2019’s TOP CHALLENGES
How execs can overcome them

Plus
DRUG PIPELINE PREDICTIONS

TELEHEALTH PROGRAM REDUCES READMISSIONS
In 8179 statin-treated adults with well-controlled LDL-C (41-100 mg/dL) and CV risk factors including elevated TG (135-499 mg/dL) and either established CVD or diabetes and other CV risk factors,\(^1,^2\)

**VASCEPA** (icosapent ethyl) 4 g/d DEMONSTRATED UNPRECEDENTED REDUCTIONS IN CV EVENTS\(^1\)

<table>
<thead>
<tr>
<th>Primary endpoint: 5-POINT MACE(*)</th>
<th>Secondary endpoint: COMPOSITE CV DEATH, MI, STROKE</th>
<th>Hard MACE CV DEATH</th>
<th>STROKE</th>
</tr>
</thead>
<tbody>
<tr>
<td>25% (NNT=21) HR=0.75 (95% CI, 0.68-0.83) (P=0.00000001)</td>
<td>26% (NNT=28) HR=0.74 (95% CI, 0.65-0.83) (P=0.00000006)</td>
<td>20% (RRR) HR=0.80 (95% CI, 0.66-0.98) (P=0.03)</td>
<td>31% (RRR) HR=0.69 (95% CI, 0.58-0.81) (P=0.001)</td>
</tr>
<tr>
<td>28% (RRR) HR=0.72 (95% CI, 0.55-0.93) (P=0.01)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Overall adverse event rates were similar across treatment groups

- Numerically more serious adverse events related to bleeding; overall rates were low (2.7% for VASCEPA vs 2.1% for placebo, \(P=0.06\)), with no fatal bleeding observed in either group and no significant increase in adjudicated hemorrhagic stroke or serious central nervous system or gastrointestinal bleeding
- Significantly higher rate of hospitalization for atrial fibrillation or flutter, though rates were low (3.1% for VASCEPA vs 2.1% for placebo, \(P=0.004\))

**FDA-APPROVED INDICATION AND LIMITATIONS OF USE FOR VASCEPA\(^3\)**

- VASCEPA\(^\circledR\) (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia
- In patients with severe hypertriglyceridemia, the effect of VASCEPA on cardiovascular mortality or morbidity or on the risk of pancreatitis has not been determined

FDA has not reviewed and opined on a supplemental new drug application related to REDUCE-IT. FDA has thus not reviewed the information herein or determined whether to approve VASCEPA for use to reduce the risk of major adverse cardiovascular events in the REDUCE-IT patient population.


Please see Important Safety Information for VASCEPA on the following pages.
Please see Important Safety Information related to REDUCE-IT\(^\text{TM}\) for VASCEPA on the following pages.
Please see accompanying Brief Summary of full Prescribing Information or go to www.vascepahcp.com.

VASCEPA\(^\circledR\) is a registered trademark of the Amarin group of companies. 
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FDA-APPROVED INDICATION AND LIMITATIONS OF USE FOR VASCEPA®

- VASCEPA® (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adults in patients with severe (>500 mg/dL) hypertriglyceridemia.
- In patients with severe hypertriglyceridemia, the effect of VASCEPA on cardiovascular mortality or morbidity or on the risk of pancreatitis has not been determined.

IMPORTANT SAFETY INFORMATION FOR VASCEPA FROM FDA-APPROVED LABEL

Data from Two 12-Week Studies (MARINE and ANCHOR) of Patients with Triglycerides Values of 200 to 2000 mg/dL (n=622 on VASCEPA, n=309 on placebo)

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- The most common reported adverse reaction (incidence >2% and greater than placebo was arthralgia (2.3% VASCEPA, 1.0% placebo).
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving treatment with VASCEPA and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- Patients should be advised to swallow VASCEPA capsules whole; not to break open, crush, dissolve, or chew VASCEPA.

NEW INFORMATION: REDUCE-IT™ CARDIOVASCULAR OUTCOMES STUDY OF VASCEPA®

The effects of VASCEPA on the prevention of cardiovascular events was evaluated in a multi-center, double-blind, randomized, placebo-controlled, event-driven trial (REDUCE-IT, NCT01492361) in 8,779 adult patients at low or low-density lipoprotein cholesterol (LDL-C) goal, with established cardiovascular disease (CVD) or at high risk for CVD, and hypertriglyceridemia (fasting triglycerides (TG) >135 and <500 mg/dL).

- Patients were eligible to enter the trial if they were at least 45 years of age and on stable statin therapy with fasting LDL-C levels of >40 and ≤100 mg/dL and fasting TG levels of >135 and <500 mg/dL. Patients also needed to have either established CVD (secondary prevention cohort), defined as documented history of coronary artery disease, cerebrovascular or carotid artery disease, or peripheral artery disease, or be at least 50 years of age with diabetes and at least one additional risk factor (primary prevention cohort).
- Key exclusion criteria included severe heart failure, active severe liver disease, hemoglobin A1c >10.0%, planned coronary intervention or surgery, history of acute or chronic pancreatitis, and known hypersensitivity to fish, shellfish, or ingredients of VASCEPA or placebo.
- 70.7% of patients were enrolled based on having established CVD (secondary prevention cohort), 29.3% were enrolled based on being at high risk for CVD (primary prevention cohort).
- Patients were randomly assigned 1:1 to receive either VASCEPA (4 grams daily) or placebo (4089 VASCEPA, 4090 placebo).
- The median follow-up duration was 58 months (4.9 years).
- Overall, 99.8% of patients were followed until the end of the trial or death.
- The median age at baseline was 64 years (range: 44 years to 92 years), with 46% being at least 65 years old; 28.8% were women.
- The trial population was 90.2% White, 1.9% Black, and 5.5% Asian; 4.2% identified as Hispanic ethnicity.
- Regarding prior diagnoses of cardiovascular disease, 44.7% had prior myocardial infarction, 6.1% prior unknown stroke or transient ischemic attack (TIA), and 9.2% had symptomatic peripheral arterial disease.
- Selected additional baseline risk factors included hypertension (86.6%), diabetes mellitus (0.2% type 1; 57.8% type 2), current daily cigarette smoking (15.2%), New York Heart Association class I or II congestive heart failure (17.7%), and eGFR < 60 mL/min per 1.73 m² (22.2%).

- Patients enrolled were treated with statin therapy at baseline with most (93.2%) on a high- (30.8%) or moderate-intensity (62.5%) statin therapy, and 6.4% were also taking ezetimibe at baseline.
- Most patients at baseline were taking at least one other cardiovascular medication including anti-platelet agents (79.4%), beta blockers (70.7%), angiotensin converting enzyme (ACE) inhibitors (51.9%), or angiotensin receptor blockers (27.0%).
- On stable background lipid-lowering therapy, the median (Q1, Q3) LDL-C at baseline was 75.0 (62.0, 89.0) mg/dL; the mean (SD) was 76.2 (20.3) mg/dL.
- On stable background lipid-lowering therapy, the median (Q1, Q3) fasting TG was 216.0 (176.0,272.5) mg/dL; the mean (SD) was 232.2 (80.1) mg/dL.

The primary results from REDUCE-IT are shown in the Table below (see CONDUCT OF REDUCE-IT AND ANALYSIS AND REVIEW OF REDUCE-IT DATA).

Effect of VASCEPA on Cardiovascular Events in Patients with Established CVD or at High Risk for CVD with Statin-treated Triglycerides ≥135 and <500 mg/dL in REDUCE-IT

<table>
<thead>
<tr>
<th>Time to first occurrence of cardiovascular death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (0-point MACE)</th>
<th>Placebo</th>
<th>VASCEPA vs Placebo Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Placebo</td>
<td>N = 4090 n (%)</td>
<td>VASCEPA</td>
</tr>
<tr>
<td>Time to first occurrence of cardiovascular death, myocardial infarction, stroke (3-point MACE)</td>
<td>901 (22.0)</td>
<td>705 (17.2)</td>
</tr>
<tr>
<td>Time to first occurrence of cardiovascular death, myocardial infarction, stroke (5-point MACE)</td>
<td>606 (14.8)</td>
<td>459 (11.2)</td>
</tr>
<tr>
<td>Time to cardiovascular death</td>
<td>213 (5.2)</td>
<td>174 (4.3)</td>
</tr>
<tr>
<td>Time to death by any cause (1)</td>
<td>310 (7.6)</td>
<td>274 (6.7)</td>
</tr>
<tr>
<td>Time to first fatal or non-fatal myocardial infarction</td>
<td>355 (8.7)</td>
<td>250 (6.1)</td>
</tr>
<tr>
<td>Time to first fatal or non-fatal stroke</td>
<td>134 (3.3)</td>
<td>98 (2.4)</td>
</tr>
<tr>
<td>Time to first emergent or urgent coronary revascularization</td>
<td>321 (7.8)</td>
<td>216 (5.3)</td>
</tr>
<tr>
<td>Time to first coronary revascularization (2)</td>
<td>544 (13.3)</td>
<td>376 (9.2)</td>
</tr>
<tr>
<td>Time to first hospitalization for unstable angina (3)</td>
<td>157 (3.8)</td>
<td>108 (2.6)</td>
</tr>
</tbody>
</table>

All presented individual and composite endpoints were statistically significant except time to death by any cause.

(1) Time to death by any cause, or total mortality, is not a component of either the primary composite endpoint or key secondary endpoint.

(2) The predefined composite secondary endpoint included emergent or urgent revascularization, the composite of all revascularization was predefined as a tertiary endpoint.

(3) Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.

VASCEPA significantly reduced the following:
- the risk for the primary composite endpoint (5-point MACE: time to first occurrence of cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization; p<0.001), and
- the key secondary composite endpoint (3-point MACE: time to first occurrence of cardiovascular death, myocardial infarction, or stroke; p<0.001).

Prespecified hierarchical testing of other secondary endpoints revealed significant reductions in the following:
- cardiovascular death (p=0.03),
- fatal or nonfatal myocardial infarction (p=0.001),
- fatal or nonfatal stroke (p=0.01),
- emergent or urgent coronary revascularization (p<0.001), and
- hospitalization for unstable angina (p=0.002).

The benefits of VASCEPA were seen on a background of predominately (93.2%) moderate- to high-intensity statin use and median baseline LDL-C levels of 75.0 mg/dL. The
The Kaplan-Meier estimates of the cumulative incidence of the primary and key secondary composite endpoints over time are shown in Figure 1 and Figure 2 below. Key secondary composite endpoints over time are shown in Figure 1 and the Kaplan-Meier estimates of the cumulative incidence of the primary and secondary endpoints were similar across treatment groups.

![Figure 1. Estimated Cumulative Incidence of Primary Composite Endpoint Over 5 Years in REDUCE-IT](image1)

![Figure 2. Estimated Incidence of Key Secondary Composite Endpoint Over 5 Years in REDUCE-IT](image2)

### Table: Treatment-Emergent Adverse Events

<table>
<thead>
<tr>
<th>Event Category</th>
<th>VASCEPA N = 4089</th>
<th>Placebo N = 4090</th>
<th>P value[1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with at Least One TEAE[2]</td>
<td>3343 (81.8)</td>
<td>3326 (81.3)</td>
<td>0.63</td>
</tr>
<tr>
<td>Serious TEAE</td>
<td>1252 (30.6)</td>
<td>1254 (30.7)</td>
<td>0.98</td>
</tr>
<tr>
<td>TEAE Leading to Withdrawal of Study Drug[3]</td>
<td>321 (7.9)</td>
<td>335 (8.2)</td>
<td>0.60</td>
</tr>
<tr>
<td>Serious TEAE Leading to Withdrawal of Study Drug[3]</td>
<td>88 (2.2)</td>
<td>88 (2.2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Serious TEAE Leading to Death[4]</td>
<td>94 (2.3)</td>
<td>102 (2.5)</td>
<td>0.61</td>
</tr>
</tbody>
</table>

Note: A treatment-emergent adverse event (TEAE) is defined as an event that first occurs or worsens in severity on or after the date of dispensing study drug and within 30 days after the completion or withdrawal from study. Percentages are based on the number of patients randomized to each treatment group in the Safety population (N). Events that were positively adjudicated as clinical endpoints are not included.

[3] Withdrawal of study drug excludes patients who were off drug in study for 30 days or more, and restarted study drug.
[4] The most common serious TEAEs leading to death by system organ class were neoplasms (1.1%); infections and infestations (0.4%); respiratory, thoracic, and mediastinal disorders (0.2%); cardiac disorders (0.2%); and vascular disorders (0.1%). No serious TEAEs leading to death by system organ class were statistically significant across treatment groups except for cardiac disorders, which occurred in 3 (0.1%) of VASCEPA patients and 15 (0.4%) of placebo patients (P=0.048).


- Peripheral edema (6.5% VASCEPA patients versus 5.0% placebo patients)
- Constipation (5.4% VASCEPA patients versus 3.6% placebo patients)
- Atrial fibrillation (5.3% VASCEPA patients versus 3.9% placebo patients)
- There was no significant difference in the prespecified adjudicated tertiary endpoint of new congestive heart failure, which occurred in 4.1% of VASCEPA patients versus 4.3% of placebo patients.
- There was no significant difference in the prespecified adjudicated tertiary endpoint of atrial fibrillation or flutter requiring hospitalization, which occurred in 3.1% of VASCEPA patients versus 2.1% of placebo patients (P=0.004).
- The rate of treatment-emergent serious adverse events for bleeding was 2.7% in the VASCEPA group versus 2.1% in the placebo group, with a nonsignificant, but trending p-value of 0.06
- There were no fatal bleeding events in either group.
- No significant increases in adjudicated hemorrhagic stroke (0.3% in VASCEPA patients versus 0.2% in placebo patients; P=0.55).
- No significant serious central nervous system bleeding (0.3% versus 0.2%; P=0.42), and
- No significant gastrointestinal bleeding (1.5% versus 1.1%; P=0.15).

### Mineral oil placebo consideration and analysis

In REDUCE-IT, a placebo containing mineral oil was used to mimic the color and consistency of the drug studied. No strong evidence for biological activity of the same mineral oil was identified in connection with FDA approval of VASCEPA in July 2012 based on the MARINE phase 3 clinical trial, in connection with FDA review of the ANCHOR phase 3 clinical trial, or after several years of quarterly review by the Data Monitoring Committee (DMC) for REDUCE-IT after FDA requested that the DMC periodically assess unblinded lipid data to monitor for signals that the placebo might not be inert. While the DMC noted variation in LDL-C measurements in both arms and that a small physiological effect of mineral oil might be possible, the DMC concluded that it was not possible to determine if the LDL-C increase in the placebo arm was a natural increase over time or due to the mineral oil, they found no apparent effect on outcomes and found that this small change was unlikely to explain the observed benefit of VASCEPA over placebo.

