THE ONLY DIRECTION IS UP

The future cost of five common diseases

Population Health
New Medicare benefits offer social support

Drug Pipeline
Trends in rheumatoid arthritis

Formulary/Pharmacy Development
Point-of-care tools take off

Technology
Apps seen in the C-suite

Oncology
Big changes in payment models

March 2020 VOL. 30 NO. 3
Managed Healthcare Executive.com
As part of a combination regimen, provide your members with the only FDA-approved treatment for refractory MAC lung disease.

ARIKAYCE, through its proprietary liposomal technology PULMOVANCE®, delivers inhaled liposomal amikacin directly to the lungs where the infection resides, and has been shown to penetrate biofilms and macrophages.

ARIKAYCE and the Lamira™ Nebulizer System were approved as a drug-device combination and are both processed under pharmacy benefits.

The Lamira Nebulizer System is shipped to patients concurrently with their first dose at no additional cost to the patient or health plan.

An animal study analyzed the in vivo uptake of various formulations of amikacin, including ARIKAYCE, IV amikacin, and inhaled IV amikacin. Five to eight times more amikacin was delivered to pulmonary macrophages treated with ARIKAYCE compared with inhaled IV amikacin. The clinical relevance of this is unknown.

INDICATION

LIMITED POPULATION: ARIKAYCE® is indicated in adults, who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. As only limited clinical safety and effectiveness data for ARIKAYCE are currently available, reserve ARIKAYCE for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

LIMITATION OF USE: ARIKAYCE has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of ARIKAYCE is not recommended for patients with non-refractory MAC lung disease.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF INCREASED RESPIRATORY ADVERSE REACTIONS
ARIKAYCE has been associated with an increased risk of respiratory adverse reactions, including hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases.

Hypersensitivity Pneumonitis has been reported with the use of ARIKAYCE in the clinical trials. Hypersensitivity pneumonitis (reported as allergic alveolitis, pneumonitis, interstitial lung disease, allergic reaction to ARIKAYCE) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (3.1%) compared to patients treated with a background regimen alone (0%). Most patients with hypersensitivity pneumonitis discontinued treatment with ARIKAYCE and received treatment with corticosteroids. If hypersensitivity pneumonitis occurs, discontinue ARIKAYCE and manage patients as medically appropriate.

Hemoptysis has been reported with the use of ARIKAYCE in the clinical trials. Hemoptysis was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (17.9%) compared to patients treated with a background regimen alone (12.5%). If hemoptysis occurs, manage patients as medically appropriate.

Bronchospasm has been reported with the use of ARIKAYCE in the clinical trials. Bronchospasm (reported as asthma, bronchial hyperreactivity, bronchospasm, dyspnea, dyspnea exertional, prolonged expiration, throat tightness, wheezing) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (28.7%) compared to patients treated with a background regimen alone (10.7%). If bronchospasm occurs during the use of ARIKAYCE, treat patients as medically appropriate.
A clinical trial investigated the safety and efficacy of ARIKAYCE - background regimen vs background regimen alone. Efficacy was assessed through a primary endpoint that was based on culture conversion (3 consecutive monthly MAC-negative sputum cultures) by Month 6. ARIKAYCE - background regimen achieved a 3-fold increase in the percentage of patients who experienced culture conversion by Month 6 (29.0% [65/224] vs 8.9% [10/112]) (P<0.0001) compared with the background regimen alone. The additional endpoints of 6-minute walk test distance and St George’s Respiratory Questionnaire did not demonstrate clinical benefit by Month 6.

Exacerbations of underlying pulmonary disease have been reported with the use of ARIKAYCE in the clinical trials. Exacerbations of underlying pulmonary disease (reported as chronic obstructive pulmonary disease (COPD), infective exacerbation of COPD, infective exacerbation of bronchiectasis) have been reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (14.8%) compared to patients treated with background regimen alone (9.8%). If exacerbations of underlying pulmonary disease occur during the use of ARIKAYCE, treat patients as medically appropriate.

Ototoxicity has been reported with the use of ARIKAYCE in the clinical trials. Ototoxicity (including deafness, dizziness, presyncope, tinnitus, and vertigo) were reported with a higher frequency in patients treated with ARIKAYCE plus background regimen (17%) compared to patients treated with background regimen alone (9.8%). This was primarily driven by tinnitus (7.6% in ARIKAYCE plus background regimen vs 0.3% in the background regimen alone). Ototoxicity (6.3% in ARIKAYCE plus background regimen vs 2.7% in the background regimen alone) closely monitors patients with known or suspected auditory or vestibular dysfunction during treatment with ARIKAYCE. If ototoxicity occurs, manage patients as medically appropriate, including potentially discontinuing ARIKAYCE.

Nephrotoxicity was observed during the clinical trials of ARIKAYCE in patients with MAC lung disease but not at a higher frequency than background regimen alone. Nephrotoxicity has been associated with the aminoglycosides. Close monitoring of patients with known or suspected renal dysfunction may be needed when prescribing ARIKAYCE.

Neuromuscular Blockade: Patients with neuromuscular disorders were not enrolled in ARIKAYCE clinical trials. Patients with known or suspected neuromuscular disorders, such as myasthenia gravis, should be closely monitored since aminoglycosides may aggravate muscle weakness by blocking the release of acetylcholine at neuromuscular junctions.

Embryo-Fetal Toxicity: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides, including ARIKAYCE, may be associated with total, irreversible, bilateral congenital deafness in pediatric patients exposed in utero. Patients who use ARIKAYCE during pregnancy, or become pregnant while taking ARIKAYCE should be apprised of the potential hazard to the fetus.

Contraindications: ARIKAYCE is contraindicated in patients with known hypersensitivity to any aminoglycoside.

Most Common Adverse Reactions: The most common adverse reactions in Trial 1 at an incidence ≥5% for patients using ARIKAYCE plus background regimen compared to patients treated with background regimen alone were dysphonia (47% vs 1%), cough (30% vs 17%), bronchospasm (20% vs 11%), hemoptysis (13% vs 13%), ototoxicity (17% vs 10%), upper airway irritation (17% vs 2%), musculoskeletal pain (17% vs 8%), fatigue and asthenia (16% vs 10%), exacerbation of underlying pulmonary disease (15% vs 10%), diarrhea (13% vs 5%), nausea (12% vs 4%), pneumonia (10% vs 8%), headache (10% vs 5%), pyrexia (7% vs 5%), vomiting (7% vs 4%), rash (6% vs 2%), decreased weight (6% vs 7%), change in sputum (5% vs 7%), and chest discomfort (5% vs 3%).

Drug Interactions: Avoid concomitant use of ARIKAYCE with medications associated with neurotoxicity, nephrotoxicity, and ototoxicity. Some diuretics can enhance aminoglycoside toxicity by altering aminoglycoside concentrations in serum and tissue. Avoid concomitant use of ARIKAYCE with ethacrynic acid, furosemide, urea, or intravenous mannitol.

Overdosage: Adverse reactions specifically associated with overdose of ARIKAYCE have not been identified. Acute toxicity should be treated with immediate withdrawal of ARIKAYCE, and baseline tests of renal function should be undertaken. Hemodialysis may be helpful in removing amikacin from the body. In all cases of suspected overdosage, physicians should contact the Regional Poison Control Center for information about effective treatment.


Please see the Brief Summary on the following pages.
ARIKAYCE® (amikacin liposome inhalation suspension)

BRIEF SUMMARY: For complete safety, please consult the full Prescribing Information.

WARNING: RISK OF INCREASED RESPIRATORY ADVERSE REACTIONS
ARIKAYCE has been associated with an increased risk of respiratory adverse reactions including, hypersensitivity pneumonitis, hemoptysis, bronchospasm, exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases (see Warnings and Precautions [5.1, 5.2, 5.3, 5.4]).

1 INDICATIONS AND USAGE
LIMITED POPULATION: ARIKAYCE® is indicated in adults who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of an underlying background regimen therapy. As only limited clinical safety and effectiveness data for ARIKAYCE are currently available, reserve ARIKAYCE use in adults when other limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as ≥3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit was not yet been established (see Clinical Studies [4.1]). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitation of Use: ARIKAYCE has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of ARIKAYCE is not recommended for patients with non-refractory MAC lung disease.

2 DOSAGE AND ADMINISTRATION
2.1 Important Administration Instructions: for oral inhalation use only. Administer by nebulization only with the Lumira® Nebulizer System. Refer to the Instructions for Use for full administration information in use of ARIKAYCE with the Lumira Nebulizer System.

Instruct patients administering the nebulizer ("nUSER") to first stir the bronchodilator following the bronchodilator's label for use information before using ARIKAYCE.

Pre-treatment with short-acting selective beta-2 agonists should be considered for patients with known hypersensitivity airway disease, chronic obstructive pulmonary disease, asthma, or bronchospasm (see Warnings and Precautions). 2.2 Recommended Dosage: The recommended dosage of ARIKAYCE in adults is once daily inhalation of the contents of one 590 mg/4.4 mL ARIKAYCE vial (590 mg of amikacin) using the Lumira Nebulizer System. Administer ARIKAYCE with the Lumira Nebulizer System only. ARIKAYCE should be at room temperature before use. Prior to opening, shake the ARIKAYCE vial well for at least 10 to 15 seconds until the contents appear uniform and well mixed. The ARIKAYCE vial is exposed by flipping up the plastic top of the vial then pulling downward to loosen the metal ring. The metal ring and the rubber stopper should be removed carefully. The contents of the ARIKAYCE vial can then be poured into the medication reservoir of the nebulizer tank.
Table 1: Adverse Reactions in ≥5% of ARIKAYCE-treated MAC Patients and More Frequent than Background Regimen Alone in Trial 1

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ARIKAYCE plus Background Regimen (n=223) n (%)</th>
<th>Background Regimen Alone (n=112) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspnea*</td>
<td>217 (97)</td>
<td>107 (94)</td>
</tr>
<tr>
<td>Cough</td>
<td>177 (79)</td>
<td>96 (85)</td>
</tr>
<tr>
<td>Bronchospasm*</td>
<td>64 (29)</td>
<td>12 (11)</td>
</tr>
<tr>
<td>Hemoptysis</td>
<td>40 (18)</td>
<td>14 (13)</td>
</tr>
<tr>
<td>Obstruction*</td>
<td>38 (17)</td>
<td>11 (10)</td>
</tr>
<tr>
<td>Upper airway illl*</td>
<td>37 (17)</td>
<td>7 (6)</td>
</tr>
<tr>
<td>Musculoskeletal pain*</td>
<td>37 (17)</td>
<td>9 (8)</td>
</tr>
<tr>
<td>Fatigue and asthenia</td>
<td>36 (16)</td>
<td>11 (10)</td>
</tr>
<tr>
<td>Exacerbation of underlying pulmonary disease*</td>
<td>33 (15)</td>
<td>11 (10)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>28 (13)</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Nausea</td>
<td>26 (12)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Rash*</td>
<td>22 (10)</td>
<td>9 (8)</td>
</tr>
<tr>
<td>Headache</td>
<td>22 (10)</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>16 (7)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Vomiting*</td>
<td>15 (7)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>14 (6)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Change in sputum*</td>
<td>12 (5)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Chest discomfort</td>
<td>12 (5)</td>
<td>6 (6)</td>
</tr>
</tbody>
</table>

*Includes aphonia and dysphonia.

+Includes cough, productive cough, and upper airway cough syndrome.

+Includes asthma, bronchial hyperreactivity, bronchospasm, dyspnea, dyspnea exertional, and inspiratory wheeze, tightness, wheezing.

+Includes diarrhea, diarrhea nosocomial, diarrhea pseudomembranous, flatulence, nausea, vomiting.

+Includes upper respiratory tract infection, infection, nasopharyngitis, pharyngitis, rhinopharyngitis, sinusitis.

+Includes back pain, arthralgia, myalgia, polyarthralgia, muscle spasm, muscle strain, myalgia, myositis.

+Includes COPD, diffuse oedema, COPD, interstitial oedema, bronchial oedema.

+Includes pyrexia, fever, infection, bronchial infection, pneumonia, respiratory infection, respiratory tract infection.

+Includes respiratory infection, bacteria, bacterial pneumonia, infection, neutropenia, pneumonia, respiratory tract infection.

+Includes fever, pyrexia, cough, pyrexia, fever.

+Includes chest pain, pyrexia, back pain, fatigue.

+Includes increased weight, increased appetite.

+Includes increased sputum, sputum purulent, sputum dyschromia.

Selected adverse drug reactions that occurred in ≥5% of patients and at higher frequency in ARIKAYCE-treated patients in Trial 1 are presented in Table 2.

