MEDICARE ADVANTAGE PLANS, on a roll, could see some cuts

Oncology
Biomarkers for lung cancer treatment

Technology
Challenge of implementing AI

Industry Analysis
CVS vs. Walgreens vs. Walmart
When adult patients with obstructive sleep apnea (OSA) or narcolepsy are struggling with excessive daytime sleepiness (EDS),

**ONCE-DAILY SUNOSI**

is the first and only WPA proven to improve wakefulness through *9 HOURS*\(^1,2\)

\(^*\)As seen at week 12.
\(^†\)The 75 mg dose did not show a statistically significant improvement for patients with narcolepsy-associated EDS.

WPA = wake-promoting agent.

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**INDICATIONS AND USAGE**

SUNOSI is indicated to improve wakefulness in adults with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA).

**Limitations of Use:**

SUNOSI is not indicated to treat the underlying obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating SUNOSI. SUNOSI is not a substitute for these modalities, and the treatment of the underlying airway obstruction should be continued.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

SUNOSI is contraindicated in patients receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of an MAOI, because of the risk of hypertensive reactions.

**WARNINGS AND PRECAUTIONS**

**Blood Pressure and Heart Rate Increases**

SUNOSI increases systolic blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion. Epidemiological data show that chronic elevations in blood pressure increase the risk of major adverse cardiovascular events (MACE), including stroke, heart attack, and cardiovascular death. The magnitude of the increase in absolute risk is dependent on the increase in blood pressure and the underlying risk of MACE in the population being treated. Many patients with narcolepsy and OSA have multiple risk factors for MACE, including hypertension, diabetes, hyperlipidemia, and high body mass index (BMI).

Assess blood pressure and control hypertension before initiating treatment with SUNOSI. Monitor blood pressure regularly during treatment and treat new-onset hypertension and exacerbations of pre-existing hypertension. Exercise caution when treating patients at higher risk of MACE, particularly patients with known cardiovascular and cerebrovascular disease, pre-existing hypertension, and patients with advanced age. Use caution with other drugs that increase blood pressure and heart rate. Periodically reassess the need for continued treatment with SUNOSI. If a patient experiences increases in blood pressure or heart rate that cannot be managed with dose reduction of SUNOSI or other appropriate medical intervention, consider discontinuation of SUNOSI.

Patients with moderate or severe renal impairment could be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of SUNOSI.

**Psychiatric Symptoms**

Psychiatric adverse reactions have been observed in clinical trials with SUNOSI, including anxiety, insomnia, and irritability. Exercise caution when treating patients with SUNOSI who have a history of psychosis or bipolar disorders, as SUNOSI has not been evaluated in these patients.

**MOST COMMON ADVERSE REACTIONS**

The most common adverse reactions (incidence ≥5%) reported more frequently with the use of SUNOSI than placebo in either narcolepsy or OSA were headache, nausea, decreased appetite, anxiety, and insomnia.

Please see Brief Summary of full Prescribing Information on next page.

References:

2. SUNOSI (solriamfetol) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

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**SUNOSI** (sobradofetel) tablets, for oral use, CIV BRIEF SUMMARY PRESCRIBING INFORMATION: Consult the Full Prescribing Information for complete product information.

Initial U.S. Approval: 2018

INDICATIONS AND USAGE

SUNOSI is indicated to treat sleep-related hypoventilation in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

Limitations of Use

SUNOSI is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating SUNOSI for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with SUNOSI. SUNOSI is not a substitute for these modalities.

**DOSE AND ADMINISTRATION**

**Important Considerations Prior to Initiating Treatment**

Prior to initiating treatment with SUNOSI, ensure blood pressure is adequately controlled.

**General Administration Instructions**

Administer SUNOSI orally upon awakening with or without food. Avoid taking SUNOSI within 9 hours of planned bedtime because of the potential to interfere with sleep if taken too late in the day.

SUNOSI 75 mg tablets are functionally scored tablets that can be split in half (37.5 mg) at the score line.

**CONTRAINDICATIONS**

SUNOSI is contraindicated in patients receiving concomitant treatment with monoamine oxidase (MAO) inhibitors, or within 14 days following discontinuation of monoamine oxidase inhibitor because of the risk of hypertensive reaction.

**WARNINGS AND PRECAUTIONS**

**Blood Pressure and Heart Rate Increases**

SUNOSI increases systolic blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion.

Epidemiological data show that chronic elevations in blood pressure increase the risk of major adverse cardiovascular events (MACE), including stroke, heart attack, and cardiovascular death. The magnitude of the increase in absolute risk is dependent on the starting blood pressure level and the underlying risk of MACE in the population being treated. Many patients with narcolepsy and OSA have multiple risk factors for MACE, including hypertension, diabetes, hyperlipidemia, and high body mass index (BMI). Assess blood pressure and control hypertension before initiating treatment with SUNOSI. Monitor blood pressure regularly during treatment and treat new-onset hypertension and exacerbations of pre-existing hypertension. Exercise caution when treating patients at higher risk of MACE, particularly patients with known cardiovascular and cerebrovascular disease, pre-existing hypertension, and patients with advanced age. Use caution with other drugs that increase blood pressure and heart rate.

Periodically reassess the need for continued treatment with SUNOSI. If a patient experiences increases in blood pressure or heart rate that cannot be managed with dose reduction or other appropriate medical intervention, consider discontinuation of SUNOSI.

Patients with moderate or severe renal impairment may be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of SUNOSI.

**Psychiatric Symptoms**

Psychiatric adverse reactions have been observed in clinical trials with SUNOSI, including anxiety, insomnia, and irritability.

SUNOSI has not been evaluated in patients with psychosis or bipolar disorders. Exercise caution when treating patients with SUNOSI who have a history of psychosis or bipolar disorder prior to initiating treatment.

Patients with moderate or severe renal impairment may be at a higher risk of psychiatric symptoms because of the prolonged half-life of SUNOSI.

Patients treated with SUNOSI should be observed for the possible emergence or exacerbation of psychiatric symptoms, if psychiatric symptoms develop in association with the administration of SUNOSI, consider dose reduction or discontinuation of SUNOSI.

**ADVERSE REACTIONS**

The following adverse reactions are discussed in greater detail in other sections of the label:

- **Blood Pressure and Heart Rate Increases**
- **Psychiatric Symptoms**

**Clinical Trials Experience**

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

The safety of SUNOSI has been evaluated in 1301 patients (ages 18 to 75 years) with narcolepsy or OSA. Among these patients, 396 were treated with SUNOSI in the 12-week placebo-controlled trials at doses of 37.5 mg (OSA only), 75 mg, and 150 mg once daily. Information provided below is based on the pooled 12-week placebo-controlled studies in patients with narcolepsy or OSA.

**Most Common Adverse Reactions**

The most common adverse reactions (incidence ≥ 5% and greater than placebo) reported more frequently with the use of SUNOSI than placebo in either the narcolepsy or OSA populations were headache, nausea, decreased appetite, anxiety, and insomnia. Table 1 presents the adverse reactions that occurred at a rate of ≥ 2% and more frequently in SUNOSI-treated patients than in placebo-treated patients in the narcolepsy population.

**Table 1: Adverse Reactions ≥ 2% in Patients Treated with SUNOSI and Greater than Placebo in Pooled 12-Week Placebo-Controlled Clinical Trials in Narcolepsy (75 mg and 150 mg)**

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Placebo (n=226) (%)</th>
<th>SUNOSI 37.5 mg (n=58) (%)</th>
<th>SUNOSI 75 mg (n=120) (%)</th>
<th>SUNOSI 150 mg (n=218) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache**</td>
<td>8</td>
<td>7</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>Nausea**</td>
<td>5</td>
<td>7</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**In OSA only.**

**Headache** includes headache, tension headache, and head discomfort. **Nausea** includes nausea and vomiting.

**Adverse Reactions Resulting in Discontinuation of Treatment**

In the 12-week placebo-controlled clinical trials, 11 of the 396 patients (3%) who received SUNOSI discontinued because of an adverse reaction compared to 1 of 125 placebo patients (<1%) who received placebo. The adverse reactions resulting in discontinuation that occurred in more than one SUNOSI-treated patient and at a higher rate than placebo were: anxiety (2/396 vs. 1/125), palpitations (2/396 vs. 1/125), and restless legs (2/396 vs. 1/125).

**In OSA only.**

**Headache** includes headache, tension headache, and head discomfort. **Nausea** includes nausea and vomiting.

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**In OSA only.**

**Headache** includes headache, tension headache, and head discomfort. **Nausea** includes nausea and vomiting.
Table 4: Maximal Mean Changes in Blood Pressure and Heart Rate Assessed at MWT Sessions from Baseline under 12- Hour (Mean ± SE)•

<table>
<thead>
<tr>
<th>Placebo</th>
<th>SUNOSI 37.5 mg</th>
<th>SUNOSI 75 mg</th>
<th>SUNOSI 150 mg</th>
<th>SUNOSI 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>52</td>
<td>51</td>
<td>53</td>
<td>53</td>
</tr>
<tr>
<td>SBP</td>
<td>(0.7, 6.4)</td>
<td>-0.1 (0.6)</td>
<td>1.8 (8.2)</td>
<td>3.2 (10.3)</td>
</tr>
<tr>
<td>HR</td>
<td>-2.7</td>
<td>2.2</td>
<td>4.2</td>
<td>4.2</td>
</tr>
<tr>
<td>DAP</td>
<td>4.5</td>
<td>-0.1</td>
<td>3.7</td>
<td>3.8</td>
</tr>
<tr>
<td>OSA</td>
<td>-10 (-11.9, 9.7)</td>
<td>0.6 (6.0)</td>
<td>1.4 (4.4)</td>
<td>3.6 (6.0)</td>
</tr>
</tbody>
</table>

SPB = systolic blood pressure, DAP = diastolic blood pressure, HR = heart rate

*For studies weeks 1, 4, and 12, SBP, DBP, and HR were assessed pre-dose and every 2 hours for 10 hours after fast drug administration. All time points at all visits, the mean change from baseline was significant and directly related to the dose administered. The table shows, by indication and dose, the mean changes from baseline for the week and time point with the maximal change in SBP or HR and the dose related adverse reactions.

