief and Economic Security (CARES) Act meant an infusion of funds; several of Kaufman Hall’s bleak numbers don’t look so bad once CARES Act money is added in.

The payer-provider teeter-totter isn’t going away, but there may be less up-and-down to it in the future. Some proponents of value-based care see the COVID-19 pandemic as acting as an unintended accelerant for their cause because providers with value-based contracts have fared better than those still dependent on fee for service. They say to look for opportunity in a crisis. Maybe COVID-19 can usher in a new equilibrium between payers and providers that is less of a seesaw and more of a balance beam.

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Transitioning to value-based care requires participants to rethink how to deliver and compensate for healthcare. Under the current system, healthcare is delivered and paid for as incremental units of care by individual practitioners — the individual doctor’s visit, for example, or a procedure. In contrast, a value-based care system recasts the “unit” of focus as the individual patient and includes all the care that patient requires (i.e., not simply the care one provider delivers). This means that a provider must be thoughtful and clear, not only about the care they themselves deliver, but about all the up- and downstream care that others are giving to that patient. It means understanding how care affects a patient’s experience and outcome, across the full continuum of care, inside and outside of one’s particular office.

This holistic approach to care leads to the natural inclusion of a variety of providers, extending from the traditional (such as physicians, nurses and therapists) to the nontraditional (such as doulas, nutritionists and mindfulness instructors, among others). Value-based care is team-based care, and all providers must work collectively to ensure the holistic care of the patient.

But most commercial insurance companies design benefit plans within the confines of the prevailing fee-for-service methodology. Within this system, providers are reimbursed for each procedure, test and treatment, regardless of patient outcome. A low-cost or nontraditional option will generally not be considered, even if the patient would benefit, because it’s not a covered benefit and so will not be paid by the health plan. Value-based care models, on the other hand, create an opportunity to really reconsider what has the biggest impact on a patient’s outcomes, and not only what is or is not a covered benefit.

This leads to important considerations of compensation. Under value-based care, payment is based on patient outcomes and the efficient use of resources, not on any particular increment of care. Therefore, each stakeholder must understand all the care that is required and make good choices about who to work with across the continuum of care.

Consider paying for a car service. A commercial health plan paying a fee for service probably would not cover the cost of a car service to take a member to a healthcare appointment. The car service is not “care” in the traditional sense, but getting people to the doctor’s office can have a major influence on their outcomes. Under value-based care, outcomes becomes paramount. There is also new emphasis put on evidence about quality and cost-effectiveness because both quality and cost of care factor into what providers are paid. Many nontraditional practices, unlike traditional medical procedures, are low cost and high impact.

The need for collaboration and team-oriented decision-making extends beyond the continuum of providers. Payers bring valuable experience and data to the table; health plans maintain longitudinal claims data. But most health plans are large, bureaucratic-to-their-bones organizations, so the transition to value-based care payment is often slow and halting. Clinicians who approach payers with lofty ideals, but no understanding of their limitations, are likely to wind up frustrated. Likewise, technology vendors wooing payers with dazzling innovations for the care and payment system will probably be turned away if they are unable to show support of providers (preferably in the payer’s market).

Most payers today are interested in engaging in value-based care models. However, they cannot do it alone, and no one would want them to. But providers and payers have been more foe than friend traditionally. It is only when fists unclench and the focus shifts to what each side brings to the mix that real change can occur.

Value-based care requires collective and comprehensive planning and a healthy respect for each other’s prospective partners in care delivery. Throw away your need to solve everything. Invite some prospective partners to brainstorm ideas that are outside the norm. What emerges may be new ways to create outstanding experiences and outcomes for your patients, all at a surprisingly lower cost.

Lili Brillstein, M.P.H., is a nationally recognized expert on value-based care and the CEO of BCollaborative, a healthcare consulting company.

Value-based care: Rethink, unclench, invite
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- Do not connect items that are not specified as part of the system.
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- Use only INOMAX, pharmaceutical grade NO/N₂.

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INOMAX® (nitric oxide gas)
Brief Summary of Prescribing Information

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Treatment of Hypoxic Respiratory Failure
INOmax® is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilator support and other appropriate agents.

CONTRAINDICATIONS
INOmax is contraindicated in neonates dependent on right-to-left shunting of blood.

WARNINGS AND PRECAUTIONS

Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation
Wean from INOmax. Abrupt discontinuation of INOmax may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. Signs and symptoms of Rebound Pulmonary Hypertension Syndrome include hypoxemia, systemic hypotension, bradycardia, and decreased cardiac output. If Rebound Pulmonary Hypertension occurs, reinstate INOmax therapy immediately.

Hypoxemia from Methemoglobinemia
Nitric oxide combines with hemoglobin to form methemoglobin, which does not transport oxygen. Methemoglobin levels increase with the dose of INOmax; it can take 8 hours or more before steady-state methemoglobin levels are attained. Monitor methemoglobin and adjust the dose of INOmax to optimize oxygenation.

If methemoglobin levels do not resolve with decrease in dose or discontinuation of INOmax, additional therapy may be warranted to treat methemoglobinemia.

Airway Injury from Nitrogen Dioxide
Nitrogen dioxide (NO₂) forms in gas mixtures containing NO and O₂. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO₂ concentration, or if the NO₂ concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO₂ analyzer should be recalibrated. The dose of INOmax and/or FI O₂ should be adjusted as appropriate.

Worsening Heart Failure
Patients with left ventricular dysfunction treated with INOmax may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOmax while providing symptomatic care.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOmax doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOmax, a result adequate to exclude INOmax mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOmax and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOmax and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOmax than on placebo) was hypotension (14% vs. 11%).

Based upon post-marketing experience, accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

DRUG INTERACTIONS

Nitric Oxide Donor Agents
Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.

OVERDOSAGE

Overdosage with INOmax is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO₂. Elevated NO₂ may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO₂ levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

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A bout six million Americans are currently living with Alzheimer’s disease, and it is now the sixth leading cause of death in the U.S. According to several estimates, the number of Americans living with the condition will almost double by 2050, partly because of the demographic bulge of baby boomers entering their oldest years.

Andrea Pfeifer, Ph.D., CEO and co-founder of AC Immune, a Swiss biotech company that has several Alzheimer’s treatments in development, says dementia is one of the greatest challenges in healthcare.

“Globally, there is a new case of dementia every three seconds, adding up to around 50 million people worldwide, and the global cost of dementia stands at about $1 trillion — and we still don’t have an effective treatment or cure.”

By some accounts, the cupboard is bare because Alzheimer’s researchers have been going after the wrong target. For years, the prevailing theory about the disease has implicated accumulation of beta amyloid plaques in the brain as a primary cause. But agents targeting beta amyloid have fizzled in clinical trials. Researchers — and drug developers — have been forced to reconsider the hypothesis.

Mesfin Tegenu, M.S., R.Ph., president of PerformRx, a PBM in Philadelphia owned by AmeriHealth Caritas, says researchers are now eyeing other targets for treatment. “One such target is the tau protein, which is believed to be integral in the formation of (neurofibrillary) tangles seen in the brains of individuals with Alzheimer’s disease,” he says. The “tauists” have been debating “beta amyloidians” for decades, and beta amyloidians have had the upper hand until recently, particularly with respect to treatments that made it into clinical trials. But there is new interest in tau as a target and in February of this year, 650 people attended Tau2020 in Washington, D.C., a global conference devoted to “taupathies.”

Agents targeting beta amyloid have fizzled in clinical trials. Researchers — and drug developers — have been forced to reconsider the hypothesis. Biogen’s aducanumab push is occurring against a backdrop of disappointing news this year about monoclonal antibodies that target beta amyloid. Most conspicuously, investigators announced that solanezumab, a monoclonal antibody, had faltered in a late-phase trial. Results showed no improvement in patients in a composite score of four different cognitive tests.

Gantenerumab, an antibody designed to degrade beta amyloid plaques, was tested in the same trial as solanezumab and, like solanezumab, it also didn’t pass muster with respect to the primary
outcome of improved results on cognitive tests. However, other results suggested it still has some promise, and patients in the original trial were invited to participate in an continuing open-label extension.

Jeffrey L. Cummings, M.D., Sc.D., a research professor at the University of Nevada School of Integrated Health Sciences, Las Vegas, and director of the Chambers-Grundy Center for Transformative Neuroscience, says that Alzheimer’s clinical trials over the past five years have shown a “progressive emphasis” on targets other than beta amyloid, including inflammation, synapse and neuronal protection, and vascular factors. Cummings also notes a marked growth in repurposed agents.

Pfeifer, at AC Immune, highlighted semorinemab, an anti-tau antibody that her company is developing in partnership with Genentech, when discussing the products her company has in its pipeline. Later this year, she says, phase 2 data for semorinemab should become available. Pfeifer says the semorinemab data will be the first for an anti-tau therapy for Alzheimer’s from a phase 2 study.

“Tau protein is mostly present in neurons and functions as a component of the cytoskeleton inside the cells and is involved in axonal transport,” Pfeifer explains. “Misfolded tau protein aggregates in AD and other tau-related neurodegenerative diseases (for example, progressive supranuclear palsy, frontotemporal dementia and others). The progression of tau pathology throughout the brain is closely associated with the onset and progression of cognitive decline, underscoring the importance of tau-targeted therapies.”

The beta amyloid versus tau divisions may be fading. Pfeifer says opinion leaders in Alzheimer’s have started to float the idea that combination therapies are going to be needed in much the same way they are used to treat HIV, cancer and other diseases.

“We think this will be the case in Alzheimer’s as well because it is a complex disease with many contributing and potentially causal factors,” says Pfeifer. “As such, it may be difficult for a drug with a mechanism of action focused on a single part of the disease process, such as beta-amyloid plaques, to make a meaningful impact, especially in symptomatic patients.”

This is excellent news for everyone involved in Alzheimer’s research, and hence for AC Immune—every new piece of data we build up as an industry is important for informing the search for a successful treatment,” she continued.

**Anti-beta amyloid not done yet**

Pfeifer sees another development on the horizon: Precision medicine to properly diagnose and treat neurodegenerative diseases, including Alzheimer’s disease. Her company is actively pursuing positron-emission tomography (PET) tracers against multiple relevant targets, including alpha-synuclein and TDP-43, as well as tau.

“Tau may be enjoying a star turn, but Pfeifer says the concept that anti-beta amyloid therapies are most effective in the early stage of the disease, and, in particular, in preclinical AD, is still a valid one.

Her company has several active anti-beta amyloid projects, including an anti-beta amyloid antibody, called crenezumab, and an anti-beta amyloid vaccine, called ACI-24. The re-analyses and potential approval of aducanumab could potentially be highly relevant for those products and the beta amyloid approach in general, notes Pfeifer.

“We will have to wait and see how the FDA responds to Biogen’s filing,” she says.

Keith Loria, a regular contributor to Managed Healthcare Executive®, lives in the Washington, D.C., area.
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Real-world evidence (RWE) is a buzzword, and there’s nothing that American healthcare likes more than the zzzzz of a good buzzword.

But the buzz of RWE has some substance to it. RWE research is changing how medications and medical devices are approved and paid for. It’s nipping at the heels of the randomized clinical trial that remains the standard by which all medical research is judged. And RWE proponents are covetously eyeing the mountains of data that patient Fitbits, Apple watches and other devices could produce.

Last year Pfizer used RWE to win expanded approval for its breast cancer drug Ibrance (palbociclib), adding male breast cancer treatment as an indication. The FDA accepted the analysis of data from electronic health records (EHRs) and medical databases as proof of Ibrance’s efficacy. The growing acceptance of RWE is due, in part, to former FDA commissioner Scott Gottlieb, M.D., who welcomed using data from outside of clinical trials.