Table 2: Selected Adverse Reactions in ≥5% of ARIKAYCE-treated MAC Patients and More Frequent than Background Regimen Alone in Trial 1

<table>
<thead>
<tr>
<th>ARIKAYCE plus Background Regimen (n=223)</th>
<th>Background Regimen Alone (n=112)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>16 (7)</td>
</tr>
<tr>
<td>Oral fungal infection</td>
<td>4 (2)</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Hypersensitivity pneumonitis</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>4 (2)</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Exercise tolerance decreased</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Balance disorder</td>
<td>3 (1)</td>
</tr>
</tbody>
</table>

| Includes chest pain and oral fungal infection.
| Includes back pain and interstitial lung disease.
| Includes chest pain.
| Includes acute respiratory failure and respiratory failure.
| Includes pyrexia, fever, infection, neutropenia, pneumonia, respiratory tract infection.
| Includes pneumophagia, pneumonitis pseudomembranous, and pneumoconiosis.

Ref to Table 1 and Table 2 for the incidence rate of hypersensitivity pneumonitis, bronchospasm, cough, dyspnea, exacerbation of underlying disease, hemoptysis, obstruc, upper airway infection, and pneumonia, dysphagia, diaphagia, dysphonia, pyrexia, fever, infection, nasopharyngitis, pharyngitis, rhinopharyngitis, sinusitis.

7 DRUG INTERACTIONS

7.1 Drugs with Neurotoxic, Nephrotoxic, or Otoxic Potential: Avoid concurrent use of ARIKAYCE with medications associated with neurotoxicity, nephrotoxicity, and ototoxicity.

7.2 Ethyl Alcohol, Acetaminophen, Naproxen, and Other Analgesics: Some diuretics can enhance aminoglycoside toxicity by altering aminoglycoside concentrations in serum and tissue. Avoid concurrent use of ARIKAYCE with ethyl alcohol, acetaminophen, naproxen, or other analgesics.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary: There are no data on ARIKAYCE use in pregnant women to evaluate for any drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Although systemic absorption of amikacin following oral ingestion is expected to be low (see Clinical Pharmacology), systemic exposure to aminoglycoside antibiotics may be associated with total irreversible, bilateral congenital deafness when administered to pregnant women (see Warnings and Precautions). Avoid pregnancy of pregnant women who are likely to conceive.
Chronic Conditions, Cancer Care, and the Patient’s Voice

This month’s issue of Managed Healthcare Executive® features a review of conditions that will tax the U.S. health system over the next decade. There are no surprises here: The related ills of heart disease, diabetes, and obesity account for billions in spending now, and CDC expects these diseases will still top the list in 2030. Obesity is especially frustrating. Despite the good news that cancer deaths are falling overall, the American Cancer Society reports that deaths from obesity-related cancers are on the rise.

While genetics play a role in all these conditions, many costs are preventable—which is why today’s health systems are tasked with population health management. Over the past decade, entrepreneurs have flooded the market with devices, software, and “solutions” that pluck at-risk patients from the crowd so they can receive extra attention, with the aim of keeping them out of the hospital.

The stakes are especially high in oncology, where the cost of new drugs and the complexity of care have forced a rethinking of the way doctors are paid. This issue explains how practices that took part in a groundbreaking experiment, the Oncology Care Model (OCM), will decide whether to move to its replacement, Oncology Care First (OCF), which could start in January 2021. As proposed by the Center for Medicare and Medicaid Innovation (CMMI), the OCF would mark a bolder step away from fee-for-service; oncologists would have to offer more services under a monthly capitated fee. Make no mistake: This is a giant step toward bundled payments in cancer care.

Under the OCM, patients have gained access to same-day appointments, and many practices report fewer ER visits. But oncologists also say they lose money on expensive new drugs, and, fortunately, the successor plan addresses this. Less clear is how the model will pay for new efforts, such as gathering electronic feedback or “patient-reported outcomes.”

Concern about the cost of gathering patient-reported outcome is justified, and at least one advocacy group has called for phasing this in. But CMMI should not waiver on hearing the patient’s voice. In most enterprises, consumer input is essential. Why should healthcare be different?

Mike Hennessy, Sr.
Chairman and Founder of MJH Life Sciences
analysis, insights, and strategies to pursue value-driven solutions.

Mission Managed Healthcare Executive® provides healthcare executives at health plans and provider organizations with analysis, insights, and strategies to pursue value-driven solutions.

Mark Boxer, PhD, is executive vice president and global chief information officer for CIGNA, where he is responsible for driving the company’s worldwide technology strategy.

Lili Brillstein is a nationally recognized thought leader in the advancement of Episodes of Care as a value-based approach for specialty care. She is the CEO of BC Collaborative, which works with stakeholders across the healthcare continuum to successfully make the move from fee for service to value-based healthcare.

Joel V. Brill, MD, is the chief medical officer for Predictive Health, LLC, which partners with stakeholders to improve coverage of value-driven care that optimizes health for people.

David Calabrese, RPh, MHP, is senior vice president and chief pharmacy officer at OptumRx, a pharmacy benefits firm that provides pharmacy care services for more than 65 million lives nationally.

Virginia Calega, MD, is vice president, medical affairs, Facilitated Health Networks at Independence Blue Cross. She oversees utilization management, medical cost, and health outcomes data, and interventions that optimize these outcomes.

Douglas L. Chaet, FACHE, is chief managed care officer, Cleveland Clinic, and chairman, American Association of Integrated Healthcare Delivery Systems.

Perry Cohen, PharmD, is chief executive officer of The Pharmacy Group and the TPG family of companies, which provides services to associations, healthcare and information technology organizations, payers and pharmaceutical companies.

Darnell Dent, is principal of Dent Advisory Services, LLC, a management consulting practice focused on helping leadership improve organizational effectiveness and overall performance. He most recently served as president and chief executive officer for the past seven years of a managed care organization.

John D. Halamka, MD, MS, is president of the Mayo Clinic Platform, and leads a portfolio of new digital platform businesses focused on transforming health by leveraging artificial intelligence, the internet of things, and an ecosystem of partners for Mayo Clinic.

Don Hall, MPH, is principal of DeltaSigma LLC, a consulting practice specializing in strategic problem solving for managed care organizations. He most recently served as president and chief executive officer of a nonprofit, provider-sponsored health plan.

Cynthia Hundorfean is president and CEO of Allegheny Health Network (AHN), an integrated healthcare delivery system that serves Western Pennsylvania. AHN is part of the Highmark Health family of companies.

John Mathewson is chief operating officer for America’s Health Insurance Plans (AHIP), the national trade association that advocates for the health insurance community and the consumers they serve across the nation.

Margaret A. Murray, MPA, is the founding chief executive officer of the Association for Community Affiliated Plans, which represents 54 nonprofit safety net health plans in 26 states.

Kevin Ronneberg, MD, is vice president and associate medical director for health initiatives at HealthPartners, an integrated, nonprofit provider and health insurance company located in Bloomington, Minnesota.

David Schmidt, is president of the TPG International Health Academy, which hosts trade/study missions around the world for U.S. healthcare executives. He also provides strategic consulting to health plans and health systems.

Paul J. Setlak, PharmD, MBA, is director of field health outcomes at AstraZeneca, where he is responsible for leading field-based clinical and health outcomes activities with payers, integrated delivery networks, health systems, and other groups.

William Shrank, MD, is Humana’s senior vice president and chief medical officer. In this role, he is responsible for leading and implementing the company’s integrated care delivery strategy. This strategy emphasizes a consumer-friendly, evidence-based, technology-enabled approach to personalized health improvement for the company’s more than 16 million Humana health plan members.
THE ONLY DIRECTION IS UP
The future cost of five of the most common diseases  PAGE 14
The Future Of Healthcare And The MSO Approach
It is not what you think it is...or should be...

By Thomas Ferkovic, CEO, Medic Management Group

As healthcare leaders, we are continually torn between maintaining market share, improving quality, and staying solvent while implementing population health strategies. With all of this responsibility, do you sometimes feel that the investment in the future practice model, and the infrastructure necessary to change for the future, are just not worth the time, energy and cash? We have been informed and somehow resolved that an MSO is the answer to all our challenges.

So, what is an MSO? Google it and your mind will explode. Most define it as entities that help with the non-clinical component of a practice or groups of providers. MSO’s may even be investor vehicles for joint ventures for-profit, nonprofits, providers and other entities. As defined by medical literature, it is a vehicle to save money through efficient operations. These are short-sided and misleading definitions because an MSO needs to be so much more.

Success in healthcare lies with a vision of the future. We have learned over the years that one vision does not fit all organizations or services in healthcare. Success, however, lies in the execution of the vision, which has two components, the first is a clinical network component, i.e., critical mass/geographic coverage. We provide clinical care to patients so the network and coverage are vital. The second is the operational component, i.e., financial sustainability. Clinical services without operational sustainability are doomed to fail, the two items are mutually dependent. Historically, we have served these separately.

These two critical components require different skill sets and investment. There is no one model that works for every organization. In fact, some organizations deploy multiple models to allow for flexibility. Success is defined by achieving both operational and network growth. The current models and definitions of a MSO that does the administrative work alone are old definitions and models. A successful MSO understands and helps clinical services to excel and achieve goals.

It’s time we reshape conventional thinking. This is necessary if traditional agents of care are to come together to maximize the healthcare experience for all patients. A shift in the thinking and implementation of an MSO moves away from the basic economics of shared resources to a transformation that focuses on the patient first. This is how the MSO becomes not “Managed” but a “Maximizing Services Organization” for solutions and execution. The new MSO optimizes the physician practice and creates a bridge, which connects the agents of care together and forms the healthcare network of the future.

Learn how the new MSO model can transform your organization to a future forward, patient-centric experience.

Join us for THE FUTURE WILL SEE YOU NOW: The MSO Approach
APRIL 23, 2020 Cleveland, Ohio, Marriott Downtown at Key Tower
REGISTER TODAY for early-bird conference pricing at futurewillseyounow2020.meetinghand.com

THE FUTURE WILL SEE YOU NOW: THE MSO APPROACH is presented by

MEDIC MANAGEMENT GROUP LLC

© 2020 Medic Management Group. All rights reserved.
Can Physicians Reduce Waste?

The healthcare industry is rapidly transforming to a consumer-based, technology-driven system that is built around the physician and patient relationship. Many of us involved in this endeavor are confident that our efforts will not only help stem the rising tide of chronic diseases that challenges our nation but will also enable us to create a more sustainable system.

While it is a common understanding that too much of the $3.6 trillion we spend on healthcare is not wisely spent, there are opportunities for the industry to make some changes. Recently, colleagues from Humana [Shrank was the lead author] and the University of Pittsburgh School of Medicine conducted a review, published in JAMA, assessing the amount of waste in the U.S. healthcare system.

The researchers concluded that 25% of the total amount spent on American health care annually, which comes out to between $760 billion and $935 billion, can be classified as wasteful spending across six waste domains: failure of care delivery, failure of care coordination, overtreatment/low-value care, pricing failure, fraud and abuse, and administrative complexity. They also calculated that savings from identified interventions that would reduce that waste, apart from administrative complexity portion, would tally up to between $191 billion and $286 billion.

So what can we do as physicians to address this waste?

Here are four actionable ways to decrease wasteful healthcare spending:

1. **INTEROPERABILITY IS ESSENTIAL FOR EMPOWERING PHYSICIANS**
   By allowing care teams to access the entire health record, quality of care is improved. Providers have context around the care that has been given and unnecessary duplication of services are eliminated.

2. **LOOKING HOLISTICALLY AT THE PATIENT. PATIENTS DON’T LIVE AT THE DOCTOR’S OFFICE.**
   Barriers exist for patients that are not obvious unless we specifically ask about them. Consider transportation. Seniors who can no longer drive may not have access to food or medicine or may not be able to use smartphones to order food or transportation. Visual and hearing impairments may contribute to loneliness and depression. We need to address these barriers to help our patients stay as healthy and independent as possible.

3. **TRANSITIONING TO VALUE-BASED CARE LEADS TO BETTER OUTCOMES.**
   As physicians and health care providers, we get significant gratification when our patients do well. Experience has taught us that putting patients at the center of the care equation improves outcomes—and better outcomes, ultimately, also help reduce costs. Accelerating our adoption of value based-payment arrangements can help usher in a new patient-centered era of American healthcare that will bring with it interoperability and a holistic view of our patient. Value-based care is also a way to address some of the domains from the JAMA study: failure of care delivery, failure of care coordination, low-value care, and pricing failure.