**The maximum recommended daily dose is 300 mg. Doses above 150 mg daily do not confer increased efficacy relative to the 150 mg daily dose and are associated with increased adverse reactions.

Table 5: Blood Pressure and Heart Rate by 24-Hour Ambulatory Monitoring: Mean Change (% CT) at Baseline under 12- Hour (Mean ± SE)•

<table>
<thead>
<tr>
<th>Placebo</th>
<th>SUNOSI 37.5 mg</th>
<th>SUNOSI 75 mg</th>
<th>SUNOSI 150 mg</th>
<th>SUNOSI 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>46</td>
<td>44</td>
<td>44</td>
<td>40</td>
</tr>
<tr>
<td>SBP</td>
<td>-0.2 (-13.5)</td>
<td>1.8 (-0.4)</td>
<td>2.2 (-0.1)</td>
<td>2.2 (-0.2)</td>
</tr>
<tr>
<td>HR</td>
<td>-0.1 (-13.9)</td>
<td>1.0 (-0.2)</td>
<td>1.4 (0.3)</td>
<td>1.4 (0.3)</td>
</tr>
<tr>
<td>DAP</td>
<td>1.0 (0.3)</td>
<td>-0.4 (3.2)</td>
<td>1.2 (1.3)</td>
<td>1.2 (1.3)</td>
</tr>
</tbody>
</table>

SBP = systolic blood pressure, DAP = diastolic blood pressure, HR = heart rate

*Number of patients who had at least 50% valid ASH readings.

**The maximum recommended daily dose is 300 mg. Doses above 150 mg daily do not confer increased efficacy relative to the 150 mg daily dose and are associated with increased adverse reactions.

**Drug INTERACTIONS**

** MAOIs (Monoamine Oxidase Inhibitors)**

Do not administer SUNOSI concomitantly with MAOIs or within 14 days after discontinuing MAOIs therapy. Concomitant use of SUNOSI and monoamine oxidase inhibitors or other drugs that may increase the risk of a hypertensive reaction may increase the risk of a hypertensive reaction. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure.

**Drugs that Increase Blood Pressure and/or Heart Rate**

Concomitant use of SUNOSI with other drugs that increase blood pressure and/or heart rate has not been evaluated, and such combinations should be used with caution.

**Dopaminergic Drugs**

Dopaminergic drugs that increase levels of dopamine or that bind directly to dopamine receptors might result in pharmacodynamic interactions with SUNOSI. Interactions with dopaminergic drugs have not been evaluated with SUNOSI. Use caution when concomitantly administering dopaminergic drugs with SUNOSI.

**USE IN SPECIFIC POPULATIONS**

** Pregnancy**

The pregnancy exposure registry that monitors pregnancy outcomes in women exposed to SUNOSI during pregnancy. Healthcare providers are encouraged to register pregnant patients, or pregnant women may enroll themselves in the registry by calling 1-877-033-6220 or contacting the company at www.Sunos/PregnancyRegistry.com.

** Lactation**

Available data from case reports are not sufficient to determine drug-associated risks of breastfeeding, neonatal or infant outcomes. Breastfeeding is not recommended for patients with end stage renal disease and in patients with moderate to severe renal impairment (eGFR ≤15 mL/min/1.73 m²). Designated nursing mothers should be informed prior to SUNOSI therapy to express milk for neonatal feedings. Available data from case reports are not sufficient to determine drug-associated risks of breastfeeding, neonatal or infant outcomes. Breastfeeding is not recommended for patients with end stage renal disease and in patients with moderate to severe renal impairment (eGFR ≤15 mL/min/1.73 m²). SUNOSI is not recommended for patients with end stage renal disease (eGFR <15 mL/min/1.73 m²).

** DRUG ABUSE AND CONTROLLED SUBSTANCE**

SUNOSI contains solriamfetol, a Schedule IV controlled substance.

** Abuse**

SUNOSI has potential for abuse. Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. The abuse potential of SUNOSI 300 mg, 600 mg, and 1200 mg (two, four, and eight times the maximum recommended dose) was assessed relative to phentermine, 45 mg (two, four, and eight times the maximum recommended dose). (SUNOSI 300 mg) and in a similar study conducted in individuals with the recommended use of stimulants. Results from this clinical study demonstrated that SUNOSI produced Drug liking scores similar to or lower than phentermine. In this crossover study, elevated mood was reported by 2.4% of placebo- treated subjects, 8% to 12% of SUNOSI-treated subjects, and 10% to 12% of phentermine- treated subjects. A feeling of relaxation was reported by 0.8% to 3.3% of placebo- treated subjects, 5% to 30% of SUNOSI-treated subjects and 5% to 40% of phentermine-treated subjects.

** Dependence**

In a term safety and maintenance of efficacy study, the effects of abrupt discontinuation of SUNOSI were evaluated following at least 6 months of SUNOSI use in patients with narcolepsy or OSA. Patients who had completed at least 6 months of SUNOSI use were also evaluated during the two-week safety follow-up periods in the Phase 3 studies. There was no evidence that discontinuations with SUNOSI resulted in a consistent pattern of adverse events in individual subjects that was suggestive of physical dependence or withdrawal.

**OVERDOSAGE**

A specific reversal agent for SUNOSI is not available. Hemodialysis removed approximately 21% of a 75 mg dose in end stage renal disease patients.

**PAIN RELIEF TREATMENT INFORMATION**

Advise patients to the FDA-approved patient labeling (Medication Guide). Patients for Abuse and Dependence

Advise patients that SUNOSI is a federally controlled substance because it has the potential for abuse. Assess patients for the abuse potential of SUNOSI. Abnormalities such as decreased alertness, decreased coordination, or fatigue. Instruct patients to store SUNOSI at room temperature and dispose of unused SUNOSI as recommended in the Medication Guide.

**MAOIs Therapy Use**

Patients that SUNOSI is not indicated to treat the urinary antidiuretic in OSA and they should use a primary OSA therapy, such as CPAP as prescribed to treat the underlying sleep disorder. SUNOSI is not a substitute for primary OSA therapy.

**BLOOD PRESSURE AND HEART RATE INCREASES**

Patients that SUNOSI can cause elevations of their blood pressure and pulse rate and that they should be monitored for such effects.

**GERIATRIC USE**

Instruct patients to contact their healthcare provider if they experience, anxiety, increased irritability, agitation, or signs of psychosis or bipolar disorders.

**Lactation**

Monitor breastfeeding infants for adverse reactions such as agitation, insomnia, anorexia, and reduced weight gain.

**Renal Use**

Safety and effectiveness in pediatric patients have not been established. Clinical trials of SUNOSI in pediatric patients have not been conducted.

**INTERACTIONS**

**MAOIs (Monoamine Oxidase Inhibitors)**

Do not administer SUNOSI concomitantly with MAOIs or within 14 days after discontinuing MAOIs therapy. Concomitant use of SUNOSI and MAOIs and other drugs that may increase the risk of a hypertensive reaction may increase the risk of a hypertensive reaction. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure.

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Concomitant use of SUNOSI with other drugs that increase blood pressure and/or heart rate has not been evaluated, and such combinations should be used with caution.

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Dopaminergic drugs that increase levels of dopamine or that bind directly to dopamine receptors might result in pharmacodynamic interactions with SUNOSI. Interactions with dopaminergic drugs have not been evaluated with SUNOSI. Use caution when concomitantly administering dopaminergic drugs with SUNOSI.

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The pregnancy exposure registry that monitors pregnancy outcomes in women exposed to SUNOSI during pregnancy. Healthcare providers are encouraged to register pregnant patients, or pregnant women may enroll themselves in the registry by calling 1-877-033-6220 or contacting the company at www.Sunos/PregnancyRegistry.com.

**Lactation**

Available data from case reports are not sufficient to determine drug-associated risks of: maternal death, minor or major malformations, or adverse maternal or fetal outcomes. In reproductive studies, oral administration of solriamfetol during organogenesis caused maternal and fetal toxicities and included maternal weight gain and maternal toxicity at doses ≥15 and >5 times and maternal toxicity at doses >15 and 5 times, respectively, the maximum recommended human dose (MRHD) of 150 mg based on mg/m² body surface area. Oral administration of solriamfetol to pregnant rats during pregnancy and lactation at doses ≥7 times the MRHD based on mg/m² body surface area resulted in maternal toxicity and adverse effects on fertility, growth, and development in offspring (see Data).

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

**Data**

Animal Data

Solriamfetol was administered orally to pregnant rats during the period of organogenesis at 15, 67, and 295 mg/kg/day, which are approximately 1, 4, and 19 times the MRHD based on mg/m² body surface area. Solriamfetol at 4 times the MRHD caused maternal toxicity, hyperactivity, significant decreases in weight, weight gain, and food consumption. Fetal toxicity at these maternal toxicity doses included increased incidences of abnormal postnatal pup mortality, reduced fetal body weight, and decreased fetal body weight.

**Solriamfetol was teratogenic at 19 times the MRHD; it increased the incidence of fetal malformations that included severe sesamoidane malalignment, hindlimb rotation, bent long bones, and situs inversus. The highest dose of solriamfetol was also associated with an increased incidence of malformations at reduced levels, including dysmorphic features, decreased fetal body weight, and decreased fetal body weight.**
Chairman’s Letter

Strengthen Medicare Advantage

Medicare Advantage (MA) has been one of the success stories in American healthcare over the past 20 years. Enrollment has grown steadily since the early 2000s, so now about 42% of the Medicare population get their Medicare coverage through MA plans. As our cover story says, the upward trend is likely to continue. Projections from the Congressional Budget Office (CBO) show that more than half of all Medicare beneficiaries will be enrolled in MA plans by the end of this decade.