Each of the three VASCEPA clinical trials, MARINE, ANCHOR and REDUCE-IT, was conducted under a special protocol, or SPA, agreement with FDA in which mineral oil was agreed with FDA as an acceptable placebo.
As published within the main presentation of the REDUCE-IT results (Bhatt DL, Steg PG, Miller M, et al. N Engl J Med. 2018.), at baseline, the median LDL-C was 75.0 mg/dL. The median change in LDL-C was 3.1% (+2.0 mg/dL) for VASCEPA and 10.2% (+7.0 mg/dL) for the mineral oil placebo arm; placebo-corrected median change from baseline of -6.6% (-5.0 mg/dL; p < 0.001). If mineral oil in the placebo might have affected statin absorption in some patients, this might have contributed to differences in outcomes between the groups. However, the relatively small differences in LDL-C levels between groups would not be likely to explain the 25% risk reduction observed with VASCEPA, and a post hoc analysis suggested a similar lower risk regardless of whether there was an increase in LDL-C level among the patients in the placebo group. Although open label, Japan EPA Lipid Intervention Study (JELIS) previously demonstrated a 19% risk reduction without a mineral oil placebo.

CONDUCT OF REDUCE-IT AND ANALYSIS AND REVIEW OF REDUCE-IT DATA

FDA has not reviewed and opined on a supplemental new drug application related to REDUCE-IT. FDA has thus not reviewed the information herein or determined whether to approve VASCEPA for use to reduce the risk of major adverse cardiovascular events in the REDUCE-IT patient population.*

REDUCE-IT results were first presented at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois and concurrently published online in The New England Journal of Medicine (NEJM).²

REDUCE-IT was sponsored by Amarin Pharma, Inc. and its affiliates and conducted under a special protocol assessment agreement with FDA.

• The REDUCE-IT steering committee, consisting of academic physicians, and Amarin representatives developed the protocol (Bhatt DL, Steg PG, Miller M, et al. N Engl J Med. 2018.) and were responsible for the conduct and oversight of the study, and data interpretation.

• The primary, secondary, and tertiary adjudicated endpoint analyses were validated by the data monitoring committee and independent statistician.

Further REDUCE-IT data assessment and data release could yield additional useful information to inform greater understanding of the trial outcome:

• Further detailed data assessment by Amarin and regulatory authorities will continue and take several months to complete and record

• The final evaluation of the totality of the efficacy and safety data from REDUCE-IT may include some or all of the following, as well as other considerations:
  
  • New information affecting the degree of treatment benefit on studied endpoints
  • Study conduct and data robustness, quality, integrity and consistency
  • Additional safety data considerations and risk/benefit considerations
  • Consideration of REDUCE-IT results in the context of other clinical studies

VASCEPA may not be eligible for reimbursement under government healthcare programs (such as Medicare and Medicaid) and certain commercial plans to reduce the risk of major adverse cardiovascular events in the REDUCE-IT patient population. We encourage you to check that for yourself.

IMPORTANT INFORMATION FOR HCPs ABOUT CONTINUED UNCERTAINTY AROUND THE BENEFIT, IF ANY, OF LOWERING TG LEVELS AFTER STATIN THERAPY IN PATIENTS WITH HIGH (200–499 mg/dL) TG LEVELS

In REDUCE-IT, cardiovascular benefits appeared similar across baseline levels of triglycerides (less than 150 mg/dL, 150 to 199 mg/dL, and 200 mg/dL or greater).

• Additionally, the reduction in major adverse cardiovascular events with VASCEPA appeared to occur irrespective of an achieved triglyceride level above or below 150 mg/dL at one year, suggesting that the cardiovascular risk reduction was not tied to achieving a more normal triglyceride level.

• These observations suggest that at least some of the impact of VASCEPA on the reduction in ischemic events may be explained by metabolic effects other than triglyceride lowering.

• VASCEPA is not FDA-approved to lower TG levels in statin-treated patients with mixed dyslipidemia and persistent high (≥200 mg/dL and <500 mg/dL) TG levels due to current uncertainty regarding the benefit, if any, of drug-induced changes in lipid/lipoprotein parameters beyond statin-lowered LDL-C on cardiovascular risk among statin-treated patients with residually high TG.

• Other cardiovascular outcomes trials (ACCORD Lipid, AIM-HIGH, and HPS2-THRIVE), while not designed to test the effect of lowering TG levels in patients with high TG levels after statin therapy, each failed to demonstrate incremental cardiovascular benefit of adding a second lipid-altering drug (fenofibrate or formulations of niacin), despite raising HDL-C and reducing TG levels, among statin-treated patients with well-controlled LDL-C.

Other cardiovascular outcomes trials that studied fish oil or mixtures of omega-3 acids that include the omega-3 acid, DHA, have reported negligible impact on cardiovascular events.

No head-to-head, randomized, well-controlled studies have been conducted to compare the effects of VASCEPA with other FDA-approved TG-lowering therapies.

POTENTIAL MECHANISMS OF ACTION

Mechanisms responsible for the benefit shown in REDUCE-IT were not the focus of REDUCE-IT, but the banked samples and array of biomarkers measured leave room for mechanistic insights through future analyses. Potential mechanisms discussed in Bhatt DL, Steg PG, Miller M, et al. N Engl J Med. 2018., include TG reduction, anti-thrombotic effects, antiplatelet or anticoagulant effects, membrane-stabilizing effects, effects on stabilization and/or regression of coronary plaque and inflammation reduction. More study is needed to determine to what extent, if any, these effects or others may be responsible for the CV risk reduction benefit demonstrated with use of VASCEPA in REDUCE-IT.*

This information is intended to ensure Amarin meets its continuing obligation to update healthcare professionals regarding off-label use of VASCEPA to assure that its communications remain truthful and non-misleading, consistent with the federal court approved settlement under Amarin Pharma, Inc. et al. v. United States Food and Drug Administration et al., 119 F.Supp.3d 196, 236 (S.D.N.Y. 2015).

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6.1 Clinical Trials Experience

Double-Blind, Placebo-Controlled Trials*

Assess lipid levels before initiating therapy. Identify other causes (e.g., diabetes mellitus, hypothyroidism, and alcohol intake that may contribute to lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed, if possible, prior to consideration of TG-lowering drug therapy.

Limitations of Use:

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. The effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

2 DOSAGE AND ADMINISTRATION

Assess lipid levels before initiating therapy. Identify other causes (e.g., diabetes mellitus, hypothyroidism, or medications) of high triglyceride levels and manage as appropriate. [see Indications and Usage (1)].

Patients should engage in appropriate nutritional intake and physical activity before receiving VASCEPA, which should continue during treatment with VASCEPA.

The daily dose of VASCEPA is 4 grams per day taken as either:

- Four 0.5-gram capsules twice daily with food; or
- Two 1-gram capsules twice daily with food.

Patients should be advised to swallow VASCEPA capsules whole. Do not break open, crush, dissolve, or chew VASCEPA.

4 CONTRAINDICATIONS

VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.

5 WARNINGS AND PRECAUTIONS

5.1 Monitoring: Laboratory Tests

In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be monitored periodically during therapy with VASCEPA.

5.2 Fish Allergy

VASCEPA contains ethyl esters of the omega-3 fatty acid, eicosapentaenoic acid (EPA), obtained from the oil of fish. It is not known whether patients with allergies to fish and/or shellfish are at increased risk of an allergic reaction to VASCEPA. VASCEPA should be used with caution in patients with known hypersensitivity to fish and/or shellfish.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

Adverse reactions reported in at least 2% and at a greater rate than placebo for patients treated with VASCEPA based on pooled data across two clinical studies are listed in Table 1.

Table 1. Adverse Reactions Occurring at Incidence >2% and Greater than Placebo in Double-Blind, Placebo-Controlled Trials*

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=309)</th>
<th>VASCEPA (N=622)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthralgia</td>
<td>n %</td>
<td>n %</td>
</tr>
<tr>
<td></td>
<td>3.0 1.0</td>
<td>14.2.3</td>
</tr>
</tbody>
</table>

*Studies included patients with triglycerides values of 200 to 2000 mg/dL.

An additional adverse reaction from clinical studies was oropharyngeal pain.

7 DRUG INTERACTIONS

7.1 Anticoagulants

Some published studies with omega-3 fatty acids have demonstrated prolongation of bleeding time. The prolongation of bleeding time reported in those studies has not exceeded normal limits and did not reflect the rates observed in practice. Adverse reactions reported in at least 2% and at a greater rate than placebo for patients treated with VASCEPA and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. It is unknown whether VASCEPA can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. VASCEPA should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus.

In pregnant rats given oral gavage doses of 0.3, 1 and 2 g/kg/day icosapent ethyl from gestation through organogenesis all drug treated groups had visceral or skeletal abnormalities including: 13% reduced ribs, additional liver lobes, testes mediately displaced and/or not descended at human systemic exposure following a maximum oral dose of 4 g/day based on body surface area comparisons. Variations including incomplete or abnormal ossification of various skeletal bones were observed in the 2 g/kg/day group at 5 times human systemic exposure following an oral dose of 4 g/day based on body surface area comparison.

In a multigenerational developmental study in pregnant rats given oral gavage doses of 0.3, 1, 3 g/kg/day ethyl-EPA from gestation day 7-17, an increased incidence of absent optic nerves and unilateral testes atrophy were observed at 20.3 g/kg/day at human systemic exposure following an oral dose of 4 g/day based on body surface area comparisons across species. Additional variations consisting of early incisor eruption and increased percent cervical ribs were observed at the same exposures. Pups from high dose treated dams exhibited decreased copulation rates, delayed estrus, decreased implantations and decreased surviving fetuses (F2) suggesting multigenerational effects of ethyl-EPA at 7 times human systemic exposure following 4 g/day dose based on body surface area comparisons across species.

In pregnant rabbits given oral gavage doses of 0.1, 0.3, and 1 g/kg/day from gestation through organogenesis there were increased dead fetuses at 1 g/kg/day secondary to maternal toxicity (significantly decreased food consumption and body weight loss).

In pregnant rats given ethyl-EPA from gestation day 17 through lactation day 20 at 0.3, 1, 3 g/kg/day complete litter loss was observed in 2/23 litters at the low dose and 1/23 mid-dose dams by post-natal day 4 at human exposures based on a maximum dose of 4 g/day comparing body surface areas across species.

8.3 Nursing Mothers

Studies with omega-3-acid ethyl esters have demonstrated excretion in human milk. The effect of this excretion on the infant of a nursing mother is unknown; caution should be exercised when VASCEPA is administered to a nursing mother. An animal study in lactating rats given oral gavage 1°C-ethyl EPA demonstrated that drug levels were 6 to 14 times higher in milk than in plasma.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 2-year rat carcinogenicity study with oral gavage doses of 0.09, 0.27, and 0.91 g/kg/day icosapent ethyl, respectively, males did not exhibit drug-related neoplasms. Hemangiosomas and hemangiosarcomas of the mesenteric lymph node, the site of drug absorption, were observed in females at clinically relevant exposures based on body surface area comparisons across species relative to the maximum clinical dose of 4 g/day. Overall incidence of hemangiosomas and hemangiosarcomas in all vascular tissues did not increase with treatment.

In a 6-month carcinogenicity study in Tg.rasH2 transgenic mice with oral gavage doses of 0.5, 1, 2, and 4.6 g/kg/day icosapent ethyl, drug-related incidences of benign squamous cell papilloma in the skin and subcutis of the tail was observed in high dose male mice. The papillomas were considered to develop secondary to chronic irritation of the proximal tail associated with focal excretion of oil and therefore not clinically relevant. Drug-related neoplasms were not observed in female mice.

Icosapent ethyl was not mutagenic with or without metabolic activation in the bacterial mutagenesis ( Ames) assay or in the in vitro mouse micronucleus assay. A chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells was positive for clastogenicity with and without metabolic activation.

In an oral gavage rat fertility study, ethyl-EPA, administered at doses of 0.3, 1, and 3 g/kg/day to male rats for 9 weeks before mating and to female rats for 14 days before mating through day 7 of gestation, increased anogenital distance in female pups and increased cervical ribs were observed at 3 g/kg/day (7 times human systemic exposure with 4 g/day clinical dose based on a body surface area comparison).

17 PATIENT COUNSELING INFORMATION

17.1 Information for Patients

See VASCEPA Full Package Insert for Patient Counseling Information

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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.

Roy Beveridge, MD is a senior vice president and chief medical officer for Humana, where he’s responsible for developing and implementing Humana’s clinical strategy with an emphasis on advancing the company’s integrated care delivery model.

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

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

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

Douglas L. Chaet, FACHE is chief medical officer, Sentara Healthcare, and chairman, American Association of Integrated Healthcare Delivery Systems.

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

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

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

Daniel J. Hilferty, MPA is president and CEO, Independence Health Group, a leading health insurance organization headquartered in Southeastern Pennsylvania with nearly 8.5 million members in 24 states and Washington, D.C.

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

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

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

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

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

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

Collaborating with community leaders is part of Blue Cross’ broader strategy for addressing the crisis

Philadelphia has a long history of multigenerational heroin-addicted families. Last year, we lost more than 1,200 people to overdose deaths in our city alone.

For years, Independence Blue Cross has worked with doctors to alert them when they are prescribing outside the CDC guidelines. Last year, Independence became one of the first insurers in the country to limit all new opioid prescriptions to five days. This policy change resulted in a substantial reduction in opioid use and prescriptions: during the last six months of 2017, the number of members using opioids dropped 22% and the number of prescriptions dropped 26% compared with the same time in 2016.

In response to evidence on the important role of medication-assisted therapy in recovery, we continued coverage for buprenorphine and naltrexone without precertification and added coverage for methadone, also without precertification.

We are also working with hospitals to support warm hand-offs, which connect people who have just overdosed on opioids to resources—including immediate access to a certified recovery specialist.

A formidable partner
An important part of connecting people to treatment and resources is making the lifesaving overdose reversal drug naloxone, or Narcan, more accessible. Independence has done that in a few ways, including funding additional Narcan for Philadelphia emergency personnel and by removing cost sharing for naloxone for our members early last year.

The numbers alone—more than 70,000 overdose deaths in the U.S. in 2017—tell a convincing story about the horrors of this disease. But the numbers cannot possibly communicate the devastation the opioid crisis has had on real people like Marissa, who lost her teenage son to an overdose. Or on Michael, Mary, and Devin, who fought and overcame their opioid addictions, and now help others get the support they need.