4. **HELP SENIORS STAY IN THEIR HOMES AND OUT OF THE HOSPITAL.**
   Working to keep seniors in their homes by delivering personalized, convenient care will improve both the patient experience and reduce costs.

The light of curiosity that guided our path as physicians into healthcare can be used to help solve these issues in our broader health care landscape. As we work to improve interoperability, address social needs, and help physicians transition to value-based care, the other domains responsible for wasteful healthcare spending will become far more manageable.

William Shrank, MD, is chief medical and corporate affairs officer at Humana and serves as an editorial advisor for Managed Healthcare Executive.

Meera Atkins, MD, a board-certified obstetrician and gynecologist, is currently participating in Humana’s Executive Immersion Physician Program.
Although there is no cure for rheumatoid arthritis, therapies have greatly improved in the past 30 years. 

“The goals of RA treatment are to stop inflammation, relieve symptoms, prevent joint and organ damage, improve physical function and overall well-being, and reduce long-term complications,” explains Julie Rubin, director of clinical services for CompleteRx, a pharmacy management company in Houston.

According to the American College of Rheumatology, RA patients should begin their treatment with disease-modifying antirheumatic drugs (DMARDs), which slow the worsening of joint damage as well as relieve symptoms. Commonly prescribed DMARDs include methotrexate, leflunomide, sulfasalazine, and hydroxychloroquine.

“DMARDs have greatly improved symptoms, function, and quality of life for nearly all patients with RA; however, RA treatment is complicated and often progressive in nature,” observes David Calabrese, RPh, MHP, senior vice president and chief pharmacy officer, OptumRx. It is common for patients to switch therapies multiple times in their lives, he notes. People with RA also take medications such as ibuprofen and corticosteroids to manage their pain and inflammation on an as-needed basis.

“While the last few years have seen a string of new drug approvals for RA, there are very few products in the drug pipeline now that are in late stage development,” observes Calabrese. The most notable, he says, is filgotinib (Gilead Sciences and Galapagos NV), a highly selective, oral Janus kinase (JAK) inhibitor. Janus kinases are tyrosine kinases that play a critical role in the signaling pathways that are seen as critical to the pathogenesis of rheumatoid arthritis and a number of autoimmune diseases. The new drug application for filgotinib was submitted in December 2019, along with a priority review voucher, which should shorten the anticipated time for review.

If gets approved and makes it on to the market, filgotinib would compete with the approved JAK inhibitors, Xeljanz (tofacitinib), Olumiant (baricitinib), and Rinvoq (upadacitinib), explains Calabrese. Rinvoq was approved just last year. ATI-450 (Aclaris Therapeutics) is an oral Mk2 (mitogen-activated protein kinase-activated protein kinase 2) inhibitor currently in Phase 1 trials for the treatment of RA. The FDA approved the investigational new drug application in May 2019, and Phase 1 clinical trials started in August 2019.

Rubin expects more DMARDs and new additions to the JAK inhibitor drug class. “The RA drug pipeline is focused on minimizing disease progression and immune system malfunction,” she says. “These new drug classes could reduce and, in some cases, reverse clinical symptoms.”

Biosimilars may not be novel therapies, but they are one of the key areas to monitor in RA therapy in Calabrese’s opinion.

Acceptance of biosimilars—by providers and patients—will be key to determining uptake and realizing their savings potential, he says. Payers are attempting to transition patients from existing branded biologics to less costly biosimilar alternatives with the goal, he adds, “of improving patient care and lowering total cost of care.”

Erin Johanek, PharmD, RPh is a staff pharmacist at Southwest General Health Center, Middleburg Heights, Ohio.
New point-of-care tools offer greater transparency. by MARIE EDLIN

ew point-of-care (POC) tools that promote communication between providers and patients are establishing themselves as next generation shared decision-making solutions, especially when it comes to medications and issues of insurance coverage, price, and out-of-pocket costs.

“When compared to traditional shared decision-making tools, there’s an increased emphasis not just on improving measures such as medication adherence by involving the patient in his or her own care but also on using this education and engagement to improve patient satisfaction,” says Chuck Lee, MD, senior director of clinical knowledge and Meducation at First Databank, a San Francisco company medical data company.

Meducation, which uses research-based health literacy approaches to simplify medication instructions, was focused solely on providing key instructional and adherence tools related to medications self-administered at home. Now its new content is designed to directly address Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient satisfaction questions on newly administered inpatient medications, including 200 new intravenous drug forms and hospital-administered medications.

Lee says that access to these point-of-care tools has been enhanced. With Meducation, all patient education materials are automatically made available through the patient portal or via a standalone portal. It’s a brand new, patient-facing world for these POC tools.

“Many of the older shared decision-making tools were designed to be used exclusively by providers of care and not to interact with patients,” notes Heidi Polek, RPh, senior manager, independent pharmacy solutions for DrFirst, an e-prescribing and patient medication management company in Rockville, Maryland.

A Humana, Epic collaboration

Joel Jones, PharmD, director, population health informatics for Epic, says the new tools are being embedded directly into physicians’ workflows with built-in next steps that allow them to easily and efficiently swap in a more cost-effective drug. Alan Wheatley, president of Humana’s retail segment, agrees that one of the primary old vs. new differences in decision-making tools is that the new ones can be integrated into a physician’s workflow. There’s also added interoperability.

Humana has partnered with Epic to integrate IntelligentRX, its real-time benefits check tool, into Epic’s e-prescribing workflow. The result is real-time access to a patient’s medical history, health insights, and treatment options.

The EHR software enables clinicians to immediately estimate the cost of a medication and share it with a patient by factoring in copayments, deductibles, and the need for prior authorization. The application sends an alert about less expensive options. The software also helps physicians to avoid gaps in care by, for example, reminding a patient that she is due to have a mammogram soon.

“Our relationship with Humana is an opportunity to help patients and prescribers work more collaboratively with payers, streamline procedures, and integrate information into a doctor’s workflow,” says Jones.

One of the benefits, Jones continues, is limiting prescribing fatigue on the part of providers because they are dealing with information that is accurate and can be acted upon, based on a patient’s coverage. It also promotes communication among payers, clinicians, and patients and puts data on a common platform, he says.

Wheatley, says there is more interest in the tool than expected, and he anticipates it will improve quality and play out positively in CMS’ Star Rating system.

Other companies are also folding insurance coverage information into workflows and platforms. Allscripts, a Chicago EHR technology company, offers a transparency feature from Veradigm, a health informa-
INOmax DSIR® PLUS DELIVERY SYSTEMS

Devoted to Delivering Ongoing Innovations in Critical Care

The INOmax DSaR Plus Delivery Systems provide innovative design and user experience to support the ever-changing demands of the critical care space and keep patient safety a top priority.1,2

• Delivering specialized, redundant, and customizable alarm features designed to help mitigate the risk of device-related rebound pulmonary hypertension
• Advanced features enable delivery of therapy specifically for the MRI suite
• Integration with neonatal transport systems to support seamless delivery of therapy

Applications
The INOmax DSaR Plus Delivery Systems deliver INOMAX® (nitric oxide) gas, for inhalation. The INOmax DSaR Plus Delivery Systems must only be used in accordance with the indications, usage, contraindications, and warnings and precautions described in the INOMAX package inserts and labeling. The approved patient population is limited to neonates. Refer to the INOMAX Full Prescribing Information prior to use.

Device Warnings
• Abrupt discontinuation of INOMAX can lead to worsening oxygenation and increasing pulmonary artery pressure (rebound pulmonary hypertension syndrome). To avoid abrupt discontinuation, use the INOBlender® or backup mode immediately to reinstate INOMAX therapy and refer to the INOMAX package insert.
• If the high NO/two.inf alarm activates, the delivery system should be assessed for proper setup while maintaining INOMAX delivery.
• Do not connect items that are not specified as part of the system.
• If an alarm occurs, safeguard the patient first before troubleshooting or repair procedures.
• Use only INOMAX, pharmaceutical grade NO/N₂.

Use in an MR Environment
• Only use a size “88” (1,963 liters) cylinder that is marked “MR Conditional. Keep cylinder at 100 gauss or less.” with the DSaR Plus MRI while in the scanner room. Use of any other cylinder may create a projectile hazard.

• The INOmax DSaR Plus MRI is classified as MR Conditional with MR scanners of 1.5 or 3.0 Tesla strength ONLY in areas where the field strength is less than 100 gauss.
• This device contains ferromagnetic components and hence will experience strong attraction close to the magnet. It should be operated at a fringe field of less than 100 gauss.
• A strong magnetic field such as that from an MRI system can affect the ability of the INOmeter to detect if the cylinder valve is open. This can cause a “Cylinder Valve Closed” alarm to occur when the cylinder valve is actually open. If this alarm occurs, reposition/rotate the INOmax DSIR® Plus MRI cart outside the 100 gauss area to reduce the magnetic interference in the area of the INOmeter until the cylinder handle graphic on the display turns green. This will resolve the “Cylinder Valve Closed” alarm. Typically the required INOmax DSIR® Plus MRI cart location adjustment is less than 6 inches (15 cm)/90 degrees. Note that interruption of INOMAX therapy will occur one hour from point when the “Cylinder Valve Closed” alarm is activated if the alarm is not resolved.

Rx Only
Consult the Operation and Maintenance Manual, which may be found at www.inomax.com/inomax-deliverysystems/support-resources, for complete information. For technical assistance, call (877) 566-9466.

For additional information, technical assistance, or a complete list of warnings regarding use of validated ventilators, please refer to the INOmax DSaR Plus Operation Manual at inomax.com/dsirplusmanual

References:
**INOmax® (nitric oxide gas)**

**Brief Summary of Prescribing Information**

**INDICATIONS AND USAGE**

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**

**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.

**Overdosage with INOmax**

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.**

**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 hemorrage, 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%).

**Drug Interactions**

Nitric Oxide Donor Agents

Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.
continued from page 10

Point-of-Care Tools in Pharmacy Take Off
Pharmacy/Formulary Development

“Many of the older shared decision-making tools were designed to be used exclusively by providers of care and not to interact with patients.” — HEIDI POLEK, DR. FIRST

Allscripts’ survey found that 60% of participants said adherence improved when patients received pricing information.

Helm says the price transparency tool also helps patients choose the best pricing model through their insurance plan—or whether to pay cash. It can also help select a pharmacy that will support the best adherence to prescription therapy.

Polek says that DrFirst offers a patient engagement tool called RxNotification, which can be used to send secure messages from participating prescribers or pharmacies to patients, giving them information on pricing and affordability, why the drug has been prescribed, clinical information, how to take the drug, and cost savings. “RxNotification helps reduce adherence barriers and alleviate cost issues,” Polek says. “It also combats issues of price transparency because patients can see prices before a prescription is filled and decide if they can afford it, thus reducing drug abandonment.” The tool has proved to reduce drug abandonment by 6%, according to Polek.

Another tool, Backline, is a web-based, HIPAA-secure service environment in which all stakeholders—providers, hospitals, long-term care facilities, and pharmacies—ask questions and share patient data via encrypted, text-style messaging, replacing phone calls, texts, faxes, and emails. Polek says Backline, sold to hospital and physician practices and later to insurers, enables participants to exchange messages about whether a drug is covered under a patient’s plan.

RxAdvance, a national, full-service PBM, leverages its Collaborative PBM cloud platform to provide all stakeholders with a comprehensive view of a patient’s health and medication regimen. The platform allows review and optimization of a member’s regimen to proactively prevent adverse drug events and eliminates duplicate therapies.

“The cloud model reduces costs and allows for more efficient and streamlined communication amongst stakeholders in the field of care,” says John Sculley, former CEO of Apple and co-founder of RxAdvance. He attributes the rise of pharmacy tools to a higher demand for streamlined, data-driven process as more patients receive care at home. He says the egregious cost of drugs is another factor. RxAdvance has enabled a 10% to 12% reduction in overall pharmacy costs; a 10% to 15% reduction in specialty pharmacy costs; and a 20% to 25% reduction in avoidable drug-impacted medical costs.

“Using RxAdvance’s collaborative PBM cloud can empower pharmacists to make critical decisions at the point of sale to help improve adherence and also to reduce avoidable medical costs,” Sculley says.

Mari Edlin is a writer based in Sonoma, California.
THE ONLY DIRECTION IS UP

The future cost of five of the most common diseases

By KAREN APPOLD
According to the CDC, heart disease, cancer, diabetes, obesity, and Alzheimer’s disease are currently among the most expensive health conditions in the United States. The price tags are simply staggering.

The CDC says chronic disease—including mental health conditions—accounts for 90% of the $3.5 trillion spent annually on healthcare in United States. But calculating healthcare spending by condition or disease is complex, with a welter of variables to consider and factor in.