The popularity of MA is easy to understand. The plans are a good deal for beneficiaries. Most of them include drug coverage and dental and vision benefits that beneficiaries in traditional Medicare have to buy separately — or do without. The basic trade-off is that MA plan members have access to a narrower network of providers — the physicians and hospitals that the plan has contracted with — than beneficiaries who stick with traditional Medicare. Surveys show that MA plan members are, by and large, happy with their provider choices. And the quality of the plans, as measured by the CMS Star Rating system, is improving.

But here’s the rub. Partly because of the demographic bulge of baby boomers, Medicare is in actuarial hot water. The CBO has predicted that the Hospital Insurance Trust Fund will be insolvent in five years. Lawmakers and others are eyeing cuts to MA plans as a way to make the numbers work. Some experts argue that the federal government has been overpaying the insurers who market MA plans. The insurers counter that the MA plans are enrolling an increasing number of people with complex, chronic conditions; that the plans have a strong track record when it comes to metrics like avoidable hospitalizations; and that MA, as a form of capitated value-based care, has incubated innovation in lowering the cost and improving the quality of care.

Perhaps some adjustments are warranted, but Medicare Advantage is a very rare beast in American healthcare; a popular form of health insurance. It should be strengthened, not weakened, as lawmakers take on the actuarial challenges of the Medicare program.
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COVER STORY

MEDICARE ADVANTAGE PLANS, on a roll, could see some cuts

Medicare funding shortfalls may trickle down to the Medicare Advantage plans and the Star Rating program bonuses, which have quadrupled in recent years. PAGE 16
Chronically and critically ill patients often need acute care after their stay in an intensive care or medical/surgical unit. While these medically complex patients make up a small part of overall care delivery, it is critical to identify the appropriate care setting for them in order to decrease the risk of costly rehospitalization.

Kindred Hospitals deliver efficient care through specialized programs that improve outcomes and patient satisfaction. Our physician-led interdisciplinary teams help reduce avoidable readmissions and guide patients home or to a lower level of care.

Visit kindredmanagedcare.com to request a conversation about how Kindred Hospitals’ level of service can help manage your critically complex patients.
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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.

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

The editors of Managed Healthcare Executive® regularly interview members of our editorial advisory board for our “Meet the Board” podcast. We ask them about their careers and jobs and current issues and controversies in healthcare. We recently caught up with David Calabrese, a longtime board member and market president, health plans/PBMs, at OptumRx.

Q Can you tell us why you went into pharmacy as a career?

I followed in the footsteps of a family member. My grandfather, Ralph Paolino, was a pharmacist. He owned Jones Pharmacy in Waterbury, Connecticut, where I grew up. It was one of those old-fashioned pharmacies with the soda fountain and all, and much of what he did was compounding medicines and creating different types of syrups and solutions and all of that.

It really hit home as I started to get older, the way he served the community and the value he brought to our community. People relied on him, often more than they did their own physicians. He got calls at home.

I was always strong in math and science. And as I started to make career decisions, it was pretty clear to me right from the get-go that was the career I was going to pursue.

I had the good fortune of going to Northeastern University, which had a cooperative education program where you’re working every other semester in the field you’re studying in. My last co-op rotation happened to be with Harvard Community Health Plan, the predecessor to what is now Harvard Pilgrim Health Care.

So I got my foot in the door working with one of the staff model HMO pharmacies and really gained an appreciation for managed care and being able to work side by side with the physicians and nurses and being part of committees that were focused on quality issues that you really had no exposure to in pharmacy school. I kind of fell in love with it and was thankfully offered an opportunity to come on when I graduated as a full-time pharmacist. The rest is history. I have stayed in managed care my entire career.

Q Your job at OptumRx has changed. Your title is now market president, health plans/PBMs. What are you doing now? How does it differ from your previous position?

For the last seven years, I’ve served as the chief pharmacy officer at OptumRx, where I oversaw much of our clinical strategy or clinical programming. At the beginning of this year, I was tapped to take on a new responsibility, which is far different, and that’s leading one of our major segments within OptumRx that contracts with health plans and PBMs across the country outside of UnitedHealthcare.

The bigger part is the health plan business. We’ve got 30-plus health plans that we contract with nationally. They range from small regional plans to large Blues plans and other sizable regional accounts. One of longest-standing clients is Independence Blue Cross in Philadelphia. One of our newest clients is Blue Cross Blue Shield of Michigan. We have Harvard Pilgrim Health Care as a client. And we’ve got smaller regional players like Health New England in the Springfield, Massachusetts, market.

My job is now really business-focused. It’s helping grow that business, maintain that business. But more importantly, it’s maintaining strong working relationships with our health plan partners, making
sure we’re meeting their needs, making sure we’re partnering with them in a proactive manner to help them address their biggest challenges, helping them to grow their businesses to differentiate themselves, particularly from a pharmacy perspective as they pursue new business in their regional markets. But I’ve really enjoyed it. I’ve learned a ton. The organization has been extremely supportive. The clients have been extremely supportive. We’ve got some great momentum behind us in terms of our growth trajectory.

Q Could you discuss some of the other services that you provide these other health plans?

We’ve been set up intentionally with very clear firewalls. I have no responsibilities for UnitedHealthcare. They’re an entirely separate team. The services will vary from client to client in terms of what their needs are, how much they want to delegate to us versus how much they want to retain in house. But, by and large, it’s everything that a PBM would provide any other client. We’ve tried to extend beyond that, given the nature of who we are, being a part of this broader Optum enterprise. One of the luxuries that I have at my disposal is the ability to extend outside of pharmacy where health plan clients need to bring in resources from other areas of the organization, whether it’s advisory consultative services to help them grow, whether it’s behavioral health support, whether it’s case management support for different disease states that are a key priority for them. That’s one of the unique parts of what we bring to the table that helps us distinguish ourselves when we’re going out there and trying to grow in the marketplace.

Q Shifting gears, what is your opinion about the FDA’s approval of Aduhelm, the Alzheimer drug. Were you surprised by the approval?

Was I surprised? I’ll say no. It’s not the first time we’ve seen the FDA make decisions that have varied from what an advisory committee may have recommended.

Do I agree with the decision? I’d have to say that as a clinician who’s prided himself on decisions based on an evidence-based hierarchy, I’m a little disappointed by the decision. But I am appreciative of the challenges that the FDA had in front of it. Alzheimer’s is a horrendous disease. The prevalence is growing as our population ages. We’ve had next to nothing in terms of new options for this patient population.

But the evidence (for Aduhelm) is very limited. I think it’s now up to the payers to make the decision as to whether this product should or shouldn’t be covered for their patient populations based on the evidence at hand. Additional studies are going to be done and real-world evidence will be accumulated that show the true impact of the drug on disease progression.

Q In early July, President Joe Biden issued a directive that touched on a wide range of healthcare issues, including getting more generics to the market. Any thoughts on that?

I think that’s a positive thing. I think anything that helps to promote competition, that helps to affect affordability for members and for plan sponsors, is welcome. We’re doing everything possible with our clients to drive value from generics as they make their way to market and ensure that we’re maximizing uptake of those generics — utilization management edits and benefit design that encourage uptake of generic drugs. So as long as it’s being managed in a clinically appropriate, high-quality manner, I’m all for it.

We’re under tremendous pressure right now, much of which is being driven by new entries into the specialty marketplace. And that’s only going to get more challenging as more and more gene and cell therapies make their way to market. The pharmaceutical industry is largely focused on rare and orphan disease now, so if it’s not cell and gene, it’s orphan.

We know what the price tags are for these products as they make their way to market. So we’ve got to have something to offset that in order to provide a well-rounded benefit and to ensure that the broadest number of patients who are appropriate candidates for these drugs have access to them.

And that’s becoming more and more challenging for a lot of plan sponsors these days.

Note: This transcript has been edited for clarity and length.

David Calabrese, RPh, is market president health plans/PBMs at Optum Rx and a longtime member of the Managed Healthcare Care editorial advisory board.
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In Brief

States tackle drug pricing

For an assortment of reasons, the federal government hasn’t taken any action on regulating drug prices, so a handful of states have taken matters into their own hands. New York, Massachusetts, Maine, Maryland and New Hampshire have established entities with drug pricing powers. Harvard Medical School researchers published an informative overview of the state government efforts in the Milbank Quarterly in August.

As happens when healthcare policy devolves to the states, there’s a lot of variety in how the state-level drug pricing regulation is playing out. The Maine and New Hampshire drug pricing boards advise non-Medicaid, state-financed health plans, but they can’t impose requirements. The Maryland board is also focused on non-Medicaid, state-financed health plans, but it can set upper payment limits on drugs. The Massachusetts board is not a separate board but the Massachusetts Health Policy Commission was set up to find ways to control overall healthcare spending in the state, not just expenditures on drugs. New York has two drug boards, one for the state’s Medicaid program and the other for state-regulated commercial health insurers.

Only the board in New York with authority over the Medicaid program has completed drug-pricing reviews. The Harvard researchers say those reviews have resulted in savings for New York. After the board decided Vertex’s Orkambi (lumacaftor/ivacaftor), a cystic fibrosis drug, was priced too high, the state reached a confidential supplemental rebate agreement with Vertex. A decision by the board that the state should peg the price for Remicade (infliximab) to the price of an infliximab biosimilar led to another supplemental rebate agreement that benefited the state, according to the Harvard researchers.

PCMA challenges disclosure rules

Prices in American healthcare are difficult to nail down because they are obscured by secret negotiations between payers and providers and, in the case of drugs, pharmaceutical manufacturers. But that is beginning to change. Despite court challenges and uneven compliance, hospitals were forced to start disclosing prices at the beginning of this year. Now, because of rules issued by the Trump administration, it is the PBMs’ turn. The price transparency rule, different parts of which go into effect next year and in 2023, would require disclosure of cost-sharing estimates to plan members, which isn’t controversial, but also the net prices that PBMs pay to drugmakers after discounts and rebates, which is. The U.S. Chamber of Commerce and the Pharmaceutical Care Management Association (PCMA), the PBM industry’s trade group, filed lawsuits challenging the net price disclosures in August.