Over the past four years, Jeff Morgan, a managing director at Deloitte Consulting LLP, has seen a significant increase in RWE in life sciences. Morgan, who leads Deloitte’s RWE unit, called ConvergeHealth, sees it as part of a trend of people becoming more engaged in their healthcare and the data associated with it. “There [are] a lot more patient data available than ever [before].”

RWE may have some financial advantages for drug developers. Traditional research, anchored in clinical trials, is becoming increasingly expensive. A study published in the March 3, 2020, issue of JAMA investigated the costs of developing 63 of 355 new therapeutic drugs and biologic agents that the FDA approved between 2009 and 2018. The researchers calculated that the research cost per product was $985 million, a figure that includes expenditures on failed trials. Experts debate estimates such as those, and there are always questions about which costs should be included. But no one would question that drug development is an expensive proposition.

Proponents of RWE say it will yield information that is both more targeted and more thorough than the evidence that clinical trials can provide. But that doesn’t mean RWE research is easy to do — or inexpensive, notwithstanding the relative cost of the randomized trial. What’s more, EHRs and insurance claims may contain a wealth of information, but neither are designed for medical research. And if wearable devices were to live up to merely half of their hype, even more data would come pouring into the mix. Collecting, organizing and understanding data requires skill, time and money, and...
many current computer systems just aren’t up to dealing with that data firehose.

**Critical to value-based pricing**

Today RWE is predominantly used by the pharmaceutical industry to help demonstrate a product’s effectiveness to both prescribers and payers when it is used outside a controlled clinical trial. Patients who are enrolled in clinical trials of a drug may differ from those who are prescribed a medication after it has been on the market, notes Morgan. Those patients are often older than the study participants, and they tend to have more comorbidities.

RWE has been used for trial design, trial recruitment and marketing insights, says Dan Riskin, M.D., CEO of Verantos, an RWE consulting company in Menlo Park, California. “None of these uses makes clinical assertions, saying one drug is better than another,” or that treatment with drug A will result in 20% better outcomes, he says. He considers the use of RWE to make clinical assertions as an “advanced use” case, when investigators pull data from multiple sources including EHR unstructured data, wearables, and the like. Advanced RWE might be used to expand indications and provide evidence-based results for use in value-based care, says Riskin, whose company provides these types of services.

A 2018 McKinsey & Co. report on RWE said that pharmaceutical companies have entered a second phase of RWE research that involves using it in a more integrated fashion. Companies have created centralized RWE teams that are often situated in their medical affairs departments. But McKinsey said there is still a problem in the industry of RWE expertise being scattered throughout the companies.

In addition to companies wanting other methods to prove safety and efficacy, payers are eyeing RWE because of drug costs. “The pressure to demonstrate the value of the product is of the highest importance,” says Morgan. “We will see a transformation in the reimbursement model from the traditional price-per-pill model. We’re seeing a lot of adoption and experimentation of value-based pricing.” And RWE research is critical to value-based pricing because it reveals the outcomes a drug produces once it is “in the wild” and on the market, in contrast to the tightly controlled environment of a clinical trial. Many value-based contracts hinge on whether there is a significant difference between the results a drug produced in clinical trials and those it produces in a particular payer’s population.

**Armies of extractors**

The amount of data that can be collected on patients is exploding. In some cases, the quality of the analysis is not keeping pace with the quantity of the data. It was simpler with “old school” RWE that relied on claims data, which Riskin says have their virtues. They’re readily available, and the databases include millions of people. But, he says, “[The data are] not very accurate. [They’re] not very rich.”

The FDA made great strides in collaborating with industry to arrive at an understanding of quality RWE. “If you look at their most recent framework in RWE, data validity, it’s trying to get at what is believable,” Riskin says. It’s a difficult task, he continues, one that requires “rich” data sources that include the narrative sections of doctor reports, representing what he says are 80% of the EHRs. According to Riskin, some large oncology companies are including that narrative data. “It’s rich information but it’s an expensive version of RWE.” The data must be moved and extracted, enriched and then tested for accuracy.

Although medical records data aggregators aren’t new, says Morgan, “we’re seeing a lot of experimentation with unstructured data and how you curate that.” Data curation includes machine learning and natural language processing to extract data from the written or typed narrative. Some organizations hire armies of human abstractors to manually abstract the data, he says. “There is no perfect solution.”

Better data access and formatting would be welcome, but each data set does what it’s supposed to do, says Riskin. “Claims data is perfectly situated for decisions...
on claims reimbursement. It’s not designed to help someone run a study,” he says. Doctor narratives are intended to be a quick reference to the patient’s important problems and what has been done to address them. A researcher would want to know more about the patient’s medical conditions, what was prescribed or tried before, and the doctor’s thought process for choosing one treatment over another.

Data are often messy, but those with expertise in knowing how to control for certain parameters or conditions can arrive at some accurate inferences, Morgan says. But there are plenty of pitfalls. Riskin points to standardized data fields, such as checked boxes, as an example. Consider when patients with cancer or heart failure are asked whether they smoke. If only 10% of smokers accurately mark the box for positive smoking status, is it fair to treat these boxes as valid data, Riskin asks. “I’ve seen entire models made on that one field where an engineer thought it was (accurate) because they checked the box.” But peer reviewed articles show that for conditions such as cancer and heart failure, the rate of filling out that box correctly is less than 50%.

Each type of medical information provides a piece of the puzzle. Morgan says there’s growing interest among RWE researchers in finding ways to link the data sources at the patient level by, for example, matching up claims data and health records that would weave together clinical and economic information. “Those links can also be to national registries and patient-reported outcomes. “This is a situation where advanced RWE has a lot of room to grow,” says Riskin. With so much information available, it has to be done the right way, with a high-quality protocol, institutional review board approval when necessary, and compliance with patient privacy rules.

**Considering quality**

The FDA is still working on its guidance for RWE. A 2018 framework established some ways to evaluate RWE in support of new drug indications or post-approval study requirements, but the agency expects to issue a more complete guidance for RWE in the next year, says Riskin. The guidance will, no doubt, be influential in setting expectations for RWE. Still, researchers, drugmakers, clinicians and payers will probably be battling it out over RWE and the quality of the evidence it produces. Making those assessments may start from the perspective of evaluating studies of variable quality, and determining what is believable and what isn’t, according to Riskin. “(Verantos) put a stake in the ground to decide what we think is believable,” he says of his company. “We are very happy that regulators are now involved. They make it their business to determine what is believable.” For Verantos, a quality RWE study has a protocol measuring data accuracy and ensuring minimum requirements for that accurate measurement. With that, “you can create a high-quality study. You will have to do a lot to achieve that.”

RWE research may vary with the study’s objective. “The FDA’s term is ‘fit for purpose.’ It means that depending on the purpose, that determines what the validity of the data is to be,” says Riskin, noting that the data required for marketing insights are not the same as those required for regulatory purposes.

**Cloud-based, rolling in**

In the next few years, Morgan anticipates a massive shift in use. “There is great promise in these data, which can drive efficiencies in research and development. We can design trials that are more patient-centric, to decrease the burden on patients.”

In addition to EHRs, the data for RWE research will come from daily at-home measurements, such as heart and respiration rates. “It’s just going to help start answering questions that a few years ago you couldn’t answer,” Morgan says. Instead of an EHR providing specific patient information a dozen times a year, or less, at visits, the information could be streaming daily. That will strain current information systems; most are not yet set up to receive this data volume. Healthcare organizations will need to move from on-premise legacy systems to cloud systems.

As cloud-based platforms are continually adopted, the data will be analyzed by more than just data scientists, says Morgan. He explains that data analytics are being democratized by increasingly accessible technology, allowing more stakeholders to work with them.

The future involves providing therapies targeted for an individual’s situation. If a 45-year-old woman has hypertension and a history of diabetes, “I want to know what works well for other people like her,” Riskin says. That may be in the future, but that’s where this is heading, he says.

Deborah Abrams Kaplan is a regular contributor to Managed Healthcare Executive®.
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Alexa Rockenstein
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What a strange time it has been for American healthcare payers and providers. When the nation’s governors issued stay-at-home order and advisories in March and April, routine healthcare came to a grinding halt. Elective procedures were canceled or postponed. Hospitals had created capacity for what many expected to be a huge influx of patients with COVID-19 who could overwhelm their finite supply of hospital beds, intensive care units, respirators and personal protective equipment. In some hotspots and at some hospitals in those hotspots, that influx occurred, and there was another surge of cases in some parts of the country in July. But in other places and for many providers, the COVID-19 pandemic led to a precipitous decline in use and with that drop, a drop in revenue.

About 1.4 million healthcare workers lost their jobs in April. The American Hospital Association said that collectively, the country’s hospitals suffered $200 billion in financial losses because of COVID-19 from the beginning of March through the end of June. Lou Ellen Horwitz, CEO of the Urgent Care Association, says urgent care centers were
a “ghost town” in March and April. Based on its financial and other data from a representative sample of 800 hospitals, Kaufman Hall said that hospital operating margins fell by nearly 300% in April 2020 relative to April 2019. In its August “flash report” on hospitals, the Chicago-based consulting firm said hospital operating margins were down 96% compared with the first seven months of 2019.

Of course, for payers the lack of utilization had just the opposite effect on their finances. By and large, premiums dollars kept on flowing in and claims, and therefore healthcare expenditures, disappeared. As a result, insurers enjoyed huge margins, especially in the second quarter and likely in the third, although probably not as large. Research by Adam Block, Ph.D., an assistant professor of public health at New York Medical College, on the Managed Healthcare Executive website shows that net operating income in the second quarter of this year had increased by an average of 136.7% relative to the second quarter of 2019 for five publicly traded insurers (UnitedHealth Group, Anthem, Cigna, Centene Corporation and Molina Healthcare).

“It makes a lot of sense because if all of the elective procedures went away and we are all still paying (the) same premiums that we were...earlier in the year, pre-COVID-19, that money all stays as retained earnings for the health plans,” Block said in an interview.

THE RESPONSE

Many providers have received federal funding through the Paycheck Protection Program and Health Care Enhancement Act and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which allocated $175 billion for healthcare providers. Kaufman Hall’s calculation of the relative decrease in operating margin for the first half of the year compared with 2019 goes from 96% to 28% once CARES Act money is included. That’s still a significant drop in operating margin, but it also shows that the CARES Act has made a significant difference.

Relatively early on in the pandemic, many payers announced that they were helping out struggling providers by making advance payments with the short-term goal of shoring up their liquidity. UnitedHealthcare, for example, made $2 billion in funds available. Premera Blue Cross in Washington state announced advance payments of $100 million, and Blue Cross and Blue Shield of Minnesota pushed out $80 million.

Joseph Restuccia, Dr.PH., M.P.H., a professor at Boston University’s Questrom School of Business, says that payers “fronting this money” to providers is “the right thing to do from an ethical, social justice and moral perspective.” He also sees it as an opportunity for payers to develop closer relationships with providers and support the move toward value-based care and payment arrangements that include some form of capitation.

More recently, payers have been announcing a flurry of “premium relief” measures for employers and individuals, often in the form of a 10% to 25% discount on a future month’s premium. UnitedHealth publicized a plan in May about premium credits and the waiving of cost sharing that it said added up to $1.5 billion. Anthem announced premium discounts in June that according to the company added up to $2.5 billion. Many of the Blues’ plans are on the premium-relief bandwagon; for example, Blue Cross and Blue Shield of Minnesota announced a plan in August that included $38 million in premium relief and $31 million in advanced 2019 medical-loss ratio (MLR) payments. “It is doing our part to help a community in need,” said Craig E. Samitt, M.D., MBA, company president and CEO, of the Minnesota Blues’ plan.