Several years ago, researchers at the Institute for Health Metrics and Evaluation at the University of Washington set out to estimate spending by disease category. They wound up using 183 different sources of data to tally up the spending on 155 different conditions. When the federal Bureau of Economic Analysis (BEA) calculated disease-based healthcare spending for 2016, the largest category, at $334 billion, was a catchall of “ill-defined” conditions that includes colds, allergies, and preventive services. To further complicate matters, cost gets defined in different ways. Sometimes it refers only to direct healthcare costs; other times, the indirect costs of lost income and productivity get factored in—and not just for the people affected by the disease but also for those who take care of them.

Despite the Rubik’s cube of variability, caveats, and judgment calls, there is fairly broad agreement on which health conditions are going to be most costly for the American healthcare system over the next decade.

CARDIOVASCULAR DISEASE

Virtually, every list puts cardiovascular disease (CVD) at the top of the cost charts. The American Heart Association’s 2019 heart and stroke update put the annual cost of CVD at $351 billion—most of it ($214 billion) in direct costs.

In the BEA’s disease-specific tallies, CVD at $249.4 billion, was second only to the ill-defined conditions category as the costliest group. Sheer prevalence is a major factor in the expenditures for CVD. The AHA says nearly half of American adults have CVD. New guidelines that expanded the definition of high blood

Continued on page 16
Continued from page 15

pressure are one of the reasons such a large proportion of American population are categorized as having CVD.

CVD is not just expensive and common. It’s deadly. In fact, heart disease remains the leading cause of death in this country despite genuine progress in prevention and treatment. In 2017, heart disease caused 647,457 American deaths, or 23% of the total for that year.

In the next 10 years, many of these numbers are expected to increase because risk factors for CVD are still major problems, notes Richard Seidman, MD, MPH, the chief medical officer for L.A. Care Health Plan, a Medicaid managed care health plan in Los Angeles that is the nation’s largest publicly operated health plan.

Smoking is a major risk factor to CVD and smoking rates have been on the decline for decades. Still, in 2017, an estimated 14% of Americans adults were “every day” or “someday” cigarette smokers. That translates into 34 million smokers, a sizable number by almost any standard. The rates of obesity, another major CVD risk factor, have been climbing for decades; almost 4 out of every 10 American adults are obese. Obesity also ticks up in the risk factor column for type 2 diabetes, and the American Diabetes Association says more than 9% of Americans have diabetes, an all-time high. Seidman points out that adults with diabetes are two to four times more likely to die from heart disease than those without diabetes.

Treating CVD involves a wide range of costly medical services: diagnostic tests, ambulance trips, hospital stays, angioplasty, bypass surgery, to name just few. The pharmaceutical armamentarium for CVD is large, and generics have lowered the expense of some classes of medications—statins are the prime example. Yet the American Heart Association reports that 1 in 8 heart patients skips their medication because of price and affordability.

“Until we can bring the costs of medications down, noncompliance will continue,” Seidman says. “People who don’t adhere to their medication regimen will get sicker, raising costs even more.”

CANCER

Cancer is common—1.8 million new cases will be diagnosed this year, according to the American Cancer Society. It’s also lethal—roughly 600,000 Americans will die from cancer this year, although the mortality rate has been dropping. The 2.2% decrease from 2016 to 2017 was the largest decline in a single year, according to the cancer society. The flip side to declining mortality is an increasing number of cancer survivors. If projections made by NCI researchers almost 10 years ago are holding up, there are now more than 18 million cancer survivors in the US.

Given these numbers, some of the cost estimates for cancer are surprisingly low. The BEA put the cancer price tag at $135.8 billion, and the Institute for Health Metrics and Evaluation arrived at a figure of $115.4 billion, which is considerably less than its estimate for CVD ($231.1 billion) and mental and substance use disorders ($187.8 billion).

However, those estimates were made before the current surge in expensive cancer treatments and, more particularly, the advent of the costly immunotherapies. Prices of more than $100,000 a year for cancer treatments are not the least bit surprising these days.

“While new therapies are more effective and individualized based on a patient’s individual genomic makeup or the cancer’s genomic makeup, overall cancer treatment is becoming much more costly on a per patient basis,” notes Richard P. Morel, MD, MMM, FACP, chief physician executive CareMount Medical, a multispecialty medical group in Chappaqua, New York.

Expensive treatment in combination with benefit design that leaves patients and their families exposed to high costs have made “financial toxicity” a major issue in oncology. Scott Ramsey, MD, PhD, director of the Hutchinson Institute of Cancer Outcomes Research in Seattle, has conducted the leading studies on financial toxicity. Ramsey and his colleagues have shown that cancer patients are 2.6 times more likely to declare bankruptcy than people without cancer. Drug companies and healthcare systems have a variety of ways of insulating patients from sky-high prices, but it isn’t complete protection by any means.

Apart from price and the vast array of prevention and treatment choices, demographics and other trends are likely to push cancer incidence and prevalence up in the coming decade. The demographic march of baby boomers into their seventh and eighth decades will be a factor.

“The number of cancer diagnoses will likely continue to climb as the population continues to age,” says Seidman, pointing out that in 10 years’ time all the boomers will be older than 65.

Alcohol consumption is a risk factor for several types of cancer, noted Seidman. Several
years ago, results reported in *JAMA Psychiatry* that were based on an analysis of data from the National Epidemiologic Survey on Alcohol and Related Conditions showed that more Americans are drinking alcohol, and more are drinking to a harmful level. Obesity is another potent, ascendant cancer risk factor. Much of the evidence comes from observational studies, so it has some ifness to it, but the association between obesity and liver, kidney, endometrial, and several other cancers is strong.

**DIABETES**

In its ranking of 2013 spending on 155 health conditions, the Institute for Health Metrics and Evaluation ranked diabetes as the most expensive one at an estimated $101.4 billion with most (57.6%) of the money paying for pharmaceuticals.

A 2018 report from the Milken Institute on the cost of chronic disease identified diabetes as the second only to CVD in direct costs ($189.6 billion vs. $294.3 billion for CVD). Prevalence, as usual, is one of the principal reasons for the size of the expenditure. The American Diabetes Association says there are 30.3 million Americans with diabetes, a figure that includes 7.2 million people who haven’t been diagnosed. A study published in *Population Health Management* in 2017 projected that number of Americans with diabetes will increase in this decade and reach 54.9 million by 2030. Latinos make up a growing proportion of the U.S. population, and diabetes is more prevalent among Latinos than other groups. Latino adults are, for example, 1.7 times more likely than non-Latino white adults to be diagnosed with diabetes.

“Diabetes will continue to be an expensive medical condition 10 years from now because of the many complications that occur, most of which are related to sedentary lifestyles and unhealthy diets,” says Richard Dal Col, MD, MPH, chief medical officer, of EmblemHealth, a nonprofit health insurer in New York. “The longer someone has diabetes that is not well-controlled, the higher their likelihood of complications over time—including renal and cardiac failure.”

The dramatic jump in the price of insulin is also having a significant impact on the cost of diabetes care. A congressional report stated...
insulin costs jumped nearly 300% from 2002 to 2013. “Government leaders at all levels have been pressuring drug companies to do something about these rising costs, but the companies argue that the high price is due to new insulin formulations,” Seidman says. The new formulations also have the effect of blunting competition from some lower-priced generics.

**OBESITY**

Whether obesity is a risk factor or its own health condition might be debated. But there’s no question that the percentage of Americans who are heavy is getting larger. The latest CDC estimate is that 39.8% of Americans adults are obese, with obesity defined as a BMI of 30 or greater. The estimate for children is 18% (obesity in children is defined by percentile, not a BMI.

“Not only are obesity rates increasing but obesity is starting earlier in life, adding more years of exposure to risk,” says Morel at CareMount. “Combined with increasingly sedentary lifestyles, the prevalence of costly complications from obesity will continue to drive higher costs of care.”

The Milken Institute report says chronic diseases caused by obesity or being overweight (a BMI of 25 to 29.9) accounted for almost half (47.1%) of the total cost of chronic disease in 2016, including $480.7 billion in direct costs and $1.24 trillion in indirect costs.

Migration patterns within the U.S. may further deepen the country’s obesity epidemic.

“There is regional variation in obesity, in part due to differences in the built environment and local lifestyles,” says Adam C. Powell, PhD, president of Payer+Provider Syndicate, a healthcare consulting firm in Boston. Many states with lower obesity rates, such as California, New Jersey, and New York, where 25%-30% of the population is obese, are experiencing net outflows of people, according to Powell. Meanwhile, states with higher obesity rates, such as Florida, Tennessee, and Texas, where 30%-35% of the population is obese, are experiencing net inflows.

**ALZHEIMER’S DISEASE**

The Milken Institute estimated the direct cost of Alzheimer’s disease at $185.9 billion. The Institute for Health Metrics and Evaluation figure of $36.7 billion is far less. In fact, according to the institute’s ranking, Alzheimer’s is the 21st most costly health condition. The discrepancy is a useful reminder that these per-disease cost figures are just estimates made with differing assumptions and criteria.

More than 5 million Americans are currently living with Alzheimer’s. As the number of Americans in their 70s, 80s, and 90s increases, that number is expected to increase dramatically. By 2050, nearly 14 million Americans are expected to have Alzheimer’s, according to the Alzheimer’s Association’s 2019 facts and figures report.

Matthew Baumgart, the senior director of government affairs for the Alzheimer’s Association, said the combination of aging baby boomers and improving outcomes for other diseases that affect older people means the incidence of Alzheimer’s is likely to increase—and with that, the cost.

Billions have been invested in Alzheimer’s research and drug development, but the results have fallen short, so high drug costs are not much of a factor—yet—in the cost of Alzheimer’s. But people often live with Alzheimer’s for many years, and that can mean years of expensive care in at home or in a facility. Often the cost tally for Alzheimer’s doesn’t include the billions of dollars of uncompensated care that more than 16 million family members and friends provide. In 2018, unpaid care for people with Alzheimer’s and other dementias totaled more than 18 billion hours, at an estimated economic value of $234 billion, according to the Alzheimer’s Association.

“Unless disease-modifying treatments are discovered, these costs will continue to skyrocket over the next decade and beyond,” says Baumgart.

The extended family, including children and grandchildren, used to be the main caregivers for many people with Alzheimer’s and other kinds of age-related dementia, observes Morel.

“But with higher rates of dual-income families, more individuals with Alzheimer’s and dementia are moving to long-term care facilities or rely on home health, adding a huge expense going forward,” he says.

In addition, there may be an increasing number of hospital admissions for the frail and elderly with cognitive issues, and many will be unable to go directly home after discharge, Morel says. “Instead they will require additional care in subacute or rehabilitation facilities, further adding to care costs.”

Karen Appold is a medical writer in the Lehigh Valley region of Pennsylvania.
Let’s Connect.

Managed Healthcare Executive® is on LinkedIn!

Network with fellow executives from across the world while you stay current on healthcare’s new developments and innovations.

Follow Us

managed healthcare executive
Intermountain Healthcare is a Salt Lake City-based nonprofit healthcare system, providing hospital and other medical services in Utah and Idaho and offering integrated managed care under the insurance brand SelectHealth.

Charles W. Sorenson, MD, FACS, has been an influential reason for Intermountain’s success, having served as president and CEO of from January 2009 until his retirement from this position in October 2016, when he became founding director of the Intermountain Healthcare Leadership Institute.

“My best trait is the ability to hang out with people who are far more capable than I am,” Sorenson quips. “I am not intimidated by working with people who are smarter than I am.”

Under his leadership, Intermountain implemented a disciplined and systemwide focus on best clinical and operational practices aimed at producing better outcomes for patients all while controlling costs: “I’ve always been focused on best care for our patients.”

Sorenson also sees the culture at Intermountain as having a ripple effect. “We had nearly 40,000 people working there who spent more time at work than with their families,” he notes. “Whatever culture they had at work, they would surely import to their children and families.”

Prior to his time in the top job, Sorenson was Intermountain’s executive vice president and chief operating officer for 11 years. He was instrumental in making clinical process improvements and developing Intermountain into an integrated delivery system. “This is a great career for making a difference for multiple people every day,” Sorenson says. “At the same time, it’s a career you continue to learn from and improve your skills. I’d do it all over again in an instant.”

Making his mark

Becoming a physician was in the cards for Sorenson. His father was a dedicated internist in Salt Lake City. Sorenson says he didn’t see much of his father growing up because of the long hours his father put in, but he knew his dad loved his patients and never once heard him complain. Sorenson’s mother was a nurse and equally dedicated.