Consumer advocates and others say disclosure of net drug prices would shed long-overdue light on the true price of drugs and how much money different players in the drug supply chain, particularly PBMs, are making. Ironically, the anti-ACA Trump administration leaned on some disclosure provisions in the health-care reform law to justify the price transparency rules. PCMA argues in its 85-page brief that this legal maneuver went way beyond the intent of the ACA provisions and that the ACA also didn’t contemplate sharing “machine readable” files that net pricing disclosures would require.

The trade group also argues that disclosure of pricing information will be bad for health plans and their members because it will undercut the ability of PBMs to negotiate price concessions. Disclosure of net prices will establish a “pricing floor,” argues the brief, and will allow for tacit collusion among manufacturers, who will not be willing to offer prices below those of their competitors.
Is Cigna’s $500 offer to patients for switching ethical?

Copays and formulary tiers involve financial incentives to use certain drugs. But is Cigna’s offer of a $500 debit card in a different category? by DEBORAH ABRAMS KAPLAN

Cigna members who switch from Cosentyx (secukinumab) or Remicade (infliximab) to an approved biosimilar will receive a $500 debit card, per a policy introduced in July by the insurance carrier. It’s marketed as an effort to lower prescription drug costs through the Shared Savings Program. Cigna is alerting treating physicians and the 7,000 affected patients individually.

Offering physicians $500 to prescribe biosimilars over name-brand drugs would clearly be unethical and likely illegal, says Leonard Fleck, Ph.D., professor at the Center for Bioethics and Social Justice at Michigan State University. But it is potentially ethically acceptable to offer the funds to patients under certain circumstances, he says. In the larger picture, financial incentives for using certain pharmaceuticals may contribute to wasteful administrative costs and does not benefit the patient, in Fleck’s view.

But Cigna estimates that in the short term, its clients will save at least 10% of Remicade’s cost for each patient who switches, with savings growth as biosimilars gain traction. “Biosimilars can save patients, their employers, health plans and the healthcare system billions of dollars over the long term,” Steve Miller, Cigna’s chief clinical officer, told Managed Healthcare Executive® in an interview in July.

Cosentyx is used to treat psoriasis, psoriatic arthritis, nonradiographic axial spondyloarthritis, and ankylosing spondylitis. Remicade is a treatment for arthritis, psoriasis, Crohn’s disease and ulcerative colitis. Patients on Remicade can switch to Avsola (infliximab-axxq) and Inflectra (infliximab-dyyb). Cosentyx doesn’t have an approved biosimilar so if patients switched, it might be to different biologic, such as Taltz (ixekizumab).

The offer could be seen as ethical if Cigna is respecting patient autonomy in deciding the best treatment. “We ought to respect patient choices in that regard,” says Fleck. However, “these drugs are called biosimilars for a reason. They are not perfect replacements of the drugs they’re intended to replace.”

Biosimilars aren’t likely to negatively affect most patients, Fleck says, but it might be problematic for some. “You’re encouraging patients to make a medical decision about something they would not fully understand, and they would look at it as an economic transaction. There is a potential problem there.” The switching is arguably for Cigna’s benefit. “Then again, you can see from the perspective of a larger consumer group — everybody who has insurance through Cigna — that it could bring down overall healthcare costs for pharmaceuticals, and that’s not a bad objective,” says Fleck.

A person’s economic situation also has to be considered. For someone who is well off, a $500 debit card may not be worth switching medications, especially if the current one works well. But for someone who is economically disadvantaged, $500 is a lot of money. “That comes closer to being a coercive bargain,” says Fleck.

Patients on long-term treatments are usually told to consult with a physician before making any changes in their regimen. In this case, physicians would be consulted because a new prescription is needed. “But patients will put pressure on physicians to write the new script, which may or may not have medical consequences,” Fleck says.

Deborah Abrams Kaplan writes about medical and practice management topics.
A patient rests comfortably in a hospital bed. Everything seems fine. Neither the patient nor the doctor or nurses realize he is about to take a life-threatening turn for the worse. Within hours, he will be septic, and his care team will race to begin aggressive fluid resuscitation and antibiotics.

Yet, although the patient’s doctor and nurses do not see sepsis coming, someone else does — or, more accurately, something else does. The patient’s electronic health record (EHR) includes an artificial intelligence (AI) tool that detects patterns imperceptible to the patient’s human caretakers. It duly sends an alert to his doctor and nurses. What could have been a shocking deterioration is instead averted.

“It sounds futuristic, this kind of thing that AI could do. But algorithms are already detecting hard-to-anticipate conditions such as sepsis in hospitals, and lives are already being saved. In fact, the underlying idea — that a set of data, put together in context, can help predict outcomes — is already very much a part of medical thinking,” says Yasir Tarabichi, M.D., MSCR, director of clinical informatics for research support at MetroHealth, a safety net healthcare system in Cleveland.

AI and machine learning based on huge medical data sets are just the latest iteration of risk stratification, Tarabichi says, which is something as old as medicine itself. Before AI, patients could be given risk scores based on simple scoring tools and scales. AI has created the opportunity to score patients using thousands of measurements not previously available, much less analyzable. “It was simpler before, because it was more of a point-based system,” Tarabichi says. “Now it (has become) a lot more complicated.”

Broad array

With opportunity comes challenges. One of the main challenges with AI is dealing with the onslaught of new products. Prem Thomas, M.D., medical director of data analytics and medical information officer at Yale New Haven Health in Connecticut, said he and colleagues get visits from software representatives the way doctors have historically received visits from drug company sales reps. “It’s interesting,” he says. “We have our weekly medical information officers’ meeting, and typically there’s somebody (from a technology vendor who) wants to present to us during that time.”

The companies hawking their AI wares range from entrenched players such as Epic Systems, the largest EHR company in the United States, which markets a sepsis prediction model, to tiny startups that have little, if any, experience in healthcare. Increasingly, tech giants such as Apple and Google have tried to gain a foothold in the healthcare technology sector, often with an AI focus.

“With predictions of increased volume reaching 300% to 400%, hospital leaders knew they would be facing a “tsunami of phone calls” from patients and members of the public asking questions or wanting to sign up for the vaccines, Montgomery says. “With predictions of increased volume reaching 300% to 400%, hospital leaders knew we needed a solution that would...”

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The Pharmacy Benefit Management Institute® (PBMI®) is excited to announce the 2021 PBMI® Annual National Conference will be hosted in Orlando, Florida from September 13-15, 2021, at the JW Marriott, Orlando, Grande Lakes.

This year’s conference will offer a unique hybrid experience, comprised of a world-class meeting in Orlando along with an interactive virtual offering. Throughout the three-day event, you’ll hear from companies operating across the PBM Industry including CVS Health, Biologics by McKesson, WellDyne, Capital Rx and more.

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Scott Gottlieb, MD

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manage the flood of vaccine-related phone calls without impacting usual operations,’ she says.

The hospital used Syllable, a conversation AI voice assistant, to automate work flow and conserve resources by making it easier for patients to find a wide array of answers without needing to speak to a human being. It also used AI to handle in-person traffic. Visitors to the facilities were screened by the temperature-monitoring platform Care.ai by standing in front of a tablet equipped to scan for fevers. “This contactless technology not only helped with conserving staff resources, but it also speeds up screening measures at point of entry,” Montgomery says.

High stakes
One reason Houston Methodist was able to implement its COVID-19 strategies fast is because it has set up an infrastructure to quickly review and vet new technologies. The Center for Innovation, launched in 2018, has a group called DIOP, which stands for Digital Innovation Obsessed People, made up of roughly half operational staff and half information technology staff. The group is charged with developing strategies for broad-scale implementation or “failing fast” — quickly identifying technology that is not a good fit. “The results of focusing on innovation before it was essential to a pandemic such as COVID-19 enabled our hospital system to embrace new technology, including AI, more seamlessly,” Montgomery says.

Still, the stakes for AI implementation vary depending on its proposed use. A temperature-screening device that stops working might mean a staff member gets temporarily reassigned to thermometer duty. An errant AI system designed to help clinicians make treatment decisions could harm patients, even kill them. Tarabichi said it is important that the public understands that hospitals do not take AI lightly.

“We don’t just blindly adopt new technology,” he says. “We make sure it’s going to work for us.”

For instance, before implementing the Epic sepsis model, MetroHealth ran the program in the background for an entire year, disabling the alerts but collecting data. Before they toggled it live, the health system wanted to make sure it worked and had a meaningful benefit. At the end of the year, they adopted the technology but limited its use to the emergency department.

Thomas says that kind of slow, evaluative approach is key to AI integration. It means taking the time to understand how an AI system works, getting an idea of the data sets used by the vendor and tailoring the program’s settings to the health system’s needs.

In other words, it takes time and money — and more time. But Thomas says the expense is worth it.

“I would recommend that community hospitals or academic hospitals invest the resources in having a redesign committee review what this model is purported to do for you and then think through how to operationalize it,” he says. Yale New Haven’s redesign committee, for instance, is an interdisciplin-ary team whose members include intensive-care unit nurses, emergency department doctors, inpatient nurses and other professionals, as well as analytics staff.

But a health system’s ability to carefully evaluate an AI system isn’t just a matter of staff expertise and representation. It also requires having access to enough data and software to fully understand a product. Because AI products are proprietary software marketed by for-profit companies, there can be tension between the company’s desire to keep proprietary information private and a healthcare system’s need to fully understand the tools they are using to take care of patients. An example of that kind of conflict had a public airing this summer when investigators from the University of Michigan reported findings of their independent evaluation of Epic’s sepsis prediction tool in JAMA Internal Medicine. Their research suggested that the product is less accurate at predicting sepsis than what the company claims in its marketing materials. The findings were controversial, in part because the sensitivity of the AI tool depends on the settings put in place. Epic disputed the findings, saying that it works closely with users to ensure the product meets their needs and to provide access to the data necessary to evaluate the model.