Sabrina Corlette, J.D., founder and co-director of the Center on Health Insurance Reforms at Georgetown University’s McCourt School of Public Policy, says insurers are well aware that legislators and policymakers know they have had a very good year financially so far. “I think to the extent that they can generate some good will and some good public relations by offering premium holidays and premium discounts that is helpful to them,” Corlette says. MLR calculations may also be a factor. Under the ACA, insurers are required to spend 80% of the premium dollar on healthcare in the individual and small group market and 85% in the large employer market. With healthcare expenditures down, so are MLRs. If an insurer can boost their MLR by getting a bit less in premiums revenue, that means paying back less in MLR rebates later, she explains. “I think a lot of carriers are thinking, ‘We are going to owe this money back to the policyholders anyway’ and right now people are suffering, people maybe have lost their jobs or lost income,” says Corlette.

GETTING PATIENTS TO COME BACK

The uptick in COVID-19 cases in July added some wobble to the uncertainty about the epidemic’s course, but patients are coming back and getting healthcare services. Horwitz, whose association represents about 4,500 urgent care centers, says her members are busier than ever with the normal run of problems seen at urgent care centers along with testing and care associated with COVID-19. Kaufman Hall’s August report showed increases from June to July in almost every measure of volume (discharges, patient days, operating room minutes and so on) and relatively modest differences between July of this year and July 2019. One exception is emergency department (ED) visits, which according to the Kaufman Hall tally are down by about 17% from last year. Jim Blake, Kaufman Hall managing director and chief author of the company’s flash reports, says the reasons for decline in ED visits are still unclear, but one possibility is that people are choosing to go elsewhere for less serious emergencies or are getting care through telehealth.

One wildcard in the resumption of routine, in-person healthcare services is the public’s perception of safety regarding visiting a doctor’s office or hospital. Many providers are going to great lengths to make their facilities...
as safe as possible with sanitizing, spacing and parking lots that are now doubling as in-your-car waiting rooms. More than a few providers are using social media to show off their efforts in hopes of assuaging fears. But they are working against a baseline of apprehension. When the Society for Cardiovascular Angiography and Interventions conducted a survey this spring, it found that about a third (36%) of the respondents viewed a hospital visit as “risky behavior,” and 61% reported believing they were somewhat or very likely to acquire COVID-19. Granted, much has changed since this spring. Presumably the worry has subsided somewhat. But if the pandemic has a second wave, as many expect, and a reliable vaccine isn’t available, the fear will likely return.

Ashraf Shehata, national sector leader for healthcare and life sciences at KPMG, the consulting firm, says the only way to make patients feel safe is to implement protocols designed by local and federal public health bodies and educate patients and community leaders about these efforts. That is what Beth Israel Lahey Health, the eastern Massachusetts healthcare system, did back in May when it emailed patients about what to expect during in-person visits:

- Designating specific areas of the office for patients with suspected or positive COVID-19
- Seeing high-risk patients during specific hours of the day
- Minimizing patients’ time in the traditional waiting area by asking them to wait in their cars until their appointment time, or escorting patients from the building lobby directly into their exam room
- Asking about COVID-19 symptoms or exposure multiple times before the appointment takes place with a set of screening questions
- Requiring all staff and patients to wear masks
- Asking all employees, including primary care providers and care teams, to report any symptoms and to stay home if they are ill
- Using approved cleaning products that are effective against human coronaviruses to disinfect settings such as exam rooms and common areas

Shehata also advises hospitals and practices to call patients to welcome them back for routine and preventive care, such as mammograms and colonoscopies. To increase a sense of safety, patients might be greeted at the entrance of a facility by a “navigator” who walks with them to their appointment, says Restuccia. There are also apps for guiding patients.

But this fall, healthcare providers are facing a whole new set of troubles on top of those posed by COVID-19. The prospective of a second wave of COVID-19 and a serious flu season is a source of dread, although the public health measures designed to reduce COVID-19 transmission (social distancing, masks, school- and work-from-home arrangements, the lack of international travel) could help make for a mild flu season. Hurricane Laura weakened fairly quickly and turned into a tropical storm, but there is still a lot of the hurricane season ahead.

“All of these things will continue to hamper and affect (providers’) ability to respond and bring back patients,” says Shehata.

Employment and the overall economy are another large variable in the complicated equation that will determine healthcare use and the return of patients. COVID-19 is proving to be a lumpy pandemic with disproportionate effects on certain populations (older people, males, Black Americans) and certain parts of the economy (restaurants, airlines). Massive job loss may lead to millions of people losing employment-based coverage, although many of the disappearing jobs are on the lower rungs of the economy and didn’t have health insurance as a benefit.

Moreover, the ACA does provide some cushion against the loss of health insurance. Thirty-nine states expanded Medicaid under the 2010 law, and roughly 11 million Americans have purchased coverage on the ACA exchanges. Commentators have noted that the ACA could be one of the many factors that will stave off a more serious economic downturn from COVID-19.

**UNINTENDED CONSEQUENCES**

The death toll is too high (more than 180,000 in the U.S. and 830,000 worldwide) and the disruption too great to sound any kind of celebratory notes about COVID-19. Still, the pandemic has had unintended consequences that could have long-term benefits for providers and payers — and let’s not forget patients. Probably the most talked about topic is the sudden, why-didn’t-we-do-this-sooner adoption of telehealth and remote care.

Others see the payer-provider dynamics of the pandemic accelerating the adoption of value-based care. Corlette says it makes logical sense that some sort of capitated payment would become more attractive. But she also notes the lack of data on any shift to value-based care and a long-standing reluctance to take on downside risk. “I just haven’t heard that there has been a real shift on that front, but this may just be one of those things that takes time to play out.”

Keely Macmillan, senior vice president of policy and solutions management at Archway Health, a Boston consulting firm that specializes in bundled payments and value-based care, is more sanguine.

“Providers in capitated or semi-capitated arrangements that had predetermined amounts to care for their patients, ...were actually faring much (better) during the public health emergency. (They) were financially better equipped to provide care for their patients and implement tele-health and weren’t forced to furlough their staff like many providers who were reliant on fee-for-service revenue,” Macmillan said in an interview. She noted that CMS has launched several alternative payment models recently (models that include some degree of capitation). “COVID-19, in many ways, makes some of these alternative payment models more attractive.”

**Aine Cryts** is a healthcare writer based in the Boston area. Peter Wehrwein is the senior editor of Managed Healthcare Executive®.
COVID-19 has seemingly reached into every corner of American healthcare, with new procedures, regulations and safety precautions required to keep patients and caregivers safe and protected from the virus.

Wearing masks and social distancing are crucial, but these low-tech strategies are hardly new; versions were used during the 1918 flu pandemic.

Videoconferencing has become part of everyday life, and telehealth, which was stuck in the doldrums for years, has taken flight.

Biotechnology firms are turning to old and new technologies to conduct research, ramp up testing, and develop and test vaccine candidates. Behind the scenes, recruitment platforms have been deployed to fill positions with trained healthcare professional, and robots are assisting in medical development and deliveries to cut down on human contact.

Here is a list of 10 technologies that have been part of the response to the COVID-19 pandemic:

**Contact tracing platform**
Healthcare tech has supported communitywide contact tracing and digital COVID-19 risk assessments. Adam Sabloff, founder and CEO of VirtualHealth, a New York City healthcare software and care management company, led a team that developed a screener survey to help identify patients who may have contracted COVID-19 or are at risk of infection.

“The pandemic has increased the need for our healthcare system to adopt a more proactive care model, an approach that is all about anticipating patients’ needs before an emergency (and costly) healthcare event,” Sabloff says.

**Payer, provider communication**
Russ Thomas, CEO of Availity, a healthcare information network company headquartered in Jacksonville, Florida, says technology has been an indispensable during the pandemic, accelerating automation of chunky, manual processes.

Providers and payers have long used electronic transactions to process claims and other data, but several processes still rely heavily on phone calls, paper or fax machines, according to Thomas. “When COVID-19 forced staff to work remotely, both providers and payers had to quickly adopt other means of communication. Fortunately, technology already existed for sending secure electronic attachments and automating prior authorization.”

A silver lining of the pandemic is...
“When COVID-19 forced staff to work remotely, both providers and payers had to quickly adopt other means of communication. Fortunately, technology already existed for sending secure electronic attachments and automating prior authorization.”

—RUSS THOMAS, CEO OF AVAILITY, A HEALTHCARE INFORMATION NETWORK COMPANY HEADQUARTERED IN JACKSONVILLE, FLORIDA

that it forced the sector to accelerate use of these tools, according to Thomas. Technology enabled the consolidation of policies and procedures into a central location for ease of use by providers, he says. Moreover, with so many people working remotely, these same technologies helped providers send relevant documentation and information to payers electronically.

AI for data mining
Robert L. Quigley, M.D., senior vice president and regional medical director of International SOS, a risk mitigation firm, notes that one of the strongest technological tools in the fight against COVID-19 is artificial intelligence (AI) and the capability to analyze enormous amounts of data. “AI can be used to evaluate a large number of patients’ medical records at once to identify which (patients) are (at) highest risk and should receive treatment first,” he says.

Remote surveillance of patients on ventilators
Some hospitals are using remote surveillance to effectively monitor COVID-19 patients on ventilators and protect care teams. Chris Gutmann, executive director of information technology (IT) for Yale New Haven Health, describes how this large healthcare system in Connecticut remotely monitors patients on ventilators at its five hospitals.

“The VPS (ventilated patient surveillance) workstation helps staff remotely see and hear the ventilators in the nontraditional ICU settings of the pandemic,” he says. The workstation analyzes livestreaming data from ventilators and makes it available to the health system’s tele-ICU group. “It escalates emergent clinically actionable events to respiratory therapists, pulmonologists and intensivists,” Gutmann says. Remote surveillance helps protect front-line workers from unnecessary exposure to infection and reduces the use of personal protective equipment (PPE).

Access to clinical histories at the point of care
Matthew Michela, president and CEO of Life Image, a healthcare interoperability company in suburban Boston that specializes in the sharing of images, says many healthcare institutions are using technology to reduce dependence on physically managing records, help control infection spread and increase access to important clinical data.

He cites a recent study that revealed that just 6% of patients had their health history available when they went to the hospital for COVID-19 treatment. “Healthcare data is notoriously siloed,” Michela says, voicing a common sentiment. But delivering acute care during a pandemic puts a premium on access to a patient’s clinical history at the point of care, he notes, and the healthcare system responded to the need. “The gap in access to important clinical information was quickly recognized, and many in the industry deployed existing technology solutions to effectively exchange data with community providers or patients to better coordinate care,” he says.

Rapid testing
New technology for rapid testing at the point of care will reduce backlogs and allow hospitals and practices to...
Some hospitals were using ultraviolet (UVC) light for SARS-CoV-2 inactivation before the COVID-19 pandemic. At Anne Arundel Medical Center in Annapolis, Maryland, a robotlike device dubbed CRIS (clean rooms inactivating SARS-CoV-2 virus) emits UVC to disinfect rooms in the emergency department and intensive care unit. UVC’s antiviral and antibacterial properties are well documented, and recently published research suggests that UVC will inactivate SARS-CoV-2. The FDA has, though, expressed some reservations: “Currently there is limited published data about wavelength, dose and duration of UVC radiation required to inactivate the SARS-CoV-2 virus,” the agency says on its website. But most agency’s comments are directed at at-home UVC devices.

Remote monitoring of patients
Justin Williams, CEO and founder of Noteworth, a digital healthcare company, says that remote technology allows monitoring of patients who are symptomatic but don’t need hospital care. “This technology not only provides key telemetry about a patient but (also) can do it asymmetrically, freeing up staff resources desperately needed in dealing with very sick patients,” he says.