“I was a pretty good student, and I wanted to go to medical school because it was the hardest thing I could think of doing,” he says. “I always felt like doing hard things was good for me, and I always felt like this is what I always wanted to do.” He dreamed of going to medical school on the East Coast. An acceptance letter from Cornell turned that dream into a reality. He quickly rose to the top of his class.

Sorenson ended up liking surgery and enjoyed his residency: “Even though it was long hours, I never felt burdened by that.” He specialized in urologic surgery and returned to Salt Lake City. In the early ‘80s, he practiced at Intermountain’s largest hospital and was on the teaching staff at the University of Utah.

In the early ‘90s, Sorenson noticed a worrisome trend in healthcare: Surgeons buying their own surgical centers, urologists buying their own lithotripters, and a general trend of physicians taking control of services that make money away from hospitals.

“In fee-for-service medicine, you get paid really well for some procedural things, and you don’t get paid at all for taking care of patients with long-term medical illnesses, behavioral health issues, and managing people on Medicaid,” says Sorenson. “I felt like things were fragmenting.”

Sorenson says he talked to some of the leaders at Intermountain
Featured Exec: Charles W. Sorenson  Industry Analysis

Charles W. Sorenson
- Originally from Salt Lake City, Utah
- Received BA from the University of Utah and MD from Weill Cornell Medical College at Cornell University
- Served as speaker of the House of Delegates of the Utah Medical Association
- Chaired the Committee on Young Surgeons for the American College of Surgeons
- Serves as adjunct professor of surgery at the University of Utah

about starting an integrated medical group. In 1994, Sorenson was one of the founding members of the Intermountain Medical Group, an integrated practice of approximately 1,500 physicians and advanced practice clinicians employed by Intermountain. He served as the founding chair of the Medical Group Board from 1994 to 1998.

“I was continuing in my clinical practice and also on the Intermountain board at the time, and they asked me a couple of times if I wanted an administrative responsibility instead of clinical work, but I didn’t really want that then,” explains Sorenson. “In late 1997, things were changing, and they asked me if I would be willing to go full-time in leadership role, and after thinking about it a long time, I felt it was important and did it.”

He admits he wasn’t excited about leaving clinical practice but hoped to spend a morning every week in the operating room helping colleagues on major surgical procedures.

Sorenson learned healthcare leadership and administration on the job. “They didn’t want me to get an MBA. They needed someone who understood the clinical processes and could relate to frontline clinicians—physicians and nurses—and focus on providing healthcare affordably and achieving Intermountain’s mission,” he says.

Jumping into the CEO and president positions wasn’t something that Sorenson was planning on doing, but when he was asked, he accepted and stayed in that role until he passed age 65. Then, Sorenson pursued something that he was really passionate about—developing leaders at the intersection of clinical and operational expertise at the Institute for Healthcare Leadership. In addition to his administrative responsibilities, Sorenson has also continued to be involved in the practice of urologic surgery, with a primary focus on urologic oncology.

The institute got off the ground because of a “very generous” gift of $20 million from Kem C. Gardner, a Utah real estate developer, Sorenson says. It is focused on values-based leadership principles to help healthcare leaders more fully develop the combination of character and competence that inspires trust, which Sorenson notes is at the core of great leadership.

“I thought it was important to train people to combine clinical expertise and knowledge with operational expertise,” Sorenson says. “There were a number of great leadership programs around, but most of them focus on business skills. Those are important, but I’d come to recognize that we needed those who also had a value-based leadership, who were focused on integrity, courage, had emotional intelligence, and people skills.”

The target audience is mid-career, high-potential clinical and operational leaders from respected nonprofit systems. The institute has a unique center where participants practice leadership scenarios using simulation and case studies.

“Our faculty has really felt the engagement of our participants in this very interactive program. It’s very motivating to see how well it’s been received,” Sorenson says. “It’s been great and the cohorts have really gelled. These are the kind of leaders it will take to change healthcare around the world.”

Family matters
Sorenson and his wife, Sharee, reside in Salt Lake City and are the parents of four adult children.

“I’m at the age when I kind of reflect back on life and I’ve spent a lot of hours in the hospital and a lot of hours at work,” he says. “I’m trying to spend more time with my kids and grandchildren.” His two oldest children followed his example and came back to Utah. Eric is a surgical oncologist at Intermountain, and Scott went the business route. His daughter is a nurse in Minneapolis, and his youngest son is a mechanical engineer in Ann Arbor, Michigan.

Sorenson and his wife spend time volunteering together and work with refugee families from Central Africa. “It’s been really fulfilling for us to spend some time doing that,” he says. “These are some wonderful people.”

He also recently joined MEDI, the largest executive coaching firm in the nation dedicated exclusively to the healthcare industry. “When I was still in the CEO job, before starting the Institute, I realized I needed to understand what coaching is,” Sorenson says. “I ended up going to Columbia’s program in 2017, and I like it in the same way I like medicine. A new client is like a new patient. You enter a relationship where you don’t know this person at all but to be successful you have to develop a high level of mutual trust and the goal is to help them.”

Reflecting on his life, Sorenson considers himself very lucky. He mentions having opportunities to learn from amazing people in college and every step of the way at Intermountain.

“I feel a big responsibility at this time in my life to give back, and if I can help people whether it’s through the Leadership Institute or doing volunteer work, that’s important to me,” he says.

Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 30 years.
Cancer is not quite the ferocious killer that it used to be. Millions of Americans are living with cancer, not just dying from it. Reasons for the diminishing death rate include lower smoking rates, earlier detection of some cancers, and advances in treatment.

But the treatment advances are coming at a high price. Treatment costs can easily exceed $100,000 a year. In response, CMS and commercial insurers are establishing alternative payment models, which, in theory, are supposed to slow down the stampeding costs while protecting, and perhaps even improving, the quality of cancer care.

The Oncology Care Model (OCM) developed by CMS’s Center for Medicare and Medicaid Innovation (CMMI) is certainly the highest profile of these alternative payment models. In November, CMMI announced a successor program called the Oncology Care First (OCF) that for the most part builds on OCM and might push episode payment for cancer care more fully into the mainstream of healthcare. Importantly, OCF will most likely include two tracks that would include downside risk right from the start, and the third will be upside-only for a limited time.

But some experts are arguing that value-based cancer care would be better served by a program involving just four of the most common cancers while also changing how costs are figured so they would relate solely to cancer care.

**OCM assessed**

OCM is a five-year pilot program that began in July 2016 and is scheduled to end next year. CMMI says 175 practices are currently participating. Each episode is six months long and is triggered by a patient receiving either oral or intravenous chemotherapy. Under OCM, care has continued to be paid for on a fee-for-service basis: This is not a prospective payment program.

But OCM has two types of payments that are supposed to serve as an incentive for controlling costs and improving care. Participating practices are paid a “monthly enhanced oncology services” — MEOS, for short — payment of $160 per patient for care coordination. They are also eligible for shared savings payments if they beat episode-based financial benchmarks and met quality improvement targets.

OCM also requires participating practices to provide a number of services, including around-the-clock access to a specialist who has real-time access to patient medical records, care plan documentation, and pharmacotherapy based on nationally recognized clinical practice guidelines.

Views differ on OCM. Some see a well-intentioned start to episodic payment but also a work-in-progress. “The OCM is an attempt to enhance the oncology care, but I am not sure it’s accomplishing the goal yet,” says Luis Raez, MD, FACP, president of the Florida Society of Clinical Oncology, and chief scientific officer and medical director of the Memorial Cancer Institute in Hollywood, Florida. Raez says OCM quality standards have led to improvements in care but that the program needs an upgrade.

Enough time has passed—and data collected—for researchers to begin studying OCM. An evaluation of its first year that was commissioned by CMMI identified declines in the use of intensive care units and emergency departments by patients of OCM practices, but not much, if any, effect on the lowering of costs.

CMMI gave some details about OCF when it unveiled the program with an “informal request for information” in November. Here are some of the important differences between OCF as proposed and OCM:

- **Broader population.** OCM limits the MEOS payments to practices to patients who are receiving chemotherapy. OCF would
expansion pertains only to the monthly payments, not to the patient population assigned to practices for the purpose of possible performance-based payment.

- **Pooling of patients.** In OCF, practices could team up and pool their patients for the purposes of hitting benchmarks for the performance-based payments.
- **Electronic patient-reported outcomes.** Under OCM, the enhanced services were 24/7 access to a clinician, patient navigation, preparation of care plans, adherence to guidelines, use of certified electronic health record, and using data for continuous quality improvement. OCF adds electronic patient-reported outcomes, or ePROs, to that list. CMMI's informal request for information says ePROs can be used to monitor patient symptoms and identify high-risk patients.
- **Access to more timely claims data.** Keely Macmillan, a senior vice president at Archway Health, a healthcare consultant that specializes in bundled payments, says that under OCM practices get claims data on a quarterly basis, which creates too much of a lag between when the care is delivered and steps that practices might take to address practice transformation issues. Macmillan says CMMI is committed to providing OCF participants claims data more frequently.
- **Expansion of care covered by monthly payments.** As proposed, under OCF the monthly payment would include payment for enhanced services and an "administration component" that covers administration of drugs. OCM's monthly payments are designed to cover just the enhanced services. Macmillan says it is still unclear whether additional services such as imaging or lab services will be included in the OCF monthly payments, but the intent is to make a greater share of the payments to practices prospective rather than fee for service.

**“The OCM is an attempt to enhance the oncology care, but I am not sure it’s accomplishing the goal yet.”**

— Luis Raez, MD, FACP, President of the Florida Society of Clinical Oncology, and Chief Scientific Officer and Medical Director of the Memorial Cancer Institute in Hollywood, Florida.

- **Risk stratification by cancer type.** Under OCM, CMMI does not set monthly payments or novel therapy adjustments specific to cancer type. Macmillan says Archway’s analysis of data from 20 OCM practices revealed problems with lumping cancers together in that way. For example, lung cancer cases were strongly correlated with negative performance-based payments, an indication of a model that doesn’t properly take into account the care needed. Likewise, colorectal and small intestine cancer were correlated with positive performance payments. As proposed the OCF monthly payment would take into account the type of cancer and whether the patient received chemotherapy or hormonal therapy. The OCF informal request for information also floats the idea of dividing a subset of cancer (breast, bladder, prostate) into high- and low-risk categories for the monthly payment “in recognition that spending patterns are significantly different for high-risk patients receiving chemotherapy or hormonal therapy.” The informal RFI also suggests calculating novel therapies adjustments by the type of cancer.

- **Downside risk.** The OCF would have three risk tracks, two with two-sided risk right off the bat. The upside-only track would be available only for two performance periods.

OCF has been characterized as a thoughtful upgrade of OCM—a tweaking that will solve some problems. Not everyone sees it that way.

“I like that OCF is moving to downside risk, but otherwise there’s not a lot I like about that program,” François de Brantes said in an email to Managed Healthcare Executive. De Brantes, a senior vice president at Signify Health, says that by emphasizing total cost, OCM and OCF mean oncology providers stand to gain (or lose) payment based on services that have nothing to do with their patients’ cancer care. He also said the programs don’t adjust enough for different types of patients and the different types of cancer.

An article published on the Health Affairs blog post in December, de Brantes and four colleagues argued that OCF could be improved by focusing on breast, lung, colorectal, and prostate cancer, partly because the treatment strategies for those cancers are well known and established. Limiting the program to those four cancers could also “sharpen the efforts to measure quality in a more meaningful way,” they wrote. De Brantes and his colleagues also made a case for focusing the model on the most effective, appropriate treatment for patients, not necessarily its price, which, they said, may be largely out of the providers’ control.

*Jennifer Gershman, PharmD, CPh, is a pharmacist and medical writer residing in South Florida.*
NEW

CAPLYTA™
(lumateperone) capsules
42 mg

NOW APPROVED
FOR YOUR ADULT PATIENTS WITH
SCHIZOPHRENIA

Visit caplyta.com to learn more
Indication
CAPLYTA is indicated for the treatment of schizophrenia in adults.

Important Safety Information
Boxed Warning: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.

Contraindications: CAPLYTA is contraindicated in patients with known hypersensitivity to lumateperone or any components of CAPLYTA.

Warnings & Precautions: Antipsychotic drugs have been reported to cause:

- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis, including stroke and transient ischemic attack. See Boxed Warning above.

- Neuroleptic Malignant Syndrome, which is a potentially fatal reaction. Signs and symptoms include: hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation of CAPLYTA and close monitoring.

- Tardive Dyskinesia, a syndrome of potentially irreversible, dyskinetic, and involuntary movements which may increase as the duration of treatment and total cumulative dose increases. Discontinue CAPLYTA if clinically appropriate.