Tarabichi has submitted his own paper, soon to be published, which contradicts some of what the Michi-
gan investigators found. Yet, even as experts disagree about the particular product, this raises important questions about the limits of using proprietary models.

The increase and growth in deployment of proprietary models has led to an underbelly of confidential, non-peer-reviewed model performance documents that may not accurately reflect real-world model performance,” wrote the corresponding author of University of Michigan study, Karandeep Singh, M.D., M.M.Sc., and his colleagues.

In the case of Epic's sepsis model, both Thomas and Tarabichi said they were satisfied that they had access to the information they needed to evaluate the product, though they both said information from the company was just one component of their implementation process.

Tarabichi cautions against hospitals “jumping on the bandwagon,” of using popular AI without first validating it and testing it in their own system. In a smaller community hospital setting, validation may not need to be as complicated as it might at a top academic medical center with a diverse patient population.

“Randomized controlled trials are the highest level of evidence, but lower down that hierarchy is post-assessment,” he says. “Run it for a couple of months and then evaluate. What changed? Can you do better?”

Not always the answer
For Thomas, it is not just about choosing the right AI system but also about being thoughtful about when and where AI is actually needed. He and his colleagues reference a “Mad Lib” created by Michael Draugelis, the chief data scientist at Penn Medicine in Philadelphia. It goes like this, Thomas says: “If I were [a physician, a physician’s assistant, a nurse, an operating room scheduler] in the health system and I knew ____, I would do ___ to change ____.

“Before we start on any project now, we say, ‘fill in the blanks,’” Thomas says. “Because if we don’t have a good answer for those, then we shouldn’t be investing the time and effort to go through with the project.”

Montgomery agrees, saying technology cannot displace patients’ status at the center of everything we do.

“AI isn’t meant to solve all the challenges in the healthcare setting,” she says, “but where these applications make sense, where they provide real benefits to our patients, that means it’s reaching its full potential.”

Jared Kaltwasser, a regular contributor to Managed Healthcare Executive®, is a freelance writer in Iowa.

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Medicare Advantage plans, on a roll, could see some cuts

Medicare funding shortfalls may trickle down to the Medicare Advantage plans and the Star Rating program bonuses, which have quadrupled in recent years.

*By JOSEPH BURNS*

In the coming years, the federal Medicare program will either need more funding or be forced to make serious spending cuts. The Medicare program is popular with voters and has support among politicians in both parties. But partly because of the expense of the response to the COVID-19 pandemic, policy makers may look to curtail Medicare spending and, more particularly, the Medicare Advantage (MA) program.

Medicare cuts may be needed because one of the two trust funds the government uses to pay for parts of the Medicare program is facing a severe shortfall, according to the Congressional Budget Office (CBO). In February, CBO predicted that the Hospital Insurance Trust Fund would be insolvent within five years.

In response, the Medicare Payment Advisory Commission (MedPAC), a nonpartisan organization established by statute to advise Congress on Medicare policies and programs, suggested eliminating the bonus payments the MA plans get as part of the Star Rating system, which rates the quality of the plans on a scale from 1 to 5.

This is not the first time the Medicare program has been on shaky financial footing; shoulders may shrug as more pressing matters dominate political and policy debates.

But it is only the second time that a projection predicted insolvency within five years, according to the Alliance for Health Policy, a nonpartisan organization that helps policy makers understand health policy. Adding to the sense of urgency is the demographic bulge of baby boomers aging into Medicare coverage at the rate of 10,000 seniors per day for the next 18 years. The past 15 years have been boom times for MA plans, and most indications are that the upswing will continue. But now there are some clouds on the horizon.

**MA has appealing margin**

| Per member, per month gross margins are larger for insurers in the Medicare Advantage market than in other markets, according to Kaiser Family Foundation calculations |

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<th>Individual market</th>
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<td>$143</td>
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*Source: Kaiser Family Foundation, Health Insurer Financial Performance in 2020, May 3, 2021*
A haircut

The Medicare program is the country’s largest purchaser of healthcare by far, spending nearly $900 billion this year to provide coverage for some 62 million Medicare beneficiaries, about 38 million of whom are in traditional Medicare, and 24 million of whom are in Medicare Advantage plans.

A growing proportion of the $900 billion is flowing to MA plans. CBO projections show that by 2030, more than half of Medicare beneficiaries will be in MA plans. Twenty years ago, only 13% of Medicare beneficiaries were in MA plans. Enrollment has grown because beneficiaries often get drug, dental and vision coverage with an MA plan. The trade-off is a narrower network of providers than traditional Medicare, but surveys show that most MA enrollees are satisfied with their choices. The MA plans say they are increasingly shouldering the burden of Medicare beneficiaries with complex, chronic conditions and health problems rooted in the social determinants of health.

MA has become a major line of business for many of the country’s largest health insurers. The largest commercial health insurers in the MA market are, in order of market size, UnitedHealthcare, Humana, the Blue Cross Blue Shield plans, CVS Health, Kaiser Permanente, Centene, and Cigna, KFF reports. According to the foundation’s researchers, the gross margins — the difference between the premiums insurers collect and the claims they pay out — are larger for insurers in the MA market than in other insurance markets. In 2020, the per-member, per-month gross margin in MA was $188, compared with $143 in the individual market and $80 in the group market, according to KFF calculations.

In its annual report to Congress in June, MedPAC made recommendations for adjusting MA payments. Among them was lowering the benchmarks that the federal government uses to set the per-beneficiary capitated payments to MA plans by about 2%, according to Gretchen Jacobson, a Commonwealth Fund vice president who focuses on Medicare issues.

The benchmarks are tied to calculations of what it costs to cover a beneficiary in traditional fee-for-service Medicare in the county or region where the MA plan has beneficiaries. Reducing the benchmark would save $10 billion over five years, MedPAC estimated.

That change would, however, have a relatively minor effect on spending compared with eliminating the Star Rating system and other bonus payments Medicare sends to health insurers when plans hit quality metrics, observes Jacobson. The targets include familiar measures such as the proportion of beneficiaries who have been screened for certain cancers, the number with controlled diabetes and hypertension, and the timeliness of insurance approvals and reviews, such as prior authorizations.

The vast majority (80%) of beneficiaries were in highly rated plans.

Up and up

Enrollment in Medicare Advantage plans has increased more than fivefold since 2003.

Star struck

Bonus payments to Medicare Advantage plans have increased under the Star rating system as enrollment in highly rated plans has increased.

Source: KFF, "Medicare Advantage in 2021: Enrollment Update and Key Trends, June 21, 2021"
Medicare Advantage plans, on a roll, could see some cuts

Eficiaries in MA plans are enrolled in plans with ratings of 4 or more stars. That’s good news from a healthcare quality perspective. If it is working as intended, the Star Rating system is supposed to be an incentive to improve care, make preventive services accessible, and encourage insurers to operate fairly and efficiently. But there are questions about how accurately the star ratings reflect quality because of how ratings are calculated. Although Medicare officials consider these questions, the amount that the federal government pays out in bonuses has grown. Over the past six years, what the Medicare program pays in Star Rating bonuses to MA insurers has nearly quadrupled, from $3 billion in 2015 to $11.6 billion this year.

In the past, MedPAC has recommended changes to the Star-Rating system, but doing so could be problematic because ending payments for quality would go against the grain of promoting value-based care, she observes. “If implemented, that recommendation (to eliminate the StarRating system) would be a very big change,” Jacobson notes. The suggestion to drop the star ratings would follow a recommendation that MedPac made in January 2020 to drop the quality-based bonus system entirely because CMS’ use of a variety of quality-based bonus systems has become extremely complicated, she adds.

Of course, any hint that payments to health plans might decline is bound to stir up fierce opposition from health insurers who rely on the growth of MA enrollment and annual increases in payments for each enrollee to increase revenues, margin and profits. But any consideration of reining in Medicare spending is a step in the right direction, in David Muhlestein’s opinion.

“It’s important that people are willing to reassess how we think about and pay for Medicare and Medicare Advantage, and to make different proposals,” says Muhlestein, the chief strategy and research officer for the consulting firm Leavitt Partners. But CMS doesn’t need to wait to reduce what Medicare spends each year because it could do so when it issues its annual fee schedules that set payment levels for physicians, hospitals and other providers.

“Medicare has the ability to lower their rates and ratchet them down over time,” he notes. “However, there is not a lot of political capital that gives them the sufficient protection they would need to lower rates.” Physicians, hospitals and health plans all say they need a raise every year.

“If you talk to members of Congress about reducing what Medicare pays, there are so many political barriers to do that with fee-for-service Medicare, and it’s likely to be difficult to do it in Medicare Advantage, too,” Muhlestein says. UnitedHealthcare, Humana and the Blues plans have about 60% of the MA market, he notes. “You can be assured that if there’s going to be any effort to reduce what Medicare pays, those companies will fight that idea tooth and nail — and probably be successful.”

Joseph Burns is an independent journalist in Cape Cod who writes about healthcare and managed care.

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The major players

According to Kaiser Family Foundation data, the largest health insurer in the Medicare Advantage (MA) market is UnitedHealthcare (UHC). The Minnesota-based company has about 72 million beneficiaries in its MA plans — about 27% of the market. Its MA partnership with AARP allows UHC to promote itself as an ally of older Americans. The two parties began the partnership in 1997 and, in 2017, extended their agreement until 2025, according to Forbes.

Another key to being successful is to have a long-term presence in the MA market, says Gretchen Jacobson, a Commonwealth Fund vice president and expert on Medicare. Humana is the second-largest MA insurer, with 4.8 million members, or 18% of the market. Humana was in the Medicare market before MA started when Congress passed the Medicare Prescription Drug, Improvement and Modernization Act in 2003, Jacobson notes. The predecessor program, called Medicare+Choice, started in 1997.
More than 30 million Americans have diabetes, according to the American Diabetes Association, and many rely on insulin. But insulin prices have been rising in recent years, and that has put many people with diabetes at risk because the price leads to people skipping doses or not taking insulin altogether.