Remote monitoring, which is part of his company’s platform, can also help gather data over a geographic area, giving a real-time view of disease, says Williams.

Interoperability
Brian Miller, CEO of Dewitt Hospital and Nursing Home in eastern Arkansas and a board member of the Arkansas Rural Health Partnership, notes that interoperable health IT makes a big difference when dealing with COVID-19, particularly in terms of data sharing.

“At the peak of the current health crisis, we finalized implementation of a cloud-based, HIPAA-compliant EHR (electronic health record) system provided by Azalea Health, which enabled us to connect our clinic and hospital to the state health information exchange to collect and securely store health data from thousands of constituents being tested at the clinic,” he says. Because of efficiency gains, physicians have been able to focus on conducting more tests, he says.

Vaccine development
Although it falls last on this list, developing an effective vaccine would be the most important technological feat of all. HHS launched Operation Warp Speed, a partnership between government and industry. Vaccine development got off to an early start, partly because of how quickly the SARS-CoV-2 genome was sequenced. The federal government is funding late-phase trials of vaccines developed by Moderna, the partnership of Oxford University researchers and AstraZeneca, and the partnership of the German company BioNTech and Pfizer. Other companies that received funds to support vaccine development include Johnson & Johnson, Novavax, and Sanofi and GlaxoSmithKline.

Keith Loria, a regular contributor to Managed Healthcare Executive®, lives in the Washington, DC, area.
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INDICATION
KESIMPTA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION
Contraindication
KESIMPTA is contraindicated in patients with active hepatitis B virus infection.

Please see additional safety information on following page.
**Warnings and Precautions**

**Infections**

An increased risk of infections has been observed with other anti-CD20 B-cell depleting therapies. KESIMPTA has the potential for an increased risk of infections including serious bacterial, fungal, and new or reactivated viral infections; some have been fatal in patients treated with other anti-CD20 antibodies. The overall rate of infections and serious infections in KESIMPTA-treated patients was similar to teriflunomide-treated patients (51.6% vs 52.7%, and 2.5% vs 1.8%, respectively). The most common infections reported by KESIMPTA-treated patients in relapsing MS (RMS) trials included upper respiratory tract infection (39%) and urinary tract infection (10%). Delay KESIMPTA administration in patients with an active infection until resolved.

Consider the potential increased immunosuppressive effects when initiating KESIMPTA after an immunosuppressive therapy or initiating an immunosuppressive therapy after KESIMPTA.

**Hepatitis B Virus**

Reactivation: No reports of hepatitis B virus (HBV) reactivation in patients with MS treated with KESIMPTA. However, HBV reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, has occurred in patients treated with ofatumumab at higher intravenous doses for chronic lymphocytic leukemia (CLL) than the recommended dose in MS and in patients treated with other anti-CD20 antibodies.

Infected: KESIMPTA is contraindicated in patients with active hepatitis B disease. Fatal infections caused by HBV in patients who have not been previously infected have occurred in patients treated with ofatumumab at higher intravenous doses for CLL than the recommended dose in MS. Perform HBV screening in all patients before initiation of KESIMPTA. Patients who are negative for HBsAg and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], should consult liver disease experts before starting and during KESIMPTA treatment.

**Progressive Multifocal Leukoencephalopathy**

No cases of progressive multifocal leukoencephalopathy (PML) have been reported for KESIMPTA in RMS clinical studies; however, PML resulting in death has occurred in patients being treated with ofatumumab at higher intravenous doses for CLL than the recommended dose in MS. In addition, JC virus infection resulting in PML has also been observed in patients treated with other anti-CD20 antibodies and other MS therapies. If PML is suspected, withhold KESIMPTA and perform an appropriate diagnostic evaluation. If PML is confirmed, KESIMPTA should be discontinued.

**Vaccinations**

Administer all vaccinations according to immunization guidelines: for live or live–attenuated vaccines at least 2 weeks prior to starting KESIMPTA for inactivated vaccines. The safety of immunization with live or live–attenuated vaccines following KESIMPTA therapy has not been studied. Vaccination with live or live–attenuated vaccines is not recommended during treatment and after discontinuation until B-cell repletion.

**Injection-Related Reactions**

Injection-related reactions with systemic symptoms occurred most commonly within 24 hours of the first injection, but were also observed with later injections. There were no life-threatening injection reactions in RMS clinical studies.

**Fetal Risk**

Based on animal data, KESIMPTA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to KESIMPTA in utero. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 B-cell depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving KESIMPTA and for at least 6 months after the last dose.

**Most common adverse reactions**

(>10%) are upper respiratory tract infection, headache, injection-related reactions, and local injection-site reactions.
WARNINGS AND PRECAUTIONS

1 Indications and Usage
KESIMPTA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

2 Contraindications
KESIMPTA is contraindicated in patients with:
- Active HBV infection [see Warnings and Precautions (5.1)].

5 Warnings and Precautions

5.1 Infections
An increased risk of infections has been observed with other anti-CD20 B-cell depletion therapies. KESIMPTA has the potential for an increased risk of infections, including serious bacterial, fungal, and new or reactivated viral infections; some of these infections have been fatal in patients treated with other anti-CD20 antibodies. In Study 1 and Study 2 [see Clinical Studies (14) in the full prescribing information], the overall rate of infections and serious infections in patients treated with KESIMPTA was similar to patients who were treated with teriflunomide (51.6% vs 52.7%, and 2.5% vs 1.8%, respectively). The most common infections reported by KESIMPTA-treated patients in the randomized clinical relapsing MS (RMS) trials included upper respiratory tract infection (30%) and urinary tract infection (10%). Delay KESIMPTA administration in patients with an active infection until the infection is resolved.

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants
When initiating KESIMPTA after an immunosuppressive therapy or initiating an immunosuppressive therapy after KESIMPTA, consider the potential for increased immunosuppressive effects [see Drug Interactions (7.1) and Clinical Pharmacology (12.2) in the full prescribing information]. KESIMPTA has not been studied in combination with other MS therapies.

5.2 Injection-Related Reactions
In Study 1 and Study 2, systemic and local injection reactions were reported in 21% and 11% of patients treated with KESIMPTA compared to 15% and 6% of patients treated with teriflunomide who received matching placebo injections, respectively [see Adverse Reactions (6.1) and Clinical Studies (14) in the full prescribing information].

Injection-related reactions with systemic symptoms observed in clinical studies occurred most commonly within 24 hours of the first injection, but were also observed with later injections. Symptoms observed included fever, headache, myalgia, chills, and fatigue, and were predominantly (99.8%) mild to moderate in severity. There were no life-threatening injection reactions in RMS clinical studies.

Local injection-site reaction symptoms observed in clinical studies included erythema, swelling, itching, and pain.

5.3 Reduction in Immunoglobulins
As expected with any B-cell depletion therapy, decreased immunoglobulin levels were observed. Decrease in immunoglobulin M (IgM) was reported in 7.7% of patients treated with KESIMPTA compared to 3.1% of patients treated with teriflunomide in RMS clinical trials [see Adverse Reactions (6.1)]. Treatment was discontinued because of decreased immunoglobulins in 3.4% of patients treated with KESIMPTA and in 0.8% of patients treated with teriflunomide. No decline in immunoglobulin G (IgG) was observed at the end of the study. Monitor the levels of quantitative serum immunoglobulins during treatment, especially in patients with opportunistic or recurrent infections, and after discontinuation of therapy until B-cell repletion. Consider discontinuing KESIMPTA therapy if a patient with low immunoglobulins develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.

5.4 Fetal Risk
Based on animal data, KESIMPTA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to KESIMPTA in utero. Transient peripheral B-cell depletion and lymphopenia have been reported in infants born to mothers exposed to other anti-CD20 B-cell depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving KESIMPTA and for at least 6 months after the last dose [see Use in Specific Populations (8.1)].

6 Adverse Reactions

The following clinically significant adverse reactions are discussed in greater detail elsewhere in the labeling:
- Infections [see Warnings and Precautions (5.1)]
- Injection-Related Reactions [see Warnings and Precautions (5.2)]
- Reduction in Immunoglobulins [see Warnings and Precautions (5.3)]

6.1 Clinical Trials Experience

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

Approximately 1500 patients with RMS received KESIMPTA in clinical studies. In Study 1 and Study 2, 1882 patients with RMS were randomized, 946 of whom were treated with KESIMPTA for a median duration of 55 weeks; 33% of patients receiving KESIMPTA were treated for up to 120 weeks [see Clinical Studies (14.1) in the full prescribing information]. The most common adverse reactions occurring in greater than 10% of patients treated with KESIMPTA and more frequently than in patients treated with teriflunomide were upper respiratory tract infections, injection-related reactions (systemic), headache, and injection-site reactions (local). The most common cause of discontinuation in patients
treated with KESIMPTA was low immunoglobulin M (3.3%), defined in trial protocols as IgM at 10% below the lower limit of normal (LLN).

Table 1 summarizes the adverse drug reactions that occurred in Study 1 and Study 2.

Table 1: Adverse Reactions in Patients with RMS with an Incidence of at Least 5% with KESIMPTA and a Greater Incidence Than Teriflunomide (Pooled Study 1 and Study 2)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>KESIMPTA 20 mg N = 946</th>
<th>Teriflunomide 14 mg N = 936</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory tract infections</td>
<td>39%</td>
<td>38%</td>
</tr>
<tr>
<td>Injection-related reactions (systemic)</td>
<td>21%</td>
<td>15%</td>
</tr>
<tr>
<td>Headache</td>
<td>13%</td>
<td>12%</td>
</tr>
<tr>
<td>Injection-site reactions (local)</td>
<td>11%</td>
<td>6%</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>10%</td>
<td>8%</td>
</tr>
<tr>
<td>Back pain</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Blood immunoglobulin M decreased</td>
<td>6%</td>
<td>2%</td>
</tr>
</tbody>
</table>

- Includes the following: nasopharyngitis, upper respiratory tract infection, influenza, sinussitis, pharyngitis, rhinitis, viral upper respiratory infection, tonsillitis, acute sinussitis, pharyngotonsillitis, laryngitis, pharyngitis streptococcal, viral rhinitis, sinussitis bacterial, tonsillitis bacterial, viral pharyngitis, viral tonsillitis, chronic sinussitis, nasal herpes, tracheitis.

Injection-Related Reactions and Injection-Site Reactions

The incidence of injection-related reactions (systemic) was highest with the first injection (14.4%), decreasing with subsequent injections (4.4% with second, less than 3% with third injection). Injection-related reactions were mostly mild to moderate in severity. Two (0.2%) patients treated with KESIMPTA reported serious injection-related reactions. There were no life-threatening injection-related reactions. Most frequently reported symptoms (2% or greater) included fever, headache, myalgia, chills, and fatigue.

In addition to systemic injection-related reactions, local reactions at the administration site were very common. Local injection-site reactions were all mild to moderate in severity. The most frequently reported symptoms (2% or greater) included erythema, pain, itching, and swelling (see Warnings and Precautions (5.2)).

Laboratory Abnormalities

Immunoglobulins

In Study 1 and Study 2, a decrease in the mean level of IgM was observed in KESIMPTA-treated patients but was not associated with an increased risk of infections (see Warnings and Precautions (5.2)). In 14.3% of patients in Study 1 and Study 2, treatment with KESIMPTA resulted in a decrease in a serum IgM that reached a value below 0.34 g/dL. KESIMPTA was associated with a decrease of 4.3% in mean IgM levels after 48 weeks of treatment and an increase of 2.2% after 96 weeks.