- Metabolic Changes, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.

- Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases). Perform complete blood counts in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. Discontinue CAPLYTA if clinically significant decline in WBC occurs in absence of other causative factors.

- Orthostatic Hypotension and Syncope. Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease.

- Falls. CAPLYTA may cause somnolence, postural hypotension, and motor and/or sensory instability, which may lead to falls and, consequently, fractures and other injuries. Assess patients for risk when using CAPLYTA.

- Seizures. Use CAPLYTA cautiously in patients with a history of seizures or with conditions that lower seizure threshold.

- Potential for Cognitive and Motor Impairment. Advise patients to use caution when operating machinery or motor vehicles until they know how CAPLYTA affects them.

- Body Temperature Dysregulation. Use CAPLYTA with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.

- Dysphagia. Use CAPLYTA with caution in patients at risk for aspiration.

Drug Interactions: Avoid concomitant use with CYP3A4 inducers and moderate or strong CYP3A4 inhibitors.

Special Populations: Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Breastfeeding is not recommended. Avoid use in patients with moderate or severe hepatic impairment.

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation (24% vs. 10%) and dry mouth (6% vs. 2%).

Please see Brief Summary of full Prescribing Information, including full Boxed Warning, on adjacent pages.

CAPLYTA is a trademark of Intra-Cellular Therapies, Inc.
© 2019, Intra-Cellular Therapies, Inc. All rights reserved.

US-LUM-1900014 12/19
INDICATIONS AND USAGE
CAPLYTA® (lumateperone) capsules, for oral use is indicated for the treatment of schizophrenia in patients who are at risk for or have a history of tardive dyskinesia.

DOSE AND ADMINISTRATION
Recommended Dosage: The recommended dosage of CAPLYTA is 42 mg administered orally once daily with food. Dose titration is not required.

Dosage Recommendations for Concomitant Use with CYP3A4 Inducers and Moderate or Strong CYP3A4 Inhibitors: Coadministration with CYP3A4 Inducers - Avoid concomitant use of CAPLYTA with CYP3A4 inducers. Coadministration with Moderate or Strong CYP3A4 Inhibitors - Avoid concomitant use of CAPLYTA with moderate or strong CYP3A4 inhibitors.

Dosage Recommendations for Patients with Hematologic Impairment: Avoid use of CAPLYTA in patients with moderate to severe hematologic impairment (Child-Pugh B or C).

CONTRAINDICATIONS
CAPLYTA is contraindicated in patients with history of hypersensitivity reaction to lumateperone. Reactions have included pruritus, rash (e.g. allergic dermatitis, pallor rash, and generalized rash), and urticaria.

WARNINGS AND PRECAUTIONS
Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in placebo-treated patients. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia). CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.

Cerebrovascular Adverse Reactions, Including Stroke, in Elderly Patients with Dementia-Related Psychosis: In placebo-controlled trials in elderly subjects with dementia, patients randomized to risperidone, aripiprazole, and olanzapine had a higher incidence of stroke and transient ischemic attack, including fatal stroke. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome: Neuroleptic Malignant Syndrome (NMS), a potentially fatal symptom complex, has been reported in association with administration of antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, delirium, and autonomic instability. Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. If NMS is suspected, immediately discontinue CAPLYTA and provide intensive symptomatic treatment and monitoring.

Tardive Dyskinesia: Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, movements, may develop in patients treated with the lowest doses of antipsychotic drugs. The risk appears to be highest among the elderly, especially elderly women, but it is not possible to predict which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown. The risk of tardive dyskinesia and the likelihood that it will become irreversible increase with the duration of treatment and the cumulative dose. The syndrome can develop after a relatively brief treatment period, even at low doses. It may also occur after discontinuation of treatment. Tardive dyskinesia may remit, partially or completely, if antipsychotic treatment is discontinued. Antipsychotic treatment itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome, possibly masquerading the underlying process. The effect that symptomatic suppression has upon the long-term course of tardive dyskinesia is unknown. Given these considerations, CAPLYTA should be prescribed in a manner that is likely to reduce the risk of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients: 1) who suffer from a chronic illness that is known to respond to antipsychotic drugs; and 2) for whom alternative, effective, and potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, use the lowest doses use and the shortest duration of treatment producing a satisfactory clinical response. Periodically reassess the need for continued treatment. If signs and symptoms of tardive dyskinesia appear in a patient on CAPLYTA, drug discontinuation should be considered. However, some patients may require treatment with CAPLYTA despite persistence of the syndrome.

Metabolic Changes: Antipsychotic drugs have caused metabolic changes, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Although all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile. Hyperglycemia and Diabetes Mellitus - Hyperglycemia, in some cases associated with ketoadipose, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. There have been reports of hyperglycemia in patients treated with CAPLYTA. Assess fasting plasma glucose before or soon after initiation of antipsychotic medication and monitor periodically during long-term treatment. In pooled data from short-term (4- to 6-week), placebo-controlled trials of adult patients with schizophrenia, mean changes from baseline to the proportion of patients with shifts from normal to greater than normal levels of fasting glucose in patients treated with CAPLYTA were similar to those in placebo-treated patients. In an uncontrolled open-label trial of CAPLYTA for up to 1 year in patients with stable schizophrenia, the percentages of patients with shifts in fasting glucose and insulin values from normal to high were 8% and 12%, respectively, 4.7% of patients with normal hemoglobin A1c (<5.5%) at baseline developed elevated levels (5.5%) post-baseline. Dose 4% for total cholesterol, triglycerides, and LDL cholesterol, respectively. Weight Gain - Weight gain has been observed with use of antipsychotics. Monitor weight at baseline and frequently thereafter. In pooled data from placebo-controlled trials of adult patients with schizophrenia, mean changes from baseline to the proportion of patients with an increase in weight >2% from baseline to end of study was similar in patients treated with CAPLYTA and placebo. In an uncontrolled open-label trial of CAPLYTA for up to 1 year in patients with stable schizophrenia, the mean change in body weight was approximately -2 kg (SD 5.6) at Day 175 and approximately -3.2 kg (SD 7.4) at Day 350.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia and neutropenia have been reported during treatment with antipsychotic agents, including CAPLYTA. Agranulocytosis (including fatal cases) has been reported with other agents in this class. Possible risk factors for leucopenia and neutropenia include pre-existing low white blood cell count (WBC) or absolute neutrophil count (ANC) and history of bone marrow depression. In CAPLYTA-treated patients, the frequency of neutropenia was 0.2% compared to 0.4% for placebo. However, the risk was observed in patients with pre-existing low WBC or ANC or a history of drug-induced leucopenia or neutropenia. In patients with a pre-existing low WBC or ANC or a history of drug-induced leucopenia or neutropenia, perform a complete blood count (CBC) frequency during the first few months of therapy. In such patients, consider discontinuation of CAPLYTA if the ANC decreases below 1000/mm3. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue CAPLYTA in patients with absolute neutrophil count < 1000/mm3.

Orthostatic Hypotension and Syncope: Atypical antipsychotics cause orthostatic hypotension and syncope. Generally, the risk is greatest during initial dose administration. In these clinical trials the frequencies of orthostatic hypotension for CAPLYTA and placebo were 0.7% and 0%, respectively. The rates of syncope for CAPLYTA and placebo were 0.7% and 0%, respectively. Orthostatic vital signs should be monitored prior to hypotension (e.g., elderly patients, patients with dehydration, hypovolemia, and concomitant treatment with antihypertensive medications), patients with known cardiovascular disease (history of myocardial infarction, ischemic heart disease, heart failure, or conduction abnormalities), and patients with cerebrovascular disease. CAPLYTA has not been evaluated in patients with a recent history of myocardial infarction or unstable cardiovascular disease. Such patients were excluded from pre-marketing clinical trials.

Falls: Antipsychotics, including CAPLYTA, may cause somnolence, postural hypotension, and motor and sensory instability, which may lead to falls and, consequently, fractures and other injuries. For patients with diseases, conditions or medications that could exacerbate these effects, complete fall risk assessments when initiating antipsychotic treatment and periodically during long-term treatment.

Seizures: Like other antipsychotic drugs, CAPLYTA may cause seizures. The risk is greatest in patients with a history of seizures or with conditions that lower the seizure threshold. Conditions that lower the seizure threshold may be more prevalent in older patients.

Potential for Cognitive and Motor Impairment: CAPLYTA, like other antipsychotics, may cause somnolence and has the potential to impair judgment, thinking, and motor skills. In short-term (i.e., 4- to 6-week) placebo-controlled clinical trials of patients with schizophrenia, somnolence and sedation were reported in 24% of CAPLYTA-treated patients, compared to 10% of placebo-treated patients. Patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that therapy with CAPLYTA does not affect them adversely.

Body Temperature Dysregulation: Atypical antipsychotics may disrupt the body’s ability to reduce core body temperature. Strenuous exercise, exposure to extreme heat, dehydration, and anticholinergic medications may contribute to an elevation in core body temperature; use CAPLYTA with caution in patients who may experience these conditions.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drugs. Antipsychotic drugs, including CAPLYTA, should be used cautiously in patients at risk for aspiration.

ADVERSE REACTIONS
The following adverse reactions are discussed in detail in other sections of the labeling: Increased Mortality in Elderly Patients with Dementia-Related Psychosis; Cerebrovascular Adverse Reactions, Including Stroke, in Elderly Patients with Dementia-Related Psychosis; Increased Mortality in Elderly Patients with Demetia-Related Psychosis; Tardive Dyskinesia; Metabolic Changes; Agranulocytosis, Neutropenia, and Agranulocytosis; Orlistatic Hypotension and Syncope; Falls; Seizures; Potential for Cognitive and Motor Impairment; Body Temperature Dysregulation; Dysphagia.