These are a few of the real-life stories we have been telling through the Independence Blue Cross Foundation as part of the “Someone You Know” public awareness campaign, in collaboration with the Justice Center for Research at Penn State University. These vignettes put a human face on this crisis, primarily aiming to de-stigmatize opioid abuse. In conjunction with the campaign, a series of local conversations about mental health and trauma as part of substance recovery provided an outlet for even more people to tell their story in a safe and welcoming place.

A highlight of the campaign was our foundation’s national conference. This event showcased these stories, as well as a discussion with U.S. Surgeon General Jerome Adams, MD, MPH, and other local, regional, and national leaders about opioid prevention, treatment, and recovery.

We are also collaborating with local legislators and advocates on a number of key public policy changes to improve care coordination and patient treatment. This includes protecting patient rights by addressing disreputable patient brokering that steers insured individuals with substance use disorders into certain treatment facilities or sober homes in exchange for commissions or payments. Additionally, we want to ensure more timely sharing of information between substance abuse treatment providers and primary care physicians, such as a patient’s recent detox or inpatient stay. This flow of information is critically important to protect patients in recovery but is currently limited by federal law.

We have a long way to go to prevent unnecessary opioid use, abuse, and overdoses, so our work won’t end here. We will continue to find new ways to partner with others until the numbers tell a different—and better—story.

Daniel J. Hilferty, a Managed Healthcare Executive board member, is the president and CEO of Independence Blue Cross.
U.S. cities are home to 62.7% of the American population, according to the U.S. Census Bureau. This number is expected to grow to 87.4% by 2050, according to data and projections by the United Nations Department of Economic and Social Affairs.

Justin Brasell, BBA, MBA, executive vice president, Transwestern, a real estate services firm, cites a variety of reasons for the influx to urban areas. Cities often have higher-paying jobs, public transportation, and top-notch entertainment, food, higher education, and healthcare. Additionally, specialized workforces are emerging in large, urban populations as demand grows for top expertise in specific fields. For example, Houston attracts specialization related to the energy sector, while San Francisco talent is focused on technology.

“As the population ages, there is not only a desire but also a necessity to be in closer proximity to people and resources,” says Andrew Renda, MD, MPH, director, office of the chief medical officer, Humana.

Furthermore, Henry W. Osowski, managing partner, Strategic Health Group LLC, which advises health plans and system leaderships, says increasing mechanization, automation, and innovation in the agriculture sector is decreasing the number of workers required to sustain agricultural production in rural areas.

Positive effects on healthcare
Healthcare organizations in urban environments have several advantages over those based in rural areas. High volume in healthcare for certain services is correlated to greater quality, says L. Allen Dobson Jr, MD, president and CEO, Community Care of North Carolina, Inc., an organization dedicated to improving community-based primary care delivery systems. “The more times a specialist performs a specific procedure, the better the expert becomes in providing it,” he says. Having a greater volume of potential patients is especially important for services that require expensive equipment and overhead, (e.g., diagnostic imaging, operating rooms, and laboratories).

Because urban areas have a more diverse population, they also have a higher representation of younger, healthier, and more affluent residents, Dobson says. “This population has a higher percentage of private sector insurance coverage, which pays higher rates than public programs such as Medicare and Medicaid. A broader payer mix coupled with the basic economic and lifestyle advantages of an urban area is attractive to many physicians and other healthcare professionals.”

Along these lines, Osowski says, “The benefits of an urban environment will likely provide a continuing source of trained professional employees at a time when manpower shortages threaten the efficient delivery of healthcare in some communities.”

From a patient perspective, access to primary care, preventive care, and community resources tends to be better in urban areas, which increases the likelihood of completing annual wellness visits, receiving regular care, and monitoring chronic conditions. “This, in turn, likely leads to better health outcomes and a lower total cost of care,” Renda says.

“The benefits of an urban environment will likely provide a continuing source of trained professional employees at a time when manpower shortages threaten the efficient delivery of healthcare in some communities.”

— HENRY W. OSOWSKI, STRATEGIC HEALTH GROUP LLC

Movement to urban areas means more people are accounted for when healthcare systems complete community needs assessments. This enables more social determinant needs, such as food insecurity and public transportation, to be addressed for more people, says Renda.

As the population shift continues to increase demand

Managed Healthcare Executive.com
in cities, urban health systems and providers will have both the opportunity and challenge of winning patient business and loyalty by decreasing wait times, increasing price transparency, optimizing patient scheduling, and providing convenient access, Brasell says.

Noteworthy downsides

While cities are drawing more residents due to their plethora of benefits, a migration toward urban areas can lead to overcrowding as well as exposure to poor air quality and limited opportunities for physical activity, says Renda. “Health systems may be faced with higher numbers of individuals with respiratory conditions, obesity, diabetes, and cardiovascular events, as well as infectious diseases spreading quickly due to people’s close proximity.”

Depending on how rapidly the population grows and the current balance of supply and demand for healthcare resources, there may be a period of time where the number of healthcare providers needs to increase in order to meet rising demand, says Todd Werner, president of Arizona Community Delivery, Banner Health, a Phoenix-based health system which operates 28 hospitals. “While this occurs, patients may experience longer wait times as more demand is being placed on resources that typically have significant lead times to bring to market, such as recruiting physicians and constructing new physical space.”

Greater competition among health systems exists in urban areas, with several large health systems often competing for patients. “While this should result in lower costs, it often has the opposite effect as more integration has led to higher commercial health insurance rates,” Dobson says.

Impact on healthcare in rural areas

At the other side of this trend, there is a move away from rural areas—which increases financial and operational pressures on rural hospitals and other providers. Like most businesses, health systems thrive based on optimal patient volumes for the mix of providers in the health system.

“When patient volumes decrease in rural areas, it becomes more difficult to operate a high-quality, well-resourced operation,” says Julie A. Jacko, PhD, professor in the Dr. Kiran C. Patel College of Allopathic Medicine, Nova Southeastern University, and professor of complex health systems, H. Wayne Huizenga College of Business and Entrepreneurship.

For example, it’s harder for providers to realize the benefits of economies of scale when making investments such as hiring staff. “When there are fewer patients to serve, operations become more expensive,” says Adaeze Enekwechi, PhD, vice president at McDermott+Consulting, a wholly owned subsidiary of the law firm McDermott, Will & Emery. “Providing care to smaller and dwindling populations becomes less efficient over time.”

A rural hospital may also have difficulty attracting physicians and other healthcare providers, and therefore face challenges in maintaining needed services, Dobson says. Consequently, rural and small suburban hospitals continue to close or be acquired by larger systems and converted to reduced-acuity services, Osowski says.

Population declines can also result in providers not being able to see enough volume to remain adequately proficient, leading to discontinuing some services, says Hoyt Skabelund, CEO, Western Division Rurals, Banner Health.

Populations in rural areas tend to be older, sicker, less affluent, and more likely to have barriers to health involving social determinants, Dobson says. “This can be a challenging population to treat, because health problems tend to be more complex and the payment mix will skew more heavily toward Medicare and Medicaid, which has a much lower profit margin for healthcare providers.”

Some patients in rural areas have to travel long distances for specialized treatment and consequently substitute local primary care providers for specialists or postpone or forego care from a specialist, Osowski says, noting that the challenges that rural residents face in accessing healthcare services contribute to health disparities.

Regarding insurers, sparse-
ly-populated rural areas can lead to a reduced pool of individuals to insure in that market, Enekwechi says. Overall, this could result in more expensive premiums or fewer plan offerings.

**How to address rural health problems**

While people who live in rural areas may appear to be at a disadvantage for obtaining healthcare, some viable alternatives to seeking care in urban areas are emerging. Telehealth, for example, is one way for people living in rural areas to receive healthcare, particularly as technology improves and telephonic and broadband infrastructure expands further to less-populated areas, Renda says.

Telemedicine solutions can address minor issues, such as the common cold and flu, and therefore drive a correct level of care and likely avoid some non-emergent emergency room visits. Telemedicine also helps to meet patients where they are and when they need care by addressing non-acute health needs in the home for people with limited transportation, hectic schedules, or a preference to avoid traditional healthcare settings, Renda says.

By treating patients more quickly, it reduces the likelihood of their conditions worsening.

Telephonic and in-home disease management services have become commonplace, with many organizations leveraging nurses, pharmacists, social workers, psychiatrists, and other healthcare providers. “Technology platforms have created web- and app-based virtual group environments for chronic disease self-management,” Renda says.

Telemedicine is also a good solution for patient wellness and prevention. Several states have instituted telehealth programs for preventing catastrophic chronic diseases such as diabetes. For example, Florida has a diabetes prevention program that distributes health-related information through telecommunication technologies to educate people who are pre-diabetic about preventing the disease. “The objective is to propagate proven research into communities,” Jacko says.

A natural and needed area of growth for telehealth is its use in patients’ homes, especially for elderly patients and individuals with chronic, debilitating illnesses, Jacko says. Furthermore, studies have demonstrated that aging in place benefits seniors. “This is more likely to become a widespread reality if telehealth becomes a fixture in seniors’ homes,” she says.

Telehealth can also increase collaboration between primary care physicians and specialists, or among specialists treating the same patient, Dobson says. “This can make the expertise of an academic medical center more accessible to small-town physicians.”

One of the challenges of telehealth is to develop more flexible payment methodologies that would allow, or even promote, such collaboration, he says. “Carriers in a value-based arrangement should be more willing to pay for telehealth because those fees would likely be lower than alternative approaches to care.”

Another challenge is the availability of high-speed Internet capabilities in rural areas, which makes delivery of such services less available.

**Other solutions**

In addition to telemedicine, online prescription subscription and delivery services are helping address rural health access problems. “These services extend prescription access to patients who might have limited access to personal or public transportation,” Brasell says. “As online subscription programs become more prevalent to meet demand, they will become more affordable.”

Osowski says another way for people in rural areas to gain access to healthcare would be for medical schools, private foundations, or local communities to offer financial incentives for physicians to practice in rural environments after graduating from medical school.

Along these lines, Dobson says medical school debt forgiveness and tax deductions or credits should be implemented to encourage new physicians to practice in rural towns.

“Even though such incentives would only last a few years, there is some evidence that doctors beginning in a rural practice tend to be more likely to want to stay in that setting, leading to long-term benefits for those communities,” he says.

Visiting specialists could also play key roles in providing specialty care services in rural settings, ultimately growing ancillary service volume and creating patient value and convenience, Skabelund says.

Another idea might be for urban-based medical centers to open clinics, urgent care centers, and other ambulatory satellites in rural markets, similar to what Geisinger Health System has done in Pennsylvania, Osowski says.

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
It was 2 a.m. Adrienne Boissy, MD, was early in her residency—"the lowest man on the totem pole," she says. One of the nurses on her team told Boissy that her patient needed her.

This was a young patient in her early 20s, remembers Boissy. The patient, recently diagnosed with multiple sclerosis, had a question.

Before heading to the patient’s bedside, Boissy, who’s now chief experience officer at Cleveland Clinic Health System, did a quick review of the medical literature on multiple sclerosis. The young intern wanted to make sure she was prepared for her patient’s questions.

She wasn’t prepared for this one: "Should I marry my boyfriend?" asked her patient.

This was a young woman who had support from a loving family and an ever-present boyfriend, says Boissy. Her patient wasn’t asking for relationship advice. She was grappling with the uncertainty of her disease; her patient wanted to know if she would be taken care of and loved.

**Being present**

That early experience taught Boissy what being a doctor meant to her. She realized she wasn’t in the business of "fixing" people. She discovered, instead, that her patients needed her to be "present."

Today, Boissy is also a neurologist at the Cleveland Clinic Mellen Center for Multiple Sclerosis, where she has an active patient panel. She points to that early morning bedside visit as an intern because it guides her approach with patients.

They’re not just worried about their diseases. Boissy’s patients are wrestling emotionally and mentally with the changes neurological disorders, such as muscular sclerosis, have on their lives—changes that require them to adapt and change.

Take, for example, one of her patients who used to run marathons and can now barely lift their left leg. Or another patient whose spouse left after their disease had progressed.

Her patients need her to slow everything down. They need her to listen. To help them navigate their personal journey with their disease and how they’ll show up to those changes.

**Being curious**

Boissy, who grew up in what she calls a dysfunctional family, studied neurology because she thought it would give her a “black
“In my dream state, I want to eliminate the wait. In this day and age, we need to predict the wait so patients can better plan their lives. We don’t want those [negative] narratives to overtake the brain.”

Knowing she gets to walk out the door at Cleveland Clinic also grounds her. “I’m at a hospital where people don’t get to walk out the door. Family members don’t get to walk out the door....That voice is in my head every day when I walk out of the building.”

And when she’s feeling particularly depleted from a stressful day? She watches funny videos of her kids. “It’s just to give me a little bit of perspective,” says Boissy. “That tough as it is, I’m very blessed. And I think laughter is critically important.”

Being flexible
Her career path has had its twists and turns. Boissy trained for many years as a ballerina. Then she taught ballet, managed a sporting goods store, and tended bar.

What changed her mind about pursuing her dream of dancing ballet professionally? The realization that a broken ankle could prevent her from dancing and impact her ability to provide for her future family, she says. “I’m told I’m not a typical neurologist. I don’t know that I aspire to be one. What’s really important to me is to lead from where [I am].”

Aine Cryts is a writer based in Boston.
Although the ACA is still the law of the land, only bits and pieces of it remain intact as President Trump continued to take actions to dismantle it in 2018. Meanwhile, it’s unclear if and when Congress will resume its quest to implement a new healthcare law.

In light of this, it’s hardly surprising that according to Managed Healthcare Executive’s 2018 State of the Industry Survey, complying with government regulations and policies top health executives’ list of challenges for 2019. Implementing value-based reimbursement is another top concern, with addressing rising pharmaceutical costs and using big data to improve healthcare quality and reduce healthcare costs rounding out the top four concerns. Nearly 200 executives from provider organizations, benefit management organizations, health plans, long-term care organizations, and group purchasing organizations responded to the survey.

Here’s a closer look at the top industry challenges, and what industry experts advise organizations to do to overcome them.

**Challenge #1**

**Complying with policy changes**

In MHE’s survey, 32% of respondents listed complying with government regulations and policies as their top concern. In addition to efforts by President Trump and the Republican Congress to get rid of the ACA, this challenge has a lot to do with the fact that some state agencies change rules and requirements yearly, while others issue multiple notices of changes to Medicaid managed care plan operations during the year.