6.2 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medication, and the underlying disease. For these reasons, comparison of the incidence of antibodies in the studies described below with the incidence of antibodies in other studies or to other ofatumumab products may be misleading.

Treatment induced anti-drug antibodies (ADAs) were detected in 2 of 914 (0.2%) KESIMPTA-treated patients; no patients with treatment enhancing or neutralizing ADAs were identified. There was no impact of positive ADA titers on PK, safety profile or B-cell kinetics in any patient; however, these data are not adequate to assess the impact of ADAs on the safety and efficacy of KESIMPTA.

7 DRUG INTERACTIONS

7.1 Immunosuppressive or Immune-Modulating Therapies

Concomitant usage of KESIMPTA with immunosuppressant drugs, including systemic corticosteroids, may increase the risk of infection. Consider the risk of additive immune system effects when coadministering immunosuppressive therapies with KESIMPTA.

When switching from therapies with immune effects, the duration and mechanism of action of these therapies should be taken into account because of potential additive immunosuppressive effects when initiating KESIMPTA.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of KESIMPTA in pregnant women. Ofatumumab may cross the placenta and cause fetal B-cell depletion based on findings from animal studies (see Data).

Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 antibodies during pregnancy. B-cell levels in infants following maternal exposure to KESIMPTA have not been studied in clinical trials. The potential duration of B-cell depletion in infants exposed to ofatumumab in utero until B-cell recovery occurs [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.2)] in the full prescribing information.

Following administration of ofatumumab to pregnant monkeys, increased mortality, depletion of B-cell populations, and impaired immune function were observed in the offspring, in the absence of maternal toxicity, at plasma levels substantially higher than that in humans (see Data).

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

Data

Animal Data

Intravenous administration of ofatumumab (weekly doses of 0, 20, or 100 mg/kg) to pregnant monkeys during the period of organogenesis (gestations days 20 to 50) resulted in no adverse effects on embryofetal development; however, B-cell depletion was observed in fetuses at both doses when assessed on gestation day 100. Plasma exposure (C_{av}) at the no-effect dose (100 mg/kg) for adverse effects on embryofetal development was greater than 5000 times that in humans at the recommended human maintenance dose of 20 mg. A no-effect dose for effects on B-cells was not identified; plasma exposure (C_{av}) at the low-effect dose (20 mg/kg) was approximately 780 times that in humans at the recommended human maintenance dose (RMD) of 20 mg/month.

Intravenous administration of ofatumumab (5 weekly doses of 0, 10, and 100 mg/kg, followed by bimonthly doses of 0, 3, and 20 mg/kg) to pregnant monkeys throughout pregnancy resulted in no adverse effects on the development of the offspring. However, postnatal death, B-cell depletion, and impaired immune function were observed in the offspring at the high dose. The deaths at the high dose were considered secondary to B-cell depletion. Plasma exposure (C_{av}) in dams at the no-effect dose (100/20 mg/kg) for adverse developmental effects was approximately 500 times that in humans at RMD. A no-effect level for morality and immune effects in offspring was not established because of the limited number of evaluable offspring at the low dose.

8.2 Lactation

Risk Summary

There are no data on the presence of ofatumumab in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. Human IgG is excreted in human milk, and the potential for absorption of ofatumumab to lead to B-cell depletion in the infant is unknown. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for KESIMPTA and any potential adverse effects on the breastfed infant from KESIMPTA or from the underlying maternal condition.

8.3 Females and Males of Reproductive Potential

Contraception

Females of childbearing potential should use effective contraception while receiving KESIMPTA and for 6 months after the last treatment of KESIMPTA [see Warnings and Precautions (5.4) and Clinical Pharmacology (12.3) in the full prescribing information].

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of KESIMPTA did not include sufficient numbers of geriatric patients to determine whether they respond differently from younger subjects.

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Healthcare goes retail

CVS Health, Walgreens and Walmart are pushing ahead with ambitious plans for in-store clinics and doctor’s offices.

by SUSAN LADIKA

With COVID-19 still leaving many Americans wary of going to the doctor’s office for in-person care, large drugstore chains and retailers are seeing an opportunity for new patients for their in-store health clinics. The clinics are “a one-stop shop” where patients can see a healthcare provider, get help managing chronic conditions, pick up medications and have laboratory tests done, says Kulleni Gebreyes, a principal and physician leader at Deloitte. She says retail clinics haven’t seen a drop in patient volumes since the outbreak began in mid-March.

Physician groups, including the American Academy of Family Physicians and the American College of Physicians, have put out policy statements expressing reservations about the clinics possibly undercutting primary care. And, clearly, Walmart is bringing its low-prices game to healthcare: A price list on Walmart’s website shows a price of $40 for an office visit, $25 for a dental exam with X-rays and $60 for a therapy session for new patients.

“Walmart is committed to making healthcare more affordable and accessible for customers in the communities we serve,” Marilee McInnis, a company spokesperson, said in an email.

One of the virtues of the retail clinics is the price transparency, a sharp contrast to the blanket of obscurity that cloaks price in most parts of the U.S. healthcare system (see page 28). Retail clinics allow patients to “clearly see upfront” the cost of care, Gebreyes says, and the retail clinic cost is often two to three times lower than more typical providers. That cost difference may loom large now with millions of Americans being laid off and losing employer-based healthcare insurance, which tends to be more generous in Medicaid or ACA exchange plan coverage.

A growth business

Walgreens’ deal with VillageMD put the drugstore chain in more direct competition with CVS Health, which pioneered the retail clinic with its MinuteClinics and now has ambitious plans for its HealthHUBs, designed to provide services to manage chronic conditions. CVS says it has plans to have 1,500 HealthHUBs operating by the end of 2021. In its first-quarter earnings call, the company said it had almost 100 locations in 17 states up and running in April, but the conversion of more stores had been put on hold because of COVID-19.

Walgreens and VillageMD say they expect to have clinics in more than 30 markets, with more than half located in underserved areas as designated by the Department of Health & Human Services. After a first phase of five years, hundreds of facilities will be added, the companies say. The offices will be located inside existing Walgreens locations, with most...
taking up about 3,300 square feet, an area approximately three-quarters of the size of a basketball court. Some will be as large as 9,000 square feet. During the first five years, VillageMD is expected to recruit more than 3,600 primary care providers. Walgreens pharmacists will be part of a patient’s care team.

The two companies tested the in-store primary care offices at five Houston-area Walgreens starting in November. “This rollout is a major advancement of one of Walgreens Boots Alliance’s four key strategic priorities, creating neighborhood health destinations,” Stefano Pessina, executive vice chairman and CEO of Walgreens Boots Alliance, said in the press release. As part of the deal, Walgreens is investing $1 billion in VillageMD over three years, and when the deal is complete, the pharmacy giant will hold a 30% stake in the company.

Last year, Walgreens seemed to be in partial retreat from the in-store healthcare clinic market. In October, the company announced it was shuttering the 150 clinics that it operated on its own. But partnership seems to be the company’s strategy. Walgreens has 230 clinics that are run in conjunction with local health systems that provide acute medical care, a spokesperson said in an email. The company also has 14 primary care locations, including five senior-focused clinics operated with Humana. Four are in the Kansas City area and one is in South Carolina, and the companies are evaluating new locations for expansion.

Walmart hasn’t said how many more of its Walmart Health centers are in the works, but McInnis said expansion is planned.

**Higher ambitions**

Although many of the current generation of retail clinics only provide urgent care for minor acute issues such as strep throat or an ear infection, or routine care such as vaccinations, others have higher ambitions and can play an important role in helping patients manage chronic conditions, Gebreyes says.

If someone has diabetes, for example, they can come to a retail clinic and get the medication and supplies they need, along with foods to help them eat healthily, she explains. Some have a greeter at the door who helps patients navigate the clinic and the services available, says Gebreyes. “(They) respond very positively to it.” The convenience factor also works in favor of the retail clinics. According to CVS Health, the company has more than 9,900 retail locations and more than 1,000 MinuteClinics. Walgreens says it has more than 9,000 drugstores.

James Beem, managing director of global healthcare intelligence at J.D. Power, says patients appreciate the opportunity retail clinics give them to consult with healthcare providers. Patients say that often at doctor’s offices they are “rushed in and out without enough time to converse.” (Some might notice the irony of MinuteClinics giving patients more time.)

Whereas telehealth has taken off during the pandemic, many patients are hesitant to get in-person care, but “(they) still want to be able to have face-to-face consultations and be examined without a digital interface,” says Beem. Now that CVS owns Aetna, the insurer may steer patients with chronic conditions to HealthHUBs, making CVS Health “100% responsible for patient care and outcomes,” notes Beem.

**One possible drawback to receiving care at a retail clinic is the lack of integration of your medical information into your core medical record, Gebreyes says. And there is concern that because of their accessibility and affordability, retail clinics could drive up unnecessary utilization of services, she says.**

The next frontier in retail clinics could be behavioral healthcare, such as that offered by Walmart, Gebreyes says. An ongoing shortage of mental healthcare providers, combined with the stress many people are feeling because of the pandemic and the rocky economy, are overtaxing behavioral health services. And even if patients can get appointments with a mental healthcare provider, they may be reluctant to visit one in person.

“People don’t have great access to behavioral healthcare,” Gebreyes says. “Retail clinics can be a great place for stigma-free care.”

**Susan Ladika is an independent journalist in Tampa, Florida, who writes about healthcare and business.**

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**MOST RATE CARE ‘EXCELLENT’ OR ‘VERY GOOD’**

Results from a survey conducted two years ago in pre-COVID times may seem stale, but they do establish a baseline. In a 2018 survey, Civis Analytics, a data science company, found that 18% of respondents had sought care at a retail clinic in the previous year. About 35% of those respondents had gone to CVS, more than 30% to Walgreens and 15% to Walmart.

Approximately 55% of respondents rated the care they had received as “excellent” or “very good.”

**Approximately**

- **55%** of respondents rated the care they had received as “excellent” or “very good.”

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**Tagline:**

Healthcare goes retail | Industry Analysis
Is it fair to say that leadership in today’s healthcare environment is more challenging than ever? The COVID-19 pandemic has tested every healthcare executive’s ability to adjust — and adjust again. From mid-March through summer and now early fall, the ups and downs of the outbreak have occurred at a furious, unpredictable cadence. The only certainty has been more uncertainty.

The following experts cited both new skills and new reasons to pursue older proficiencies. Although they made their statements before the outbreak of COVID-19, the insights they shared became more relevant than ever.

Eyes are on you
“Leaders are constantly observed and modeled,” says Darnell Dent, CEO of Dent Advisory Services and member of the Managed Healthcare Executive editorial advisory board. Closed-minded, top-down leaders cannot hide, especially now. They are judged by what they say and don’t say and what they do and don’t do. And when a leader is not visible, misinformation will spread.

As a result, healthcare executives need to be transparent in a way that is more real than ever. For important decisions, they should involve more, not fewer stakeholders. True collaboration makes for greater alignment, better decisions and better execution. “Executives don’t have to give up their power to make the ultimate decision,” says Dent, but they need to keep in mind that leadership is a team, not an individual, sport.

Sometimes transparency means saying, and doing things that make people unhappy or uncomfortable. Executives need to be careful about overcommitting and overpromising. They have to be willing to say no to requests they cannot fulfill, and then be clear about the reasons why.

Keep lines of communication open
“Whenever there are three or more emails in a chain, it’s time to talk,” advises Virginia Calega, M.D., vice president of medical affairs for facilitated health networks at Independence Blue Cross in Philadelphia, who is also a member of the Managed Healthcare Executive editorial advisory board. “The richness of conversation helps avoid misunderstandings,” she says. In today’s social media–fueled world, it’s easy to mistake the quantity of our communication for quality. Of course, COVID-19 has put a premium on video conferencing and real-time talk, be it through Microsoft Teams or Skype — or the old-fashioned cell phone.