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates observed in clinical trials of another drug and may not reflect the rates observed in practice. The safety of CAPLYTA has been evaluated in 1724 adult patients with schizophrenia exposed to one or more doses. Of these patients, 811 participated in short-term (4- to 6-week), placebo-controlled trials with doses ranging from 14 to 84 mg/day. A total
of 329 CAPLYTA-exposed patients had at least 6 months of exposure and 108 had at least 1 year of exposure to the 42-mg dose of CAPLYTA. There was no single adverse reaction leading to discontinuation that occurred at a rate of >2% in CAPLYTA-treated patients. The most common adverse reactions (incidence of at least 5% of patients exposed to CAPLYTA and greater than twice the rate of placebo) were somnolence/sedation and dry mouth. Adverse reactions associated with CAPLYTA (incidence of at least 2% in patients treated with CAPLYTA and greater than twice the placebo rate) and those with an incidence of at least 1% are listed in Table 1. The following findings are based on the pooled short-term (4- to 6-week), placebo-controlled studies in adult patients with schizophrenia in which CAPLYTA was administered at a daily dose of 42 mg (N=406). Table 1 in the full Prescribing Information displays Adverse Reactions during short-term administration of CAPLYTA-Treated Patients in 4- to 6-week Schizophrenia Trials. Adverse reaction is followed by percentage of patients treated with CAPLYTA 42mg (N=406) and Patients treated with Placebo (N=412) in parentheses. Somnolence/Sedation (24%, 10%); Nausea (9%, 5%); Dry Mouth (8%, 2%); Dizziness (5%, 3%); created a phosphohyl- nolism (5%, 3%); Fatigue (5%, 3%); Weight Decrease (2%, 1%); Increased AST, ALT, hepatic enzymes increased, or liver function test abnormal. Dystonia: Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: Spasm of the neck muscles; sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. Although these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and higher doses of first-generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups. Extrapyramidal Symptoms: In the 4- to 6-week, placebo-controlled trials, the frequency of reported events related to extrapyramidal symptoms (EPS), including akathisia, extrapyramidal disorder, muscle spasms, restlessness, muscular skeletal stiffness, dyskinesia, dystonia, muscle twitching, tardive dyskinesia, tremor, drooling, and involuntary movements was 23%, compared with the placebo rate of 3%. Extrapyramidal symptoms were reported in 6% of patients treated with CAPLYTA and 3% of placebo-treated patients. In the 4- to 6-week trials, data were collected using the Simpson Angus Scale (SAS) for EPS (total score ranges from 0 to 40), the Barnes Akathisia Rating Scale (BARS) for akathisia (total score range from 0 to 14), and the Abnormal Involuntary Movement Scale (AIMS) (total score range from 0 to 28). The mean changes from baseline for CAPLYTA-treated patients and placebo-treated patients were 0.1 and 0 for the SAS, 0.3 and 0 for the BARS, and 0.1 and 0 for the AIMS, respectively. DRUG INTERACTIONS Table 2 in the full Prescribing Information displays Drugs Having Clinically Important Interactions, Moderate or Strong CYTP43A4 Inhibitors: Concomitant use of CAPLYTA with moderate or strong CYP3A4 inhibitors increases lumateperone exposure, which may increase the risk of adverse reactions. Avoid concomitant use of CAPLYTA with moderate or strong CYP3A4 inhibitors. Examples of CYP3A4 inhibitors include: Moderate inhibitors - Carbamazepine, phenytoin, rifampin, St. John’s wort, bosentan, efavirenz, fluoxetine, verapamil, Strong inhibitors - Clarithromycin, grapefruit juice, itraconazole, voriconazole, nefazodone, ritonavir, nefavirin CYP3A4 Inducers: Concomitant use of CAPLYTA with CYP3A4 inducers decreases the exposure of lumateperone. Avoid concomitant use of CAPLYTA with CYP3A4 inducers. Examples of CYP3A4 inducers include: Carbamazepine, phenytoin, ritampin, St. John’s wort, bosentan, elavatrine, etravirine, modafinil, nafcinil, aripnet, armodafinil, pioglitazone, prednisone. UGT Inhibitors: Concomitant use of CAPLYTA with UGT inhibitors may increase the exposure of lumateperone and/or its metabolites. Avoid concomitant use of CAPLYTA with UGT inhibitors. Examples of UGT inhibitors include: Valenic acid, probenecid. USE IN SPECIFIC POPULATIONS Pregnancy: Pregnancy Exposure Registry – There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to atypical antipsychotics, including CAPLYTA, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Atypical Antipsychotics at 1-866-963-2107 (http://www.womenshealthaccess.org/campaigns-clinical-and-research-projects/ pregnancyregistry/). Risk Summary: Neonates exposed to antipsychotic drugs during the third trimester are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Available data from case reports on CAPLYTA use in pregnant women are insufficient to establish any drug associated risks for birth defects, miscarriage, or adverse maternal or fetal outcomes. There are risks to the mother associated with untreated schizophrenia and with exposure to antipsychotics, including CAPLYTA, during pregnancy. In animal reproduction studies, no malformations were observed with oral administration of lumateperone to pregnant rats and rabbits during organogenesis at doses up to 2.4 and 9.7 times, respectively, the maximum recommended human dose (MRHD) of 42 mg/day on a mg/m2 basis. When pregnant rats were administered lumateperone during the period of organogenesis through lactation, the estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcome. The estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15 to 20%, respectively. Clinical Considerations: Disease associated maternal and/or embryo/fetal risk: There is risk to the mother from untreated schizophrenia, including increased risk of hospitalization, and suicide. Schizophrenia is associated with increased adverse perinatal outcomes, including preterm birth. It is not known if this is a direct result of the illness or other comorbid factors. Fetal/neonatal adverse reactions: Extra- pyramidal and/or withdrawal symptoms, including agitation, hypertonia, hypotonia, tremors, dyskinesia, muscle spasms, respiratory distress, and feeding disorder have been reported in neonates who were exposed to antipsychotic drugs during the third trimester of pregnancy. These symptoms have varied in severity. Monitor neonates for extrapyramidal and/or withdrawal symptoms and manage symptoms appropriately. Some neonates recovered within hours or days without specific treatment; others required prolonged hospitalization. Data: Animal Data: Pregnant rats were treated with oral doses of 3.5, 10.5, 21, and 85 mg/kg/day lumateperone (0.8, 2.4, 4.9, and 14.6 times the MRHD on a mg/m2 basis) during the period of organogenesis. No malformations were observed with lumateperone at doses up to 2.4 times the MRHD. Findings of decreased body weight were observed in fetuses at 4.9 and 14.6 times the MRHD. Findings of incomplete ossification and increased incidences of visceral and skeletal variations were recorded in fetuses at 14.6 times the MRHD, a dose that induced maternal pregnancy. Pregnant rabbits were treated with oral doses of 2.1, 7, and 21 mg/kg/day lumateperone (1.0, 3.2, and 9.7 times the MRHD on a mg/m2 basis) during the period of organogenesis. Lumateperone did not cause adverse developmental effects at doses up to 9.7 times the MRHD. In a study in which pregnant rats were administered oral doses of 3.5, 10.5, and 21 mg/kg/day lumateperone (0.8, 2.4, and 4.9 times the MRHD on a mg/m2 basis) during the period of organogenesis and through lactation, the number of live-born pups was decreased at 2.4 and 4.9 times the MRHD, and early postnatal deaths increased at a dose 4.9 times the MRHD. Impaired nursing and decreased body weight gain in pups were observed at 4.9 times, but not at 2.4 times, the MRHD. Pregnant rats were treated with a human metabolite of lumateperone (reduced ketone metabolite) at oral doses of 15, 60, and 100 mg/kg/day (1.2, 19, and 27 times the exposure to this metabolite at the MRHD of lumateperone based on AUC plasma exposure) during the period of organogenesis. This metabolite did not cause adverse developmental effects at a dose 1.2 times the exposure at the MRHD of lumateperone; however, it caused an increase in visceral malformations (cleft palate) at 27 times and skeletal malformations at 19 times the exposure at the MRHD of lumateperone, a dose that induced maternal toxicity. Lactation: Risk Summary - There are no available data on the presence of lumateperone or its metabolites in human milk or animal milk, the effects on the breastfed infant, or the potential for adverse reactions to the breastfed infant. Nursing mothers should be advised not to breastfeed while receiving treatment with lumateperone. Females and Males of Reproductive Potential: Infertility - Based on findings from animal studies, lumateperone may impair male and female fertility. Pediatric Use: Safety and effectiveness of CAPLYTA have not been established in pediatric patients. Geriatric Use: Controlled clinical studies of CAPLYTA did not include patients aged 65 or older to determine whether or not they respond differently from younger patients. Antipsychotics increase the risk of death in elderly patients with dementia-related psychosis. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis. Hepatic Impairment: Use of CAPLYTA is not recommended for patients with moderate (Child-Pugh class B) to severe hepatic impairment (Child-Pugh class C). Patients with moderate and severe hepatic impairment experienced higher exposure to lumateperone. No dosage adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A). OVERDOSAGE No specific antidotes for CAPLYTA are known. In managing overdose, provide supportive care, including close medical supervision and monitoring and consider the possibility of multiple drug involvement. In case of overdose, consult a Certified Poison Control Center (1-800-222-1222 or www.poisong.org). HOW SUPPLIED/ STORAGE AND HANDLING CAPLYTA (lumateperone) capsules are supplied in boxes of 30. Each box contains 3 blister packs of 10 capsules. © 2020 Intra-Cellular Therapies, Inc. New York, NY 10016 CAPLYTA is a trademark of Intra-Cellular Therapies, Inc.  © 2020 Intra-Cellular Therapies, Inc. All rights reserved 1/2020 US-LUM-190016
The opioid epidemic is far from over, but after years of increasing relentlessly, the trendline for the number of drug overdose deaths in the United States finally turned the other direction. According to federal health statistics, there were 67,367 drug overdose deaths in the United States in 2018, a notable 4.1% decline from the 70,237 deaths that occurred in 2017. The rate of overdose deaths from natural and semisynthetic opioids (oxycodone, hydrocodone) and heroin were lower in 2018 than in 2017. It’s not all good news: The rate for synthetic opioids (fentanyl, tramadol) increased from 2017 to 2018.

Combating the opioid epidemic is a popular cause, and many organizations, government entities, and healthcare groups have responded.

Here are four examples:

**BOSTON MEDICAL CENTER, BOSTON**

Mothers are more likely to show up for their infants’ check-ups than they are for their own check-ups. It’s a simple maxim followed by clinicians at Boston Medical Center’s Supporting Our Families through Addiction and Recovery—SOFAR, for short—clinic to “hook” mothers into managing their health and maintaining their recovery from dependence on opioids. Launched in July 2017, the program, which is run by largest safety-net hospital in Massachusetts, has seen 200 mother-child pairs.

The mother-child pairs are connected to SOFAR through Project RESPECT, another Boston Medical Center program that provides obstetric and substance use disorder treatment for pregnant women and their newborns. While the infant participates in their well-baby visit, the mother receives treatment for her dependence on opioids in the SOFAR clinic, including access to medication-assisted treatment and a mentor who has been through a similar life experience.

Eileen Costello, MD, chief of ambulatory pediatrics at Boston Medical Center and medical director at SOFAR, and other specially trained pediatricians engage with mothers by asking them about family support, their living situations, and their children. Many of these women are raising children without the help of a partner, notes Costello. Some are living in group homes or struggling with custody issues. If they are taking one of the drugs used in medication-assisted treatment, such as methadone, they often must deal with criticism from family members and others. To help, says Costello, clinicians educate mothers about the research that shows that...
managed healthcare needs when they are dire and need to be treated in the emergency department—helped secure leadership support for the partnership with East Harlem nonprofit, says Brianna Norton, DO, a general internal medicine physician at Montefiore. Seed funding came from New York State, although the program has been self-sustaining since March 2019, when the health system started billing public and private payers.

A typical client is a 50-year-old African American or Latino male, says Norton. Often, the client’s family members live in his country of origin—or have died. Many are homeless and come to the nonprofit to get clean needles or a rapid hepatitis C test. Some just want to take a shower.

Montefiore clinicians saw 118 unique patients in the first three months of the partnership. “These are patients who would otherwise likely never see a physician at all,” observes a spokesperson.

PRIORITY HEALTH, GRAND RAPIDS, MICH.

Michigan has been hit hard by opioid epidemic. In 2017, its opioid overdose death rate was 15th highest in the country.

Christina Barrington, PharmD, vice president of pharmacy programs at Priority Health, Michigan’s second-largest health insurer, says the company is trying to make sure that members have adequate pain relief while also working to prevent accidental overdoses and misuse of opioids.

Starting in November 2017, the Grand Rapids, Michigan, nonprofit started limiting access to short-acting opioids for acute pain to a 15-day fill and long-acting opioids for chronic pain to a three-day fill. It also reduced its copay for Narcan (naloxone), the drug for reversing opioid overdoses.

In other moves, Priority Health took steps to reduce opioid dosage to a maximum of 120 MEqD (morphine-equivalent dose) daily and keep track of members who get opioid prescriptions from multiple physicians.

Barrington says Priority Health has also introduced “pain contracts.” The patient agrees to receive opioid-based medications from a single physician. The physician who signs the contract receives a report of all the doctors who prescribed opioids to their patients. If patients get opioid prescriptions from other physicians, the physician who signed the pain contract can choose to stop treating those patients or taper their medications.

Within a year of launching the program, use of opioids by Priority Health members has declined by 47% among commercial members, 36% among Medicare members, and 18% among Medicare members.

CAPITAL BLUE CROSS, HARRISBURG, PA.

Research results published in JAMA Internal Medicine several years ago showed that acupuncture is effective when managing chronic pain. The study focused on patients with non-specific back or neck pain, shoulder pain, chronic headache, or osteoarthritis. Another study published in JAMA Internal Medicine last year found that acupuncture is helpful as an adjunctive therapy to treat pain associated with chronic stable angina.

Last year, Capital Blue Cross in Harrisburg, Pa., started covering acupuncture to treat pain. More than 200 members “took advantage of the opportunity to use an alternative treatment for their pain,” says Jennifer Chambers, MD, the insurer’s chief medical officer.

“I’m a personal proponent of [acupuncture] to treat chronic neck pain,” adds Chambers, who currently takes no medication for her neck pain. She’s also interested in using acupuncture to treat dry mouth that can be a side effect of cancer treatment and for heart pain. “The conclusion here is we need to be more open to nontraditional, non-Western medicine approaches to treating chronic pain,” says Chambers, adding that biofeedback and mindfulness techniques can also help address the anxiety and stress associated with chronic pain.

Aine Cryts is a writer based in Boston.
Medicare Advantage Plans Covering More SDOH Benefits

By KEITH LORIA

Healthcare experts agree that nonmedical, social factors such as housing, nutrition, and access to recreation can play a significant role in shaping people’s health. CMS has responded, so now Medicare Advantage (MA) plans can offer benefits that tackle some of these social determinants of health (SDoH).

But it’s early days. Last year, a relatively low percentage of plans offered the benefits. A Milliman report identified only 102 plans that do. Concerns about cost and the novelty are some of the impediments. MA plans can use their rebate money—the difference between their estimated costs (and profit) and county-level financial benchmarks—to pay for SDoH and other “supplemental” benefits for their members (the rebate money can also be used to lower cost sharing). However, according to an Urban Institute report, the average rebate in 2019 was $107 per member per month. That is not much money for untangling the complex, often deep-seated problems that come under the SDoH rubric.