To learn more about our State of the Industry and see all of the results, check out the full story online at bit.ly/IndustrySurvey2018
At the federal level, CMS issues more than 400 Health Plan Management System (HPMS) memoranda a year. Some of these communications require operational, reporting, and information technology changes. CMS also issues National Coverage Determinations that may require a health plan to pay for procedures or prescription drugs that they previously didn't have to cover. “All of these changes require analysis, planning, budgetary and staffing analysis, and implementation,” says Shelley Stevenson, director, Government Programs Practice, Change Healthcare, which leverages technology to improve patient care. “Many changes impact profitability, provider relationships, and member communication.”

Insurers who offer state or federally regulated lines of business are directly impacted by any change in regulations. “Payers that have hospital systems and integrated healthcare systems in their networks are always affected by any policy changes,” Stevenson says. “While integrated health plans often have access to hospital and physician [EHRs], non-integrated plans have to do outreach to access clinical data, such as that to support a prior authorization request. Hospitals and integrated healthcare systems are challenged by regulatory changes that only pertain to medical institutions, such as billing requirements.”

**HOW TO DEAL**

C-suite executives need to stay on top of challenges associated with regulation changes, and then rely on experts in those areas to help them navigate those changes in light of their business goals. “Regulatory considerations need to be front and center as business decisions are made,” says Joe Geraci, partner, Husch Blackwell, an industry-focused law firm.

Susan Feigin Harris, JD, a partner in the law firm Morgan, Lewis & Bockius LLP, says lawyers and compliance officers can be helpful in preventing violations by identifying any weaknesses that require attention as well as performing periodic reviews in order to show a proactive focus on compliance or identify areas that need improvement.

Joe Paduda, MS, principal, Health Strategy Associates, LLC, advises working with an established and connected association or lobbying group that can demonstrate consistently accurate insights into potential changes to policy and regulation. “When planning, build flexibility and adaptability into systems, contracts, and work processes so significant alterations in policy don’t require wholesale revamps or revisions to key business operations and systems,” he says.

**Challenge #2**

Implementing value-based care

Only 40% of respondents to our survey have started initiatives toward value-based care. Furthermore, only 30% said their compensation is value driven.

“Most payers and providers have been operating under a fee-for-service model, so changing to value-based care can be intimidating, complicated, and expensive,” says Jay LaBine, MD, chief medical officer, navicare, a post-acute care management company that manages risk.

While health plans aim to create value and provide better member experiences through improvements in the quality of care and reduced costs, providers have their own ideas and priorities for how to create value. “This is particularly evident as consolidation activity for healthcare providers has escalated over the past 10 years,” LaBine says. “Hospital consolidation has created more buying power on the provider side, therefore putting more strain on payers to implement their own member-focused programs to drive value.”

Kate Grohall, product executive for value-based care at SKYGEN USA, which offers technology solutions for payers and providers, says now that payers are accepting more risk for outcomes under value-based care, they need to build programs and infrastructure that support a more concierge type relationship with...
members, enabling member engagement and improved healthcare choices. "In other words, they need to go from being the bank when it’s time to pay for care to being a trusted resource and advocate of member savings, quality outcomes, and overall care experience," she says. “This isn’t an easy transition.”

Meanwhile, providers have huge concerns about how they will transition their business models away from being primarily fee-for-service. “They will have to redesign work flows and create new clinical pathway management strategies with their frontline clinical staff to become successful at managing an entire episode of care,” Grohalla says. "Hospitals must also completely revamp their provider contracting strategies and compensation models to align with value-based care delivery and payment models.”

**HOW TO DEAL**

To overcome challenges associated with creating a value-based environment, health plan executives should collaborate with large health systems to foster greater change within the care continuum. LaBine says this can be accomplished through value-based contracts focused on improving patient experience, patient quality of care, and reducing costs. Health plan executives can overcome challenges by communicating their goals for improved value for their members to patients and providers.

Health plan executives should also consider communicating price transparency directly to their members, LaBine continues. By going straight to healthcare consumers, health plans can encourage members to elect less expensive procedures or services that still achieve the same outcome. “Health plans need to engage with and educate their members, and providers will follow suit,” he says.

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**Top 2019 Challenges**

**Challenge #3**

**Addressing rising pharmacy costs**

In MHE’s survey, 15% of respondents listed addressing rising pharmaceutical costs as their top concern. Although data show that drug price increases have actually slowed down since 2014, pharmaceutical drug spend by insurers and in turn by patients with high deductibles and copayments has been rising due to increased use, says Yana Paulson, PharmD, chief pharmacy officer at LA Care Health Plan in Los Angeles. For example, in 2017 two-thirds of specialty drug spending growth was due to more individuals being treated and the number of prescriptions being dispensed.

“Payers must increase their focus on structuring drug benefits to not only keep premiums low, but to also ensure that patients with high copays can afford treatment and that enough alternatives are available for specific conditions,” Paulson says.

Another challenge in this area relates to new products coming to market—specifically biopharmaceuticals. “ Manufacturers can set high price tags for these drugs, which rarely face competition from alternative products, resulting in high copays for consumers,” says Nancy Taylor, co-chair of the healthcare and FDA practice at the law firm Greenberg Traurig LLP. “In many cases, patients must use these products routinely for certain chronic diseases and there is little ability to negotiate a lower price.”

Health insurers also face challenges in determining when and how to cover new biopharmaceuticals and whether to use prior authorization or limitations on coverage to reduce over or inappropriate use, Taylor says. Hospital systems may not be able to effectively limit prescribing to a formulary due to a physician’s ordering practices and patient needs.

Ron E. Peck, Esq., JD, senior vice president and general counsel, The Phia Group, LLC, which provides cost containment strategies for health plans, says communication between participants—pharmacists, physicians, and payers—is of the utmost importance to ensure that the most effective, efficient, and easy-to-follow regimen is prescribed and that patients understand the health and financial benefits of compliance. “Perhaps it even makes sense to incentivize such behavior, such as reducing or waiving copays for medications initially prescribed to treat a condition, but increasing copays for more intensive...”

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**Q:** Where would you say your organization is in the shift toward value-based care?

- **10%** We have not yet started.
- **50%** We have a few initiatives started.
- **26%** We have many initiatives started.
- **14%** Most of our business/operations is focused on the value.
treatments, needed if and when a patient fails to comply with their treatment plan—eventually worsening their condition,” he says, noting that 20% of new prescriptions go unfilled and 40% of patients do not adhere to prescribed medications. This leads to greater costs down the road for patients and payers.

**HOW TO DEAL**

In order to keep pharmaceutical prices down, health plans need to employ cost containment programs to manage resources. According to Paulson, here are six initiatives that LA Care has done in this area:

1. **Maximize use of generics** by prudent and careful formulary management.
2. **Increase the use of biosimilars** in the specialty drug area. Biosimilars are substitutes for biologics (drugs made using a biological method) similar to the way generics are substitutes for brands (drugs made by a chemical method) and like generics they are usually less expensive.
3. **Carefully negotiate drug rebates** with pharmaceutical manufacturers.
4. **Negotiate network pharmacy prices**, such as discounted prices for in-network pharmacies.
5. **Carefully select specialty drugs**. Don’t base decisions solely on price; instead choose drugs based on safety and efficacy first to maximize value. Then, employ frequent clinical monitoring to ensure efficacy and adherence.
6. **Offer clinical programs** such as reminding patients to get medication refills for chronic conditions in order to avoid hospitalization or emergency room visits and having clinical pharmacists provide medication therapy management consultations, which can, among other benefits, avoid polypharmacy by discontinuing unnecessary drugs.

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**Q**: What do you think will have the biggest impact on controlling rising specialty drug costs?

- **23%** Value-based (outcomes-based) pharma contracts
- **21%** Government interference
- **13%** Integrated pharmacy and medical benefits
- **11%** Cost-effective pharmacy plan design
- **10%** Utilization management
- **8%** Biosimilars
- **6%** Other
- **5%** Pharmacy benefit managers and specialty pharmacies
- **3%** Increasing member copays

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**Top 2019 Challenges**

**Change in Commercial Payer Drug Spending, Traditional vs. Specialty Drugs, by PBM, 2017**

<table>
<thead>
<tr>
<th>Change in traditional (non-specialty) drug spending</th>
<th>Change in specialty drug spending</th>
<th>Overall change in drug spending</th>
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<tr>
<td>-4.9%</td>
<td>12.9%</td>
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<td>-4.3%</td>
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Source: Drug Channels Institute analysis of PBM drug trend reports. Figures represent commercially insured beneficiaries only.

Published on Drug Channels (www.DrugChannels.net) on May 22, 2018.
“Big data, data science, and artificial intelligence will only deliver value if innovations can be translated to patient care and clinical work flow.”

— PAUL ALEXANDER CLARK, DIGITAL REASONING

**Challenge #4:**

**Using big data effectively**

Only 12% of the survey respondents said their organization is effectively using big data to improve healthcare quality and reduce healthcare costs. 46% said they’ve made some progress toward using big data, but there’s still a lot of work to do; and 42% reported little or no progress in using big data.

Will Hinde, managing director of healthcare at West Monroe Partners, a management and technology consulting firm, believes that many organizations have made little progress in this area because health insurance and health system executives are weighed down by legacy technology that simply isn’t agile or scalable, which prevents them from leveraging big data to its potential. This is further complicated by unreliable and unclean data that result from most organizations lacking master data management discipline. “The result is disparate and lagging reporting, gaps in real-time data, and a lack of clinical analytics, making it difficult to manage populations and drive better quality and cost outcomes,” he says.

Along these lines, Paul Alexander Clark, director of healthcare research at Digital Reasoning, which builds artificial intelligence care management software for health systems, says healthcare leaders struggle to apply information technology innovations and information technology leaders struggle to understand healthcare. “Big data, data science, and artificial intelligence will only deliver value if innovations can be translated to patient care and clinical work flow,” he says. “Bridging the gap between these disciplines demands extraordinary vision, leadership, and committed partnership from healthcare executives and their technology partners.”

Providers and payers look to big data and analytics to do different things. Providers are more focused on the care they deliver, with less insight into cost, says Marcel Tetzlaff, vice president of provider experience and benefits management, SKYGEN USA. Providers have detailed clinical information to use when evaluating a patient’s overall health, whereas the information payers have is more oriented toward identifying the best practitioner who should provide it based on appropriateness of care (quality), efficiency of care (cost), and other measures such as patient satisfaction.

Payers are concerned about the whole breadth of care members receive, because they pay for all of it. Payers also seek to understand member health challenges so they can help them stay healthier. “They have the added responsibility of managing their provider networks—making sure they do a good job for members and that they deliver cost-efficient care,” Tetzlaff says.

A health system or hospital may look at the efficiency of individual physicians within various specialties from time to time, especially as they work to standardize care and reduce costs, but they’re usually not trying to affect the patient’s decision of which physician to use like payers do.

**HOW TO DEAL**

Clark advises healthcare organizations to build partnerships with best-in-class enterprises that will fill the gaps in core competencies to enable the organization to apply and derive value from leading-edge technologies.

“Don’t evaluate and select technology partners solely on their name recognition or success in other industries,” Clark says. “Deeply engage and ensure that they have the knowledge, understanding, and an effective plan to translate their technology into healthcare. To create value, big data, and artificial intelligence innovations must drive down the costs of care, improve care, and drive down cost efficiency of individual physicians within various specialties from time to time, especially as they work to standardize care and reduce costs, but they’re usually not trying to affect the patient’s decision of which physician to use like payers do.”

Tetzlaff says the optimal situation is when payers and providers share data with one another to fill in gaps in their understanding. “Big data analytics work best when they have bigger data sets to work from and have meaningful and actionable results,” he says. “Full transparency allows patients to make the best possible choice for themselves.”

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
More than 1.5 million people live in Philadelphia, and the city is an economic, education, and healthcare hub to many in the state and in New Jersey and Delaware. In 2012, stakeholders from Philadelphia-area healthcare organizations came together to launch the HealthShare Exchange (HSX), a health information exchange (HIE) between provider organizations with a goal to improve healthcare communications and data interoperability throughout the area.

Today, HSX’s membership includes more than 100 independent ambulatory practices, 85 post-acute care organizations, eight health plans, seven behavioral health organizations, six accountable care organizations and nine skilled nursing/long term care facilities that share interoperable data with more than 15,000 providers in the region. Nearly 8 million patients are a part of HSX’s data depository.

HSX is the largest HIE in a major metropolitan city, and CEO Martin Lupinetti says the organization hopes it will reduce overall healthcare costs and patient confusion.

“We have all these assets: a notification service, a patient matching algorithm, an application program interface. We have all these things that if assembled in the right way, can solve a lot of different healthcare challenges,” Lupinetti says. “So, the short-term goal is really to embrace the power, and how we put those things to good use. We see ourselves as morphing, not just as an HIE, but really as a data company, a data aggregator that offers health information and exchange services.”

Richard Snyder, MD, chief medical officer at Independence Blue Cross, assisted with the launch of HSX. He says payers and providers realized that the risk of not creating a viable HIE would be more higher costs due care overlap and lack of continuity in treatment.

“This region is saturated with academic health systems and their affiliated providers and facilities,” says Snyder, noting that many patients receive healthcare services in more than one system and use varying EHRs. “Initial use cases for HSX were built on the premise that avoidable redundancy in testing and prescribing coupled with real-time knowledge of a patient’s history and use of healthcare services would prevent avoidable readmissions.”

**True meaningful use for the region**
It was not easy to get competing healthcare organizations to agree that sharing data and patient information would benefit their organizations, says Snyder.

“After previous statewide and regional failed attempts at implementing health information exchanges to address ‘meaningful use,’ we took a different approach,” he says.

That meant identifying pain points for clinicians and administrative staff and coming up with ways to use the proposed HIE to solve those pain points, rather than taking an off-the-shelf, government-dictated solution.

Snyder says that the homegrown model was more attractive to payers and providers. Because stakeholders within the healthcare community assisted with developing by-laws and a participation agreement, Snyder says competing businesses felt protected.

“As a payer HSX member, we have created and maintain a clinical activity history that includes up to four years of documentation of diagnoses, treating physicians and facilities, inpatient stays, emergency department visits, prescriptions, procedures, and lab results based on claims data,” says Snyder. “This clinical activity history can be pushed to emergency department physicians real-time or retrieved by a treating provider to round out the clinical picture that is not contained in their [EHR]. A competing health insurer or payer cannot request this information.”
**Diversity of organizations**

HSX is a 501(c)(3) organization, funded by membership fees and grants, so it is able to onboard a diversity of healthcare organizations, says Lupinetti. “We have a founding principle that any federally qualified health center or city clinic, including heavy Medicaid or underserved clinical practices, do not have to pay for any services,” he says. “That’s based on the fact that we receive grants from CMS really with a purpose of directing the benefit to those in most need.”