Does this mean that C-suite executives need to talk to everyone who has a problem or raises an issue? Of course not. “Middle management is still necessary to prioritize and direct the flow of information up and down the chain of command,” says Don Hall, M.P.H., principal of DeltaSigma LLC and member of this publication’s editorial advisory board.

“You’ve got to be informed on what’s happening in your market,” adds Hall. Critical information — emphasis on critical — must be allowed to flow quickly from the front line of an organization to the top. Hall likens the ideal flow of information within an organization to the body’s nervous system. “You may not actively think about your toes, but when you hit them against something, your body sends a distinct message!”

“I was wrong” is OK
“Healthcare executives need to consider the ‘what-ifs’ seriously,” says Sherry Rohlfding, who is a principal at DeltaSigma with Hall. Whether it’s the latest twist and turn of COVID-19, an unexpected competitor, or a disruptive technology, change doesn’t call ahead and make an appointment. It’s there, at your door.

But you don’t need to be caught flat footed. “Leaders need to look within their organizations to find and appoint others to research and prepare for these changes, should they occur,” says Rohlfding.

Leaders should strive to make the right decisions (of course) but also be prepared to be wrong. “You need to save yourself from being the emperor who has no clothes,” says Dent. “People in your organization must feel free to tell you both bad (and good) news.” With some notable exceptions in some very high places, gone are the days...
of being the last to acknowledge a wrong decision.

**Avoid groupthink**

“You need to learn to appreciate people who do not think like you,” says Donald Pirc, vice president of managed care at Promedica Health System in Toledo, Ohio. Building teams of like-minded people results in weak teams, without different points of view, expertise and experience. Attempting to clone one member, regardless of performance, results in a weak team. Leaders of all levels can play to their strengths when they are not imitating others. And often, varying skills and ideas are required to maximize a team’s results.

Dent recalls his transition from Marine Corps officer to corporate America. "One of the first things my mentor told me is that, here in the corporate world, you can no longer simply issue orders and expect them to be followed." Collaboration, vertically and horizontally, and between organizations, is essential.

When leaders democratize the flow of ideas, they can receive them fresh, from unexpected places. "Not only can frontline employees warn you of what’s coming, but they’re sometimes the best source for understanding what’s happening right now," says Hall.

**Integrate behavioral health**

"Many well-meaning leaders of insurance companies are physicians who received limited training in behavioral health," says Sam D. Toney, M.D., a psychiatrist and healthcare consultant in Tampa, Florida. Part of the problem is discordant measurement. “One measures a patient’s LDL with blood work. The severity of major depression is measured using patient feedback,” says Toney.

So, how can providers and payers work to offer behavioral services in a cost-effective way? "With the extensive data sets we have today, we can correlate the risk between physical and behavioral conditions,” comments Toney. “We can see, for example, how a patient’s level of depression affects their adherence to diabetes care.”

**Cost control as a quality booster**

“I believe that everyone has the best intentions, which is to help people get and stay healthy," says Calega. "However, ours is a complex business, especially when it comes to ensuring people get the right care at the right time in the right setting.”

Cost containment may seem to run counter to delivering the best care; it often looks that way to outsiders. But many times, just the opposite is true. "Higher-cost care tends to result in lower-quality outcomes,” says Hall. More visits and tests and can be a sign of a treatment path gone awry.

Data and their analysis can help strike a balance between cost control and good outcomes. “The data we collect through our value-based contracts and share with our providers help us to explore problem areas and collaboratively design programs to address potential solutions,” says Calega.

**Value-based payment: Embrace it**

"Many healthcare executives grow comfortable with their current system of compensation,” says Dent. In some cases, they have figured out how to maximize their current system for personal gain. Plus, as Dent notes, “every organization has a certain level of inertia.”

Instead of fighting value-based payment, Dent adds, healthcare executives need to pause and ask themselves, “How do I get that done?” The answer to this question again requires transparency and collaboration.

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Chris Pawar is a medical writer based in Cleveland, Ohio.
For price transparency, the outlook is murky

The Trump administration’s attempts at pulling back the curtain have ended up in court.  

by JARED KALTWASSER

Martin Moll, J.D., advises medical practices of all shapes and sizes in his role as founder and advisor at Breakaway Bookkeeping & Advising. When the topic of price transparency comes up, he immediately points out a fundamental problem.

“If you talk about price transparency, it actually requires transparency,” he said. “And at the end of the day, that’s the hard part for doctors, because they actually don’t know what things cost.”

Typically, doctors don’t calculate the individual costs of services, he said. Instead, they tend to add up their overall expenses and reimbursements and declare it a success if they end up in the black. Price transparency is another item on the miles-long list in healthcare for which the saying is far easier than the doing. Nearly two decades after the introduction of health savings accounts and high-deductible health plans and a full decade after the Patient Protection and Affordable Care Act (ACA), which required hospitals to publish their chargemasters, it’s more idea than actuality.

As an idea, price transparency is easy to grasp because it is so familiar to people living in an economy fueled by consumer spending. For decades, U.S. healthcare has been paid for primarily by third parties, insurers and public payers, and that makes people heedless of cost and not especially interested in shopping for less expensive care. But, the theory goes, if Americans knew the price of healthcare services and had to pay a substantial share of the cost, they would be more inclined to shop around, and expensive American healthcare would benefit from a healthy dose of market competition.

But pulling the curtain back on prices isn’t so easy. Despite efforts from presidents on both sides of the political aisle, healthcare prices remain obscure, confusing or both.

The Trump attempts

In November 2019, President Donald Trump signed an executive order that translated into two new price-transparency rules, one governing hospitals and the other, health plans. Both are scheduled to take effect next year. The hospital rule would require hospitals to make public their rates under negotiated agreements with insurers, as well as how much they are willing to accept in cash payments from patients for particular services. For 300 common “shoppable services,” hospitals would need to make such data available in a consumer-friendly format rather than merely a machine-readable file.

For insurers, the “transparency in coverage” rule would require them to provide cost-sharing information to members, including estimates for covered items and procedures. They would also need to publicly disclose negotiated rates for in-network providers and allowed amounts for out-of-network providers. According to CMS Administrator Seema Verma, the rules would give consumers the information they need to make practical and informed healthcare decisions — and more. “Today’s rules usher in a new era that upends the status quo to empower patients and put them first,” she said in a press release.

But the hospital rule quickly became ensnared in court challenges by the American Hospital Association. In June, a federal district judge ruled in favor of the administration and against the hospital association, referencing the argument that patients who know about prices will put pressure on providers to lower costs. The hospital association said it will appeal the decision. The insurance rule had yet to be finalized by as of this summer; once it has been, there is little doubt that it too will

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Industry Analysis

For price transparency, the outlook is Murky

Continued from page 28

face legal challenges.

Katie Keith, J.D., M.P.H., a healthcare consultant who blogs about the ACA for Health Affairs, said these rules are deeply unpopular among insurers and hospitals. “I don’t think anyone in the industry wants their prices — their negotiated rates — to be public,” she says. Brian Blase, Ph.D., a former Trump health administration official who was influential in developing price transparency policies, said in a recent Health Affairs blog that hospitals aim to maximize profits and they oppose price transparency because they believe it will reduce those profits.

Other Trump administration attempts at price transparency have also become bogged down. A 2019 executive order that would have required drug companies to disclose the wholesale acquisition costs of drugs in advertisements was blocked after a court ruling that the Department of Health & Human Services did not have the authority to compel such disclosures. In response, the president began calling on Congress for a bipartisan drug price transparency bill. A number of members have been working on such bills, but so far no major proposal has made it to the president’s desk.

Although the administration has moved to trim regulations in a number of different industries, Keith said healthcare is one area in which Trump has pushed to add new consumer-friendly regulations, even when that has meant going to war with industry. “They have really doubled down on interoperability too,” she says. “It’s not quite the same thing as transparency, but it’s kind of that same concept that they want patients to have access to (information).”

Does it even work?

Eric Ellsworth, M.S., MBA, director of health data strategy at Consumers’ Checkbook says many of the current forms of healthcare price transparency are not meaningful to consumers. For instance, although some insurance sites give estimates of costs, he says, “you still can’t really take that to the bank. You can’t do anything with that. It’s just sort of an awareness tool.”

In response to the proposed insurance rule, American’s Health Insurance Plans (AHIP), the main trade group for the health insurance industry, submitted a 57-page comment in which they assert that transparency could end up harming consumers. “It will undermine competitive negotiations and push healthcare prices higher — not lower — for patients, consumers and taxpayers,” wrote Matthew Eyles, M.S., AHIP president and CEO. The group argues that if a hospital suddenly found out it was receiving less than a competing hospital for the same procedure, it would demand a higher price. AHIP also criticizes the scope of the transparency, arguing that the rule should focus only on “shoppable” services.

Moll notes that although hospitals are better than smaller medical practices at putting price tags on services, those prices don’t necessarily translate into the cost of the service alone. Hospitals can have drastically different prices on similar services, in part, because they have unreimbursed costs, such as indigent care, that they must account for through billing for reimbursed procedures. The cost of the unit care is almost irrelevant, he says, because hospitals are focused on their overall hospital margin. Moll says there’s currently a gap between reimbursement and value. He described a scenario in which an orthopedic surgeon has significantly lower readmission rates. That surgeon may save the payer money but usually has had little luck convincing insurers to recognize such that with a higher reimbursement rates.

Ellsworth believes the fundamentals of the healthcare marketplace will need to be adjusted before price transparency works the kind of consumer empowerment magic that its proponents envision. He sees the episode-based payment models as a step in the right direction because they give providers an incentive to control costs. Such payment models would also help consumers to see their care for a particular medical problem as a unit, he notes. By choosing between packages of transparently priced treatment options, consumers could make informed decisions about what they are truly want to pay for, says Ellsworth.

“People have to get a little more used to defining their own goals,” he says. Keith says asking consumers to make decisions based on cost-effectiveness might be a bridge too far. However, she believes that having price data publicly available could help improve the healthcare system in other ways by, for example, aiding cost-effectiveness research. “I don’t buy that it’s effective at the individual consumer level,” she said. “But for the system, I think it could be really valuable.”

Jared Kaltwasser is a healthcare reporter based in Iowa.
Secondary Progressive Multiple Sclerosis: Patient Impact and Coverage Implications for New Therapies

Secondary progressive multiple sclerosis (SPMS) is an advanced form of multiple sclerosis (MS) thought to be caused by neurodegeneration within the central nervous system and involves steadily increasing neurologic dysfunction and disability without clear recovery or stability periods. It develops from relapsing remitting multiple sclerosis (RRMS), typically 10 to 15 years after a diagnosis of MS. Among patients with RRMS, up to 80% may progress to SPMS within 20 years. Additionally, among those who do not receive disease-modifying therapies for MS, 33% progress to SPMS within eight years.

Treatment of SPMS is associated with many challenges, perhaps most significantly the historical lack of treatment options developed specifically for the condition. The therapeutic armamentarium has evolved significantly since 2019, however, with the approval of 2 oral therapies with indications for the treatment of SPMS. Additionally, many therapies already approved for RRMS have seen their labels broadened to include SPMS. Given these recent and significant shifts, health plans are challenged with selecting appropriate therapies for coverage for SPMS while offsetting the broadly escalating costs of MS treatment.

THE CLINICAL AND ECONOMIC BURDEN OF SPMS

Diagnosis — Diagnosing SPMS can be difficult because it relies entirely on clinical judgement. There are no clear diagnostic criteria, and patients may not notice a symptomatic change during the early stages of SPMS because of the brain’s ability to compensate for the loss of neurons. For this reason, diagnosis may be delayed up to three years and is often given retrospectively.