But Sean Creighton, a managing partner at Avalere Health, says MA plans are beginning to ramp up their SDoH-related coverage. Many are creating partnerships and referrals to community and other organizations. Examples include Humana’s Bold Goal program, a population health strategy focused on both community and business integration to improve the clinical and social health outcomes, and CVS Health’s Building Healthier Communities, a five-year, $100 million commitment that supports critical programs and partnerships with local and national nonprofit organizations.

Social determinants of health can be defined in many different ways. At a simple level, they can be thought of as almost anything nonmedical that influences health. Some definitions emphasize the notion of “place”—conditions in the environments where people are born, live, learn, work, and play. There are various estimates of the effects of SDoH; some say they account for 80% of people’s health status. But teasing out the effect of just one of them to focus on may be difficult. A further complication is the effects can be measured in myriad ways: quality of life, years of life lost, morbidity, mortality.

Among the supplemental benefits that CMS allowed MA plans to offer last year were adult day care services, home-based palliative care, in-home support services, medically approved nonopioid pain management, transportation, and home and bathroom safety devices. This year, CMS expanded the meal delivery benefit and added transportation for nonmedical needs like grocery shopping and “home environment services” if they relate to the chronic illness. In a press release, CMS gave the example of an MA plan covering home air cleaners and carpet shampooing for someone with asthma.

So far, MA SDoH supplemental benefits have focused mainly on housing, nutrition, transportation, and social support, according to Creighton.

Wren Keber, managing partner at Cardinal Consulting Group, a Los Angeles healthcare consulting firm, says payers, providers, and public officials are all starting to realize the value of addressing SDoH and how the efforts can improve both physical and mental health outcomes.

SDoH programs are nothing if not varied. When researchers at NYU and Columbia searched LexisNexis and Google to find public announcements about health system SDoH programs in 2017, 2018, and most of 2019, they identified 78 different programs involving about $2.5 billion in funds. Housing-focused programs accounted for $1.6 billion of the spending. They reported their results in the February 2020 issue of Health Affairs.

The Urban Institute conducted 10 “semi-structured” interviews to prepare its September 2019 report titled, “Are Medicare Advantage Plans Using New Supplemental Benefit Flexibility to Address Enrollees’ Health-Related Social Needs?” The answer to that question is yes, but in a limited way. None of the insurers that the institute interviewed had extended coverage on nationwide basis.

Robert W. Seligson, executive vice president and CEO of North Carolina Medical Society, is among those spearheading the state’s efforts to address SDoH. North Carolina recognized the importance of SDoH impact early on and has embedded SDoH within the financial incentives and quality measures of its Medicaid
program, he says. North Carolina’s Section 1115 Medicaid waiver allows the state to implement a five-year, $650 million pilot program that will test the impact of using Medicaid dollars to pay for evidence-based SDoH programs.

“We are hoping to improve outcomes so others can recognize that SDoH are an important focus area that all healthcare stakeholders need to address to deliver high-quality care and maximizes resources,” he says.

By incorporating SDoH in payment and care delivery reform, physicians will be given the tools necessary to improve their patient’s health holistically while reducing costs and administrative burdens, says Seligson. Maybe the acronym has come on strong the last several years, but physicians are hardly SDoH neophytes; they have long recognized the impact of social and environmental conditions on patient outcomes, costs, and the physician-patient relationship, Seligson points to a 2018 survey by the Physician Foundation of more than 8,500 physicians. Ninety percent reported that patients had a serious health problem linked to poverty or other social conditions.

SDoH is buzzy but quality and financial metrics haven’t caught up to the trend and are largely silent on the subject. For example, the metrics the CMS uses in its ACO Shared Savings Program don’t use SDoH-related measures or adjustments. "If we are to improve health and bend the cost curve, 'social risk' and SDoH must be accounted for in payment models and risk adjustment," Seligson says.

Theresa Hush, CEO of Roji Health Intelligence LLC in Chicago, sees the inclusion of SDoH-related benefits for MA plans as an important first step for improving services for vulnerable individuals, especially dual eligibles covered by Medicare and Medicaid.

"Since MA plans typically attract healthier and younger beneficiaries, the specific provision of SDoH should enable plans to broaden coverage within the Medicare population," she says.

But just adding benefits is not enough, says Hush, who noted that accurately assessing patient needs is difficult. Add to that identifying the interventions that will be effective in addressing those needs. "Plans must measure and assess individuals’ needs better and standardize quality and outcome measures, data capture, and risk assessments," she says.

Hush sees an opportunity for MA plans and providers collaborating to achieve lower costs and better outcomes.

Creighton at Avalere suggests a "pick-your-battles" approach.

“One challenge is narrowing down actionable items for a health organization," he says. "Healthcare organizations’ impact on communities can be huge, but organizations must decide where to direct their resource."

But he also sees an opportunity for the impact of larger health systems’ efforts to extend well past patient outcomes to employment, improved income, and possibly even environmental improvements in their surrounding communities.

"If you look at the social support aspect of this, there’s also been a big increase in the provision of in-home services which get at social support and other aspects of social determinants."

— SEAN CREIGHTON, A MANAGING PARTNER AT AVALERE HEALTH.

Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 20 years.

There’s a need, though, for better data collection to identify and prioritize, on a micro level, people’s greatest need, Creighton says. "It’s a huge issue because while there is data that will tell you about the relative advantage or disadvantage of particular communities, we need to get down to a very local level to figure out who needs something done to improve their health."

Right now, plans are offering what Creighton calls a "smorgasbord of approaches and ideas."

"The aim is to get to a certain nexus between our day-to-day social and economic life and our health by integrating aspects of the healthcare system with the social and community services delivery systems," he says. "And there are a lot of different initiatives going on to do so."

Creighton sees progress in the growing number of programs in the "food category" of meals and nutrition as well as those involving wellness and housing. The SDoH surge is bringing back the house call.

"If you look at the social support aspect of this, there’s also been a big increase in the provision of in-home services which get at social support and other aspects of social determinants," says Creighton.

“I am interested in the intersection of population health management with HR and business strategy to create a win-win environment for employees and organizations.” — JENNIFER GODFREY, CEO, LEA.
The Apps Healthcare Execs Can’t Live Without

Managed Healthcare Executive asked thought leaders: “What apps do you use the most on your phone?” Here’s what they said. by STEPHANIE STEPHENS, MA

With approximately 2 million apps available from either Google Play or the App Store from Apple, it’s true that for lots of things there is, in fact, “an app for that.” We asked 12 healthcare executives what apps they have on their phones, whether for work or play.

CONNECT
For Nicole Latimer, CEO of Staywell, a leading health and wellbeing organization in multiple locations, it’s got to be FaceTime to stay connected with her family while she’s away on business. “I use LinkedIn to stay updated on new trends and industry news, Amazon for my next good book and, of course, StayWell to track my steps and workouts and participate in fun challenges against coworkers,” Latimer says.

E-PRESCRIBE
Jay Wohlgemuth, MD, is senior vice president of research and development, medical, and chief medical officer for Quest Diagnostics Health & Wellness. He likes the hometeam’s Quanum. “Quanum allows me to order labs for patients I see and has an option for e-prescribing at any pharmacy in the United States,” he says. He uses Tarascon Pharmacopoeia to check on drug prescribing by drug class or disease area, verify what is indicated, and review side effects and other considerations. For his own well-being, it’s Headspace’s mindfulness and meditation app, and Duolingo to polish Spanish language skills.

SHARE
Carrot Health in Minneapolis provides healthcare business intelligence solutions powered by social determinants of health. Stephen Sigmond, co-founder and chief financial officer, says he constantly uses Slack. “It’s the primary way our team members communicate—for everything from product development to sharing vacation pictures.”

TRACK
Nick Woods is co-founder and chief technology officer of Hazel Health in San Francisco, which provides free healthcare for K-12 students in school via virtual medical clinics. “I use Health Mate because it’s connected to my digital scale. Apple’s Activity app to keep an eye on my exercise, and One Medical’s app if I have an appointment or follow-up,” he says.

MANAGE
“My apps tell the story of my weekday life, somewhat pitifully, but then again, they make things manageable,” says Darcey Schoenebeck, executive vice president of business development at RxSense, a digital health company in Boston. For administering her life from a different state, she uses Honey. “It finds me deals on whatever I’m buying, then applies the discount automatically and makes it so cheap I can’t afford not to buy it!” Because vision is important in daily work, it’s Handy Loupe. “Oh man, this one: It’s a magnifying glass. If you are age 50 plus, no explanation needed," laughs Schoenebeck.

She says life as a sales executive requires Curb, “for no futzing with the credit card to pay the taxi guy, and no taxi guy asking me to pay cash. It’s a win-win!” And "for getting from Point A to Point B, she’s all about Delta "with its bag tracking notifications that are genius.”
TRAVEL
Delta’s app also gets points from Chris Ingersoll, vice president of product development for R1 RCM in Chicago, a technology-enabled revenue cycle company.

“This app gives me an excellent, seamless, and comprehensive experience—one our own consumer-focused industry should emulate,” says Ingersoll. “I can schedule and purchase my flight, choose a seat, check in, check upgrade status, track my incoming plane, and board—all without interacting with staff, making it highly efficient for all involved and promoting brand loyalty to high-revenue customers.” Forward-thinking providers will invest in building a similarly inclusive mobile capability, in Ingersoll’s opinion.

RELATE
Cloudbreak Health in El Segundo, California, is a telemedicine platform that provides more than 1 million minutes of consultation each month. CEO Jamey Edwards is a fan of Twitter. "Twitter’s concise format forces you to choose your words. Its ability to break news and create value via curated feeds of information is the way relationships that start on Twitter turn into real-life relationships, partnerships and friendships," says Edwards. The #pinksocks campaign may be the best evidence of how an effective community of mission-driven people can built via social media, he says.

ACHIEVE
A self-described “fitness freak,” CJ Xia is also CEO of Boster Biological Technology in Pleasanton, California, offering high-quality antibodies and enzyme-linked immunosorbent assay kits to the scientific community since 1993. He’s a huge fan of MyFitnessPal, for anyone dieting or trying to muscle up. The app, he says “is your true friend rather than making fun of you.” It calculates calories consumed and advises how much to eat to achieve a weight goal and connects you with others also seeking to get a daily dose of motivation. “Amazing infographics make data more readable,” he says.

GIVE
Let’s hear it for the American Red Cross and its apps, Jim Higgins, CEO and founder of Solutionreach, a patient relationship management company, in Lehi, Utah, says “I really admire American Red Cross and what they have done digitally to change the perception of giving blood—turning an otherwise ‘bad’ experience good. It is a charitable act to give blood, and they really see it through to help donors. Kudos to them!” Higgins starts his day with the Wall Street Journal app to stay on top of the news.

COMPARE
Lee Baxter is vice president of brand strategy and communications for MyMedicalShopper, a Portsmouth, New Hampshire, company that has developed digital platforms for comparing healthcare prices. Yes, there is an app, and yes, he uses it.

Baxter never leaves home without Waze. “It remembers my favorite destinations and alerts me to potential issues like accidents or roadwork along the way,” he says. He also champions Medscape, because “it covers everything health-related from the latest news to ready reference on conditions, guidelines, pill interactions, and more.”

ADMINISTRATE
“Adobe Scan allows me to take a photo of a document—or anything else for that matter—and turn it into a PDF I can email from my phone,” says John Specht, vice president of sales and marketing at eQHealth Solutions, a population health management and technology solutions company based in Baton Rouge, Louisiana. “It’s an absolute game changer when doing admin tasks on the road.”

CONFERENCE
“In a modern work world where so much of what we do is remote and it’s easy to feel disconnected, it’s important for our teams to maintain connections,” says Jacob Reider, MD, and CEO of Alliance for Better Health in Albany, New York, an IT and SDoH company.

His team uses the video conferencing app, Zoom, on their phones. “I like it for device-agnostic, face-to-face conversations from remote locations. I like being able to see nonverbal cues from others during our calls—for example, I can see someone nodding their head in agreement, or can tell when someone is trying to jump in, or when it looks like something isn’t resonating. Mobile video conferencing is definitely better than traditional voice-only calls.”

Stephanie Stephens, MA, is a journalist, producer, and host in Orange County, California.
We are not finished.

People in treatment for HIV are living longer. That means your members with HIV will face different challenges. At ViiV Healthcare, we're working to help meet their changing needs.

Learn more about what we are doing at www.us.viivhealthcare.com

Trademark is owned by or licensed to the ViiV Healthcare group of companies.

©2020 ViiV Healthcare or licensor.
HVUADV1200001 February 2020
Produced in USA.