Russ Allen, communications coordinator for HSX, says the organization continues to branch out to post-acute care and other continuity of care entities because those end-to-end connections are important to the healthcare community and patients.

“This is vital information that is at their fingertips,” Allen says. “In some cases, it’s auto routed or auto pushed to them so they don’t have to physically pull it. We’re giving them insight that they didn’t have before. We have yet to encounter any organization in the continuum that’s really not a good fit.”

**Membership benefits**

Independence Blue Cross associates in care management and other member support functions use the HSX data, including the real-time admission discharge and transfer (ADT) data to access discharge plans, facilitate care, and ensure timely follow-up appointments and document discharge dates for purposes of closing out cases.

“Also, the data supplements HEDIS and STARS data collection efforts,” Snyder says. “Often, better coordination of care with primary care physicians has resulted from having this information, such as the avoidance of emergency department visits.”

Lupinetti says health plans, accountable care organizations, and providers find the encounter notification service valuable, because it sends an alert when one of their patients is hospitalized or goes to an emergency department. It can also send alerts when patients are discharged from hospitals or post-acute care facilities.

“We’re starting to use the data and population health for trends analytics, and report on various interesting aspects of that data,” Lupinetti says.

**Regional expansion**

In July 2018, HSX expanded into New Jersey, joining the New Jersey Health Information Network, a statewide health information organization between providers that has a goal to join a national network of providers called the eHealth Exchange. Lupinetti says that because of the large number of healthcare organizations within the tri-state region, expansion is an important effort to ensure patient continuity of care.

Lupinetti hopes HSX can navigate some of the regulatory and business barriers in New Jersey and Delaware to help the region become more interoperable.

“Some [of the other regional HIEs] are very hospital-focused data sharing exchanges,” he says. “Some are very health plan focused. But they all haven’t quite synced together and we think given our neutral status and given we have such a diverse membership that we’re a logical choice to really help kind of advance the agenda of regional data sharing.”

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**Using data to innovate**

The HIE’s nonprofit status allows it to establish trust with competing hospitals, health plans, and systems, in order to leverage data for future initiatives that could benefit the community, says Lupinetti. “The data is valuable. The data can be used in a lot of ways that aren’t acceptable,” he says. “We clamped down on that with our agreement that everyone signs, so everyone’s clear on what it can be used for and what it can’t.”

Using patient data to innovate is one of HSX’s goals, but meaningful innovation is essential, Lupinetti says. Current and upcoming uses for HSX data include creating applications and population health disseminations. Examples include:

**1 HSX MarketStreet**

HSX announced this data repository, open to application developers, in 2017. The goal of the HSX Marketplace is to create patient facing, provider facing, population health, and system application interfacing applications for collaborative and business uses.

**2 HSX Population Health program**

Allows members and other participants to access large data sets, including demographics, encounter data, diagnosis, allergy, insurance, medication, and other clinically-relevant variables. Organizations can request historical data, standard or custom reports, and live data or dashboards in daily, weekly, monthly, or annual increments.

Current uses for HSX’s population health data include: electronic clinical quality measures for hospitals, monthly quality reports for hospital readmissions, acute and emergency department use reports to executives, and opioid abuse and overdose reporting to the City of Philadelphia Department of Public Health.

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Donna Marbury is a writer in Columbus, Ohio.
The 8 Most Exciting Drugs in the 2019 Pipeline
Some of the most important drugs that could launch this year

by NICHOLAS HAMM

While the pipeline is never a sure thing, looking at the current pipeline is a useful way to peek into the future of healthcare. What are the next blockbuster drugs going to be? Where will big expenses be coming from? What disease states are going to get the most attention?

Predicting the pipeline is by no means a perfect science, but we took a look at what could be some of the most exciting releases this year. The following are eight of what could be the most important new drugs of 2019, in order of their expected PDUFA date.

Siponimod
Company: Novartis
PDUFA: 3/2019

**Indication:** A selective modulator of specific subtypes of the sphingosine-1-phosphate (S1P) receptor for the treatment of secondary progressive multiple sclerosis (SPMS).

**Why it’s exciting:** The National MS Society estimates that around 1 million Americans have MS. Of those diagnosed with MS, 85% will have relapsing-remitting MS, and 80% of those with relapsing-remitting MS will develop SPMS.

If the FDA approves siponimod, it would serve as another treatment option as the condition progresses from relapsing forms of MS. No other drug has been consistently able to slow disease progression with in patient with SPMS, but clinical trials have demonstrated some ability for siponimod to achieve those results.

Arash Sadeghi, PharmD, clinical pharmacist of Pipeline and Drug Surveillance at OptumRx, says this drug could generate between $1 to $3 billion in peak revenue.

Esketamine nasal spray
Company: Janssen, PDUFA: 3/4/2019

**Indication:** Nasal spray for treatment-resistant severe depression.

**Why it’s exciting:** About 9.5% of the population experiences depression during a single year. About half of all patients with depression do not respond to one therapy, and up to 20% of patients do not respond to multiple treatments.

The drug is touted as a fast-acting alternative to SSRI and SNRI antidepressants, and if approved would be the first new mechanism to treat depression in 30 years.

Pharma Intelligence predicts a $4.3 billion market for depression in 2019—while also predicting that esketamine could achieve over $2.3 billion in sales by 2024.

For more on esketamine nasal spray, see Special Report, page 28.

Zynquista (sotagliflozin)
Company: Sanofi, PDUFA: 3/22/2019

**Indication:** SGLT-1 and SGLT-2 inhibitor to improve blood sugar control in adults with type 1 diabetes, in addition to insulin therapy.

**Why it’s exciting:** If sotagliflozin is approved, it would be the first oral treatment for type 1 diabetes on the market. According to Datamonitor Healthcare, type 1 diabetes is over a $5 billion market this year alone.

Joshua D. Miller, MD, MPH, assistant professor of endocrinology and metabolism at Stony Brook University in Stony Brook, New York, says that while the potential market effects—and potential patient side effects—of this drug remain to be seen, the drug is “newsworthy because all we’ve had is insulin.” He points out that diabetologists have long used medications off-label to treat diabetes, though they have never used an SGL-2 inhibitor. He says that the drug could be a gamechanger—if its benefits outweigh potential problems (especially concerning diabetic ketoacidosis).

Sotagliflozin is also currently in phase 3 trials for type 2 diabetes, which could receive a PDUFA for later this year.

For more on sotagliflozin, see Special Report, page 28.
**Risankizumab**  
Company: Boehringer Ingelheim/AbbVie  
PDUFA: 4/25/2019

**Indication:** An interleukin-23 (IL-23) inhibitor for the treatment of patients with moderate-to-severe plaque psoriasis.

**Why it's exciting:** It's no secret that the psoriasis market is huge—according to Pharma Intelligence, it’s projected to be a nearly $7.5 billion U.S. market this year alone. In its first year on the market, Pharma Intelligence predicts that it will capture $12 million in sales and $31 million by 2020, with a CAGR through 2025 of 85.27%.

One reason for its predicted success is its efficacy. Psoriasis medication efficacy is measured with a Psoriasis Area and Severity Index (PASI). Patients with PASI90 improved 90% or more during the treatment period. According to Sadeghi, 75% of patients achieved PASI90 with risankizumab, compared with Stelara's 48%.

The drug is also currently in phase 3 trials for Crohn’s and ulcerative colitis.

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**AVXS-101**  
Company: Novartis  
PDUFA: 6/18/2019

**Indication:** Gene therapy for the treatment of spinal muscular atrophy (SMA).

**Why it's exciting:** While there is currently a treatment for spinal muscular atrophy, nusinersen (Spinraza), it’s also wildly expensive for the around 20,000 SMA patients in the United States. According to Sadeghi, AVXS-101 would be a direct competitor to Spinraza’s $750,000 per year price tag.

AVXS-101 could shake that up, but being a gene therapy, it too is wildly expensive—Novartis announced that it believes the treatment would be cost-effective with a $4 to $5 million per patient price tag. But, like other gene therapies, if it does indeed work long-term, even that hefty of a price tag could result in savings over time.

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**NKTR-181**  
Company: Nektar  
PDUFA: 5/28/2019

**Indication:** A selective mu-opioid agonist for pain relief.

**Why it’s exciting:** With the opioid crisis in full swing, it seems odd to bring yet another opioid into the market. But NKTR-181 promises to be an opioid with a lower risk of dependence. According to Nektar, this is because NKTR-181 does not produce the same high levels of euphoria present in other opioids—it has a low permeability across the blood/brain barrier.

Unlike many other addiction resistant opioids—which are often merely different formulations of existing drugs with some tamper-evident mechanism added or a long-acting formulation—NKTR-181 is a new molecular entity, a first-in-class opioid.

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**Viaskin Peanut**  
Company: DBV Technologies  
PDUFA: 6/22/2019

**Indication:** Immunotherapy for the treatment of peanut hypersensitivity in children aged 4- to 11 years.

**Why it’s exciting:** Peanuts are one of the most common food allergies—a National Institute of Allergy and Infectious Diseases 2010 report lists the prevalence as 0.6% of Americans, or approximately 2 million people.

Currently, there is no definitive treatment for peanut allergy—the only actions available are separating patients with allergies from any possible allergens.

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**Evenity (romosozumab)**  
Company: Amgen and UCB  
PDUFA: 7/12/2019

**Indication:** Monoclonal antibody that inhibits the protein sclerostin for treatment of osteoporosis in postmenopausal women at increased risk of fracture.

**Why it’s exciting:** According to Sadeghi, there are 10 million with osteoporosis in the U.S. currently, with another 18 million people at risk. Those numbers add up to a large market for osteoporosis treatments. According to Pharma Intelligence, the osteoporosis market will be around $4.1 billion in five years, Evenity could capture around $550 million of that.

Nicholas Hamm is an editor with Managed Healthcare Executive
Eight Simple Ways Healthcare Providers Can Make Patients Happier

You can’t make every patient satisfied every time, but it’s worth a shot. Here are eight simple strategies for providers to consider

by MARK ROWH

Tip 1
Get comfortable talking about money
“Tie the financial conversation to the clinical conversation. Patients today are being encouraged to ask questions upfront, including whether there are lower-cost treatment options, and may even price shop. Providers should include information about financial responsibilities and options to pay as part of the medical conversation. This change will be a huge step in creating transparency—and turning a potential negative into a competitive advantage.”

—Kent Ivanoff, CEO, healthcare payment firm VisitPay, Boise, Idaho

Tip 2
Listen more
“The best way to make patients happier is to really listen to them. Look them in the eye, convey sincere care and concern for their well being and their feelings. When people are ill or in crisis, it frightens them further when they perceive fragmented care, no one talking to each other, and staff paying more attention to the computer than to patients. Also listen to employees. When care providers are happy and supported by administration it always trickles down to the patients. It impacts the entire corporate culture when administration actively supports and empowers the staff. Happy staff leads to happier patients.”

—Teri Dreher, RN, iRNPA, owner/CEO, NShore Patient Advocates, Chicago

Tip 3
Focus on cultural competency
“Ensure you have the best front desk team and waiting area experience because poor customer service (rushing them, talking down to members, lack of empathy) may discourage them from seeking future treatment. Also educate all office staff in cultural competency, so that they know the basics about the dominant ethnic cultures you are likely to encounter and where to find useful information.”

—Karen Dale, market president/CEO, AmeriHealth Cartas District of Columbia, a Medicaid managed care plan

Tip 4
Get smart
“Patients often start their visit with a manual and time-consuming check-in process that heavily relies on paper and staff time, which can leave a bad first impression in the minds of patients. Instead, providers can leverage the smartphones that patients already bring to their visits to let them check-in easily with pre-populated demographic and benefit information. Plus, they can set up a digital wallet and automatic payments during the BYOD (bring your own device) check-in experience.”

—Deirdre Ruttle, VP of strategy, healthcare payments network InstaMed, Philadelphia

Tip 5
Upgrade technology
“If you look at other industries such as e-commerce, they’ve used technologies such as data science, digital communications, and increased transparency to deliver highly-personalized consumer experiences. It’s time to do the same with patient billing. By implementing a patient-first approach to billing and incorporating modern technology, like data analytics and machine learning, to an antiquated process, providers can make measurable progress towards achieving long-term patient engagement and satisfaction. This means reaching patients at the right channel, at the right time, with the right message—
How to Keep Patients Happy—and Engaged—with Hyper-Targeted Health Reminders

By Robert S. Oscar, RPh

One of the standard tropes in any movie showing military battles from the pre-gunpowder era is the line of archers standing at the ready. (See: “Wonder Woman,” “300,” “The Lord of the Rings.”)

When the command is given, they unleash a volley of arrows into the air, which then rain down randomly on the enemy. While some find their marks, the majority are wasted.

This is similar to what can happen when health plans reach out to members with health reminders. Historically, reminders such as, “Time for your flu shot,” or “You may need to schedule a mammogram,” have gone out across large swaths of patient populations, with the hope that they will drive at least some to take action.

These random volleys of messages are not very efficient—or effective—because they lack context about who the member is, what specific health challenges he or she faces, and what has or hasn’t been done recently to address them.

As a result, these communications can miss the mark, and members may stop paying attention to them.

Leveraging analytics for better member targeting

Increasingly, newer types of analytics solutions are enabling payers to dig deep into member data to build highly precise, hyper-targeted lists that are tailored to the health needs of each member.

Here’s an example. Typically, payers will send a message to all women within certain age parameters reminding them of the importance of getting a mammogram.

But what about women who have had a double mastectomy? Not only do they not need the mammogram, sending the message could serve as a painful reminder of a difficult time. It could also hurt the relationship between the member and the payer.

Then there’s the women who just had a mammogram last week. Sending a message after the fact makes the payer again look like they don’t know what’s going on, and can even create confusion if members with low health literacy misunderstand and think they must go for another mammogram.

Analytics that are capable of creating hyper-targeted lists can take these and other factors into account, eliminating everyone for whom the message is not relevant or timely.

Analytics can also identify who the physicians are for patients who have had a recent medical crisis and inform the providers of the new findings so they can change prescribing patterns if needed, reach out to reinforce the message, and add a note to the EHR.

Achieving value-based care goals

By fine-tuning member engagement programs using advanced analytics, payers can ensure that their arrows hit the right targets in order to drive engagement and desired behaviors—and achieve their value-based care goals.

Robert S. Oscar is CEO/president of RxEOB, an industry leader in member engagement applications for pharmacy benefits.