Efforts have been made to improve SPMS diagnostics. Screening tools, including the MS Progression Discussion Tool, the MS prediction score and the SPMS nomogram have been developed to leverage data to predict the risk of progression and diagnose early-stage SPMS accurately. Newer imaging technologies, such as unconventional MRIs and optical coherence tomography, may provide higher sensitivity biomarker measurements to aid in detecting disease risk and progression. Emerging biomarkers, measured by either images or tests of cerebral spinal fluid or blood, include neurofilament light chain levels in serum or cerebrospinal fluid (CSF), CSF sCD27, chemokine (C-C motif) ligand 18 plasma levels, the MS risk allele HLA-DRB1*15 and chitinase-3-like protein 1. Larger-scale trials are needed for further data generation before these markers can be used clinically.

Once diagnosed, SPMS is further categorized into active and nonactive disease states. First established in 2013, the term “active” is defined as relapses, acute or subacute episodes of new or increasing neurologic dysfunction followed by full or partial recovery, in the absence of fever or infection and/or the occurrence of contrast-enhancing T1 hyperintense or new or unequivocally enlarging T2 hyperintense lesions. A clinical assessment for disease activity is recommended annually.

Disability and comorbidities — With SPMS, patients experience cognitive and physical decline, such as sleep changes, fatigue, incontinence, sexual dysfunction, and spasticity. Spasticity typically increases with disease progression and can eventually become refractory. Disability associated with MS, which is primarily measured by the ability to walk, can substantially affect patient quality of life and socioeconomic status. Disability progression is typically influenced most by the duration of disease; this differs from the disability progression associated with other diseases, which is often most influenced by patient age. Adjusting to disability and other decline can be difficult and stressful for patients. Key determinants for a successful adjustment involve developing healthy coping strategies, participating in patient support networks and maintaining appropriate activity levels.

In addition to dealing with physical and psychological burdens, patients with MS also experience a higher prevalence of comorbid conditions. Results from a recent study demonstrated that approximately 62% of patients with MS had comorbidities; the most common conditions included depression (24%), anxiety (23%), hypertension (13%), migraine (12%), smoking or history of smoking (10%) and obesity (9%). Comorbidities may affect MS severity and outcomes, which implicates the importance of screening and monitoring for comorbidities.

Economic impact — MS has the second-highest all-cause medical costs associated with chronic conditions (after congestive heart failure), with total all-cause per-patient healthcare costs — direct and indirect — of up to $54,244 annually. As the disease progresses and disability increases, costs also escalate. For a patient with severe disability, average annual healthcare costs can reach $100,000 or more. Direct costs associated with MS, comprising, on average, 77% of costs, can be primarily attributed to prescription medications, which are taken by 57.5% of people with MS in the United States. Although high, the cost of medications may be offset by medication efficacy in preventing relapse and disability. Use of certain therapies may also relate to improved rates of employment among patients with MS, according to a study conducted in Australia. Unemployment related to MS disability is higher than for any other reason, and loss of productiv-
“Secondary progressive MS starts out in patients who have relapsing remitting disease and then enter a phase where they’re gradually worsening independent of any relapses, and it’s actually a difficult characterization to make because ... there [are] no criteria.”

Fred Lublin, M.D.
Saunders Family Professor of Neurology
Director of the Corinne Goldsmith Dickinson Center for Multiple Sclerosis
Mount Sinai Medical Center, New York, New York

To view this and other videos, visit managedhealthcareexecutive.com/expert-interviews.

Evolving Treatment Strategies and Coverage Implications

Historically, drug development and approval within the MS treatment spectrum have been focused toward RRMS. However, the treatment spectrum for SPMS in particular is rapidly expanding. As of 2019, 34 randomized trials have evaluated 21 therapies for SPMS, most of which already received approval for RRMS. Of the trials, only 38% achieved the primary endpoint. At that time, the intravenous immunosuppressant mitoxantrone was the only approved therapy for SPMS. Although evidence supported its efficacy for treating disability, adverse effects (AEs) included cardiac complications and malignancy risk. In addition, patients could only receive a total of 140 milligrams (mg) which limited the therapeutic value of mitoxantrone for SPMS to approximately a two-year period. In 2019, the oral therapies Mayzent (siponimod) and Mavenclad (cladribine) were approved for the treatment of active SPMS, warranting consideration for inclusion in health plan formularies.

Cladribine is indicated for the treatment of relapsing forms of MS to include relapsing-remitting disease and active secondary progressive disease in adults. It is administered for two weeks per year for two years. In CLARITY — a phase 3, randomized, double-blind, placebo-controlled clinical trial — patients with relapsing forms of MS were randomized to receive cladribine 3.5 mg/kg (n = 433), 5.25 mg/kg (n = 456), or placebo (n = 437). At 96 weeks, 81% of patients receiving cladribine were relapse-free compared with 63% receiving placebo (nominal P < .05), and 87% of patients receiving cladribine had no confirmed three-month Expanded Disability Status Scale progression compared with 81% on placebo. In addition, cladribine significantly reduced the median number of lesions across MRI endpoints versus placebo (P < .001). The most common AEs (n = 440) were upper respiratory tract infection (38%), headache (25%) and lymphopenia (24%). In a post hoc analysis, 44% of patients receiving cladribine achieved no evidence of disease activity versus 16% receiving a placebo (P < .0001).

Siponimod is indicated for treatment of relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease in adults. The phase 3, randomized, double-blind EXPAND trial evaluated siponimod, at 2 mg, for SPMS-related disability progression in patients with moderate to advanced disability. Results demonstrated a 21% relative risk reduction in disability progression for patients receiving siponimod (n = 1105) versus those receiving placebo (n = 546; P = .013). In addition, the T2 lesion volume changed from baseline 184 mm³ for patients on siponimod and 879 mm³ for patients on placebo. The most common AEs were headache (15%), hypertension (13%), and increased transaminase (11%). Results from an analysis presented at the 2019 conference for the European Committee for Treatment and Research in Multiple Sclerosis showed the clinically relative benefits of siponimod were highest regarding disability progression, cognitive processing speed and MRI inflammatory disease activity.

In 2019, the Institute for Clinical and Economic Review's (ICER's) Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC) reviewed the clinical and cost effectiveness of siponimod for active and nonactive SPMS. The clinical effectiveness of siponimod was compared to that of best supportive care, which was estimated based on the placebo group in EXPAND. Midwest CEPAC panel members voted 15-2 that adequate evidence demonstrated clinical superiority of siponimod compared to best supportive care for patients with active SPMS. However, they voted unanimously that there was not enough evidence to make this case for patients with nonactive SPMS.

Regarding long-term cost effectiveness, ICER evaluated siponimod versus best supportive care using a Markov model that estimated confirmed disability progression, patient survival, ambulation time, quality-adjusted survival, and lifetime healthcare costs. The model used the initial wholesale acquisition cost of siponimod. Results from the Markov model showed that, for the entire SPMS patient population, the incremental cost-effectiveness ratios were more than $1 million per quality-adjusted life year. For those with active SPMS, the ratios were $433,000 per quality-adjusted life year.

Challenges Regarding Coverage for New SPMS Therapies

The managed care challenges associated with the MS care...
spectrum have become increasingly complicated with the influx of new therapies, particularly in relation to determining a benefits design for SPMS that balances patient access to the right treatment while accounting for high treatment costs — which are growing more rapidly than those of most other disease states. Prior to 2009, many health plans’ formularies included all MS therapies with adequate accessibility. When several new drugs were introduced to the market after 2009, pharmacy and therapeutics committees (groups responsible for determining which drugs to include in the formularies) became more selective. Agents are now chosen based on clinical trial data regarding safety, efficacy and cost/value. Designated efficacy outcomes, which have evolved over time, must be evaluated against the safety of the agent. Short- and long-term safety are particularly important for consideration; however, long-term safety in newer therapies has not yet been established. Health plans must also make accommodations, as some of these therapies are associated with serious safety concerns that necessitate monitoring with administration.

Regarding the increasing costs of SPMS therapy, in addition to selecting SPMS agents with a favorable cost-effectiveness ratio, health plans may offset the costs by developing formulary tiers that incentivize providers to prescribe the most affordable therapies, using generic medication, establishing arrangements with drug manufacturers to fix costs or offer discounts in exchange for a top placement in the formulary and requiring that therapy initiation or switching is preceded by authorization.

Recent labeling inconsistencies among newer, approved treatments have also contributed to the complexities experienced by health plans when determining appropriate patient access. As discussed earlier, the active and nonactive designations for SPMS were established in 2013. They were first included in FDA-approved indications in 2019 when siponimod, cladribine and other disease-modifying therapies entered the market. All therapies for MS have since adopted this terminology for their labeling and all are now indicated for the treatment of active SPMS. A treatment for nonactive SPMS has not yet been developed. Including the active/nonactive terminology in labels can be useful for treatment selection, but standardized definitions do not exist; regulatory authorities have established differing definitions. Although U.S. regulators defined activity based on clinical relapses, European regulators required inclusion of imaging results, indicating inflammation. In addition, product labels have not been required to include a time frame within which patients experienced disease activity. Because all patients with SPMS have experienced activity at some point, any could receive an active status. This challenge may be alleviated if U.S. labels for approved MS therapies included the full definition of activity.

CONCLUSIONS

Substantial personal and economic burdens are associated with MS. As the second most common and debilitating form of MS, SPMS necessitates attention and collaboration from health plans, healthcare providers and the health community to establish tailored, standardized management strategies and evidence-based treatment options. Emerging biomarkers and screening tools may improve clinicians’ abilities to promptly and accurately diagnose SPMS, and newer therapies approved for SPMS may offer a more tailored treatment approach for patients with this condition. There are still opportunities, however, for improvement regarding SPMS diagnosis and treatment. As health plans navigate an increasingly complex and costly treatment landscape, individualized care approaches and shared decision-making should be prioritized.

REFERENCES


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C\textsuperscript{OVID-19 is certainly important. But oncologists, people with cancer, and complex ecosystem of cancer care in the U.S. are grappling with other important issues as well — reimbursement, distorted incentives, the implications of the massive amount of data that is available, and, of course, high costs and prices. Below are thoughts from five experts on these challenges and how they might be met.

1 \textbf{REFORM THE REIMBURSEMENT MODEL}

Oncologists hired New Century Health in Brea, California, to help them navigate the CMS Oncology Care Model and other new ways of paying for cancer care. This gave the company's chief medical officer, Andrew Hertler, M.D., FACP, a front-row seat in the struggle to bring value-based care to organized oncology, which he views as being a long time coming.

"Today's fee-for-service oncology business model misaligns incentives by rewarding practices for keeping margins and service volumes high — even when it's wasteful — rather than for optimizing patient outcomes," he says. "While discussions of drug pricing dominate the cost-control conversation, we as practitioners have been abdicating responsibility and missing the opportunity to address cancer's financial toxicity." The term "financial toxicity" was coined to describe the health effects that high out-of-pocket costs can have on patients if they skip treatment, as well as the financial distress itself as they go through their life savings to cover their treatment costs.

In 2018, spending on cancer drugs in the U.S. reached $57 billion, double the total from 2013. The average cost of a new cancer drug was $150,000 in 2017. Under the buy-and-bill system used in Medicare Part B, CMS pays physicians the average sales price (ASP) of a drug, plus a markup, which had been traditionally been set at 6% but is now 4.3%. It is a common critique of buy-and-bill that it creates an incentive to prescribe more expensive drugs (or, at the very least, that it removes any incentive to prescribe less expensive ones) because the markup is a percentage of that higher cost. Moreover, some physicians and hospital outpatient departments get drugs below the ASP.