The latest figures from the American Action Forum show that the price of insulin rose 14% a year, on average, between 2012 and 2018, and the past few years have followed this growth trajectory.

Many patients, policy makers and experts blame companies that manufacture insulin for dialing up the price of an established therapy. Sally Pipes, president and CEO of the Pacific Research Institute, a California-based think tank that favors free markets and limited government, says it’s easy to point the finger at pharmaceutical companies, but she finds fault elsewhere: in a dysfunctional market for insulin and many other prescription drugs and in pharmacy benefit managers.

“Pharmacy benefit managers — midlemen hired by insurance companies to manage their prescription drug plans — are driving those list prices up,” she asserts. The Pharmaceutical Care Management Association, the trade group for PBMs, says its member have done quite the opposite with programs that cap out-of-pocket costs or eliminate them. A spokesperson for the group says insulin makers have used patent extensions to avoid competition.

States take action
In the summer of 2020, then-President Donald Trump signed an executive order aimed at reining in prescription drug costs, requiring federally qualified health centers and hospitals, which purchase insulin through the 340B Drug Pricing Program, to pass along any savings they receive from discounted drug prices to medically underserved patients. The Biden administration halted its implementation. The National Association of Community Health Centers, among others, expressed support for the new administration’s move, saying the Trump rule would not have lowered the cost of insulin (and EpiPens) for most Americans.

Some states are moving to control insulin prices. This summer, Colorado joined Illinois in passing legislation that caps out-of-pocket costs of insulin. Maine, New Mexico, New York, Utah, Washington and West Virginia are considering similar legislation.

Prices may also come down if interchangeable biosimilars start coming on the market. In July 2021, the FDA designated Semglee (insulin glargine-yfgn) as an interchangeable biosimilar to Lantus (insulin glargine), a long-acting insulin analog. The designation means a pharmacist can switch the brand-name product for the presumably less expensive biosimilar, although state pharmacy laws can put some limits on interchangeability. Even so, the FDA approval should result in some competition between Semglee and Lantus and price decreases for patients and payers.

Keith Loria is a freelance writer in the Washington, D.C., area.
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The INOmax DS IR® 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

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- Integration with neonatal transport systems to support seamless delivery of therapy

Applications
The INOmax DS IR® Plus Delivery Systems deliver INOMAX® (nitric oxide) gas, for inhalation. The INOmax DS IR® 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 NO2 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.

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

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**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**

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

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

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

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

If there is an unexpected change in NO₂ concentration, or if the NO₂ concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO₂ analyzer should be recalibrated. The dose of INOmax and/or FiO₂ should be adjusted as appropriate.

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

**ADVERSE REACTIONS**

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

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

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

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

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

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

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

**DRUG INTERACTIONS**

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

**OVERDOSAGE**

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

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

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Value-Based Decision-Making in Metastatic Breast Cancer

In this Managed Healthcare Executive® KCast, Ian Krop, M.D., Ph.D., oncologist and associate professor of medicine at Dana-Farber Cancer Institute in Boston, and Debra Patt, M.D., Ph.D., MBA, executive vice president at Texas Oncology in Austin, provide key insights into the value-based care model for patients with HER2-positive metastatic breast cancer (mBC). This article summarizes the highlights of the discussion.

HER2-Positive mBC Standard of Care: Chemotherapy Plus HER2-targeted Therapy

For patients with newly diagnosed HER2-positive mBC, Krop and Patt explained that the current standard-of-care regimen includes both chemotherapy and HER2-targeted therapy, as the combination has been demonstrated to be more efficacious than using either alone. They added that treatment typically involves a taxane, such as Taxol (paclitaxel) or Taxotere (docetaxel), combined with the monoclonal antibody Herceptin (trastuzumab), but recently, chemotherapy combined with dual HER2-directed therapies, Herceptin and Perjeta (pertuzumab) has demonstrated increased survival benefit.

Advances in the Therapeutic Landscape

There have been several advancements in the therapeutic landscape of HER2-positive mBC, many of which have created additional treatment options in later lines of therapy. Nerlynx (neratulinib) in combination with Xeloda (capecitabine) was approved by the FDA in February 2020 for adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. Soon after, in April 2020, the FDA approved Tukysa (tucatinib) in combination with Herceptin and Xeloda for the treatment of adults with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. Later that same year in December, the FDA approved Margenza (margetuximab-cmkb) in combination with chemotherapy for adults with HER2-positive mBC who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

Additional combinations are being explored in ongoing clinical trials in patients with HER2-positive mBC. The phase 3 DESTINY-Breast09 trial aims to evaluate Enhertu (trastuzumab deruxtecan) with or without Perjeta versus the standard-of-care regimen (taxane, Herceptin and Perjeta) in the first-line metastatic setting. The primary end point of the study is progression-free survival (PFS; assessed by blinded independent central review); some of the secondary end points include investigator-assessed PFS, overall survival, objective response rate, duration of response, time to second progression or death and health-related quality of life. Previously, Enhertu was granted accelerated approval by the FDA in December 2019 for patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

Although the therapeutic landscape for HER2-positive mBC has experienced recent innovations, numerous challenges have the potential to affect the overall delivery of care.

Challenges With Current Treatment Approaches

Most patients with HER2-positive mBC will be treated with chemotherapy in combination with HER2-directed therapy, but clinicians must still make treatment decisions that consider patient-specific factors, as well as systemic obstacles that may affect the delivery of appropriate care.

Treatment Toxicity

Krop and Patt agreed that therapeutic approaches in HER2-positive mBC can be associated with treatment toxicity, which can have lasting effects on the patient’s quality of life. Numerous patient-driven factors can influence how therapy is tolerated, including patient age, performance status, comorbidities and location of metastases, according to Patt. She added that when patients are overburdened with toxicity from treatment, they may be less able to maintain productivity in the workforce, compounding the financial burden of treatment.

Financial Burden and Access Barriers

The financial burden of treatment can be an obstacle to care. “These drugs are all incredibly expensive, and it’s a big challenge for the healthcare industry and for our society,” Krop noted. “It’s a societal problem that we’re going to have to deal with.” Patients with HER2-positive mBC are typically treated using combination regimens, which can compound the overall cost of therapy. Many of the available HER2-targeting agents are costly, with those entering the treatment landscape more recently being particularly expensive. However, treatment may still be cost prohibitive even when biosimilars enter the market, Patt added. Additionally, she indicated that the overall cost of treatment is also likely to increase as HER2-directed agents have the potential to receive FDA approval for use in earlier lines of treatment.

Both Krop and Patt emphasized that it is critical for clinicians to recognize that there may be challenges associated
with insurance coverage when it comes to treating HER2-positive mBC. Among patients with commercially available insurance, prior authorization can pose a significant challenge, delaying appropriate therapy and imaging. Patients with Medicare may encounter unique obstacles to care related to formulary choice, reimbursement and single-dose vials. Patt further explained that patients who are uninsured are likely to encounter significant barriers to appropriate treatment; there may be charitable care pathways available, but these are highly variable by region and other factors.

Administration and Dose Schedules
According to Krop and Patt, the use of chemotherapy in combination with HER2-directed agents can increase the overall treatment burden for patients with HER2-positive mBC. When on combination therapy, patients may have medications with multiple routes of administration and dosing cycles. This can be challenging for patients to keep track of, so they sometimes require additional coaching about when to take their medication at home and when to come into the clinic for infusion, Krop explained. To accommodate the difficulty of managing complex treatment regimens, Patt noted, “When you use those other agents at different cycles, sometimes people do consider alternative schedules of these therapeutic interventions to try to keep treatment more convenient for the patient.”

Health System Utilization
Patients with HER2-positive mBC may also encounter obstacles associated with their overall healthcare system utilization, particularly because disease management typically involves monitoring and treating potential side effects of therapy. Patt described how patients require follow-up echocardiograms to evaluate their cardiac function, for example. Managing this side effect of treatment involves numerous added touch points with the healthcare system. Even without side effects complicating treatment, additional steps such as surgical or radiological intervention may complicate already challenging cost and access issues, Patt added. She explained that the scope of healthcare utilization required by patients with HER2-positive mBC can exacerbate problems associated with overburdened and understaffed healthcare systems. This can result in critical delays to receiving lab results, scheduling imaging and performing biopsies, she noted.

COVID-19 Contingencies
Patt described how, in the era of COVID-19, there have been pervasive decreases in cancer screening, biopsies, diagnoses and subsequent therapeutic intervention. In addition to these reductions in cancer care diagnoses, she said, there have been challenges with managing patients with metastatic disease: “We have been burdened by a global pandemic, (so) all the work-up (that) patients need in the metastatic setting is a little delayed. It’s taking longer. There are capacity limitations in the ability to do biopsies or additional imaging.”

Physicians have needed to adjust their treatment strategy to accommodate existing patients. According to Krop, some healthcare providers have reconsidered the use of immunosuppressive regimens or started using longer-acting therapies to minimize the number of clinic visits necessary. Visiting nurse services and phone- or internet-based forms of communication have also been used, but Krop indicated that the degree to which these will remain cost-effective or feasible at scale post-pandemic is unclear.

National Comprehensive Cancer Network (NCCN) Guidelines
Krop commented on the value of current treatment guidelines for HER2-positive mBC by stating, “If you look at the NCCN Guidelines, they’re not very directive.” He explained that this can make it challenging to navigate patient-specific factors when deciding whether to use upfront chemotherapy versus an alternative therapy. Current guidelines do not specify which patients may derive benefit; they provide helpful guardrails, but there are many reasons why a patient’s treatment plan may deviate from the guideline-directed approach.