Editor’s Note: The full version of this article is available at: https://bit.ly/2zXE0id
Eight Tips for Running More Effective Meetings

How can healthcare execs prevent their days from being overtaken by meetings? Here are eight ideas

by AINE CRYTS

Thirty seven. That’s the average number of meetings executives have each week, according to a recent Harvard Business Review article, which also reveals that executives are spending a whopping 72% of their work day in meetings.

Schedule planning time
Terry Platcheck, MD, vice president of performance improvement at Stanford Children’s Health, blocks out one to two hours of prep time per hour of meeting. His planning starts with setting a thoughtful, reasonable, and actionable agenda.

Another tip? Put the topic that requires the most discussion at the top of your agenda.

Engage in active problem solving
Meetings shouldn’t be about getting updates from members of the team, says Kelly Johnson, RN, PhD, vice president of patient care services and chief nursing officer at Stanford Children’s Health. Instead, set the expectation that everyone will be tackling the tough issues and coming up with solutions during the meeting.

Create a fair and safe environment
That’s advice from Ed Clark, MD, associate vice president for clinical affairs and president of the University of Utah Medical Group. “Everyone’s perspective must be respected, and everyone must contribute either voluntarily or by invitation,” he says.

Watch for nonverbal cues and body language
This is a great way to make sure everyone is participating, says Clark. If a meeting participant seems distracted, he invites them to “lean in.” Just as important is managing meeting participants who attempt to dominate the conversation, he adds.

Allow time for humor
Why’s that? Enjoying work builds resilience and leads to better decisions, says Platcheck.

Hold people accountable for action items
Clark ends a meeting with this question: “What have we accomplished?”

He recommends having a team member who isn’t running the meeting summarize the meeting and reframe accountabilities. This technique frees up the meeting leader to focus their undivided attention on participants and the process.

Consider TED Talk’s 18-minute format
That’s according to Kaveh Safavi, MD, head of consulting firm Accenture’s global health practice. The format’s short enough to keep everyone focused and precise enough so that everyone takes it seriously, he says.

Be strict about start and end times—and attendance
That’s a recommendation from Colleen Swedberg, MSN, vice president of strategy at Bridgeport, Connecticut-based St. Vincent’s Health Partners, a nonprofit integrated delivery network. For ongoing meetings, she requires that participants attend at least 50% of meetings.

Aine Cryts is a writer based in Boston.
**INDICATION**

BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen for ≥3 months with no history of treatment failure and no known resistance to any component of BIKTARVY.

**IMPORTANT SAFETY INFORMATION**

**BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B**

- Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.

**Contraindications**

- Coadministration: Do not use BIKTARVY with dofetilide or rifampin.

**WARNING**

**Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.

**Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.

**New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of BIKTARVY, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. **Renal monitoring:** Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, also assess serum phosphorus.

**Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

See the possibilities at biktarvyhcp.com
SIMPLE DOSING With BIKTARVY®

BIKTARVY® combines the FTC/TAF® backbone with bictegravir, in a small and powerful unboosted STR² ⁴

Once-Daily STR
Taken Any Time of Day
No Food Requirement
No Booster

IMPORTANT SAFETY INFORMATION (cont’d)

Adverse reactions

Most common adverse reactions (incidence ≥5%; all grades) in clinical studies were diarrhea (6%), nausea (5%), and headache (5%).

Drug interactions

Prescribing information: Consult the full prescribing information for BIKTARVY for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.

Enzymes/transporters: Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.

Drugs affecting renal function: Coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

BIKTARVY® is not recommended in patients with severe renal impairment (estimated CrCl < 30 mL/min) or severe hepatic impairment (Child-Pugh Class C)²

IMPORTANT SAFETY INFORMATION (cont’d)

Dosage and administration

- Dosage: 1 tablet taken once daily with or without food.
- Renal impairment: Not recommended in patients with CrCl <30 mL/min.
- Hepatic impairment: Not recommended in patients with severe hepatic impairment.
- Prior to or when initiating: Test patients for HBV infection.
- Prior to or when initiating, and during treatment: As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

Pregnancy and lactation

- Pregnancy: There is insufficient human data on the use of BIKTARVY during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for FTC shows no difference in the rates of birth defects compared with a US reference population.
- Lactation: Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

Please see Brief Summary of full Prescribing Information for BIKTARVY, including BOXED WARNING, on the following pages.
BIKTARVY® (bictegravir 50 mg, emtricitabine 200 mg, and tenofovir alafenamide 25 mg) tablets, for oral use

Brief Summary of full Prescribing Information. See full Prescribing Information. Rx only.

WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted [see Warnings and Precautions].

INDICATIONS AND USAGE

BIKTARVY is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of BIKTARVY.

DOSAGE AND ADMINISTRATION

Also see Warnings and Precautions and Use in Specific Populations.

Testing Prior to or When Initiating: Test patients for HBV infection.

Testing Prior to or When Initiating, and During Treatment: As clinically appropriate, assess serum creatinine, estimated creatinine clearance (CrCl), urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.

Dosage: One tablet taken once daily with or without food.

Renal Impairment: BIKTARVY is not recommended in patients with CrCl <30 mL/min.

Hepatic Impairment: BIKTARVY is not recommended in patients with severe hepatic impairment.

CONTRAINDICATIONS

Also see Drug Interactions.

BIKTARVY is contraindicated to be co-administered with:

- dofetilide due to the potential for increased dofetilide plasma concentrations and associated serious and/or life-threatening events
- rifampin due to decreased BIC plasma concentrations, which may result in the loss of therapeutic effect and development of resistance to BIKTARVY

WARNINGS AND PRECAUTIONS

Also see BOXED WARNING, Contraindications, Adverse Reactions, and Drug Interactions.

Severe Acute Exacerbation of Hepatitis B in Patients Coinfected with HIV-1 and HBV: Patients with HIV-1 should be tested for the presence of chronic hepatitis B virus (HBV) before or when initiating ARV therapy. Severe acute exacerbations of hepatitis B (e.g., liver decompensation and liver failure) have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing FTC and/or TDF, and may occur with discontinuation of BIKTARVY. Patients coinfected with HIV-1 and HBV who discontinue BIKTARVY should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. If appropriate, anti-hepatitis B therapy may be warranted, especially in patients with advanced liver disease or cirrhosis since post-treatment exacerbation of hepatitis may lead to hepatic decompensation and liver failure.

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions: Coadministration of BIKTARVY with certain other drugs may result in known or potentially significant drug interactions; this may lead to loss of efficacy and development of resistance to BIKTARVY or clinically significant adverse reactions from greater exposures of concomitant drugs. Consider the potential for drug interactions and review concomitant medications prior to and during therapy. Monitor for adverse reactions associated with concomitant drugs.

Immune Reconstitution Syndrome (IRS): IRS has been reported in patients treated with combination ARV therapy. During the initial phase of treatment, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment. Autoimmune disorders have been reported to occur in the setting of immune reconstitution; the time to onset is variable, and can occur many months after initiation of treatment.

New Onset or Worsening Renal Impairment: Renal impairment, including acute renal failure and Fanconi syndrome, has been reported with the use of tenofovir prodrugs in animal studies and human trials. In clinical trials of BIKTARVY in subjects with no antiretroviral treatment history with eGFRs >60 mL/min, and in virologically suppressed subjects switched to BIKTARVY with eGFRs >50 mL/min, renal serious adverse events were encountered in less than 1% of subjects treated with BIKTARVY through Week 48. BIKTARVY is not recommended in patients with CrCl <30 mL/min. Patients taking tenofovir prodrugs who have renal impairment and/or are taking nephrotoxic agents including NSAIDs are at increased risk of developing renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Renal Monitoring: Prior to or when initiating BIKTARVY, and during treatment with BIKTARVY, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, also assess serum phosphorus.

Lactic Acidosis/Severe Hepatomegaly with Steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including FTC and TDF. Treatment with BIKTARVY should be suspended in any individual who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

ADVERSE REACTIONS

Also see BOXED WARNING and Warnings and Precautions.

In Adults with No ARV Treatment History:
The safety assessment of BIKTARVY is based on Week 48 data from two randomized, double-blind, active-controlled trials: 1489 (n=314) and 1490 (n=320), in HIV-1 infected, ARV treatment-naive adults. Through Week 48, 1% of subjects discontinued BIKTARVY due to adverse events, regardless of severity.

Adverse Reactions: Adverse reactions (all Grades) reported in ≥2% of subjects receiving BIKTARVY through Week 48 in Trials 1489 and 1490, respectively were: amylase >2.0 x ULN and creatinine kinase >10.0 x ULN occurring in ≥2% of subjects receiving BIKTARVY through Week 48 in Trials 1489 and 1490 included vomiting, flatulence, dyspepsia, abdominal pain, rash, and depression. Suicidal ideation, suicide attempt, and depression suicidal occurred in <1% of subjects administered BIKTARVY; all events were serious and primarily occurred in subjects with a preexisting history of depression, prior suicide attempt, or psychiatric illness.

Laboratory Abnormalities: Laboratory abnormalities (Grades 3–4) occurring in ≥2% of subjects receiving BIKTARVY through Week 48 in Trials 1489 and 1490, respectively were: amylase >2.0 x ULN (2%, 2%), ALT >5.0 x ULN (1%, 2%), AST >5.0 x ULN (2%, 1%), Creatine Kinase >10.0 x ULN (4%, 4%), Neutrophils <500/mm3 (2%, 2%), and fasted LDL-cholesterol >190 mg/dL (2%, 3%).

Changes in Serum Creatinine: Increases in serum creatinine occurred by Week 4 of treatment and remained stable through Week 48. In Trials 1489 and 1490, median serum creatinine increased by 0.10 mg/dL from baseline to Week 48 in the BIKTARVY group and was similar to the comparator groups.

Continued on next page.
Changes in Bilirubin: In Trials 1489 and 1490, total bilirubin increases were observed in 12% of subjects administered BIKTARVY through Week 48.

In Virologically Suppressed Adults: The safety of BIKTARVY in HIV-1 infected, virologically suppressed adults is based on Week 48 data from 282 subjects in a randomized, double-blind, active-controlled trial in which virologically suppressed subjects were switched from either DTG + ABC/3TC or ABC/DTG/3TC to BIKTARVY; and Week 48 data from 290 subjects in an open-label, active-controlled trial in which virologically suppressed subjects were switched from a regimen containing atazanavir (ATV) (given with cobicistat or ritonavir) or darunavir (DRV) (given with cobicistat or ritonavir) plus either FTC/TDF or ABC/3TC, to BIKTARVY.

Adverse Reactions: Overall, the safety profile in virologically suppressed adult subjects was similar to that in subjects with no antiretroviral treatment history.

DRUG INTERACTIONS
Also see Indications and Usage, Contraindications, and Warnings and Precautions.

Other Antiretroviral Medications: BIKTARVY is a complete regimen for the treatment of HIV-1 infection, BIKTARVY coadministration with other ARV medications for treatment of HIV-1 infection is not recommended. Complete information regarding potential drug interactions with other ARV medications is not provided.

Potential for BIKTARVY to Affect Other Drugs: BIC inhibits organic cation transporter 2 (OCT2) and multidrug and toxin extrusion transporter 1 (MATE1) in vitro. Coadministration of BIKTARVY with drugs that are substrates of OCT2 and MATE1 (e.g., dofetilide) may increase their plasma concentrations.

Potential Effect of Other Drugs on BIKTARVY: BIC is a substrate of CYP3A and UGT1A1. A drug that is a strong inducer of primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion, coadministration of BIKTARVY with drugs, which may increase their plasma concentrations.

Established and Potentially Significant Drug Interactions: The listing of established or potentially clinically significant drug interactions with recommended prevention or management strategies described are based on studies conducted with either BIKTARVY, the components of BIKTARVY (BIC, FTC, and TAF) as individual agents, or are drug interactions that may occur with BIKTARVY. An alteration in regimen may be recommended.

- Antiarhythmics: dofetilide. Coadministration is contraindicated due to potential for serious and/or life-threatening events.
- Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin. Coadministration with alternative anticonvulsants should be considered.
- Antimycobacterials: rifampin. Coadministration is contraindicated due to the effect on BIKTARVY. Rifabutin, rifapentine. Coadministration is not recommended.
- Herbal Products: St. John’s wort. Coadministration is not recommended.
- Iron: BIKTARVY and supplements containing calcium or iron can be taken together with food. Routine administration of BIKTARVY under fasting conditions simultaneously with, or 2 hours after, supplements containing calcium or iron is not recommended.
- Metformin: Refer to the prescribing information of metformin for assessing the benefit and risk of concomitant use of BIKTARVY and metformin.

Consult the full Prescribing Information prior to and during treatment with BIKTARVY for important drug interactions; this list is not all inclusive.

USE IN SPECIFIC POPULATIONS Also see Dosage and Administration, Warnings and Precautions, and Adverse Reactions.

Pregnancy: Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to BIKTARVY during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263. Risk Summary: There are insufficient human data on the use of BIKTARVY during pregnancy to inform a drug-associated risk of birth defects and miscarriage. BIC and TAF use in women during pregnancy has not been evaluated; however, FTC use during pregnancy has been evaluated in a limited number of women as reported to the APR. Available data from the APR show no difference in the overall risk of major birth defects for FTC compared with the background rate for major birth defects of 2.7% in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP). The rate of miscarriage is not reported in the APR.

Lactation: The Centers for Disease Control and Prevention recommend that HIV-infected mothers not breastfeeding their infants to avoid risking postnatal transmission of HIV. Based on published data, FTC has been detected in human milk; it is not known whether BIKTARVY or all of the components of BIKTARVY are present in human breast milk, affects human milk production, or has effects on the breastfed infant. FTC was detected in the plasma of nursing rat pups likely due to the presence of BIC in milk, and tenofovir has been shown to be present in the milk of lactating rhesus monkeys after administration of TDF. It is unknown if TAF is present in animal milk. Because of the potential for HIV transmission in HIV-negative infants, developing viral resistance in HIV-positive infants, and adverse reactions in nursing infants, mothers should be instructed not to breastfeed.

Pediatric Use: Safety and effectiveness of BIKTARVY in pediatric patients less than 18 years of age have not been established.

Geriatric Use: Clinical studies of BIKTARVY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Renal Impairment: BIKTARVY is not recommended in patients with severe renal impairment (CrCl <30ml/min). No dosage adjustment of BIKTARVY is recommended in patients with CrCl >30ml/min.

Hepatic Impairment: No dosage adjustment of BIKTARVY is recommended in patients with mild (Child–Pugh Class A) or moderate (Child–Pugh Class B) hepatic impairment. BIKTARVY is not recommended for use in patients with severe hepatic impairment (Child–Pugh Class C) as BIKTARVY has not been studied in these patients.