Hertler says that some of the expensive oncology drugs, old and new, are true game changers that have extended lives by many years. "But oncology is also rife with examples of therapies that dramatically increase the costs to our healthcare system while bringing relatively minor improvements," he says. "If you're among the two additional individuals in every 100 who benefit, it's a winning proposition." Hertler continues. "But on a population level, however, the costs to our healthcare system and to society can be significant if we routinely make this decision for all cancers."

That is why, in his opinion, continuing this reimbursement model of rewarding the selection of more expensive, less efficacious drugs is not sustainable or acceptable, and if unchecked will ultimately limit patient access to care.

New Century Health and Hertler see clinical pathways as a way to deal with drug costs. "These care pathways guide oncologists in their selection of treatment regimens based on the latest clinical data and help prioritize the most effective treatments with the fewest side effects and lowest cost," says Hertler, who also talks about the need to engage oncologists and keep them involved. "Taken together, this approach is key for allowing oncology practices to take costs into their own hands and drive savings and improvements across the patient journey," he says.

2 \textbf{CURB THE COST OF SPECIALTY DRUGS}

Jeff Patton, M.D., CEO of OneOncology, believes the biggest issue facing oncology is the high cost of specialty drugs.

"It's unsustainable for patients, physicians, employers and even health plans," says Patton, who was named CEO of the large specialty network headquartered in Nashville, Tennessee, in May. "Even when community oncologists don't bill for their work, the cost of therapies causes too much financial toxicity for patients and difficult decisions..."
about coverage and value for employers and plans. Also, says Patton, an analysis by OneOncology showed that the high cost of specialty drugs "poses challenges" for practices in value-based care arrangements, such as the CMS' Oncology Care Model.

Patton says drugmakers could fix the problem of high prices with more rational pricing — or Congress should give CMS the power to negotiate prices.

3 HELP OVERBURDENED ONCOLOGISTS
Dane Dickson, M.D., a practicing oncologist and CEO and founder of Taproot Health in Salt Lake City says oncologists are being asked to do so much more with so much less.

"Decreasing reimbursement, increasing regulations, endless payer requirements and difficulties accessing needed drugs — not to mention the challenges of COVID-19 — are critical problems on their own," he says. "As oncologists, our priority has always been to patients. How can we provide excellent care for today's patients, plus participate in valuable cancer research initiatives to help the patients of tomorrow, when reimbursement is being slashed and administrative burdens are outrageous?"

Dickson believes the real-world data that clinics generate can become a powerful method of advancing cancer research and provide financial resources to clinics.

"But (these) data (have to be) organized and shared to have the greatest value," he says. "Data (are) a commodity worth billions of dollars, yet many oncology clinics ignore this potential revenue stream and may allow it to be siphoned off by others. Oncology clinics need transparent solutions to empower them to collect and share quality data."

4 IMPROVE PATIENT CONSENT
Speaking of data, Dickson pointed to its ownership and patient consent as another trouble spot in oncology. Should patients be asked before their data are taken and sold for private gain? Should clinics have transparent control over the data they are generating?

"Currently, most of the real-world data being provided to third parties is being done without patient consent," he says. "Some patients may have agreed to a vague disclaimer in any of the endless forms they have to sign before receiving care, but this is not informed consent by any stretch."

This issue is further complicated by genetic-testing data, which could easily identify patients, especially those with rare cancers.

"The right thing to do is ask patients and clinics if we can collect, organize and transparently share data, so all parties know how their information is being used," Dickson says.

5 SIMPLIFY CLINICAL TRIALS
According to Claire F. Verschraegen, M.D., director of the Division of Medical Oncology at The Ohio State University College of Medicine, even although oncology is seeing the approval of many new drugs, there's a need to simplify clinical trials. There are a lot of new approvals for new drugs in oncology, and the complexity of the approval process is still challenging. "I feel like we've created a monster of administration when we run clinical trials," she says.

For example, a randomized phase 3 trial may be conducted worldwide at hundreds of sites. Verschraegen believes fewer sites are needed. She also says researchers could pare down the amount of data they are collecting. "If the goal of the study is to measure these 10 items, why are we recording all the things that happen that may have no bearing on the study? Why don't we just focus on the essentials?" she asks. "I think we should come up with an international reorganization of how we run clinical trials to make them more efficient."

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Are we there yet? A look at 4 value-based care programs.

The work of moving away from fee for service is in progress.
The results so far? Mixed. by KEITH LORIA

Will COVID-19 accelerate or put the brakes on the move toward value-based payment? Christopher Chen, M.D., CEO of Miami-based ChenMed, says doctors will embrace value over volume as layoffs and work reductions hit hospitals and medical practices that depend on fee for service. Others expect a tendency to hit the pause button as payers and practices sort through the uncertainty stirred up by the pandemic.

Here are snapshots of four current value-based efforts:

1. **Blue Cross Blue Shield of Massachusetts’ Alternative Quality Contract:**

   Lauded as one of the earliest and most successful value-based care programs in the country, the Blue Cross Blue Shield of Massachusetts Alternative Quality Contract (AQC) sets a global budget for patient care. In the now-familiar arrangement seen with ACOs, providers receive a percentage of the “savings” if they deliver care below budget and pay out losses if they exceed the budget.

   “The program is a pioneer in encouraging providers to treat the whole person — the medical, behavioral and social needs of patients,” says Maria Perrin, chief growth officer of HMS, a population health and healthcare payment company in Irving, Texas. Perrin points to the 2019 study by Zirui Song, M.D., Ph.D., and colleagues AQC saved, on average, $461 per year per member. The study covered an 8-year period from 2009 to 2016.

   The AQC was launched in 2009 as a development project by the Massachusetts Blues plan and providers in Massachusetts, a state with a recent history of experimentation and innovation in healthcare coverage and payment. The 2006 law that expanded healthcare coverage in Massachusetts — so-called Romney-care — was a forerunner of the ACA. The AQC program, which is itself a prototype for ACOs, now has more than 80% of Massachusetts providers participating.

   “While the results of many value-based care programs are still developing and, in some cases, such as with CMS’ Hospital Readmissions Reduction Program, highly debated, the AQC is an example of a very successful VBC (value-based care) program with clear benefits,” Perrin says. “The AQC was also ahead of trends in recognizing the need for integrated care, addressing medical, behavioral and social determinants. Further, the
structure of the AQC is one that does not require regulatory or legislative actions, so it can be adopted by other health plans and health systems with relative ease.

"It’s a drastic change and challenging for payers and providers to operate on a bundled case rate or episodic payment structure."

—CHRISTOPHER J. KUTNER, A PARTNER AT RIVKIN RADLER

2 Hospital Readmissions Reduction Program
The CMS Hospital Readmissions Reduction Program is a Medicare value-based program focused on reducing post-discharge readmission rates. Started in 2012 as part of the ACA, the program imposes financial penalties on hospitals with higher-than-expected readmission rates. Last year, 2,583 of 3,129 hospitals, or 83%, were penalized under the program. The penalty, which varies with the readmission rate, is collected by lowering the Medicare payment to hospitals. According to Kaiser Health News, the lower payments will cost the hospitals, collectively, $563 million during the 2020 government fiscal year.

Hospitals have objected to the readmissions program. But John E. Morrone, a partner in the healthcare department of Frier Levitt, explains that the program is intended to connect reimbursement to quality hospital care, prudent discharge planning and better coordination of care with post-discharge providers. The program is limited to several condition and procedures, including acute myocardial infarction, chronic obstructive pulmonary disease, coronary artery bypass surgery and total knee and hip replacements.

"Those diagnoses lend themselves to frequent readmission due to poor discharge planning and/or poor post-discharge compliance with drug regimen, physical therapy and behavior modification (such as diet and exercise)," says Morrone. Conversely, he notes, multidisciplinary programs, chronic care management and remote patient monitoring are effective approaches to those conditions and procedures.

Moreover, there is good evidence that some relatively straightforward interventions are associated with fewer readmissions. For example, heart failure patients who are prescribed an ACE inhibitor or an angiotensin receptor blocker when they are discharged from hospital have lower readmission rates than those who don’t get such a prescription.

3 Oncology Care Model and its successor, Oncology Care First
The Oncology Care Model (OCM) is CMS’ most important value-based care payment program in oncology, and it is scheduled to be followed in 2022 by a successor program, the Oncology Care First (OCF) Model. Started in 2016, OCM is a voluntary program that CMS says currently includes 138 practices, down from close to 200 several years ago, and
10 payers. As with many value-based payment arrangements, the practices participating in OCM can earn shared savings if they beat certain financial benchmarks; downside risk, which involves paying a penalty if spending exceeds the target but also a chance at greater shared savings, is an option. The participating practices are also paid a Monthly Enhanced Oncology Services (MEOS) payment of $160 per patient for care coordination and other “care transformation” improvements, such as giving patients around-the-clock access to a clinician who has ready access to their medical services and some patient navigation services. OCF nudges oncology payment further along toward capitation by combining payment for evaluation and management services and drug administration with the MEOS payment into a single prospective payment. CMS incorporated some other changes into OCF that are generally seen as advantageous to oncology practices, such as considering adjustments for expensive new therapies on a cancer-by-cancer basis instead of grouping them together.

OCM has received mixed reviews, but an evaluation of its first three performance periods that came out in May was quite damning. It found that OCM showed no overall effect on per-episode payments (the modest $145 per-episode decrease was not statistically significant) and little evidence that the program incentives led to less low-value care (some combination of higher expense and poorer outcomes) and more high-value care (lower expense, better outcomes). Moreover, during the first two pay periods, OCM ended up costing the Medicare program money because the small decline in per-episode payment was offset by what it paid out in MEOS payments and performance-based bonuses for beating the financial benchmarks.

Christopher J. Kutner, a partner at New York State law firm Rivkin Radler who represents managed care organizations and physician groups, says commercial payers want to expand value-based models to better predict the cost of care. But he also points out claim systems were designed for fee-for-service reimbursement. “It’s a drastic change and challenging for payers and providers to operate on a bundled case rate or episodic payment structure.”

“Success hinges on oncologists being incentivized and enabled to deliver high-quality care alongside measurable cost savings,” Kutner adds. “Cancer care is extremely expensive, so I am encouraged that there are some emerging opportunities that stakeholders must examine in order to realize value in today’s oncology reimbursement models.”

CMC’s hypoglycemia measure
Between 30% to 40% of hospital inpatients (with or without diabetes) require insulin therapy during their stay. And despite its impact on health outcomes and the fact that it is largely preventable, hypoglycemia remains a very common occurrence. A study published by the Office of Inspector General shows that hypoglycemia is the third most common adverse drug event among Medicare patients.

Robby Booth, senior vice president of research and development and founder of Glytec, a company that sells insulin-dosing technology, says the new CMS hypoglycemia measure will gain a lot of buzz as the industry shifts more toward value-based care models.

“The program is designed to incentivize safer insulin management practices for hospitalized patients in order to reduce the incidence of insulin overdoses and hypoglycemia, which has a significant impact on the quality and cost of care,” Booth says. “The new CMS hypoglycemia measure (will) address these troubling statistics by incentivizing hospitals to implement clinical workflows that reduce the likelihood of hypoglycemia events.”

The measure hasn’t gone into effect yet, but it is in the final approval stages. The program is a stand-alone measure, but Booth expects that it will be followed up by another measure focused on hyperglycemia.

The program requires health systems to report severe hypoglycemia rates that are tied to a bonus payment. If the health systems don’t track the data, they lose the additional money.

“The agency will eventually use the collected data to establish a penalty for hospitals that report high levels of hypoglycemic events, which could add up to millions depending on the size of the health system,” Booth says.

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