Value-based Care Models in mBC
Taking a value-based approach to the care of HER2-positive mBC requires an analysis of the potential benefits and costs of treatment to provide appropriate care for patients. For the future management of patients with HER2-positive mBC, both Krop and Patt agreed that the healthcare system should provide patients with treatment that is both medically effective and cost effective to maximize disease control without causing undue burden on patients and the healthcare system.

Patt addressed value-based care in HER2-positive mBC: “The most important value-based initiative is that patients go on to live disease free. You can’t discount that because I think superior efforts and the best possible evidence for disease control [are] the most appropriate value-based choices,” she said. “Patients with HER-2 positive metastatic breast cancer can benefit from these long disease-free intervals (for) more than a decade. And so I think a question remains: ‘How can we give the most effective therapy upfront, and then keep them on some chronic therapy in perpetuity to keep their disease controlled, and (do this in) the most cost-efficient way?’ And with so many innovator products in this space, I think we’re going to have better answers there in the next years to come.”

References are available at ManagedHealthcareExecutive.com
When Terri Kirkpatrick, a community health worker, meets a new client, the first question she asks is, “how are you feeling today?” The question isn’t just an ice-breaker. It’s laying the foundation for the relationship Kirkpatrick hopes to build with her clients. She knows how vulnerable and anxious women coming into Strong Beginnings feel. She was once a client of the program for pregnant Black mothers with behavioral health needs. “I can truly say that I was born to be community health worker,” Kirkpatrick says, adding that she has an experiential understanding of the disparities the program’s clients live with.

Kirkpatrick has been a Strong Beginnings community health worker for 23 years. The program, a partnership between Spectrum Health, a Michigan-based managed care organization, and nine community organizations, facilitates home visits by nurses, nutritionists and community health workers.

Like most community health workers, Kirkpatrick has a job that takes her outside the traditional boundaries of healthcare. She helps the women in the program with whatever needs they might have, including food and housing, job and career support. “Whatever their priority is, that’s what I focus on,” she says. “I’m here for them.”

**Boom times**
The community health worker model has been around, in one form or another, for 100 years, says Scott Tornek, chief strategy officer for the Penn Center for Community Health Workers at the Penn Medicine. “It’s not a new concept,” says Tornek. “It has gone through boom-and-bust cycles for decades.”

Now it is booming. It started after passage of the ACA in 2010 and the subsequent move toward risk-based contracts that create incentives to reduce the cost of care and prevent illness. According to the CDC, more than 23 states have or are considering community health worker programs.

Yet community health workers have not been fully embraced by the U.S. healthcare system. Even if they result in overall savings, the programs can be expensive to operate. Pilot projects may get off to a good start but then shut down when the funding runs out.

But many experts, physicians and healthcare executives see the community health workers as a way to deal with much-talked-about social determinants of health. The question, then, concerns how hospitals, health systems, payers and government health officials can make community health workers part of the everyday reality of American healthcare. “It’s a complicated question,” Tornek says. “But I think it starts with sustainable funding, especially for Medicaid and for people who are underserved — marginalized people who are in those insurance groups.”

**Penn’s program**
About a decade ago, Shreya Kangovi, M.D., M.S., a pediatrician caring for patients in West Philadelphia, asked herself that same question. In the ensuing years, Kangovi, along with a team of researchers from the Perelman School of Medicine at the University of Pennsylvania, created the Individualized Management for Patient-Centered Targets, or IMPaCT, program. Some key aspects of IMPaCT were developed based on interviews with more than 1,500 patients. Each was asked what was stopping them from staying healthy. The answers: food, housing, transportation and other needs.

Continued on page 26
Diana Do, MD, of Stanford University School of Medicine, and Steven Peskin, MD, MBA, FACP, of Horizon Blue Cross Blue Shield of New Jersey, discuss clinical and managed care considerations for wet age-related macular degeneration (wet AMD), including varying approaches to disease management.

Speakers

Diana Do, MD
Stanford University School of Medicine
Palo Alto, California

Steven Peskin, MD, MBA, FACP
Horizon Blue Cross Blue Shield of New Jersey
Belle Mead, New Jersey

Stream Now!
“The community health worker quarterbacks the nonclinical and nonmedical relationship with the patient.”

— SCOTT TORNEK, CHIEF STRATEGY OFFICER FOR THE PENN CENTER

Continued from page 24

Three controlled, randomized studies showed positive results. But a study showing that community health workers could save money had not been done. That changed in February 2020, when Kangovi, now the executive director of the Penn Center, reported results in Health Affairs. The study followed 302 patients considered at high risk for health problems between July 2013 and October 2014.

The patients were randomly divided: 150 in an intervention group that received services from the community health workers and 152 in a control group. All patients came from “high-poverty neighborhoods” and each had at least two chronic diseases. At the study’s one-year follow-up, 98 patients in the control group had been hospitalized, compared with 68 patients in the intervention group. The total inpatient and outpatient bill for intervention patients was about $2.5 million compared with $3.9 million for the control group. Kangovi and her co-investigators reported that the team of community health workers saved Medicaid $1.4 million. They calculated that the savings divided by program expenses ($567,950.82) yielded a return on investment within a single fiscal year of $2.47 for every dollar invested.

Over the past seven years, IMPaCT and Penn Center’s 30 community health workers have seen 13,000 patients. Depending on the goals they are trying to achieve, most patients work with program’s community health workers for three to six months. Some return, but most don’t.

Penn has exported its IMPaCT program to 20 states and 50 healthcare organizations, large health systems, payers, nonprofit organizations and departments of health. The adopters include ChristianaCare in Delaware, BJC HealthCare in St. Louis and Blue Cross Blue Shield of North Carolina.

But even successful programs like Penn Center and Strong Beginnings are constantly concerned about funding. Strong Beginnings runs on an annual budget of $2 million and includes funding from federal and state sources plus a $500,000 contribution from Spectrum Health. Penn Center does not publish its annual budget, but Tornek says the organization’s external work is self-funded and that Penn Medicine pays for the patients it refers. “We are doing a lot with pretty limited resources, quite frankly,” Tornek says.

Community health worker programs need to be on a firm financial footing to help vulnerable patients and reduce admissions, Tornek says. He would like to see Congress and the federal government’s various health agencies increase funding and help build a sustainable, long-term infrastructure to support community health programs.

“It’s a compressed question,” Tornek says. “There is institutional racism and health equity issues. How do we level the playing field? It’s a complicated question, but I think it starts with sustainable funding.”

Robert Calandra is an independent journalist in the Philadelphia area who writes about healthcare and other issues. Aine Cryts contributed reporting.

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Retailers such as CVS Health and Walgreens Boots Alliance may force traditional providers to rethink the way they deliver healthcare. The drugstores ramped up care during the heart of the COVID-19 pandemic, often providing more convenient and less costly alternatives.

“Traditional providers have to think like retail providers going forward: convenient, transparent and cost-effective,” says Arielle Trzczinski, a principal healthcare analyst at Forrester, a research and advisory company. The retail clinics tend to be less expensive for consumers than traditional providers and urgent care centers, Trzczinski notes, and the walk-in access is an advantage over having to schedule an appointment.

By offering COVID-19 testing and vaccinations and providing medical care at their in-store clinics, retailers built up “a lot of goodwill that they will carry forward beyond the pandemic,” Trzczinski adds. “It’s an opportunity for them to continue to build on the trust consumers have started to have in them.”

A survey of 2,200 adults conducted in the spring of 2021 by the Morning Consult, a survey company, found that 35% of the respondents had received care at a retail clinic since the pandemic began in early 2020 and that 8% had received care at the clinics often.

A different survey of 500 consumers and 250 retail healthcare executives released by the technology company UPshow found consumers were inclined to go to retail health clinics during the pandemic because they wanted to avoid doctors’ offices that might be crowded. The clinics in the chain drugstores also allowed them to combine medical care and shopping so they could limit trips away from home. Not all of the findings from the UPshow survey are positive for retail health clinics. Almost half (47%) of those surveyed indicated that they were not “completely confident” in the quality of care provided at retail health clinics.

Although CVS and Walgreens have made sizable bets on retail healthcare being part of their futures, their approaches vary. CVS is focusing on developing in-store HealthHUBs where its customers can get a variety of healthcare services, including primary care for chronic conditions and behavioral healthcare. Rather than developing its own healthcare services, Walgreens has focused on relationships with other providers, including a partnership created last year with VillageMD to develop doctors’ offices in its stores. But Dan Clarin, managing director at Kaufman Hall, says neither Walgreens nor CVS “offers every service to every customer on their own — they’re a convener of services.” He compares the companies to Amazon as a platform to connect consumers with the products they want.

The drugstore chains don’t have the retail healthcare business entirely to themselves. Walmart has set up clinics in some of its stores, offering a variety of services, including dental, optometry, primary care and X-rays. Walmart has acquired MeMD, a telehealth provider. With that acquisition, Walmart has filed paperwork to do business in 37 states, according to the Insider. The retailers are hopeful that their retail clinics will attract younger people, Clarin notes. The Morning Consult survey found that half of 18- to 34-year-olds had gone to a retail clinic during the pandemic, compared with just 1 in 5 of those aged 65 years and older. Younger consumers are less likely to have a primary care physician. They also have “less brand loyalty,” Clarin says, and focus on “experience and convenience.”

Minute to hub
CVS has offered healthcare at its MinuteClinics for 25 years and has expanded to hundreds of locations.
inside its drugstores and in Target’s brick-and-mortar stores. But its more recent focus is on its HealthHUBs, which are billed as providing a wider array of services and services consumers will use over time, not just on an emergent basis. Part of the investment in HealthHUBs is a consequence of the company’s acquisition of Aetna in 2018 for $69 billion. CVS calls itself “the leading health solutions company.”