OVERDOSE: If overdose occurs, monitor the patient for evidence of toxicity. Treatment consists of general supportive measures including monitoring of vital signs as well as observation of the clinical status of the patient.

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Cancer and diabetes remain top therapeutic areas for managed healthcare executives to watch in 2019, and are joined by heart disease, chronic obstructive pulmonary disease (COPD), and mental health.

“These five conditions are extremely complex with disease processes that often impact multiple systems. Diagnosis and effective, individualized treatment for these conditions are also very important,” says Christopher Peterson, PharmD, director, Emerging Therapeutics, Express Scripts.

DIABETES

Eric Bricker, MD, chief medical officer and cofounder of Compass Professional Health Services, an Alight healthcare technology company based in Dallas, says diabetes is a key area of concern because of its prevalence. As many as 30.3 million Americans have diabetes, with 23.1 million diagnosed and 7.2 million undiagnosed, according to the CDC. Bricker says it is due to the obesity epidemic that is a primary risk factor for type 2 diabetes.

“It’s hard to treat and difficult to control without medications, and patients face the consequences of stroke, heart disease, kidney failure, neuropathy, and retinopathy,” he says. “In addition, physicians don’t always diagnose patients soon enough because they are asymptomatic.”

One concern of Bricker’s is failure of physicians to initiate or intensify therapy when people with type 2 diabetes do not achieve glycemic control right after diagnosis.

Bricker doesn’t believe insulin is a magic bullet. “While it can effectively control type 1 diabetes, it inhibits the body’s ability to break down fat. Insulin for type 2 diabetics may treat the short-term high blood sugar with insulin, but that insulin prevents reducing an underlying cause—obesity. You have short-term gains for a long-term problem,” he says.

He is optimistic, however, that diabetes prevention will draw more attention. For one thing, manufacturers will be required by January 1, 2021, to include the percent of added sugars in grams and percent daily value on their food labels.

Although Bricker says no breakthrough diabetes drugs are expected for 2019, there
2019 diabetes drugs

The FDA has set PDUFA target dates for two drugs. Zynquista (sotagliflozin), an oral dual inhibitor of sodium-glucose cotransporter 1 and 2 proteins (SGLT) for use in combination with insulin to improve blood sugar control in patients with type 1 diabetes, has a PDUFA date of March 22, 2019.

Bricker expects the price of Zynquista to be on par with Januvia (sitagliptin), the highest-selling and most popular drug for diabetes costing about $380 for a 30-day prescription.

Eli Lilly is in phase 3 clinical studies for Ultra Rapid Lispro (ultra rapid formulation), while Adocia plans to offer BioChaperone, another ultra rapid insulin, to lower HbA1c in patients with type 1 and type 2 diabetes.

Mylan and Biocon gained approval for Semglee (insulin glargine) from the European Commission in March 2018, and received a complete response letter earlier in 2018 from the FDA. “Depending on timing of resubmission and resolution of ongoing patent litigation, approval could occur in 2019,” Peterson says. “This product would compete with Lantus, as well as the other long-acting, insulin products.”

In late October 2018, the FDA accepted for review Xeris Pharmaceuticals’ ready-to-use glucagon rescue pen for the treatment of hypoglycemia. The FDA has assigned a PDUFA goal date for completion of the review of the product on June 10, 2019.

In July 2018, Eli Lilly submitted a new drug application (NDA) for a nasal glucagon to treat severe hypoglycemia and is developing a subcutaneously administered gastric inhibitory polypeptide to stimulate insulin secretion.

Novo Nordisk is close to launching the first GLP-1 oral medication for diabetes. Peterson says it is expected to submit for review in 2019, and be approved in 2020.

Julie Rubin, PharmD, director of clinical services, Houston-based CompleteRx, which provides hospital pharmacy management solutions, sees potential in combination therapies of an agonist and a long-acting insulin, such as Soliqua 100/33 (insulin glargine & lixisenatide injection). It is a once-daily injectable that contains insulin glargine, a long-acting basal insulin analog, and lixisenatide, a glucagon-like peptide-1 (GLP-1) receptor agonist that may improve blood sugar control in adults with type 2 diabetes.

She highlights the cost of Soliqua—about $20/a day—and its side effects, such as weight loss, bloating, gas, and diarrhea.

Although she touts combination therapies, she believes it is less expensive and safer to use two separate drugs together. “If there is an adverse reaction, you wouldn’t know which medication caused the issue,” Rubin says.

Although Trulicity (dulaglutide) was approved in 2014, a phase 3b study in early 2018 indicated that adding the drug to a SGLT-2 inhibitor significantly improved A1c levels in patients with type 2 diabetes.

In addition, a recent large clinical trial showed that the drug is the first type 2 diabetes medication to show a statistically significant reduction in heart risk, according to its manufacturer Eli Lilly.

Rubin agrees with Bricker that diabetes will continue to be an area of concern because of its prevalence in the population, but says that leaves the door open for improving adherence through oral and injectable medications.
lector of clinical oncology for Vizient Inc., a healthcare performance improvement company based in Irving, Texas. Its estimated WAC cost is around $3,700 per vial.

Lutathera (lutetium Lu 177 dotatate), targeting GI tumors, is another expensive drug, pricing out at $49,600 for a course of treatment (generally given intravenously every eight weeks for a total of four doses). Dolan says Poteligeo and Lutathera are two of the most expensive therapies approved in 2018. Poteligeo is a humanized monoclonal antibody and the first biologic drug used to target CC chemokine receptor 4 (CCR4), while Lutathera is attached to a radioactive isotope.

Dolan believes that two other drugs approved in 2018 will have a substantial effect on pharmacy—Talzenna (talazoparib), a poly ADP-ribose polymerase (PARP) inhibitor approved to treat BRCA-mutated, HER2-negative, locally advanced or metastatic breast cancer and Libtayo (cemiplimab-rwlc), a PD-1 inhibitor. “Talzenna is in a much-needed therapeutic category, and Libtayo is the first drug approved for its indication; however, its target population is small,” she says.

Receiving approval in early 2018, Erleada (apulutamide) is the first FDA-approved treatment for non-metastatic castration-resistant prostate cancer. Dolan expects it to have a large impact and substantial utilization due to the size of its targeted population.

As 2018 ebbs, two other cancer drugs have been approved: Empliciti (elotuzumab) in combination with Pomalyst (pomalidomide) and dexamethasone for the treatment of relapsed or refractory multiple myeloma and Lorbrena (lorlatinib), a third-generation drug for anaplastic lymphoma kinase ALK-positive metastatic non-small cell lung cancer whose disease has progressed on other medications.

For Empliciti, the ELOQUENT-3 trial indicated a reduced risk of disease progression or death by 46% compared with pomalidomide and dexamethasone alone.

Lorbrena received accelerated approval based on tumor response rate and duration of response. Continued approval for this indication might be contingent upon verification and description of clinical benefit in a confirmatory trial.

In November, CMS granted two unique assigned Q codes to Retacrit (epoetin alfa-epbx) injection, the first available biosimilar to Procrit (epoetin alfa) and Epogen (epoetin alfa) in the United States, at a substantial discount. Pfizer began shipment of Retacrit to wholesalers in the United States on November 12, 2018.

Retacrit will be introduced at a WAC of $11.03 per 1,000 units/mL, which is 57.1% below the WAC of Procrit, and 33.5% below that of Epogen, its reference product.

COPD

Albert Rizzo, MD, chief medical officer for the American Lung Association, says COPD is worthy of attention as the third leading cause of death in the United States; 11.3 million people in 2016 were diagnosed with COPD, but millions more may have the disease without even knowing it, according to the American Lung Association.

“COPD also has a socioeconomic impact on healthcare because exacerbations or flares often require hospitalization and chronic care, and COPD is often diagnosed when it might already be in the late stages.”

—ALBERT RIZZO, MD, AMERICAN LUNG ASSOCIATION

“Not only does it affect a large population, but patients with COPD often have significant comorbidities, such as heart disease, diabetes, and arthritis. COPD also has a socioeconomic impact on healthcare because exacerbations or flares often require hospitalization and chronic care, and COPD is often diagnosed when it might already be in the late stages,” he says.

He says that most available medications only alleviate symptoms—neither curing nor slowing the condition’s progress—“but at least the current drugs can keep sufferers independent and functional in many cases.”
The majority of COPD medications are administered via inhalers or nebulizers, some with steroids to lessen the tightness of the airway. "It is not always easy to find the right drug for the right patient at the right cost but fortunately, there are many molecules and devices from which to choose," he says.

There are currently no biologics indicated for COPD, but there are three non-biologics entering the space—Yupelri (revenefacin) inhalation solution, Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol), and Duakir (aclidinium/formoterol).

The FDA-approved Yupelri, a long-acting muscarinic antagonist (LAMA) administered via a standard jet nebulizer for the maintenance treatment of patients with COPD, on November 9, 2018. It is the first once-daily, nebulized bronchodilator to be approved for COPD in the United States, say manufacturers Theravance Biopharma and Mylan.

In April 2018, Trelegy Ellipta received an expanded indication for a long-term, once-daily, maintenance treatment for patients with COPD, including chronic bronchitis and/or emphysema; it also reduces exacerbations of COPD. The objective is to include a broader population of COPD patients with airflow limitation or who have experienced an acute worsening of respiratory symptoms.

The FDA accepted an NDA from AstraZeneca for Duakir, a twice-daily combination of a long-acting beta2-agonist and a LAMA, with a Prescription Drug User Fee Act (PDUFA) date of March 31, 2019.

Rizzo recommends that primary care physicians consider performing spirometry or breathing tests more often when patients have symptoms so that they can diagnose COPD sooner and put patients on the right medications.

"Physicians and patients also have to face the stigma that patients with COPD sadly endure because the disease is often associated with smoking. We are working toward removing that stigma, along with advocating for more research dollars for COPD to get more patients treated and to move toward better drugs that can slow down or cure the disease; increasing access to pulmonary rehabilitation programs; and more patient and caregiver education about COPD," Rizzo says.

**MENTAL HEALTH**

With so many different behavioral health disorders, Megan Ehret, PharmD, associate professor at the University of Maryland, says mental health is a huge area of concern that presents many challenges.

The CDC estimates that 50% of all Americans will be diagnosed with a mental illness or disorder at some point in their lifetimes.

"While many effective therapies are available generically, there will be continued development to help address patients who do not adequately respond to or cannot tolerate current therapies," Peterson says.

**RECENTLY APPROVED DRUGS FOR MENTAL HEALTH DISORDERS**

Approved in July 2018 for the treatment of schizophrenia in adults are Aristada Initio (aripiprazole lauroxil), a long-acting injectable, atypical antipsychotic, and Perseris (risperidone), the first once-monthly subcutaneous risperidone-containing, long-acting injectable.

According to IQVIA, the market for long-acting antipsychotics was $3 billion in 2017. Perseris’ manufacturer, Indivior, expects the drug to earn $200 to $300 million in sales.

For the first time, Aristada Initio, in combination with a single 30 mg dose of oral aripiprazole, provides physicians with an alternative regimen to initiate patients onto any dose of Aristada (aripiprazole lauroxil) extended-release injectable suspension on day one. Its cost, about $1,500 a month, is comparable with other long-acting antipsychotics.

Ehret says the difference between these two drugs and older ones on the market are their administration and longer-lasting effects.

Esketamine is a small-molecule N-methyl-D-aspartate (NMDA) receptor antagonist nasal spray for treatment-resistant depression. Janssen submitted an NDA on September 4, 2018; its estimated PDUFA date is May 4, 2019. If it is approved, it would be the first new mechanism of action for treating depression in 30 years. The drug, however, hit a snag in a phase 3 study in September 2018, in which it failed to demonstrate a statistical significance for the primary end point, Janssen says.

Zulresso (brexanolone) from Sage Therapeutics is an allosteric modulator of GABA AA receptor for postpartum depression and would be the first indicated for treatment of the condition. Because of its IV administration over 60 hours, it could require inpatient hospitalization, which would be a limiting fac-
tor due to convenience and cost, Ehret says.

Zulresso received breakthrough therapy designation in September 2016, and consequently submitted an NDA. On November 2, an advisory panel to the FDA recommended approval of the drug with a caveat—recommendations for a monitoring period after women receive the injection and no home use. The FDA extended the PDUFA date from mid-December 2018 to March 19, 2019.

Sage is also studying another product (SAGE-217) for the treatment of major depressive disorder and postpartum depression, that is a similar compound for once-daily, oral administration, but a timeline is not yet available. Ehret says that no other medication exists with this indication.

Alkermes’ ALKS-5461 (buprenorphine/samidorphan), a combination of a non-addictive opioid modulator and buprenorphine for treating major depressive disorder in patients who have had an inadequate response to standard therapies, received a different fate than Zulresso. On November 2, an FDA panel failed to support ALKS-5461, the majority agreeing that the sponsor had not provided significant evidence of efficacy and that there were some inconsistencies across studies.

“Its mechanism is not something that has been approved for depression. Most depression medications work on serotonin, noradrenaline, or dopamine,” Ehret says. “This would be the first medication in this class to be approved and would provide a medication in the opioid class for depression.”

The company has set an estimated PDUFA date for ALKS-5461 of January 31, 2019.

“Both Zulpresso and ALKS-5461 are quite novel in mechanisms for the treatment of subtypes of depression, and both come with risks and administration concerns; one is an IV drug, and the other is an opioid product, respectively,” Ehret says. “The new mechanisms and development of novel compounds speak to the continued need for additional treatments for depression, as one-third of patients ultimately don’t respond to current treatment modalities.”

HEART DISEASE
Similar to the other therapeutic areas on the radar for 2019, heart disease has tremendous consequences and affects a large swath of the population. According to the CDC, about 610,000 people die of heart disease in the United States every year—one in every four deaths—and is the leading cause of death for both men and women.

Robert A. Harrington, MD, president-elect of the American Heart Association, professor of medicine and chairman of the Department of Medicine, Stanford University, says heart disease not only places a financial burden on the healthcare system for treatment, care, and drugs, but also causes loss of economic productivity.

Care for heart disease suffers from disparities with poorer populations having worse outcomes, according to Harrington. “Coronary artery disease, which contributes to other heart conditions, can be caused by obesity, diabetes, smoking, poor diets, and lack of exercise, all of which are more dominant in lower socioeconomic groups and contribute to the burden,” he says.

But paradoxically, he says there is a migration away from investing in heart medications in the last eight to 10 years—more for cancer and rare diseases. He attributes the problem to expensive clinical trials.

On the positive side, Harrington says many of the important statins, antithrombotics, and ACE inhibitors are now generic, such as the anticoagulant warfarin. According to GoodRx, it is available for $18.26 per month, while the average price for Eliquis (apixaban), a much newer blood thinner, is $522.36 per month.

Harrington says Eliquis might be more expensive, but its ease of use and safety profile make it cost-effective—as found in a June 2013 study in Stroke. A generic version of Eliquis has not yet hit the marketplace.

To mitigate the high cost of some branded heart medications, Amgen recently reduced the price of Repatha (evolocumab), a PCSK9 that treats high cholesterol, by 60% to $5,850 a year, which Harrington says is a “big deal” in cardiac circles.

Although there are a limited number of novel drugs in development for heart disease, Peterson says the NDA for bempedoic acid, a small molecule compound with a dual mechanism of action to lower LDL cholesterol for those who cannot tolerate statins, is expected during the first half of 2019, leading to a 2020 approval.

Mari Edlin, a frequent contributor to Managed Healthcare Executive, is based in Sonoma, California.
Top Pharmacy Challenges of 2019

Six emerge as the most striking by MARI EDLIN

While pharmacy assumes different challenges every year, affordability has stayed at the top of the list. Last year, non-adherence and pharmacist compensation capped off the top three, but in 2019, industry experts are identifying new barriers that have even more impact.

Here are the six top pharmacy challenges health executives can expect in 2019:

1. Affordability

Similar to last year, specialty drugs are hiking up the cost of pharmacy. “Innovation with gene therapies and precision medicine increase the fight to afford specialty drugs,” says Susan A. Cantrell, RPh, CEO, Academy of Managed Care Pharmacy (AMCP).

In 2016, the United States spent 18% of its GDP on healthcare—nearly twice the rate of 10 other high-income countries, according to a study in the Journal of the American Medical Association. This country also claims the highest pharmaceutical spending among its peers.

Although Steve Lucio, associate vice president, Vizient, a performance improvement company located in Irving, Texas, recognizes the effectiveness of specialty drugs, like those for immunotherapy, he says they can saddle patients with high costs. He also believes that patients have to weigh a drug’s relative value against its price tag.

“The challenge of high costs is lessened if you have control of your healthcare budget and access to drugs,” Lucio says.

“Drugs are eating up more and more of the healthcare pie,” says Jane Lutz, executive director, Pharmacy Benefit Management Institute (PBMI). “Pharmacy is the most frequently-used benefit, and it’s a real-time benefit—you know what you are going to pay when you pick up a prescription.”

She is concerned that the price of drugs is outweighing income when the average annual cost of a specialty drug is $52,000 and the median wage in 2016 in this country was $48,665.

Lucio is looking forward to potential biosimilars—especially in oncology—entering the marketplace in 2019 to help mitigate costs through competition.

On the other hand, Lutz believes that no model exists that can support the development and distribution of orphan and genomic drugs and biosimilars.

Jonathan Gavras, MD, senior vice president and chief medical officer of Prime Therapeutics, a PBM headquartered in Eagan, Minnesota, believes it is important to anticipate what’s coming down the pipeline, especially high-cost specialty drugs; develop appropriate policies around cost to be affordable for payers and patients; and keep ahead of drug approvals, many of which are fast tracked.

As a solution, he recommends developing a strong, proactive pipeline management system anticipating costs and ensuring the right indication, right drug, and right person are aligned.

“Negotiating for best drug price shouldn’t present a barricade,” Gavras says. “We need to change reimbursement to a value-based model; manage outcomes and patients; and tie reimbursement to outcomes to prevent adverse effects and hospitalization to increase survival.”

Multiple prescriptions also add to the cost of drugs for individuals. As many as 57% of U.S. adults have less than $1,000 in savings to cover health expenses, and nearly 25% have less than $100, according to PBMI. On the positive side, about 85% of people with commercial insurance pay less than $20 a month out of pocket.

2. Opioid crisis

“Solving this problem takes a multi-stakeholder approach; it is important to manage utilization without compromising care,” Cantrell says. In early 2018, AMCP launched an Addiction Advisory Group to promote better practices and improve addiction prevention...
and treatment services.

Fred Massoomi, PharmD, senior director, Visante Inc., a medication management consulting company headquartered in St. Paul, Minnesota, agrees with Cantrell that the epidemic is a multifactorial problem, placing blame on the inability to accurately document doses and dispose of waste.

Gavras says that Prime Therapeutics has been identifying high prescribers since 2010, along with users abusing opioids based on a predictive modeling process. The PBM also works with providers to manage therapy and with retailers to prevent patients from filling the same prescription in multiple pharmacies.

In addition, the PBM developed a built-in fraud use system and has created an Opioid Safety Guide on safety storage, disposal of opioids, and overdose prevention, which Walgreens pharmacists provide to Florida Blue members. The intervention resulted in a four-fold increase in members receiving naloxone, an overdose reversal agent.

3 Separation of medical/pharmacy benefits

“Today’s healthcare system is highly complex and segmented, especially in how medications and other aspects of care are paid for. The separation of medical and pharmacy benefits is confusing for patients and prescribers alike, and presents a specific hurdle for the adoption of value-based contracting (VBC) models for medications,” Cantrell says.

“Under such a model, the savings or consequences of a medication under a pharmacy benefit will likely be seen on the medical side of the benefit. But capturing and recording that event in the pharmacy benefit, which is needed to execute the VBC model, is hampered by the segmentation of the two benefits.

In other words, those responsible for managing the pharmacy benefit may not have access to medical data,” she says.

“Specialty medications are responsible for churn and volatility because they can be covered under both medical or pharmacy benefits but require a high-touch model because of side effects, changes in dosages, and comorbidities. It is up to PBMs and plans to decide which benefit should cover specialty,” Lutz says.

Gavras emphasizes the need to look at the total cost of drugs, not just the pharmacy benefit, especially because many specialty drugs fall under the medical benefit and never touch the pharmacy benefit; “however, no matter which benefit, these drugs affect healthcare delivery and produce the same cost impact,” he says.

4 Drug shortages

Shortages of some drugs have also presented a challenge to the industry—something Lucio partially attributes to natural disasters such as Hurricane Maria in Puerto Rico, and to low margins on certain drugs which force manufacturers to stop production. “Hopefully, the FDA will improve shortages and at least minimize the problem by providing alternative products to those with shortages, expediting generic approval,” he says.

According to the FDA, shortages decreased to 39 in 2017 from a peak of 251 in 2011. The biggest shortages have hit older, generic, injectable medications produced by only a small number of manufacturers: epinephrine as exemplified by Mylan raising the price of EpiPen 400%, and injectable analgesics. The FDA approved the first generic competitor to EpiPen in August 2018 made by Teva Pharmaceuticals.

Massoomi calls drug shortages the “silent epidemic.”

5 Multitude of regulations

Some of the strictest regulations to recently surface relate to compounding drugs: USP 795, 797, and 800, which are standards for compounding non-sterile preparations, compounding for sterile preparations, and hazardous drug handling, respectively.

“The rigor of all three sets of standards and a lack of administrative understanding of these standards, resources, and commensurate reimbursement present a struggle to pharmacists,” says Massoomi. “Administrators do not fully appreciate the complexity of these standards or the need for constant monitoring,” he adds, leading to his recommendations to hire a compliance expert and develop a compliance policy with living documents to support each product and environment.

6 Technology

Lucio says technology is expensive but enables the pharmacy industry to work more safely and effectively.

“We want pharmacists to operate a patient-safe environment, where there are so many products and technologies that can cause problems; however, a business model doesn’t exist to enable that to happen,” says Norman Tomaka, BS, Pharm, MS, clinical consulting pharmacist based in Melbourne, Florida.

Lutz is all for technology, considering it to be a critical part of keeping drug costs down—especially the use of online tools. “Technology can help us make informed decisions by using data analytics, enhance reporting, and provide better access to data, helping us put the best programs into place,” she says.

Mari Edlin, a frequent contributor to Managed Healthcare Executive, is based in Sonoma, California.
Leadership Skills
HELP YOUR ORGANIZATION SUCCEED

Six Ways Health Execs Can Advance Their Careers More Quickly

Sometimes, healthcare executives have trouble advancing their careers. Here are some tips from top executive coaches.

by KEITH LORIA

There’s nothing wrong with wanting to get ahead and move up the career ladder, but sometimes, healthcare executives have trouble advancing their careers the way they’d like. Here are some tips from top executive coaches.

1. It’s not all about vertical movement

Healthcare organizations can be somewhat flat once you reach a director level, as there are often limited opportunities for upward advancement without leaving a place of employment because those positions are already filled.

Ted Beasley, lead instructor for Emergent Execs, Austin, Texas, says that before you start posting your resume online, you should consider two alternate paths for advancement.

The first is horizontal—opportunities in other departments that can help you gain more valuable experience. For example, one of Emergent Execs’ clients hit a ceiling in her career, and the next level up on a traditional career path was CFO—but her entrenched CFO was blocking that route. So, she opted to make a lateral move and helped transform the company through her efforts, gaining exposure in another area that she never would have otherwise.

“While you may not have some of the technical expertise required, your hard-won executive skills can make you an instant asset working in a different functional area. Sometimes you need to move sideways before you can move up.”

— TED BEASLEY, EMERGENT EXECS

2. Work on communication skills

When it comes to career advancement, Carol Vernon, an executive coach with Communication Matters, Washington, D.C., says the most important thing she recommends to healthcare executives is focusing on their communications skills.

“Too often, leaders wait until they are in executive roles to focus on building executive level communication skills,” she says.

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“I’d strongly recommend leaders focus on building next-level communication skills now, including seeking opportunities to develop their formal presentations skills as well as their informal communications with their various stakeholders.”

To develop your communication skills, Vernon recommends you start by getting input from different stakeholders about what is working well in terms of how you are communicating both informally as well as in more formal presentations.

“Check to see if you are concise, contextualized, and clear,” she says. “Once you have the input, you can use traditional tools and training (such as courses, speaking opportunities, etc.) to grow specific skills, seek support from a colleague (perhaps a mentoring relationship) or work with an external coach.”

Communicating ideas clearly not only develops relationships but is a key indicator of longer-term potential for higher-level success.

3 Improve your team
When looking to move up the ladder, it’s important for an executive to have a team below them that is just as successful as he or she is.

“You will advance your career if you put the emphasis on advancing other people’s careers,” says Jim Vaselopulos, founder & CEO of Rafti Advisors, Inc., Chicago. “It’s not just about making your boss look good, it’s about building leaders. Your mindset shouldn’t be just building your own career, but building the success of the people in the organization as a whole.”

Shifting your focus from own career to the careers of everyone reaps benefits that will play out in career advancement.

4 Seek out a mentor
Carrie A. L. Arnold, PhD, principal coach and consultant with Denver-based The Willow Group, believes a great way for someone to advance their career is to find people in higher levels of leadership who will champion them and work with them to unleash their full potential.

“Do not wait for someone to tap you on the shoulder with a request to join a formal mentoring program,” she says. “Seek out your next mentor and be willing to advocate for yourself. Ask for time and attention and be willing to listen and learn.”

5 Develop your successor
Ironically, one of the primary reasons executives are not promoted is that they are indispensable in their current position, Beasley says that’s why it’s important to develop someone “on the bench” to replace you if you were moved to a higher role.

“In order to get that promotion you want, your organization needs to be confident that they can backfill your responsibilities,” he says. “Identify the best candidates for replacing you in terms of their performance and potential. Make the time to fill in their gaps and prepare them for the day you move on.”

One company he worked with knew that their director of operations was their best internal candidate for replacing the CEO, yet the CEO stayed in that position for two additional years. The CEO’s reasoning? The director of operations was a lynchpin, and there was no one to replace him.

“It took two years to hire and onboard a new operations exec before the new CEO could be promoted,” Beasley says.

6 Keep developing
An executive should never rest on laurels and feel they have nothing else to learn.

Arnold recommends people stay as current as possible on the issues facing their particular scope of work. This can be done by being involved in conferences, reading journal articles, and being part of peer groups that contribute to learning.

“Do not stay isolated thinking you can learn things on your own,” she says. “The job will quickly take up all available space if things are not already blocked off and reserved for development needs.”

Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 20 years, on topics as diverse as sports, business, and healthcare.
Philadelphia-based Einstein Medical Center, the largest independent academic medical center in the Philadelphia region, wanted to decrease readmissions for liver failure patients by half. Patients often would come to the clinic and be readmitted directly because they were too sick, or would be called to come to the hospital for severe laboratory abnormalities, or would present to the emergency department feeling ill due to noncompliance.

“Chronic liver disease is associated with high readmission rates and is a disease manifested through disorders in a variety of systems including the brain, kidney, and heart,” says Richard Kalman, MD, assistant professor of medicine Sidney Kimmel Medical College in the department of digestive disease and transplantation in the division of hepatology at the Albert Einstein Healthcare Network. “Therefore, it was felt that the chronic liver disease population would be a great group of patients to include in a telehealth endeavor.”

Remote patient visits

The medical center uses remote patient monitoring technology from Vivify Health that allows patients to have a remote visit within 48 hours of discharge with one of their liver providers, and also allows the patient to relay information including symptom assessment and vital signs to the liver clinic as well as to Einstein’s visiting nurse program partner. “We try to schedule a 48-hour televisit with everyone enrolled in the program. We have hit this target all but one or two times,” says Gaesenee Kongsubto, telehealth project manager, Einstein Healthcare Network.

Over a five-month period since starting the program, the hospital has had zero readmissions for patients with liver failure. “The 30-day readmission rate is a benchmark for quality, and so therefore it was chosen,” says Kalman. “We also wanted to limit the number of devices out at any given time, and focus on the time when the patient was in the most precarious position.”

So far, more than 30 patients have used telehealth kits, says Kongsubto. Kits come with a 4G connectivity tablet and can be customized with various monitoring devices (liver patients use a scale, blood pressure cuff, and pulse oximeter). There is also an option to do virtual visits using the camera on the tablet.

“We ramped up slowly because we wanted to work out any work flow issues that might arise with trying to schedule a home health visit that included a televisit with one of our advanced practitioners,” says Kongsubto. “We only cover a limited geography right now but we are hoping to expand to serve all our patients in southeast Pennsylvania, along with Delaware and New Jersey.”

As a result of the technology, patients feel more connected to their care team and have better outcomes, while providers are able to do more targeted data-driven care, she says.

Program expansion

Currently, no managed care partner is involved in the program, but Kongsubto says that dashboards are being developed that can show how effective the telehealth program is in reducing readmissions and providing better coordinated care for patients at home.

Einstein is also using remote monitoring for chronic heart failure, COPD, and sleep apnea. Diabetes and postpartum hypertension are being considered for the future.

Tracey Walker is content manager for Managed Healthcare Executive.