“Over the last few years, we have pushed the boundaries to change people’s perception of their neighborhood drugstore, as well as to add value, offer more innovative services and provide convenient, affordable and accessible care,” Ryan Rumbarger, senior vice president of retail store operations for CVS Pharmacy, said in an email to Managed Healthcare Executive. At the end of the first quarter of 2021, the retailer had about 800 HealthHUBs, Karen Lynch, president and CEO of CVS Health, said in a call with investors. According to previously announced plans, the company’s goal was to have 1,500 of the hubs up and running by the end of 2021, but Lynch said the company would have about 1,000 in operation by that time.

CVS is offering COVID-19 vaccinations at 9,600 sites and providing testing for the virus at thousands of locations, many of which serve vulnerable communities, Rumbarger said.

CVS’ most recent move is adding licensed therapists at certain HealthHUB locations as demand for behavioral health services has soared in light of the pandemic.

**Walgreens partners up**
Walgreens is focusing on partnering with providers. In late 2020, it announced it was closing 150 clinics that it operated on its own.

It still partners with local health systems to operate clinics. But the company’s major play in retail healthcare is its partnership with VillageMD, a primary care company headquartered in Chicago. The plan is to develop at least 600 VillageMD clinics, which operate under the name Village Medical, in more than 30 markets over the next four years, with hundreds more to follow.

Rick Gates, Walgreens’ senior vice president of pharmacy, said in an email to MHE. Currently there are more than 50 Village Medical clinics in Walgreens stores, most of them in the Sunbelt.

During the pandemic, the drugstore giant has conducted more than 8 million COVID-19 tests and provided more than 25 million vaccinations, Gates said. With millions losing their jobs, the company has lowered prices on hundreds of medications, he said.

Physicians and others have raised concerns about retail healthcare further fragmenting American healthcare. But Gates said data from the current Village Medical clinics indicate improvements in medication adherence and fewer emergency room visits, unnecessary hospitalizations and readmissions for patients with chronic conditions.

**Walmart adds telehealth**
Walmart is calling its in-store clinics Walmart Health. The retail giant opened its first clinic in Dallas, Georgia, about 30 miles outside Atlanta, in 2019. Now it has clinics in stores elsewhere in Georgia, Texas and Arkansas. A price list on the company website for Dallas, Georgia, showed that a Walmart Health office visit costs $40; a dental exam with X-rays, $25; and a new patient therapy session, $60. The retailer’s wide range of services and low prices make it “convenient and cost-effective,” says Trzcinski, the Forrester analyst. Walmart has also priced many generic medicines at $4, which may help with getting people to take their medication as prescribed. “Cost is a huge barrier for folks being able to adhere to their medications,” Trzcinski says.

In late June 2021, Walmart acquired telehealth provider MeMD. “Today people expect omnichannel access to care, and adding telehealth to our Walmart Health care strategies allows us to provide in-person and digital care across our multiple assets and solutions,” says Cheryl Pegus, executive vice president of Walmart Health & Wellness, said in a news release announcing the planned acquisition.

Although Walmart doesn’t have as large a footprint as CVS and Walgreens do, it has a strong presence in rural areas, where access to healthcare may be hard to come by, notes Clarin.

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**“Traditional providers have to think like retail providers going forward: convenient, transparent and cost-effective.”**

— ARIELLE TRZCINSKI, A PRINCIPAL HEALTHCARE ANALYST AT FORRESTER

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

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The mainstreaming of targeted lung cancer treatment

Treatments aimed at certain mutations have proliferated and moved upstream to earlier-stage lung cancers. But there are many questions about insurance coverage and which tests to use to identify the biomarkers that help guide treatment. by KEITH LORIA

In lung cancer especially, the ability to identify genomic alterations in patients’ tissue or blood samples has opened the door for more widespread adoption of targeted and immunotherapies, says Luca Quagliata, Ph.D., BCMAS, vice president and global head of medical affairs at Thermo Fisher Scientific, a healthcare tech and testing company headquartered in suburban Boston. Therapies tailored to lung cancers with certain genomic signatures have replaced chemotherapy as a first-line treatment for patients with lung cancer, he says, and advances in biomarker testing have decreased the turnaround time for results.

“We are no longer trying to convince people that genomic testing is valuable in lung cancer,” Quagliata says. “There is enough evidence to show its clinical utility.”

Quagliata also says testing has shifted from being done almost exclusively for patients with late-stage cancer to those with cancers diagnosed at an early stage as more targeted treatments prove to be effective in patients who are treated with surgery. This move “upstream” means fewer patients need to be treated with chemotherapy and radiation. Quagliata is also upbeat about the future of liquid biopsies, which detect early signs of cancer in blood samples rather than on samples of tissue from site of the tumor.

“The value of liquid biopsy is that it is much less invasive to patients and has a simpler laboratory workflow when compared to acquiring and testing tissue samples,” Quagliata says. “Thermo Fisher has a liquid biopsy product.

Raymond U. Osarogiagbon, M.D., FACP, the director of the multidisciplinary thoracic oncology program at the Baptist Cancer Center in Memphis, Tennessee, notes that as recently as 2012, almost half of advanced nonsquamous non-small cell lung cancers (NSCLCs) had no known biomarker that could be targeted for treatment. Now only about 1 in 10 of such cancers lacks biomarkers, he says, and the list of biomarkers — typically, a mutated gene — for which there are FDA-approved has grown from just two treatments to 10.

Targeted therapy for certain subsets of biomarker-specified lung cancer significantly improve survival. But Osarogiagbon says use of targeted therapy in patients lacking the specific target can cause harm. If the cancer doesn’t have the target, a targeted therapy is tantamount to no treatment. The longer that continues, the greater the harm. Therefore, biomarker testing is a key, fundamental part of successful targeted therapy. Several of the biomarker-delineated subsets of lung cancer are infrequent, occurring in fewer than 5% of all patients, notes Osarogiagbon. “There is no clinical means of identifying patients with the relevant biomarker-delineated subsets. Therefore, there is the need for comprehensive genomic testing, so no patient gets left behind.” Additionally, there’s evidence that immune checkpoint inhibitor therapy, with drugs such as Keytruda (pembrolizumab) and Yervoy (ipilimumab), is ineffective in patients whose cancer is driven by certain genomic abnormalities, such as EGFR and ALK gene mutations. “Prior therapy with immune checkpoint inhibitors seems to significantly increase the danger of pneumonitis (inflammation of the lungs) — which can be debilitating, even life-threatening — when the correct targeted oral therapy agent is subsequently used,” Osarogiagbon says.

When it approves a targeted therapy, the FDA also often approves a companion test that can identify the biomarker for that targeted therapy. There are also tests developed by research-
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ers and laboratories that haven’t been approved by the agency. “For companion diagnostic tests, the FDA has set the bar very high for accuracy and validation,” Quagliata says. “For assays that are not FDA approved, including LDTs (laboratory developed tests), Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists (there are) standards for high-complexity laboratories to safeguard the quality of tests.”

When it comes to the expense of testing, Quagliata says it is essential to pull back and the see the situation from a broader perspective. “Rather than put patients on inefficient therapies as a first-line treatment, genetic testing allows clinicians to make more informed decisions, becoming more efficient in their prescribing, thus helping save on downstream treatment costs,” Quagliata says.

Osarogiagbon says American healthcare is moving rapidly from tests for a single biomarker to comprehensive genomic testing because the broader approach is faster, safer and more cost-effective for patients. “Unfortunately, even though the cost of so-called next generation sequencing (NGS) is dropping as more testing options and vendors enter the market, there remains the perception that these tests are expensive and might not be paid for by third-party payers,” he says. Another major concern is the turnaround time. Getting an NGS result can take several weeks.

Insurance coverage of biomarker testing is a wild card into biomarker testing. “Reimbursement has become a complex matter as even within the non-small cell lung cancer space, differences exist in several areas that impact payer coverage, including sample type, test size, test content, use case, and the stage of disease,” Quagliata says. In general, among patients with late-stage NSCLC, Medicare provides coverage, Medicaid does not, and commercial plans vary, according to Quagliata.

But as more studies are done, Quagliata believes the evidence for NGS being more efficient and cost-effective will get stronger. Matching patients with targeted therapies at an earlier stage will reduce unnecessary spending for payers and patients.

Andrew Hertler, M.D., chief medical officer at New Century Health, a subsidiary of Evolent Health, says the cost of the biomarker testing ranges from $2,000 to $4,000, though there can be additional costs if there’s a need to re-biopsy the tumor. Hertler sees a challenge in making sure the tests are accurate. “There have been some very disturbing studies done where people have sent the same specimen out to multiple different laboratories and not had consistent results — I think somewhere on the order of 50% of the time — so we clearly still badly need to come up with standardized validated reliable procedures,” he says. But Hertler notes that variability may also be in the cancer itself. “We know cancers are genetically unstable.”

Avoiding ineffective treatments
The challenge in getting biomarker testing and targeted therapy is not so much with the patients as with their doctors and the healthcare systems in which they practice, as well as third-party coverage policies for these rapidly emerging options. Osarogiagbon is an adviser on the No One Missed campaign by LUNGevity Foundation, which brings essential education to the public around comprehensive biomarker testing in lung cancer. “Patients quickly understand the benefit of this approach, given the striking improvements in results and greater convenience,” he says. “The main barriers are not patient-level; they are provider-, institutional- and social policy-level.”

Most clinicians are recommend- ing comprehensive biomarker testing, which includes NGS and PDL1 Tumor Proportion Score testing.

“Single-gene tests waste time and expose patients to the danger of inordinate delay in identifying potentially lifesaving biomarkers that guide treatment,” Osarogiagbon says. “Ideally, these tests should be done reflexively when the patient diagnosed and the testing is automatically ordered, thereby saving precious time.”

Hertler says that when talking with patients, providers should explain biomarker testing methods clearly and note that they don’t work for everybody, and even when they do work, the enthusiasm can have people carried away about the prospects. “People are doing better and have less side effects from their therapy and can live a more normal life, but we don’t have a cure.”

Keith Loria is a freelance medical writer in the Washington, D.C., area.